

3.13 An optional local exhaust hood is built into the top panel of the sterilizer. Its purpose is to remove residual ethylene oxide gas from the chamber when the door is opened at cycle completion. The hood must be connected to a dedicated exhaust system that is supplied by the customer and meets 3M specifications. The local exhaust system can reduce operator exposure during load transfer to well below OSHA's 1 ppm Permissible Exposure Limit, 0.5 ppm Action Level and 5 ppm Excursion Limit. If no local exhaust hood is connected the unit remains locked for three hours after the sterilization cycle.

During this three hour mandatory aeration time, airborne ethylene oxide within the chamber is removed. This reduces the operator exposure during load transfer to well below OSHA's 1 ppm Permissible Exposure Limit, 0.5 ppm Action Level and 5 ppm Excursion Limit.

3.14 After the sterilization cycle, the chamber is purged or aerated continuously until the door is opened.

This prevents a buildup of ethylene oxide from items aerating in the chamber.

3.15 The sterilizer can aerate items after sterilization. The sterilization-aeration process can be continuous in one chamber and thereby eliminate gas exposure during load transfers to aerators.

4. STERILIZER LISTINGS

The Steri-Vac 4XL gas sterilizer is listed with the Underwriters Laboratories, Inc. (UL) and the West German Technischer Überwachungs-Verein (TUV). 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.

5. STERILIZER SPECIFICATIONS

5.1 Dimensions	Width	Depth	Height	Diagonal
Exterior Dimensions	80 cm (31-1/2 in)	73 cm (28-1/4 in)	69.8 cm (27-1/2 in)	N/A
Additional Service Space Required	51 cm* (20 in)	19 cm** (7-3/4 in)	51 cm*** (20 in)	N/A
Chamber Dimensions (15 liters (4 cu ft))	46 cm (18 in)	61 cm (24 in)	41 cm (16 in)	81.2 cm (32 in)
Basket Dimensions	43 cm (17 in)	60 cm (23-1/2 in)	20 cm (8 in)	N/A

\* On each side in addition to 80 cm width

\*\* At rear

\*\*\* Above

5.2 Chamber Material: Anodized Aluminum

5.3 Exterior Finish: Baked enamel black body; Brushed stainless steel door.

5.4 Net Weight: 93.7 Kg (207 lb.)

5.5 Shipping Weight: 102 Kg (225 lb.)

5.6 Power Requirements:

Voltage: 220 Volts AC ± 10%

Frequency: 50/60 Hz

Phase: Single (1)

Current: 15 Ampere (Dedicated)

Power Cord: 220 Volt, 15 amp, NEMA 6-15, plug and an IEC 320/CEE-22 "Hot" -120°C, 250 Volt, 10 amp receptacle. Power cords furnished with sterilizers sold outside the USA will meet local electrical requirements.

**5.7 Compressed Air Requirements:**

- Air Pressure:** 3.5 Kg/cm<sup>2</sup> (50 psig) minimum  
10.5 Kg/cm<sup>2</sup> (150 psig) maximum
- Airflow:** 3.4 liters/second (7 scfm) at 3.5 Kg/cm<sup>2</sup> (50 psig)
- Cleanliness:** Clean air supply with a maximum allowable dirt particle size of 5 microns and free of oil.
- Moisture Content:** Moisture content less than 10°C (50°F) dewpoint.



A compressed air source that does not meet the specifications can cause early machine failures which may lead to ethylene oxide exposure to the operator.

**5.8 Water Requirements:** No external water connection. The operator must add distilled water to the water reservoir. The minimum temperature of the steam generator is 105°C (221°F).  
Reservoir Capacity: 1 liter (provides humidification for approximately 10 cycles)

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

**5.10 Optional Exhaust Hood Requirements:**  
The optional exhaust hood is built into the top panel of the sterilizer for customers who want immediate access to the load at the end of the cycle. Its function is to remove residual ethylene oxide gas from the chamber 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 and exhaust to the outside atmosphere or to an emission control system.

<b>Air Flow Through Hood</b> 283 decaliters/min. (100 scfm)	<b>Air Velocity in 10.2 cm (4 in) Line to Hood</b> 350 meters/min. (1150 fpm)	<b>Static Pressure (Water Gauge) at Hood</b> -0.15 cm (-0.06 in.)
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**5.11 Standard Cycles:**

Cycle	Temperature in °C (°F)	Approximate Time in Hours	
		Gas Exposed Phase	Full Sterilization Cycle
WARM	55 (131)	1	2.5
COOL	37 (99)	4	5.5

**6. STERILANT SPECIFICATIONS**

**6.1 Use unit dose cartridges containing 100 grams of 100% ethylene oxide, e.g., Steri-Gas cartridge 4-4-100. The retainer ring of the cartridge holder is color coded green to match the green label on the Steri-Gas cartridge 4-10. Do not use the Steri-Gas cartridge 4-134 in the Steri Vac 4XL gas sterilizer. Refer to the Steri-Gas Consumer Product Profile in Accessory Section for detailed information.**

**6.2 Steri-Gas Cartridge Specifications**

**6.2.1 Shelf Life & Cartridge Weight**

The shelf life of Steri-Gas cartridges is considered to be indefinite when stored at temperatures between 15-30°C (59-86°F). The manufacturing date for Steri-Gas cartridges is stamped on the bottom of each cartridge box. Weigh cartridges older than 24 months before use. Use Steri-Gas cartridges 4-100 with gross weights of 130 grams or more in the Steri-Vac 4XL gas sterilizer. Follow the instructions listed in the Steri-Gas Consumer Product Profile, (see Accessory Section), for handling underweight cartridges.

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### 6.2.2 Cartridge Dimensions

Length: 16.5 cm (6.5 in)  
Diameter: 3.8 cm (1.5 in)

### 6.2.3 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).

- 6.3 EPA registered 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.

## 7. GENERAL ETHYLENE OXIDE DATA

Boiling Point:	10.7°C (51.3°F)
Vapor Pressure:	1094 mm Hg at 20°C $\frac{457 \text{ g}}{\text{sq cm gauge}}$
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 - 750 ppm

## 8. HEALTH & SAFETY INFORMATION



Ethylene oxide is both flammable and toxic. It is important that Steri-Vac users understand the chemical's hazards and the necessary precautions.

### 8.1 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.

### 8.2 Toxicity



- 8.2.1 **Acute Inhalation** may cause irritation of the respiratory tract, dizziness, weakness, nausea and vomiting (immediate or delayed), dizziness, weakness, chest pain and neurotoxic effects. Repeated overexposure may result in olfactory fatigue (i.e., increasingly difficult to smell ethylene oxide).
- 8.2.2 **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 reproductive hazard.

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

**8.2.4 Skin Contact.** Liquid ethylene oxide in contact with the skin may cause irritation, dermatitis, and chemical blisters.

**8.2.5 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.

### **8.3 OSHA Limits**

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 exceed the Excursion Limit of 5 ppm averaged over a 15-minute sample period. Direct contact with ethylene oxide as a liquid or in solutions must be prevented.

### **8.4 Statement of Practical Treatment/First Aid**

**8.4.1 Inhalation.** Immediately get fresh air for over exposure to ethylene oxide gas. Contact a physician as soon as possible.

**8.4.2 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 immediately.

**8.4.3 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.

**8.4.4 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.

## **9. ETHYLENE OXIDE LEAKS OR SPILLS**

### **9.1 Characteristics of a Leak or Spill**

Do not confuse gasket oozing or an oily residue, described in the Steri-Gas Cartridge Consumer Product Profile (Accessory Section), with ethylene oxide leakage. The following indicate Steri-Gas leakage:

**9.1.1** liquid ethylene oxide spurting or rapidly dripping from a cartridge,

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

**9.1.3** cartridge weight loss.

### **9.2 Emergency Plan and Procedures**

#### **9.2.1 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. Consult OSHA's standards on ethylene oxide (29 CFR 1910.1047), employee emergency plans (29 CFR 1910.38), and alarm systems (29 CFR 1910.165) for more detailed information. Refer to the Steri-Gas cartridge Consumer Product Profile (Accessory Section) for more detailed information.

**9.2.2 3M Recommendations for a Gas Leak or Spill Response**

- 9.2.2.1 Avoid direct contact with ethylene oxide.
- 9.2.2.2 Evacuate personnel from the immediate department.
- 9.2.2.3 Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the ethylene oxide.
- 9.2.2.4 Immediately contact the appropriate personnel designated in the department's emergency plan.
- 9.2.2.5 If necessary, follow the practical treatment measures listed in Section G.
- 9.2.2.6 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).
- 9.2.2.7 Contact the cartridge manufacturer. If the spill is associated with the sterilizer, contact the sterilizer manufacturer's representative.
- 9.2.2.8 Do not wear clothing contaminated with ethylene oxide until it has been laundered. Discard contaminated leather items.
- 9.2.2.9 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.

