MAR 18 1992

Medical-Surgical Division
3M Health Care
3M Center Bldg. 270-4N-01
Saint Paul, Minnesota 55144-1000

Attention: Marvin L. Hart

Subject: Steri- Gas Brand Cartridges, Steri-Vac Sterilizer
EPA Registration Number 7128-1
Your Submission Dated October 15, 1991
EPA Received Date October 22, 1991

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, Rodenticide Act is acceptable.

The revised Confidential Statement of Formula agrees with the label and is acceptable.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-305-6966.

Sincerely yours,

John H. Lee
Product Manager-31
Antimicrobial Program Branch
Registration Division (H7505-C)

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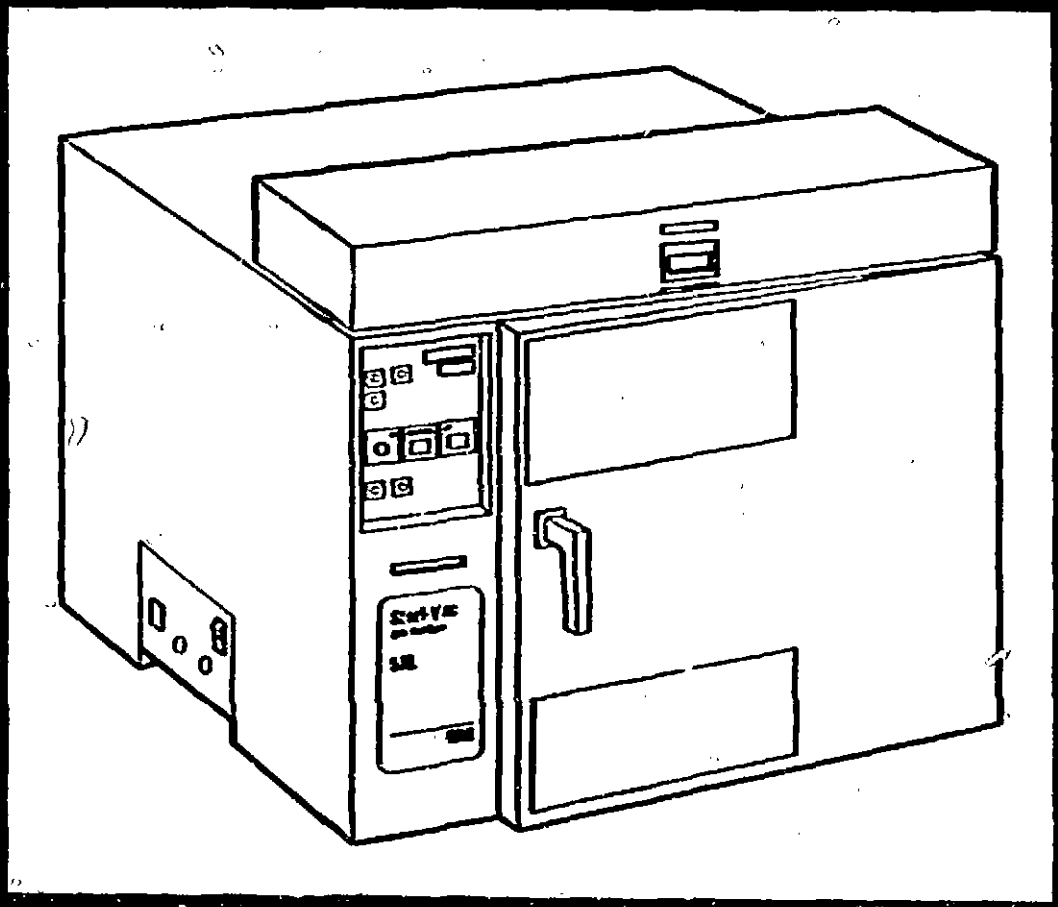
SURNAME								
DATE								

EPA Form 1 [illegible] (12-70)

5XL Gas Sterilizer/Aerator



Operator's Manual

EPA Reg. No. 7182-

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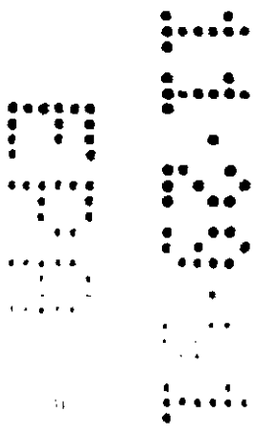

I. Introduction

Health and Safety Information

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⚠ 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 over exposures 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

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Boiling Point:	10.7°C (51.3°F)
Vapor Pressure:	1094 mm Hg at 20°C (457 g/cm² 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
- 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.

BEST AVAILABLE COPY

Sterilizer Listings

The Steri-Vac 5XL gas sterilizer/aerator 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 (17 in)	82.6 cm (32.5 in)	38 cm (15 in)	96.5 cm (38 in)

Basket Dimensions

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

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: 127 kg (280 lb.)
Shipping Weight: 145 kg (320 lb.)

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

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

Compressed Air Requirements

Air Pressure:

3.5 Kg/cm^2 (50 psig) minimum

10.5 Kg/cm^2 (150 psig) maximum

Airflow: 3.4 liters/second (7 scfm) at 3.5 Kg/cm^2 (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.

⚠ DANGER

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.

Water Requirements

No external water connection. The operator adds 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)*

Airflow Through Hood:
283 decaliters/min (100 scfm)

Air Velocity in 10.2 cm (4 in) Line to Hood
[illegible] (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.

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 and on the label of each Steri-Gas 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 5XL gas sterilizer. Follow the instructions listed in the Steri-Gas Consumer Product profile, (see Accessory Section), for handling underweight cartridges.

Insert a Steri-Gas cartridge 4-100 into its holder inside the chamber. Push the cartridge down and slightly inward until the cartridge is seated, do not attempt to force the cartridge into its holder if you can feel a clear resistance. The green label on the cartridge matches the green retainer ring of the holder.

⚠ DANGER

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

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.

7182-1

II. Sterilizer Operating Procedure

Notice: User Responsibility

Only healthcare professionals or other appropriately trained personnel in health care and industrial use areas should use this equipment. It is a violation of Federal Law (USA) to use this product in a manner inconsistent with its labeling. Injury to 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 to monitor the operation continuously. The sterilizer will be in standby except during sterilization or aeration.

Load the Baskets

Thoroughly wash and rinse all items to be sterilized to remove any mucous, 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. An 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 chamber 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

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.

Open Door—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.

Open Door—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 while lifting the DOOR RELEASE on the exhaust hood.

The sterilizer has the following 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 manufacturer's recommendations for aeration time and temperature.