**PREPARING FOR STERILIZATION**

**10. CLEANING**

Thoroughly wash and rinse all items to be sterilized to remove any exudate, mucus, dried blood, or other matter. Ethylene oxide will not kill microorganisms hidden and protected in dried organic matter.

**11. HUMIDIFICATION-PRECONDITIONING**

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.

**11.1 Sterilizer Humidification**

The Steri-Vac gas sterilizer is equipped with an effective humidification system. Sub-atmospheric pulses of low temperature steam are injected repeatedly into the chamber. The combination of steam and vacuum ensures that moisture penetrates hard to reach areas.

**11.2 Preconditioning Hard Surfaced Items**

11.2.1 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 for at least one hour. Rinse and dry the articles until there are no visible liquid droplets.

11.2.2 Keep articles in an area with a relative humidity of 30% or greater overnight before packaging and sterilization.

11.2.3



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.

## 12. PACKAGING

### 12.1 Packaging Material Characteristics

Before sterilization, package articles that are to be stored before use. Use packaging materials with the following characteristics:

- 12.1.1 permit rapid penetration of the sterilant and moisture
- 12.1.2 permit release of the gas after sterilization
- 12.1.3 are strong enough to withstand normal handling
- 12.1.4 allow easy filling, sealing, removal (aseptic presentation), and handling
- 12.1.5 are suitable barrier to bacteria and permit extended shelf life
- 12.1.6 provide proven seals (i.e. do not delaminate or reseal if opened)
- 12.1.7 do not pile or delaminate

### 12.2 Packaging Materials

12.2.1 The following materials are compatible with ethylene oxide sterilization.

- 12.2.1.1 Tyvek®/film
- 12.2.1.2 paper/film
- 12.2.1.3 glassine
- 12.2.1.4 paper or nonwovens
- 12.2.1.5 muslin or wovens
- 12.2.1.6 sterile container systems designed for EO sterilization
- 12.2.1.7 polyethylene

**Wash (prehumidify) items wrapped in polyethylene film which can be a barrier to water vapor and prevent sterilization.**

12.2.2 Do not use the following materials which are unsuitable for ethylene oxide sterilization.

- 12.2.2.1 nylon film
- 12.2.2.2 polyester film
- 12.2.2.3 aluminum foil
- 12.2.2.4 glass or metal jars

## 13. BASKET LOADING

- 13.1 Load sterilizer baskets in a loose, orderly manner.
- 13.2 Totally contain packages within the basket. Packages should not contact the chamber walls.
- 13.3 Place packages on their edge to eliminate undue pressure on pouches and to facilitate gas penetration.
- 13.4 Do not stack packages.
- 13.5 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.
- 13.6 When possible, sterilize full loads of items having common aeration times. Otherwise, place the items with shorter aeration times at the top of the load for easy retrieval and transfer to an aerator.

## 14. BIOLOGICAL MONITORING

- 14.1 A biological indicator should be included in each load of items sterilized with ethylene oxide to monitor the effectiveness of sterilization processing. The biological indicator contains a known population of bacterial spores, the most resistant form of microbial life. The self contained Attest Ethylene Oxide Indicators No. 1264 and 1264P are available from 3M for easy and economical monitoring. (In some countries, additional specific biological tests may be required.)
- 14.2 **Frequency**  
A number of organizations 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)<sup>1</sup>, the American Hospital Association (AHA)<sup>2</sup>, the Association of Operating Room Nurses (AORN)<sup>3</sup>, the U.S. Army<sup>4</sup>, and the Veterans Administration<sup>5</sup>.

### 14.3 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

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- 1 AAMI, "Good Hospital Practice: Performance Evaluation of Ethylene Oxide Sterilizers - Ethylene Oxide Test Packs", 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, July 22, 1983. USA, additional biological tests may be required.)

# STERILIZER OPERATING PROCEDURE

## 15. OPERATING INSTRUCTIONS

### 15.1 User Responsibility



Operating the sterilizer with a compressed air source that does not meet the specifications can cause early machine failures which may lead to ethylene oxide exposure to the operator.

Only medical professionals or appropriately trained personnel in medical and industrial use areas should use this equipment. Use only under the direction of a qualified supervisor. 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.

### 15.2 Power on Continuously

15.2.1 Leave the **POWER SWITCH** located on the back of the sterilizer on at all times. The sterilizer will be in **STANDBY** except during sterilization or aeration. Leaving the sterilizer in **STANDBY** simplifies operation and enables the sterilizer to monitor the operation continuously.

15.2.2 Turn on the **POWER SWITCH** located on the back of the sterilizer if it has been turned off.

### 15.3 Loading the Sterilizer

15.3.1 Clean and precondition all articles to be sterilized. Refer to Sections 9 and 10 of this manual for details.

15.3.2 Load the articles in the basket loosely and orderly. Refer to Sections 13 for details.

15.3.3 Place a test pack containing a biological indicator in the center of the load. See the instructions in Section 12 for **Biological Monitoring**.

15.3.4 Check that the sterilizer is in **STANDBY**. A standby indicator in one of the **TEMPERATURE SELECT** switches should be lighted. Other panel lights should be off.

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

15.3.6 Pull the door open while lifting the **DOOR RELEASE** on the exhaust hood.

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



Forcing the cartridge into the holder may cause a premature puncture of the cartridge which leads to ethylene oxide exposure to the operator.

15.3.8 Place the basket in the sterilizer.

15.3.9 Close the door.

15.3.10 Turn the handle clockwise until it stops.



**15.4 Starting a Sterilization Cycle**

**15.4.1** Press either the **WARM** or **COOL TEMPERATURE SELECT SWITCH**. Check that the light in the upper left corner of the switch selected is on.

Standard Cycle Parameters		
Cycle	Temperature In °C	Approximate Cycle Time in Hours
WARM	55	2.5
COOL	37	5.5

**15.4.2** Press the **START SWITCH**.

The cycle now continues automatically to completion. The cycle temperature now appears in the digital display in the upper right corner of the Operator Control panel. The following panel lights indicate the progression of the cycle.

**PRECONDITION**

**GAS EXPOSE**

**AERATE**

**15.5 Stopping a Sterilization Cycle**

Press the stop switch to interrupt a sterilization cycle. See Section 16.1.4.

**15.6 End of Cycle**

**15.6.1** The **AERATE** light comes on after the sterilization cycle. The audible alarm sounds for 15 seconds. Aeration begins; the digital display in the upper right corner of the operator control panel becomes a digital timer showing elapsed aeration time. The aeration temperature will be the same as the temperature of the sterilization cycle.

**15.6.2** Follow the instructions from the manufacturer of the biological indicator for removing the test pack from the load and processing the indicator. See the **Biological Monitoring** instructions in Section 12 of this manual.

**15.7 Aeration**

**15.7.1** Aerate items according to the device manufacturers' recommendations (time and temperature).

**15.7.2** Aerate items in the sterilizer or transfer the basket of items to an aeration cabinet. Follow the instructions below for using the Steri-Vac 4XL gas sterilizer as an aerator.

**15.8 Aerating In the Sterilizer**

**15.8.1** The digital display in the upper right corner of the front panel shows the elapsed time of aeration in hours and minutes.

**15.8.2** Open the door at any time during aeration to remove or transfer aerated items. Follow the instructions in Section 15.9. The time clock stops while the door is open and resumes timing when the door is closed.

**15.8.3** Close the door and turn the handle clockwise to continue aerating any remaining items in the sterilizer. Do not press any of the switches.

**15.9 Door Opening**

**15.9.1** If the local exhaust hood feature is connected, ensure that the digital display is not flashing a "cl" caution message. This warning indicates a malfunction of the local exhaust system. Correct the problem before opening the sterilizer door.

**15.9.2** Turn the door handle counter-clockwise all the way.

**15.9.3** Wait approximately 30 seconds.

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15.9.4 Pull the door open to the latched position. Keep the door in this position for at least 5 minutes.

Note: If door is not opened within two minutes, AERATION resumes. Turn door handles to vertical position and repeat door opening procedure.