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

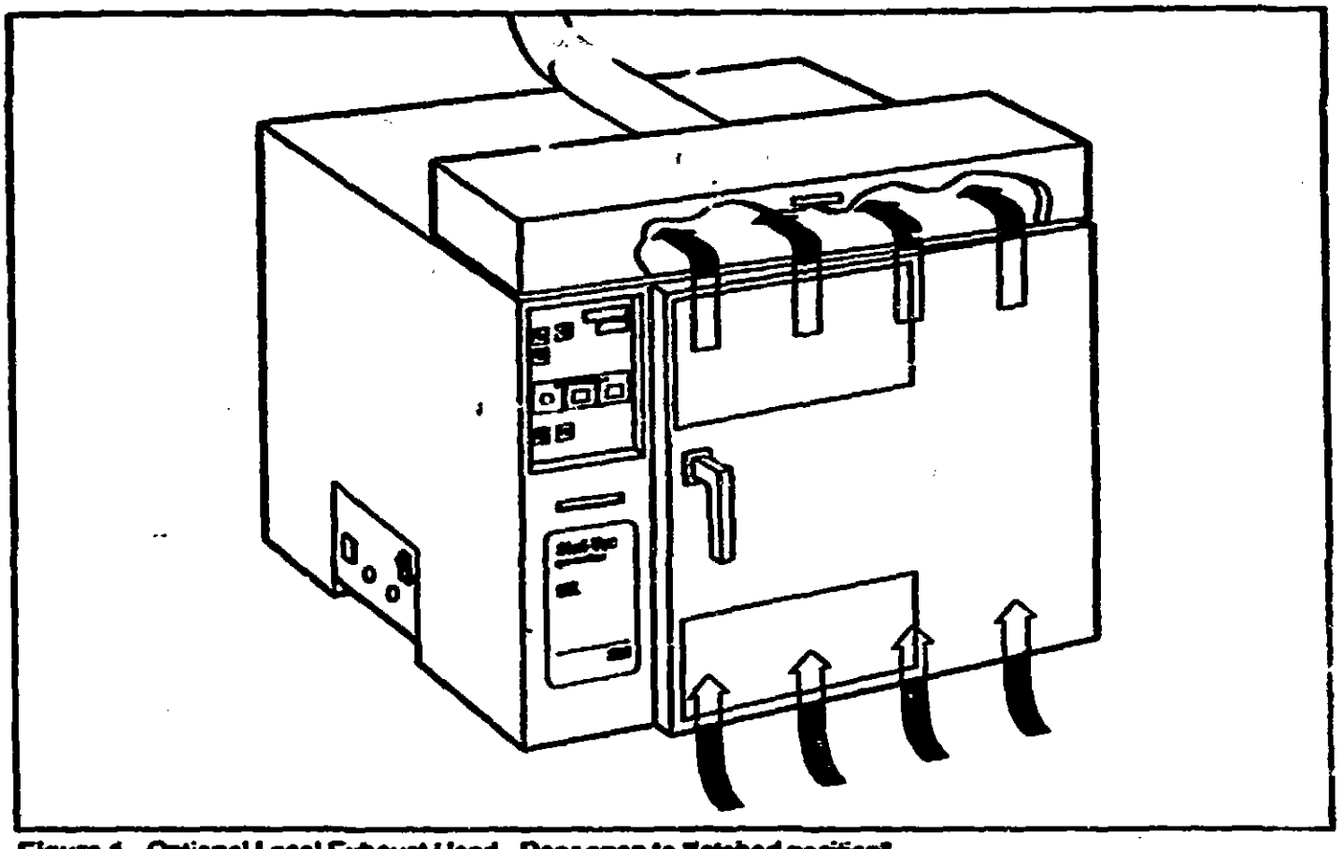

Figure 1. Optional Local Exhaust Hood. Door open to "latched position".

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 indicato Quickly transfer the basket of unaerated or incompletely aerated items to an aeration cabinet.

Terminate 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.

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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 prepackaged, 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 during 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

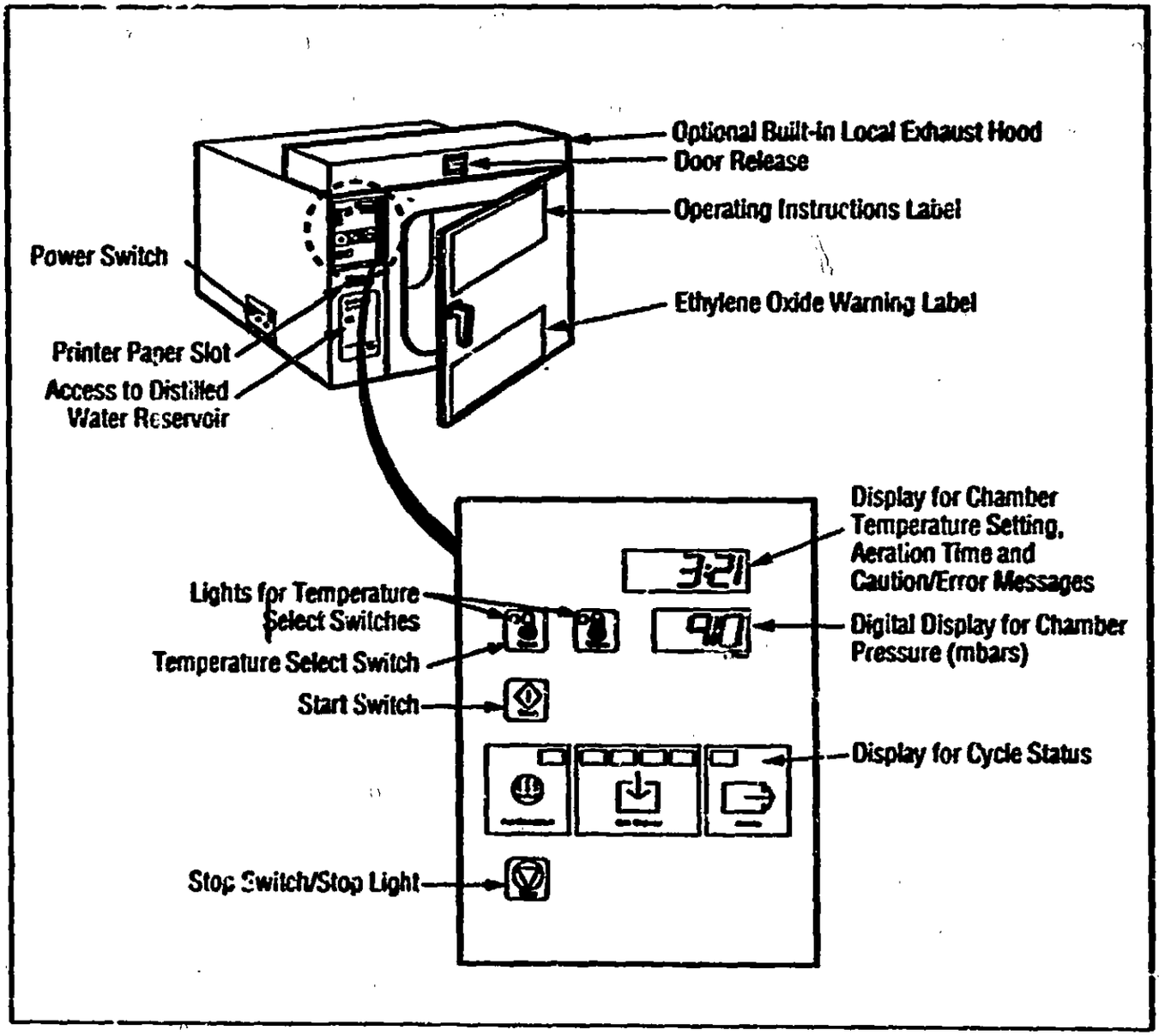

Figure 2. Sterilizer controls.

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 the selected sterilization temperature.

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 approximately equals 1 atmosphere at sea level.)*

Temperature Select Switch Light
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.

PRE-CONDITION Status Light
Indicates the beginning of a sterilization cycle during which vacuum is drawn, the chamber is heated and goods are humidified. There is no gas in the chamber during this phase.

GAS EXPOSE Status Lights
Indicates the presence of EO in the chamber. This includes cartridge puncture, gas expose time, final vacuum and fresh air purge. The four status lights each represent approximately 25% of this phase.

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.

Explanation of the Sterilization Stages

1. 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 35% 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.

2. 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

3. 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.