15.9.5 Pull the door fully open while lifting the DOOR RELEASE on the exhaust hood.

15.10 Unloading the Sterilizer

15.10.1 Remove the basket of sterilized items.

15.10.2 Remove the empty gas cartridge from the holder. Place it on top of the basket of goods to be aerated. You do not need to continue to aerate an empty cartridge that aerated in its sterilizer holder for two or more hours.

15.10.3 Transfer the basket of unaerated or incompletely aerated items to an aeration cabinet.

15.10.4 Dispose of the empty cartridge with non-incinerated waste.

15.10.5 Press the STOP switch while the door is open to reset the sterilizer to standby.

15.10.6 Close the sterilizer door. The sterilizer remains in Standby until the next cycle is started.

15.11 Cycle Caution/ Error Message

Refer to Section 19 of this manual for an explanation of any caution/error messages (e.g. C2, E10) appearing in the digital display of the front panel.

16. EXPLANATION OF STERILIZER CONTROLS

Refer to Figure 1 showing the sterilizer controls.

16.1 Switches

16.1.1 Power Switch

Controls power to the sterilizer. The switch located on the back of the sterilizer should be left on at all times to simplify operation.

16.1.2 Temperature Select Switches

Controls the chamber temperature. During the sterilization and aeration cycles, the selected temperature cannot be changed.

16.1.3 Start Switch

Starts the automatic sterilization cycle.

16.1.4 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 advances to FINAL VACUUM EXHAUST ending in an audible abort. The sterilizer ends aeration and reverts to standby if the STOP switch is pressed while the AERATE light is on and the door is open.

16.2 Cycle Status Display/Lights

16.2.1 Temperature - °C

Digital display indicates chamber temperature setting in degrees Centigrade. Temperature is displayed during the PRECONDITION and GAS EXPOSE phases.

16.2.2 Aeration Time - Hours and Minutes

Digital display indicates elapsed time of the AERATION cycle up to a maximum of 99 hours and 59 minutes. The timer automatically starts when the sterilization cycle is completed.

### 16.2.3 Pressure - Bars

Digital display indicates the absolute pressure of the chamber in millibars during the sterilization and aeration cycles. One thousand millibars are approximately equal to one atmosphere.

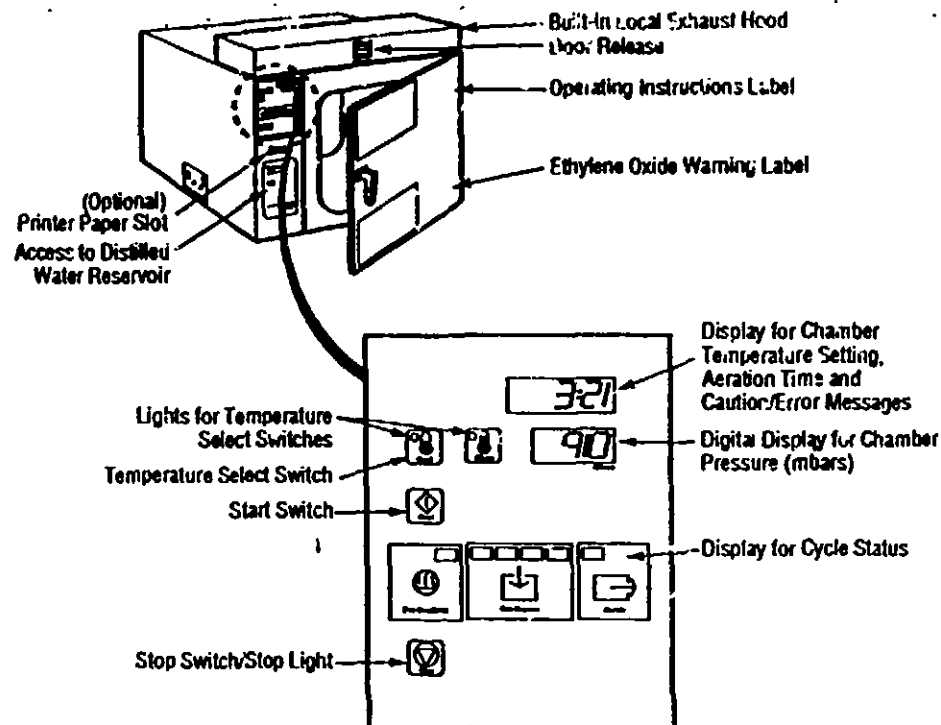


Figure 1: Steri-Vac 4XL Sterilizer Operator Control Panel

### 16.2.4 Lights In Temperature Select Switches

Indicates that either WARM or COOL switch was pressed. Remains lit after cycle completion and during STANDBY until the other temperature switch is pressed.

### 16.2.5 Pre-Condition Light

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

### 16.2.6 Gas Expose Light

Indicates phase during which the cartridge is punctured, the load is exposed to ethylene oxide, the gas is exhausted, and the chamber is purged for 15 minutes.

### 16.2.7 Aerate Light

Indicates final phase when door is unlocked and sterilized load is being aerated.

### 16.2.8 Stop Light

Indicates STOP switch was pressed. See Section 16.2.10.

### 16.2.9 Caution Codes

Indicated by flashing message (e.g., c1) in digital display. Will not stop cycle in progress. Operator must check the Caution/Error Message Explanation Chart in Section 19 and correct the problem to clear code.

### 16.2.10 Error Codes

Indicated by nonflashing message (e.g. E10) in digital display. This stops the sterilization cycle in progress, turns on STOP indicator, turns off status lights, and turns off heaters. Operator must check Section 19 and correct problem. There are three categories of error codes.

16.2.10.1 Codes E1-E49: These occur before cartridge puncture. Operator must open door, press STOP SWITCH and take corrective steps indicated.

16.2.10.2 Codes E50-69: These occur after cartridge puncture. The machine will advance through final exhaust vacuum and 15 minute purge, unlock door, and then will give a constant audible alarm. Operator must open door and press STOP switch to stop alarm and take corrective steps.

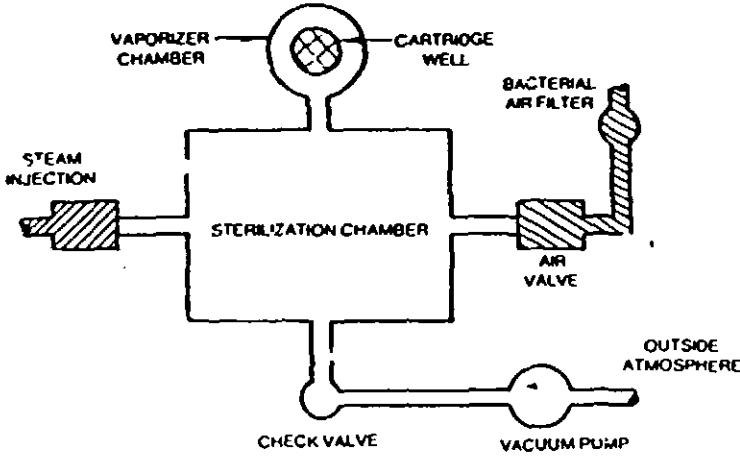
16.2.10.3 Codes E70-89: These occur if sterilizer cannot complete final exhaust vacuum and 15 minute air purge. Usually requires service call; check Section 19. Door is locked. No alarm. STOP Indicator is lit.

16.3 Door Release

Latch that holds sterilizer door in a semi-open position during operation of local exhaust hood.

17. GENERAL SEQUENCE OF OPERATION

17.1 Standby



\* Leave the POWER SWITCH (located at the back of the sterilizer) on at all times. An indicator in one of the TEMPERATURE SELECT switches should be lit. Other panel lights should be off.

\* Door is unlocked.

\* Open door, insert cartridge, load chamber, and close door.

\* Press either WARM or COOL Temperature Select switch. Check that light in upper left corner of selected switch is on.

NOTICE

Warning codes for low airflow in exhaust hood (c1) or low water in reservoir (c2) may flash in digital display. Use Section 19 of manual to determine corrective steps.

\* Press START switch.

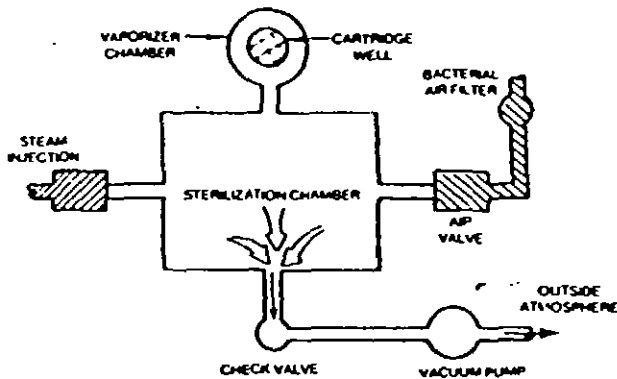
\* The door locks and the cycle is now automatic.