4. 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.

5. 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 and aeration time than the COOL cycle.

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

6. PRE-CONDITION
The sterilizer locks the door and begins to precondition the load for sterilization. The

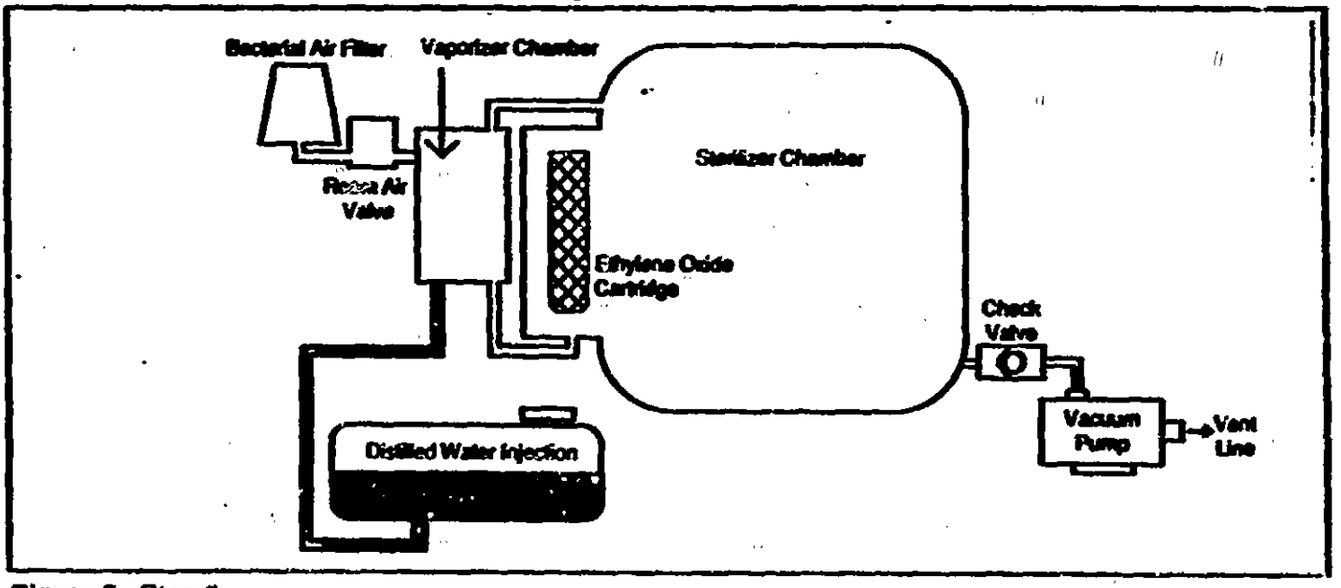

Figure 3. Standby.

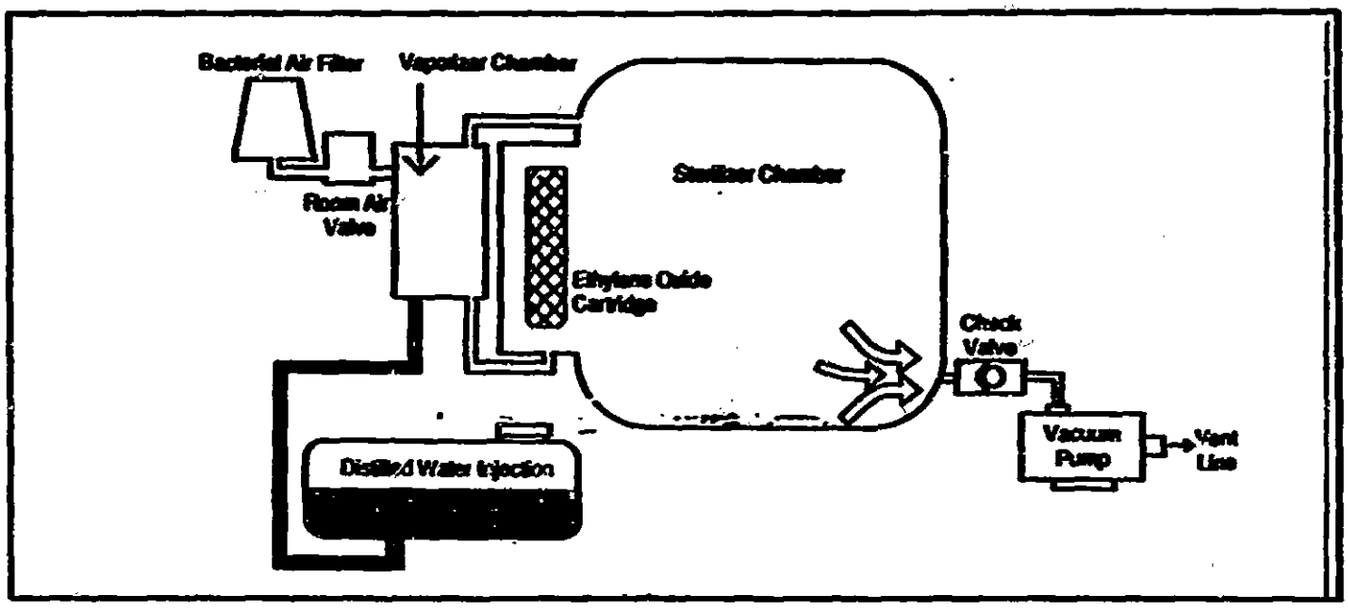

Figure 4. Initial vacuum.

PRE-CONDITION phase takes approximately 45 minutes and establishes chamber vacuum, temperature and humidity.

7. 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.

8. 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.

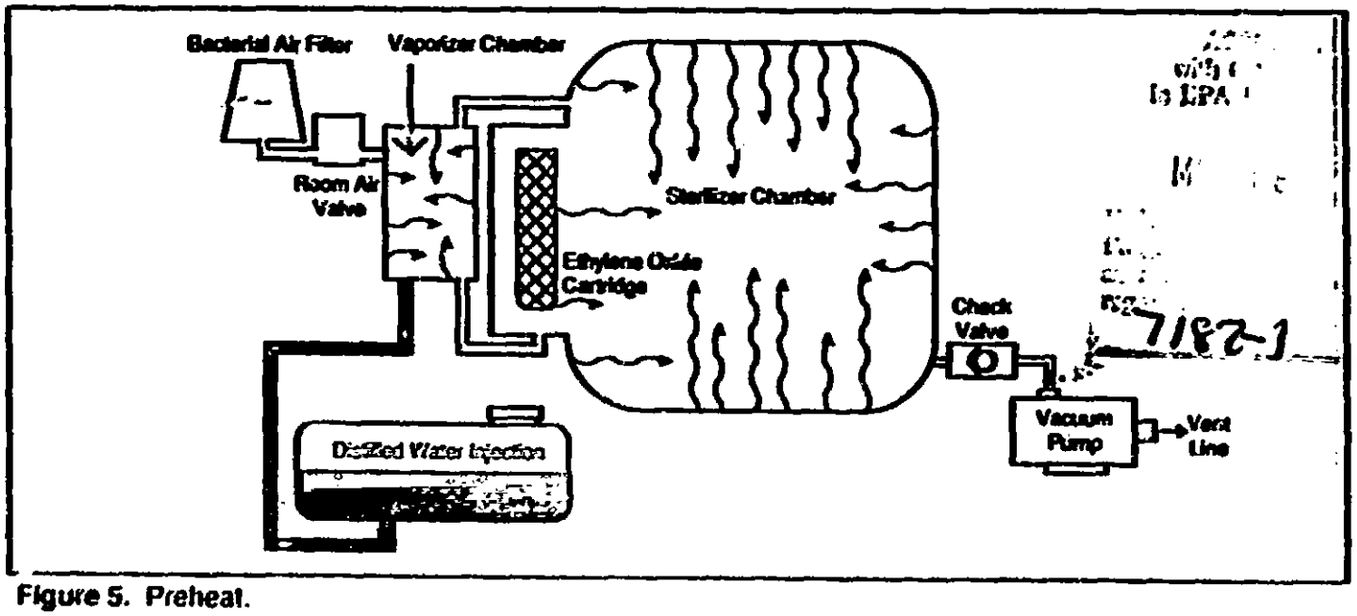

Figure 5. Preheat.

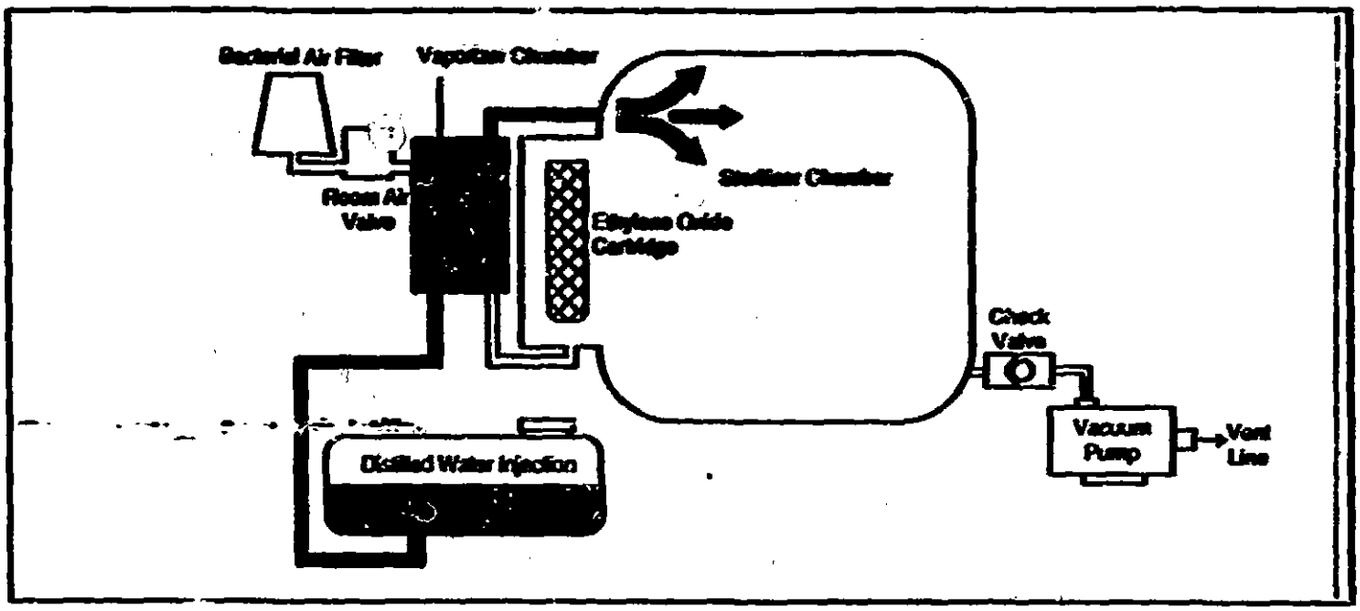

Figure 6. Humidification.

9. 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 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.

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10. 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	Approximate Time In GAS EXPOSE
WARM	100 minutes
COOL	220 minutes

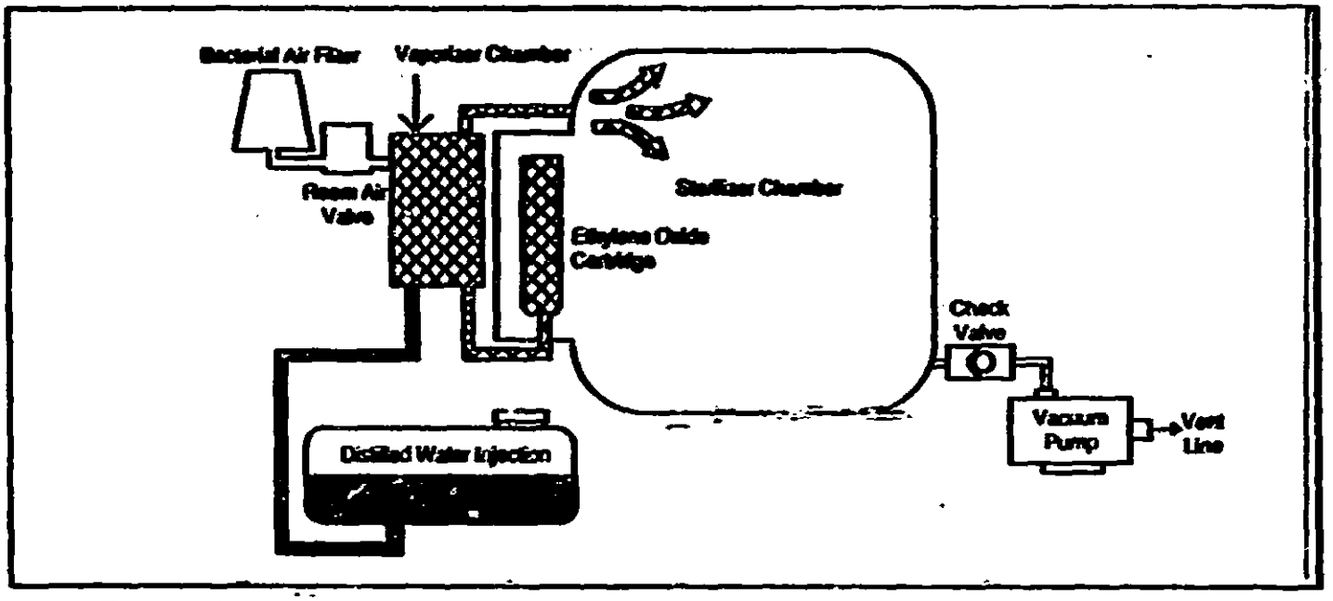

Figure 7. Gas injection.

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.