\* The vacuum pump is on.

\* The panel light marked PRECONDITION illuminates.

\* The digital display shows chamber temperature.

17.2 Initial Vacuum

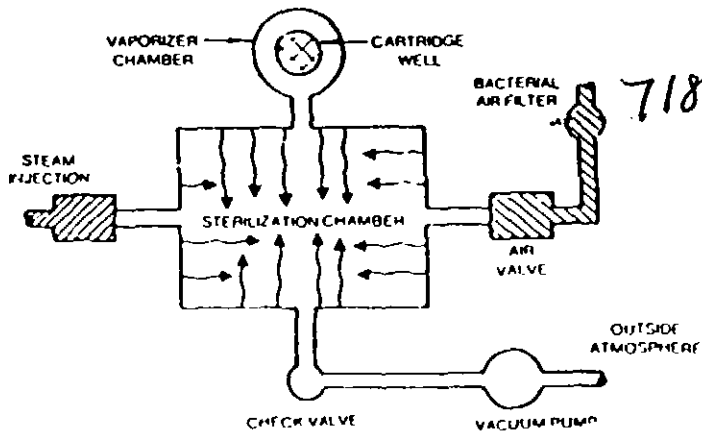


\* The chamber simultaneously draws a vacuum and heats to the selected temperature.

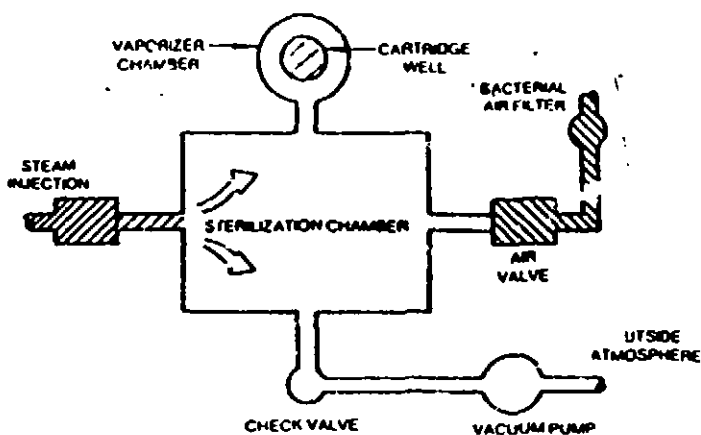
\* The pump solenoid and venturi pump evacuates air from the chamber until the pressure reaches 240 millibars. This must occur within 20 minutes. Refer to E22 error explanation in Section 19. The chamber pressure must decrease by at least 50 millibars in the first minute the pump is on. Otherwise, the sterilizer issues an error code E21 in the digital display indicating no vacuum.

\* The chamber heaters and heatsink heater are on. The chamber is heated to the selected temperature. The heatsink heats to a minimum of 105°C and a maximum of 115°C. Warmup must occur within 45 minutes; otherwise either the E23 or E24 error codes appear.

17.3 Preheat



### 17.4 Humidification

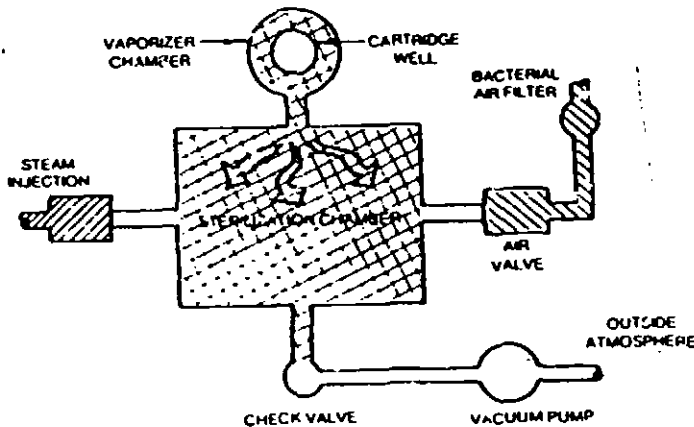


\* The sterilizer draws an additional two minutes of vacuum and measures to ensure the pressure is below 240 millibars. For higher pressures, the vacuum system will stay on up to eight minutes until reaching adequate vacuum. Otherwise, the E27 error code will appear.

\* Moisture is injected as low temperature steam into the chamber. A minute pause follows for steam formation and load penetration. Another two minute vacuum precedes the next humidification period.

\* The humidification-vacuum sequence is repeated ten times for warm and four times for cool cycle. The total humidification time for either cycle is 30 minutes.

### 17.5 Gas Injection



\* There is an 13 minute delay after the 4th injection for cool cycles to allow equal time for water to be absorbed.

\* The vacuum pump runs again for a minimum of two minutes. The chamber must be below 240 millibars. Otherwise, the vacuum is left on for a maximum of eight more minutes. An error code E31 appears if the vacuum is not reduced below 10 millibars.

\* The heaters are turned off.

\* The locked door is checked. The error code appears if the door is unlocked.

\* The temperature and pressure are checked again. One of the following error codes will appear if there are problems: E29, E30, E31.

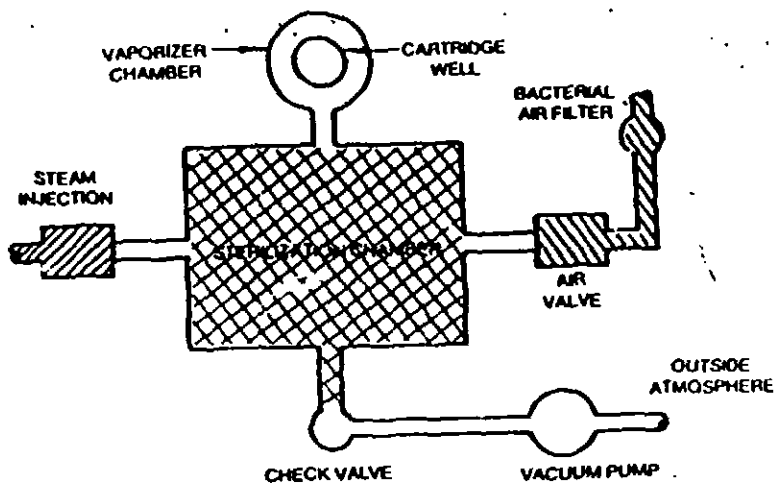
\* The cartridge is punctured. Ethylene oxide gas enters the chamber.

\* The chamber heaters are turned on to control the temperature.

\* The pressure is checked one (1) minute after puncture to ensure it rises by at least 200 millibars. A lower pressure reading indicates that a cartridge is either empty or missing (E50) or not completely full or punctured (E75).

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## 17.6 Gas Exposure



\* The length of the gas exposure phase is monitored after puncture. Cycle temperatures may be different in some countries.

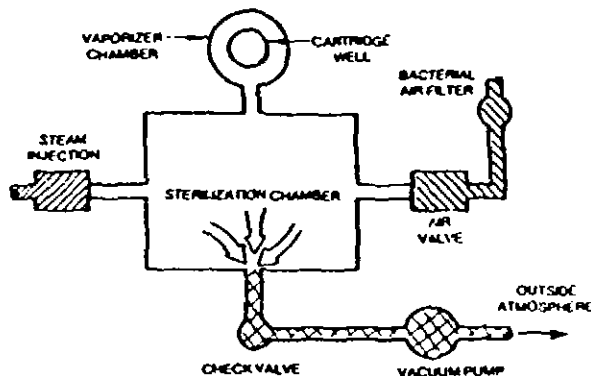
Cycle	Time in Minutes
WARM	62
COOL	250

\* The pressure is monitored to ensure it remains 80 millibars below atmospheric pressure. Otherwise, the vacuum system turns on a maximum of eight times and draws the chamber to 180 millibars below atmospheric pressure. The E51 error code appears if the vacuum system turns on more than eight times.

\* The temperature is maintained to within  $+3^{\circ}\text{C}$  of that selected. One of the error codes, E52 or E53, appears if the temperature varies  $4^{\circ}\text{C}$  or more from the set point at any time.