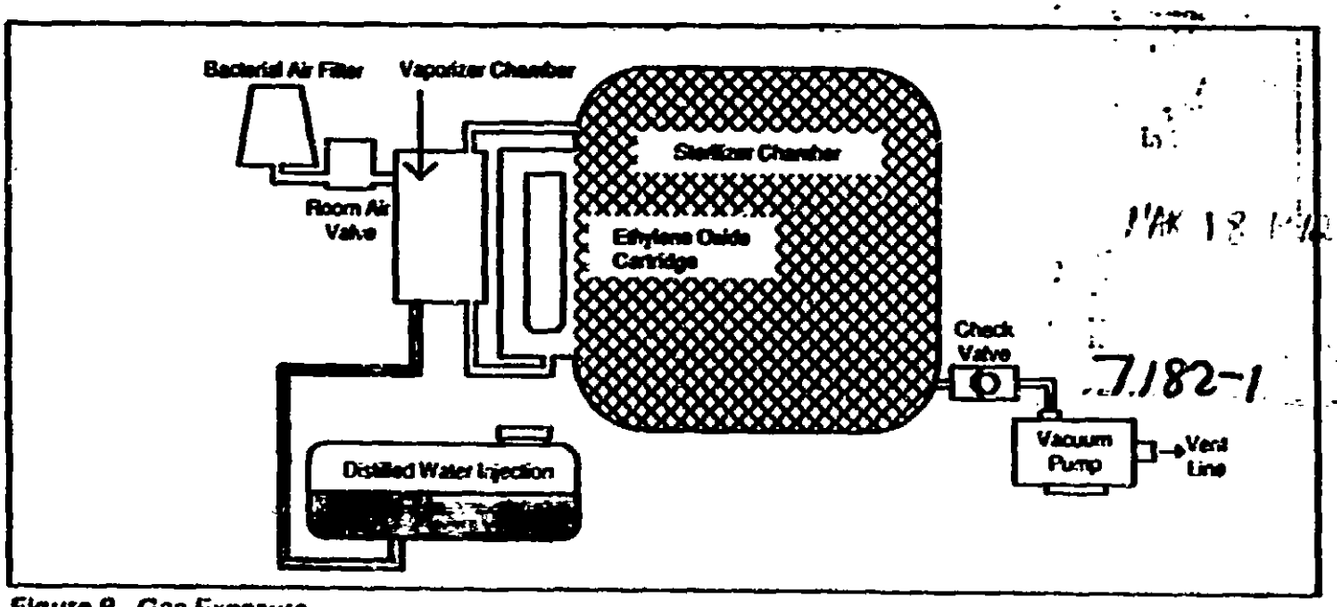

Figure 8. Gas Exposure.

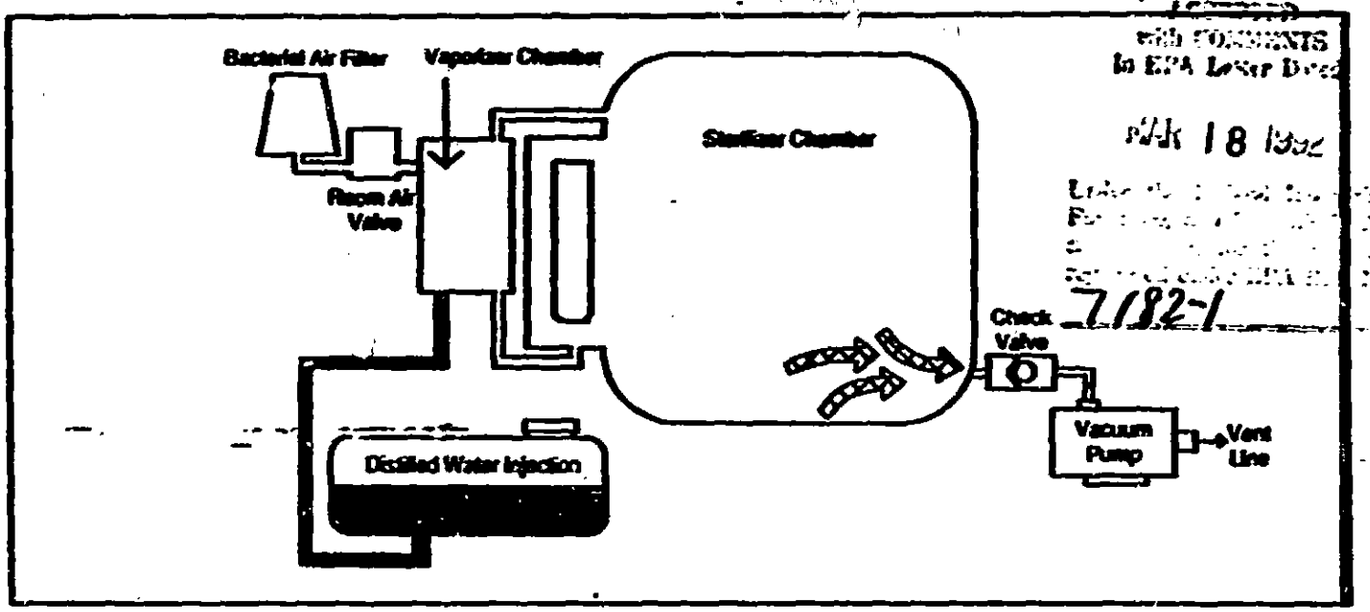

Figure 9. Final vacuum exhaust

Gas Exposure

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

11. 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.

12. AERATE

The Steri-Vac 5XL sterilizer/aerator 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

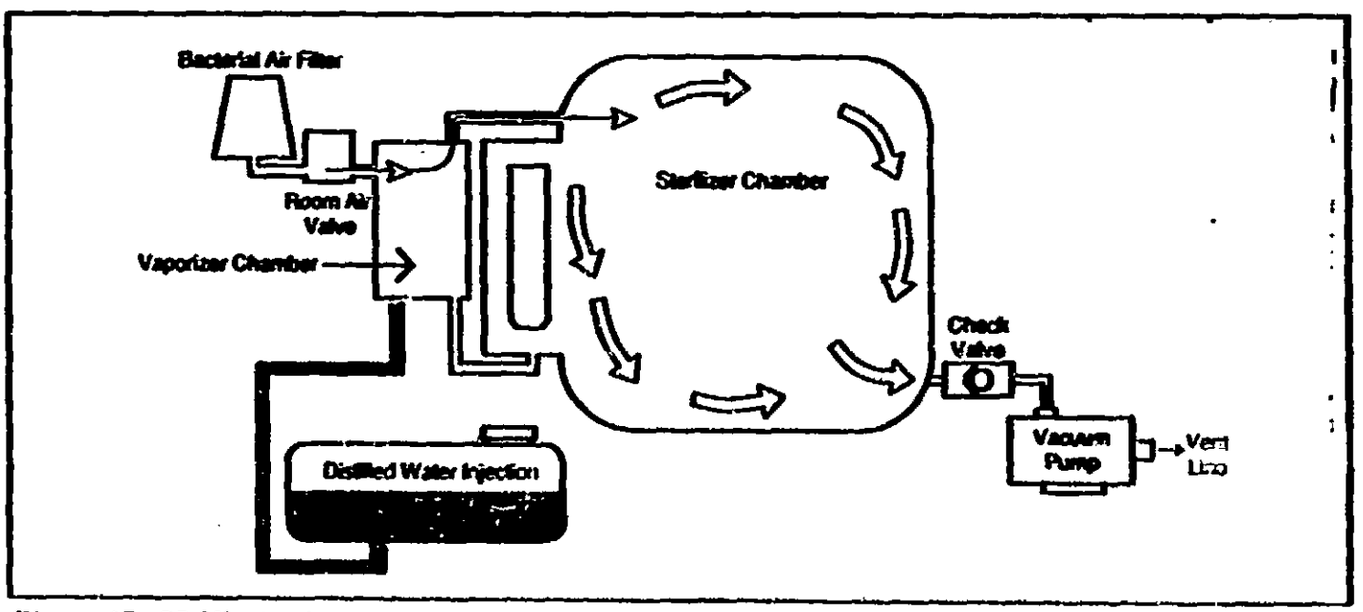

Figure 10. 30-Minute air purge

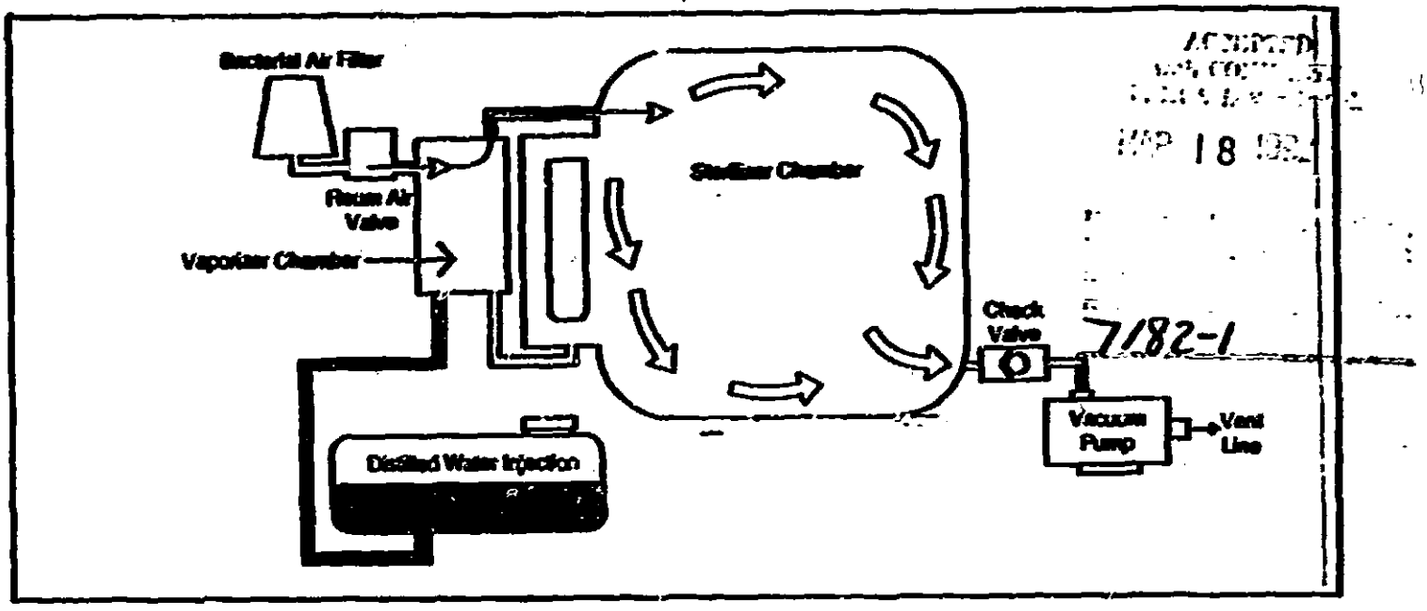

Figure 11. Continuous aeration—open door

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 gas 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 an incompletely aerated 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.

13. 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.

14. Ending the Cycle
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.

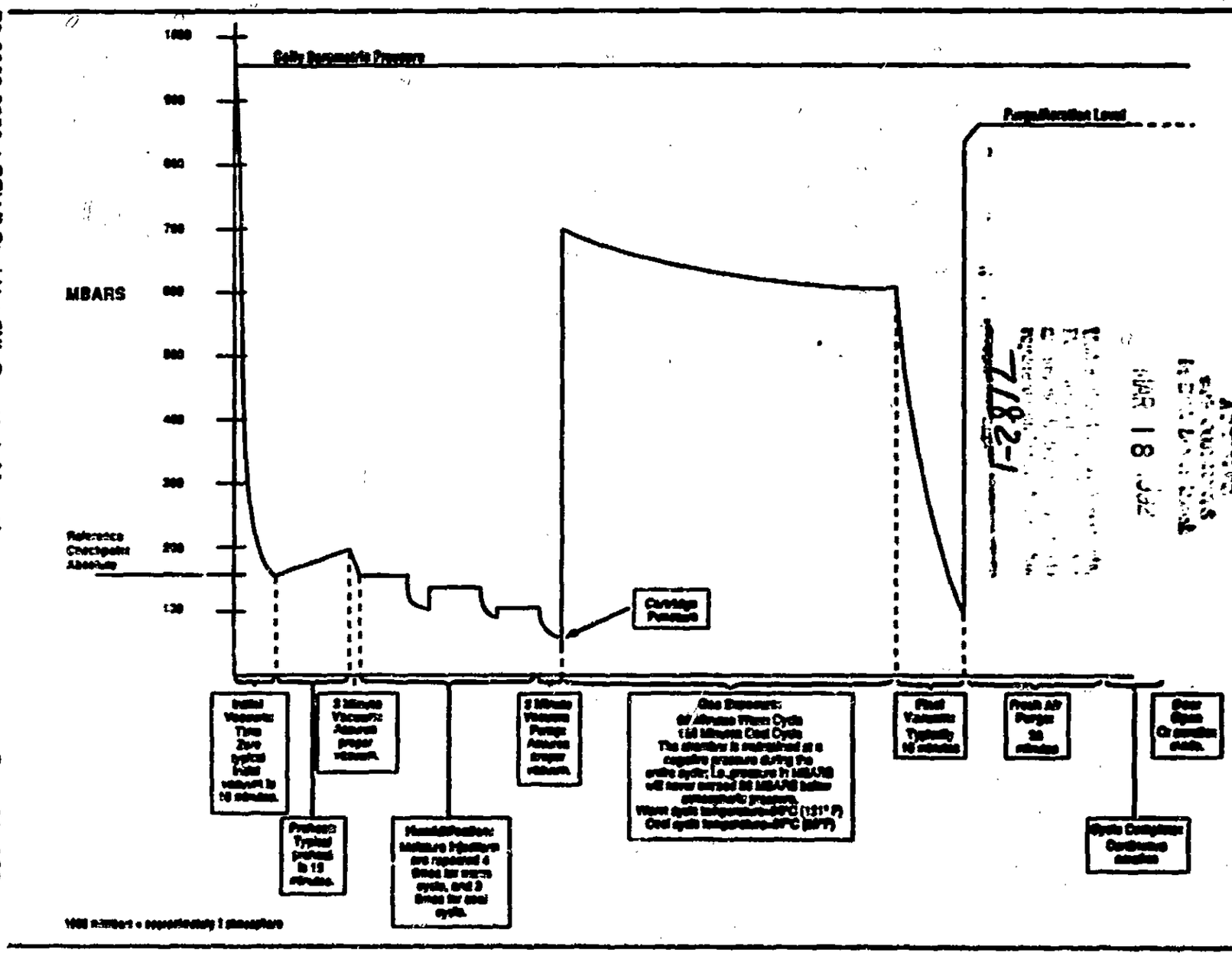

Figure 12. Time and pressure diagram.

Caution 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 or standby	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	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	Electronics	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	Recent warm cycle	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

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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

Caution and Error Codes Explanation
Use the 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 on the chart, if a code appears that is not listed, 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. The [illegible]

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.

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IV. Maintenance

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 Compressed Air Line Filters
Daily drain any moisture/oil that collects in the bottom of the air filter reservoirs. 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.

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.

⚠ DANGER

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.

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 55144-1000
(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.

V Accessory Equipment

Steri-Vac Printer Operating Instructions
The Steri-Vac printer is built into the front of the 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.