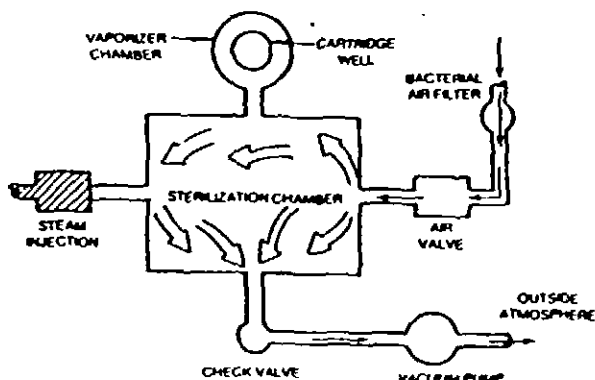
\* The GAS EXPOSURE lights show cycle progression.

## 17.7 Final Vacuum Exhaust



\* The vacuum system turns on to exhaust ethylene oxide from the chamber. The chamber vacuum is drawn to 240 millibars. An E71 error code appears if pump down is not complete in 20 minutes.

## 17.8 15 Minute Air Purge

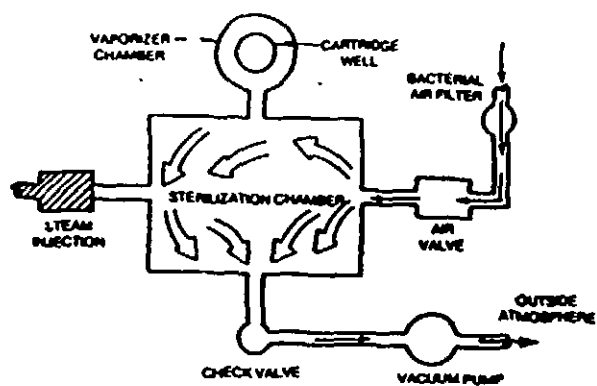


\* The air valve opens to draw in bacterial filtered air after the chamber pressure reaches 240 millibars. An E72 abort code appears if the pressure does not rise above 860 millibars in the first six minutes.

\* Fresh air continues to purge the chamber for 15 minutes.

\* If the chamber pressure rises to within 40 millibars of atmosphere during the purge the air valve closes until the vacuum drops to 80 millibars below atmospheric pressure.

### 17.9 Continuous Air Aeration – Open Door



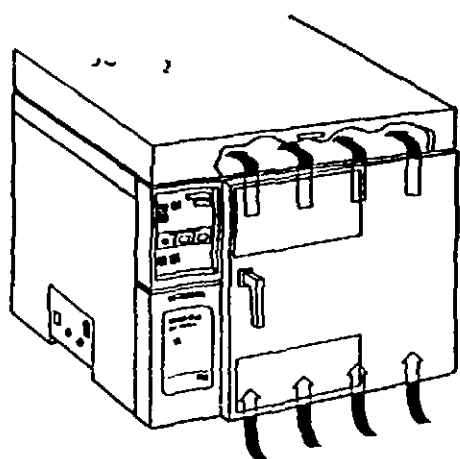
\*The *AERATE* light comes on.

\*The door alarm sounds for 15 seconds and the door unlocks.

\*Aeration begins. The digital display becomes a clock showing elapsed aeration time.

\*Open the door at any time during aeration to remove or transfer items. The time clock stops while the door is open and resumes timing when the door is closed. Close the door and turn the handle to continue aerating any remaining items in the sterilizer. Do not press any switches.

### 17.9 Continuous Air Aeration – Open Door



\*A local exhaust hood is built into the top of the sterilizer. The hood must be connected to a dedicated, customer-supplied exhaust system (e.g. fan, ductwork) that meets 3M specifications.

\*When the door is opened to the open-latched position, the hood captures and exhausts ethylene oxide gas that otherwise may escape into the room during basket removal.

\*Keep the door in the open=latched position for at least 5 minutes before fully opening the door and removing items.

A c1 caution message will flash in the digital display if there is insufficient air movement in the exhaust hood.

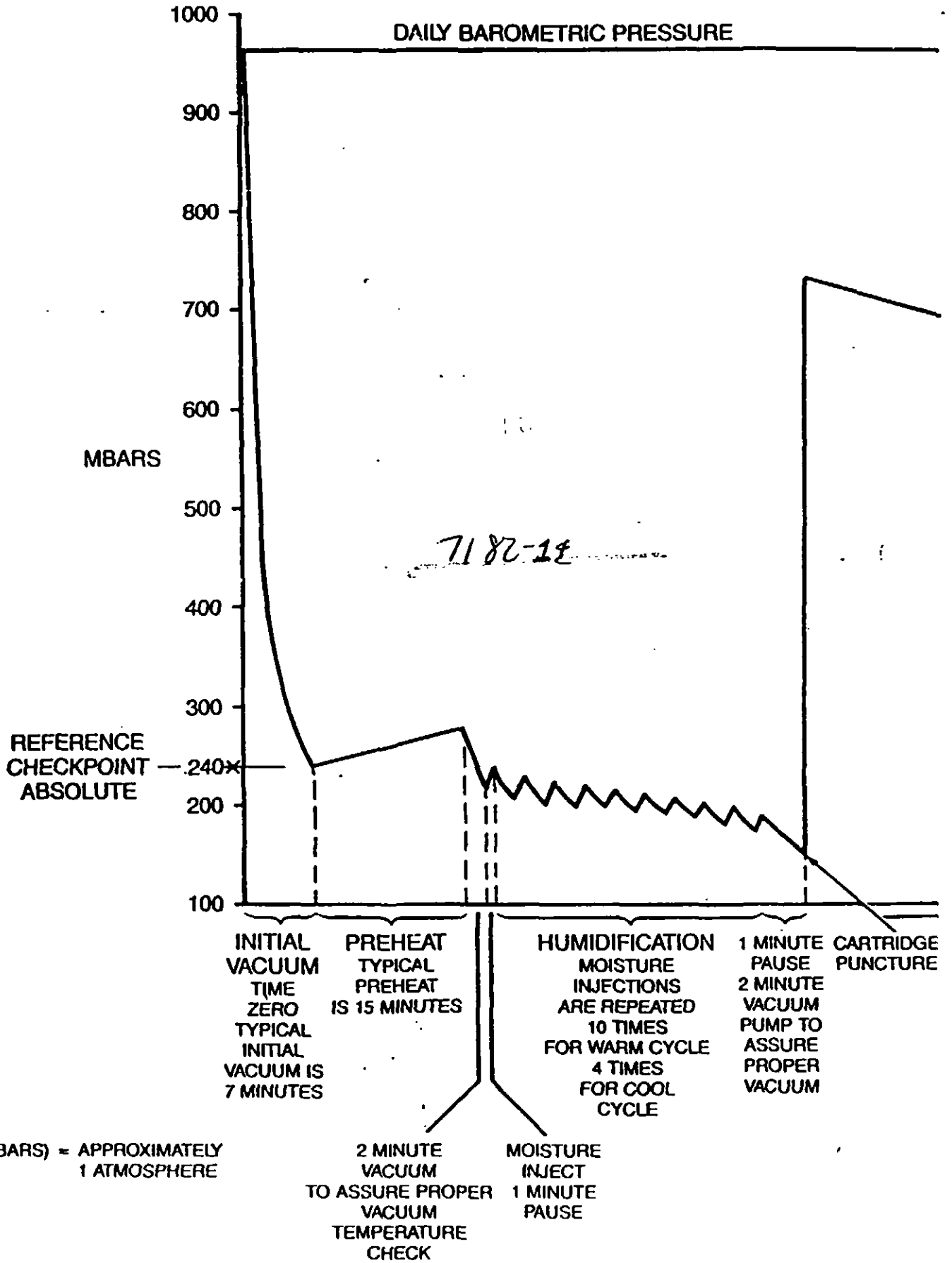
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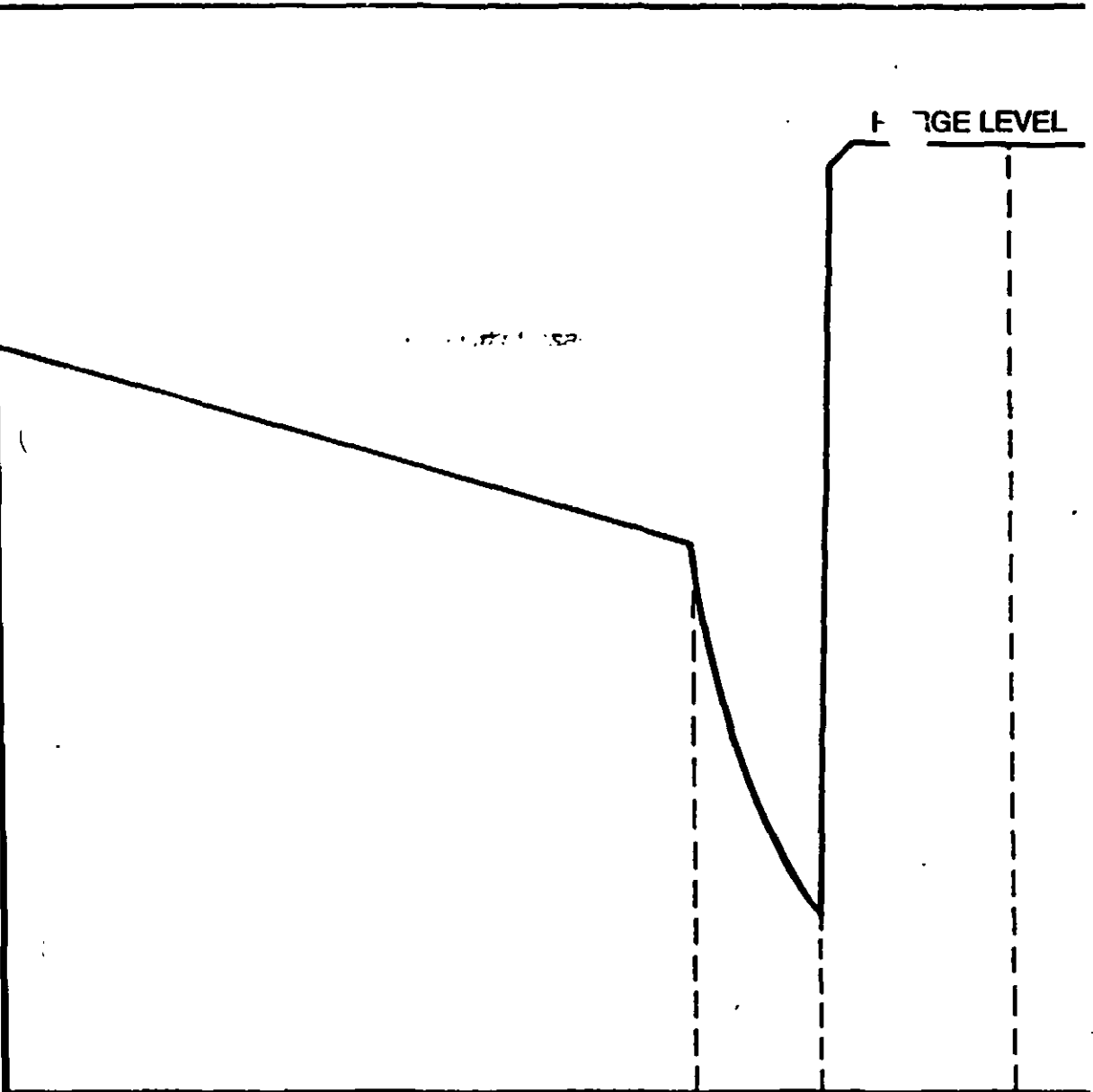
CYCLE EXPLANATION TIME AND PRESSURE DIAGRAM