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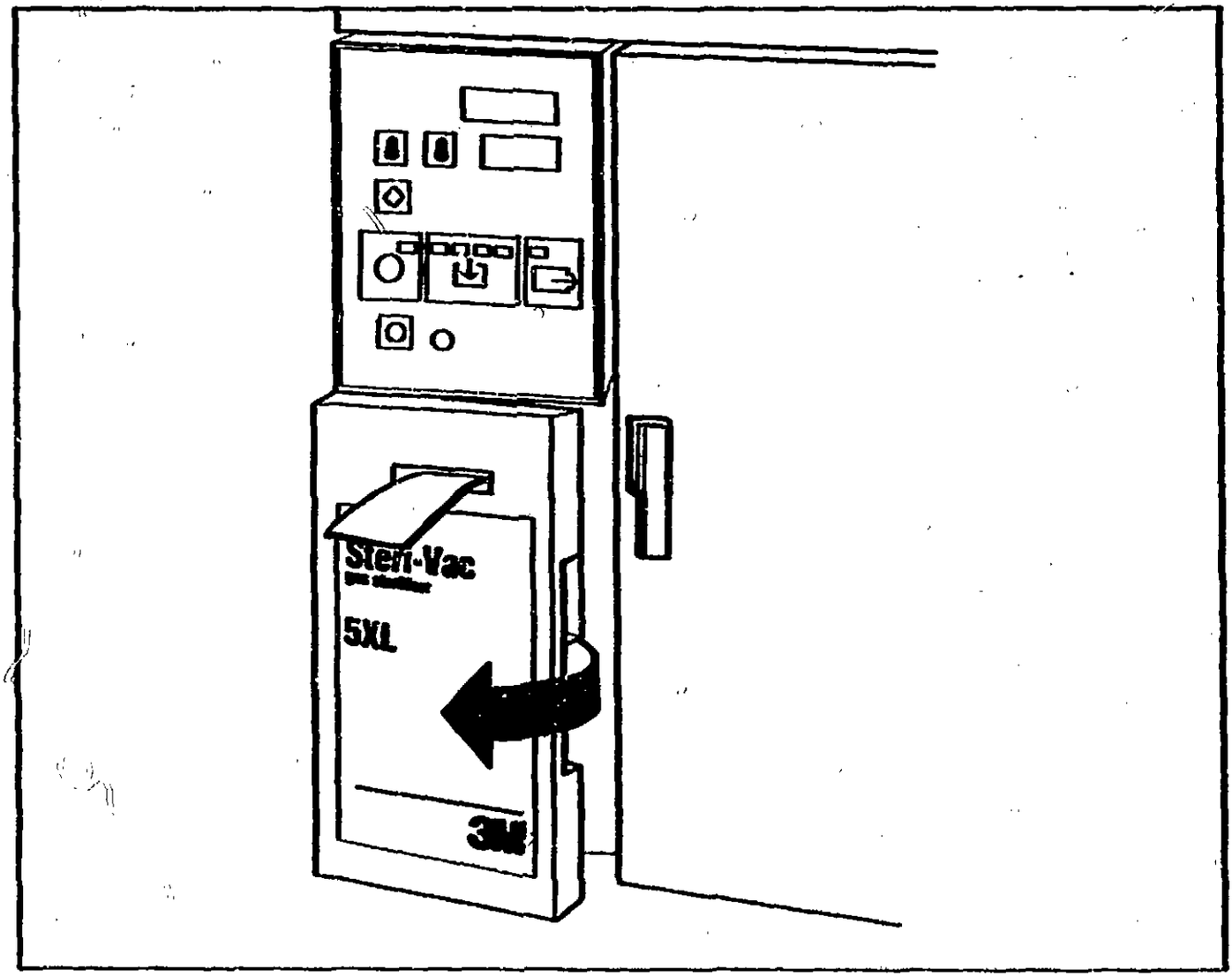


Figure 13. Printer Location.

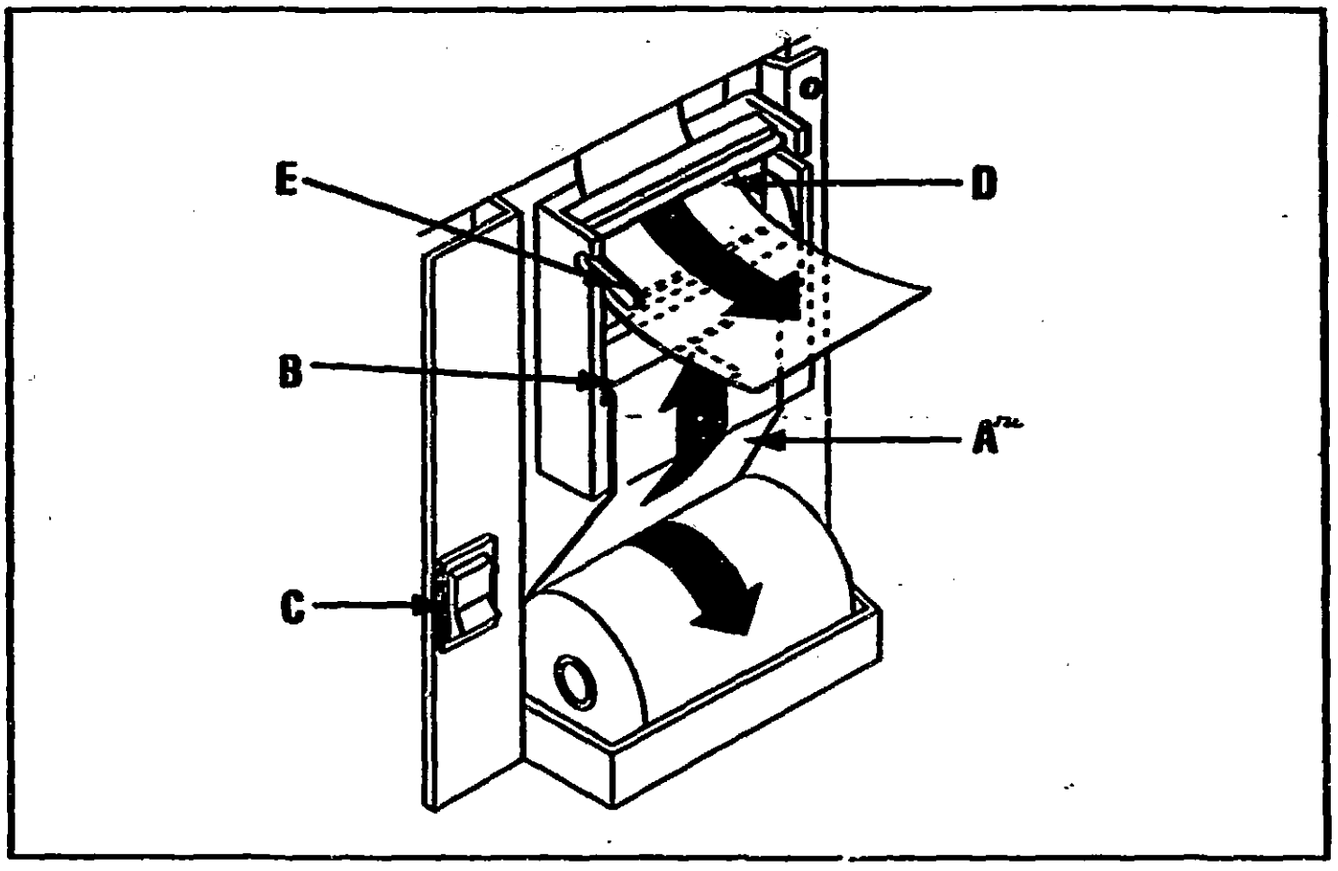


Figure 14. Loading the printer paper.

Paper Loading

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

1. Place paper roll in tray so that paper rolls off the back of the roll as shown (A).
2. Make sure printer roller tension lever (E) 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 in) of paper advances from the upper paper slot (D).
5. Feed paper through the slot in the door as the door is closed .
6. To obtain cycle printout, ensure that the printer power/control switch (C) is in the ON position before starting a cycle.