D MODEL 4XL CYCLE EXPLANATION TIME/PRESSURE DIAGRAM

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7182-1

**GAS EXPOSURE**  
 62 MINUTES WARM CYCLE  
 250 MINUTES COOL CYCLE  
 (THE CHAMBER IS MAINTAINED AT A NEGATIVE PRESSURE DURING THE ENTIRE CYCLE, I.E. PRESSURE IN MBARS WILL NEVER EXCEED 80 MBARS BELOW ATMOSPHERIC PRESSURE  
 WARM CYCLE TEMPERATURE = 55°C (131°F)  
 COOL CYCLE TEMPERATURE = 37°C (99°F)  
 CYCLE TEMPERATURES WILL BE DIFFERENT IN SOME COUNTRIES.

**FINAL VACUUM**  
 TYPICALLY 10 MINUTES

**FRESH AIR PURGE**  
 15 MINUTES

**DOOR OPEN OR AERATION MODE**

**CYCLE COMPLETE CONTINUOUS AERATION**

19. CAUTION/ERROR MESSAGE EXPLANATION

Use the following chart to determine the cause of a caution/error message appearing in the digital display. Follow the corrective steps designated. Call your 3M Service Representative when: (1) indicated below, (2) a code appears that is not listed below, or (3) you have any questions.

Be alert to any codes appearing. These indicate a problem or potential problem that requires corrective action. Refer to Section 16 for an explanation of the sterilizer controls associated with these codes.

Caution codes (e.g. c1), which appear as flashing messages, will not stop a cycle in progress. An operator must correct the problem, as indicated below, to clear the caution code.

Error codes (e.g. E10) appear as nonflashing error messages. The sterilization cycle in progress will stop. The cycle status lights will turn off and the STOP indicator will turn on. Follow the steps listed below to correct the problem and clear the code (see 16.2.10). Contact your 3M Service Representative if you have any questions.

Caution or Error Code	Message	Possible Reasons	Corrective Steps
<i>Caution Messages - Do Not Stop Cycle</i>			
c1	Low Air in Exhaust Hood	Fan Malfunction Duct Plugged/Disconnected Airflow Sensor Failure	Check Fan and Fan Belts Check Ductwork Call Service Representative
c2	Low Water During Standby	Reservoir Needs Water	Add Water
c3	Power Interruption	Power Outage	Cycle Resumes 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 Adjust Aeration Time
c6	Temperature Offset Error	Controller Board Note: Temperature control may be out of specification	Call Service Representative
<i>Self Test Errors Occurring on Power Up or at the Start of a Cycle</i>			
E1	Processor Memory Failure	Controller Board	Call Service Representative
E2	Program Memory Failure	Controller Board	Call Service Representative
E3	E <sup>2</sup> ROM Failure	Controller Board	Call Service Representative
E4	Chamber Temp Sensor Fail	Bad Sensor or Connection	Call Service Representative
E5	Heatsink Temp Sensor Fail	Bad Sensor or Connection	Call Service Representative
E6	Pressure Sensor Failure	Bad Sensor or Connection	Call Service Representative
E7	Pressure Fail w/Door Open	Bad Sensor or Connection	Call Service Representative
E8	Sensor Conversion Failure	Controller Board	Call Service Representative

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Caution or Error Code	Message	Possible Reasons	Corrective Steps
<i>Errors That are Detected Before Puncture</i>			
E10	Low Water	Water Reservoir Needs Water Float Switch Failure	Add Water to Reservoir Call Service Representative
E20	Chamber Needs to Cool Down	Tried to Run COOL Cycle Too Soon After WARM Cycle	Open Door, Let Chamber Cool
E21	No Vacuum	Blockage at Vacuum Port No Compressed Air Connection Defective Vacuum Pump	Clear Pkg. from Chamber Port Check Air Lines & Pressure Call Service Representative
E22	Initial Pumpdown Timeout	Improper Air Pressure	Check Air System
E23	Chamber Preheat Timeout	Chamber Too Cold Defective Temp. Control	Rerun Cycle Call Service Representative
E24	Heatsink Preheat Timeout	Chamber Too Cold Defective Temp. Control	Rerun Cycle Call Service Representative
E25	Interrogation #1 Over Temp	Heater Relay Failure Defective Temp. Control	Call Service Representative Call Service Representative
E26	Interrogation #1 Under Temp	Heater Relay Failure Defective Temp. Control Defective Controller Board	Call Service Representative Call Service Representative Call Service Representative
E27	Interrogation Pressure #1	Leak in Chamber Defective Pressure Sensor	Call Service Representative Call Service Representative
E28	No Water Injected	Reservoir Float Switch Stuck Water System Plugged	Add Water to Reservoir Call Service Representative
E29	Interrogation #2 Over Temp	Heater Relay Failure Defective Temp. Control	Call Service Representative Call Service Representative
E30	Interrogation #2 Under Temp	Heater Relay Failure Defective Temp. Control	Call Service Representative Call Service Representative
E31	Interrogation #2 Pressure	Leak in Chamber Defective Pressure Sensor	Call Service Representative Call Service Representative
E32	Door Unlocked	Door Latch Hung up on Bolt	Turn Handle Completely Vertical
E33	Latching Relay	Control Error Latching Relay Failure Controller Board Failure	Call Service Representative Call Service Representative Call Service Representative
E34	Door Open	Door Not Closed Defective Switch	Close Door - Rerun Cycle Call Service Representative
E40	User Interruption	User Pressed STOP Switch	Rerun Cycle
<i>Errors Found During Gas Exposure</i>			
E50	Empty Cartridge	Empty Cartridge Loaded Puncture Mechanism Failed	Use New Cartridge Call Service Representative
E51	Chamber Vacuum Leakage	Air Leak in Chamber	Call Service Representative
E52	Under Temperature Abort	Heater Relay Failure Defective Sensor Defective Controller Board	Call Service Representative Call Service Representative Call Service Representative
E53	Over Temperature Abort	Heater Relay Failure Defective Sensor	Call Service Representative Call Service Representative
E54	Extended Power Outage	Could Not Resume Cycle After Outage	Call Service Representative Rerun Cycle
E60	User Interruptic	User Pressed STOP Switch	Rerun Cycle

Caution or Error Code	Message	Possible Reasons	Corrective Steps
<i>Errors That Leave the Chamber Locked with Gas Possibly in the Chamber</i>			
E71	Final Pumpdown Timeout	Compressed Air Problem Vacuum System Failure	Correct and Press START Call Service Representative
E72	Obstructed Air Inlet	Bacterial Filter Plugged	Press START; if Code Repeats, Call Service Representative
E73	Pressure Sensor Out of Range	Sensor Failure/Controller Board	Call Service Representative
E75	Low Gas Injected	Partially Filled Cartridge Partially Punctured	Call Service Representative Call Service Representative
E76	Latching Relay Won't Reset	Latching Relay Failure Door Handle Binding	Call Service Representative Turn Handle Clockwise and Press START
		Compressed Air Problem	Correct and Press START

**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 to the latched position and pressing the STOP switch.

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## 20. CUSTOMER MAINTENANCE

### 20.1 Cleaning

Clean the following parts of your Steri-Vac 4XL gas sterilizer at least weekly, preferably daily, with a mild soap and warm water. Use a damp cloth.

- 20.1.1 chamber floor and walls
- 20.1.2 outer chamber lip, and door gasket
- 20.1.3 inner door surface
- 20.1.4 outer cabinet

Clean and polish the stainless steel door daily. 3M Stainless Steel Cleaner and Polish, available from 3M Building Service and Cleaning Products Division, is recommended.

### 20.2 Servicing Filters, Moisture Trap, and Vent Line

#### 20.2.1 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.

#### 20.2.2 Vent Line Moisture Trap (if applicable)

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



These filters are provided for precautionary purpose only and not as a replacement for a clean air supply that meets the specifications listed. 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 complete air supply meeting such specifications.

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## 21. 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 nationwide service organization to provide factory-trained technicians to care for your equipment. Contact your local 3M Service Representative or the 3M Service Center at the following address for servicing information.

3M Medical-Surgical Service Center  
 Building 582-1E-02, 3M Center  
 St. Paul, MN 55144-1000  
 612/733-7865

Outside the USA, contact your 3M Medical-Surgical Representative or the nearest 3M office.

## 22. PREVENTIVE MAINTENANCE AGREEMENT

For your convenience, 3M provides maintenance agreement (PMA) for purchase with the Steri-Vac equipment. The PMA assures you of periodic checks of your sterilizer and emergency coverage. Contact your local 3M Service Representative or the Service Center for PMA information.

## 23. SERVICE MANUAL

A Service Manual for the Steri-Vac 4XL 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 Service Center. Outside the USA, contact your 3M Medical-Surgical Representative to determine if a manual is available

# Steri-Vac 4XL Printer Operating Instructions

## 1. DESCRIPTION

The Model 412 printer is a thermal printer requiring no ink or ribbon. 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.

The Model 412 printer is built into the Steri-Vac Model 4XL and is located in the front of the sterilizer immediately beneath the operator control panel and behind the printer/water supply access door. (Figure 1).

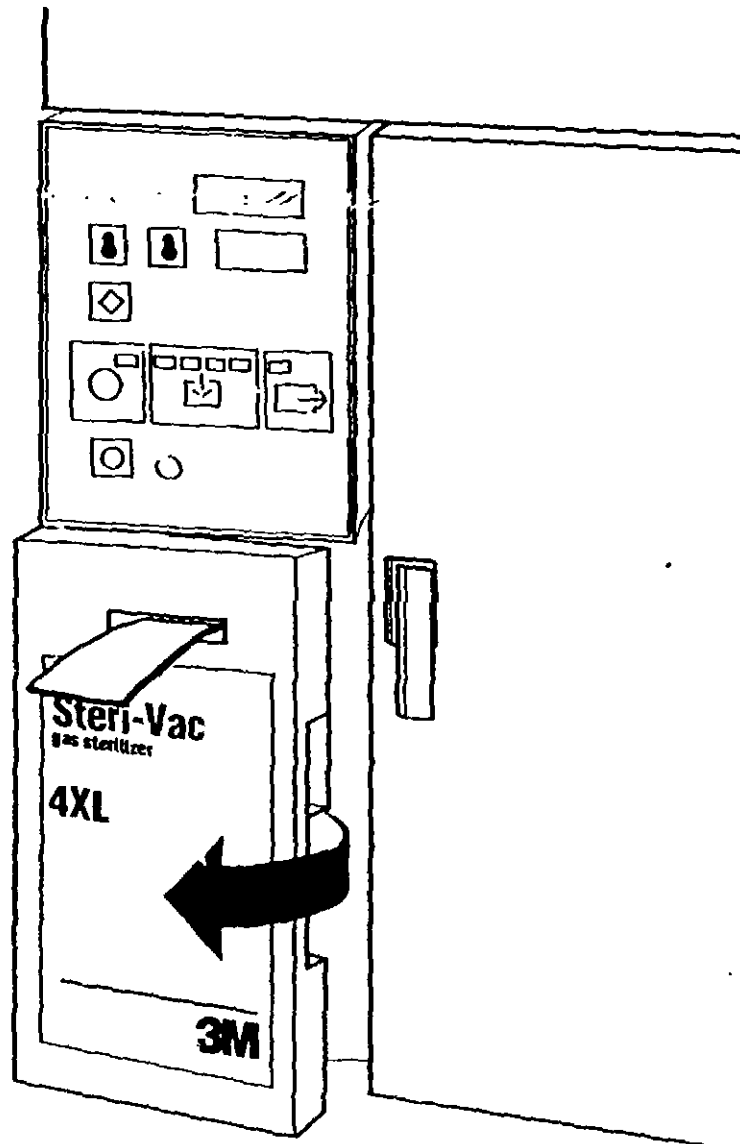


Fig. 1. Location of Model 412 Printer

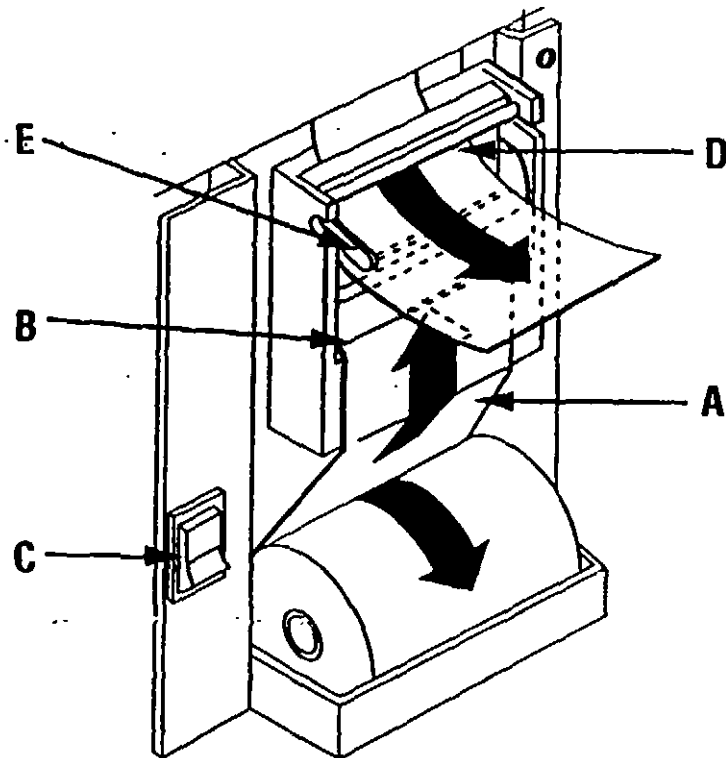


Fig. 2. Paper Loading

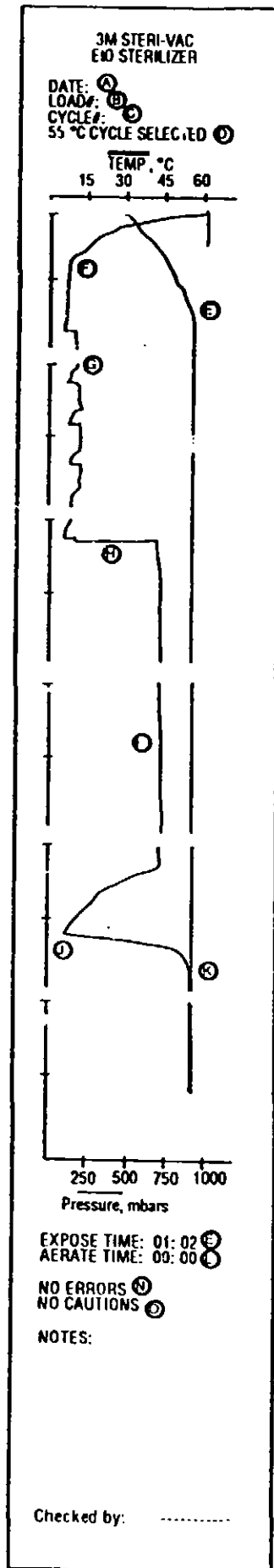
## 2. PAPER LOADING

Loading the printer paper is a very easy operation and should be done as indicated in Figure 2.

Note: Letters in text correlate with letters in Figure 2.

- A. Place roll in tray so that paper rolls off back of roll as shown.
- B. Make sure printer roller tension lever is in the "down" position.
- C. Hand feed paper into lower paper slot.
- D. Push printer rocker switch into feed position and hold it in this position until about four (4) inches of paper advances from the upper paper slot. (D)
- F. Feed paper through slot in door as the door is closed.

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Fig. 3. Print-out



### 3. PRINTER OPERATION

Verify that the 4XL gas sterilizer is turned on. Open the printer/water supply door of the 4XL gas sterilizer and verify that it is loaded properly (B). Before cycle starts, turn on the printer by switching the printer On/Off/feed rocker switch to the On position (C). Close the compartment door. Feed the printer paper through door slot while closing the door. The printer will start its print-out once a sterilization cycle begins.

### 4. PRINT-OUT

The print-out indicates various cycle parameters with a graph and alpha-numeric characters. Figure 3 shows a print-out of a typical sterilization cycle.

#### Detail of Print-out

- A. Date: To be filled in by operator
- B. Load #: To be filled in by operator
- C. Cycle #: Indicates the total number of cycles run
- D. Selected cycle temperature in degrees Celsius
- E. Cycle temperature in graphic form
- F. First vacuum pump-down
- G. Precondition phase (water injection)
- H. EO gas injection
- I. Exposure phase
- J. Final pump down
- K. Purge
- L. Total exposure time
- M. Total aeration time
- N. Error codes displayed during the cycle
- O. Caution messages displayed during the cycle

### 5. PRINTER PAPER ORDERING INFORMATION

Replacement paper can be ordered through:

3M Service Center  
Building 582-1E-02  
St. Paul, MN 55144-1000  
(612)733-7865

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Part No.	Description
70-2005-4368-7	Paper rolls for Model 412 printer Dimensions: 2.375in x 100 ft. Two rolls per package

**NOTE:** Do not attempt to use any paper other than that specified. Paper other than that specified may cause damage to the printer. Do not touch the print head with any foreign objects.

119 54 119

70-2008-1409-6

Litho in U.S.A.

**Medical-Surgical Division/3M**


St. Paul, MN 55144-1000

The 3M logo is rendered in a large, bold, black sans-serif font. The '3' and 'M' are connected, with the '3' having a distinctive shape where the top and bottom curves meet at the sides.

Date of Draft: December 17, 1986

DRAFT LABEL TEXT

REASON TO ISSUE: To update the site/pest statement adding the words "... for ethylene oxide sterilization..." and to add the word "sterilizers" after STERI-VAC 400 AND 400B as shown on the draft text below.

**INSERT THIS END** 

**Steri-Gas**

**Cartridge 4-134**

Active Ingredient: Ethylene Oxide 100% • Net Wt 127 grms (4.50 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. Reuse empty Steri-Gas cartridges. After aeration, dispose of immediately with normal nonincinerated waste.

**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 ON STERI-VAC 400 AND 400B STERILIZER

ETHYLENE OXIDE VAPOR HARMFUL MAY CAUSE BURNS

Keep Container Closed-Avoid Breathing Vapor.  
Avoid inhalation and contact with skin or eyes.  
In case of contact remove contaminated clothing and flush skin or eyes with plenty of water.  
For eyes get medical attention. Avoid contact with oxidizing materials.

This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical and industrial use areas.

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

**3M**

RED on WHITE

WHITE on BLACK

BLACK on WHITE

RED on WHITE

BLACK LETTERING

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

**BLACK LETTERING**

RED LETTERING (CAPS ONLY)

RED LETTERING

**ACCEPTED**

FEB 1987


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registered under  
EPA Reg. No. 7182-1

**BEST AVAILABLE COPY**

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DRAFT LABEL TEXT

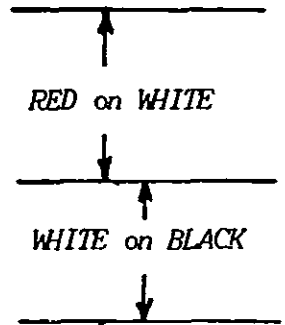
REASON TO ISSUE: To add the following site/pest statement to the label on the cartridge: "This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical and industrial use areas."; and to add the word "sterilizers" after STERI-VAC<sup>®</sup> 202 AND 202B.

**INSERT THIS END** 

**Steri-Gas 3M**

**Cartridge 2-67**

Active Ingredient Ethylene Oxide 100%  
Net/Wt 67 gms (2.37 oz)



RED LETTERING (CAPS ONLY)

**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.

BLACK LETTERING

**DANGER—EXTREMELY FLAMMABLE  
DO NOT USE NEAR FIRE OR FLAME**

NYFDC nIA No 933

USE ONLY IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS IN STERI-VAC<sup>®</sup> 202 AND 202B STERILIZERS.

ETHYLENE OXIDE VAPOR HARMFUL - MAY CAUSE BURNS

Keep Container Closed - Avoid Breathing Vapors. Avoid inhalation and contact with skin or eyes. In case of contact remove contaminated clothing and flush skin or eyes with plenty of water; for eyes get medical attention. Avoid contact with oxidizing materials.

This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical and industrial use areas.

RED on WHITE

BLACK LETTERING

RED LETTERING

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

E.P.A. Reg. No. 7132-1  
E.P.A. Est. No. 3657-WI-2

BLACK LETTERING

ACCEPTED


FEB 18 1987

EPA Reg. No. 7182-1

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DRAFT LABEL TEXT

REASON TO ISSUE: To update the site/pest statement adding the words "... for ethylene oxide sterilization..." and to add the word "sterilizers" after STERI-VAC<sup>®</sup> 400C AND 4XL as shown in the draft text below.

**INSERT THIS END** 

**Steri-Gas** **3M**

**Cartridge 4-100**

Active Ingredient: Ethylene Oxide 100% • Net Wt 100 g

**GREEN LETTERING (CAPS ONLY)** • **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.

**DANGER—EXTREMELY FLAMMABLE**  
**DO NOT USE NEAR FIRE OR FLAME**  
 NYFDC of A No. 933

USE ONLY IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS IN STERI-VAC<sup>®</sup> 400C AND 4XL STERILIZERS  
 ETHYLENE OXIDE VAPOR HARMFUL - MAY CAUSE BURNS

<p>Keep Container Closed—Avoid Breathing Vapor.          Avoid inhalation and contact with skin or eyes.          In case of contact remove contaminated clothing and flush skin or eyes with plenty of water:          for eyes get medical attention. Avoid contact with oxidizing materials.</p>	<p>This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical and industrial use areas.</p>
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GREEN on WHITE

WHITE on BLACK

BLACK ON WHITE

GREEN on WHITE

BLACK LETTERING

GREEN LETTERING

Medical-Surgical Division/3M  
St. Paul, MN 55144 Made in U.S.A.  
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E.P.A. Reg. No. 7182-1  
E.P.A. Est. No. 3657-WI-2

BLACK LETTERING

**ACCEPTED**

FEB 18 1987

Registered under EPA Reg. No. 7182-1

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