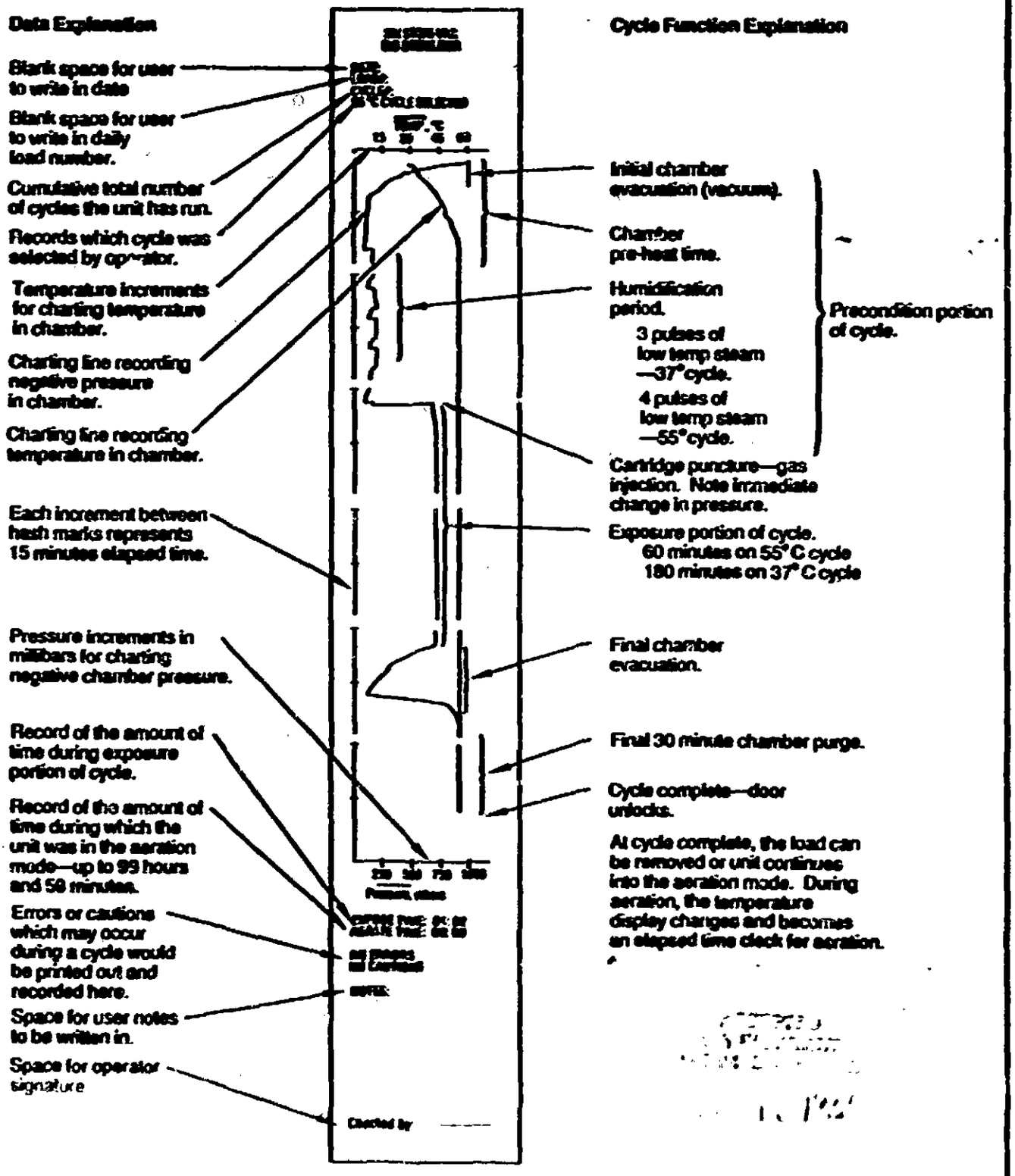


Figure 15. Printout explanation chart.

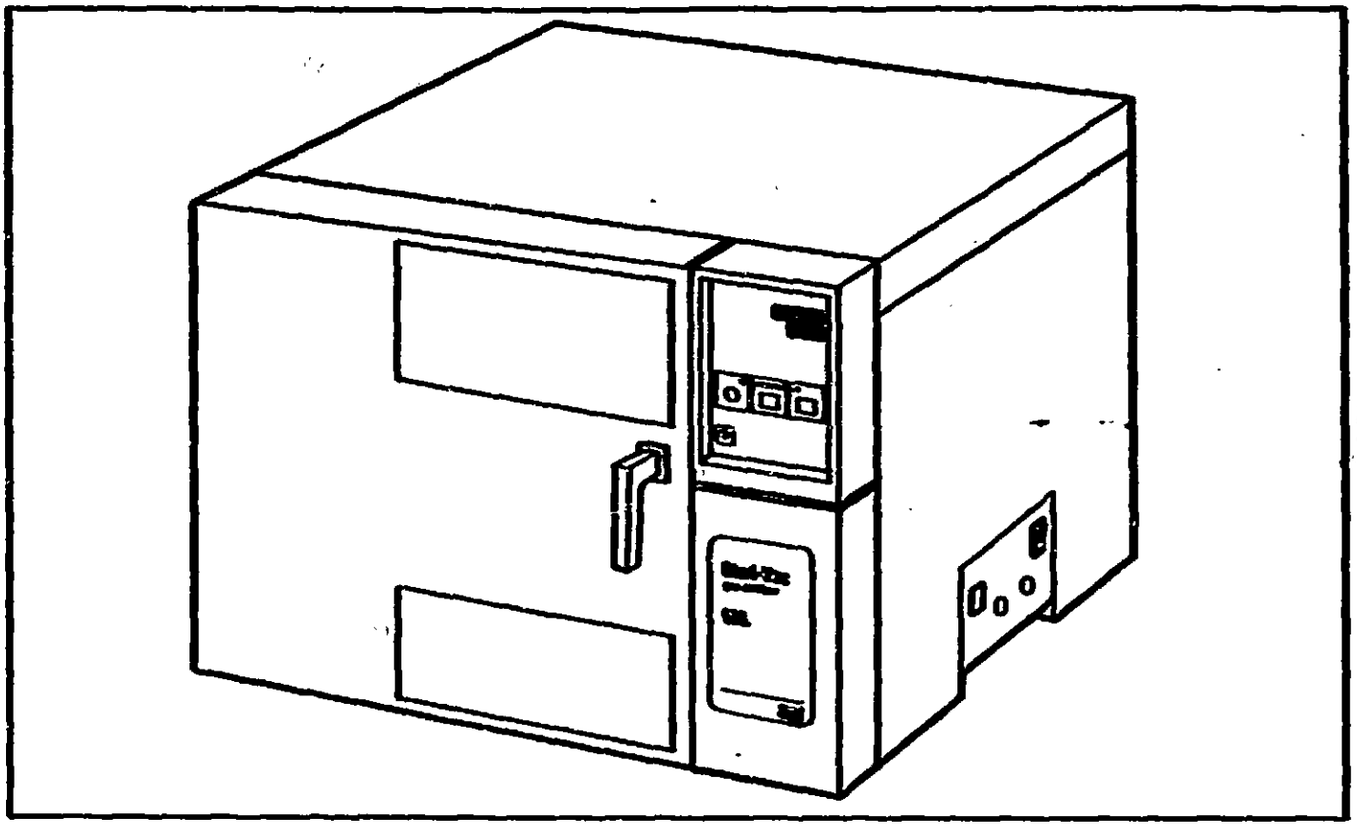


Figure 16. Unload side of two-door unit.

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 facility 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 operator for 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.

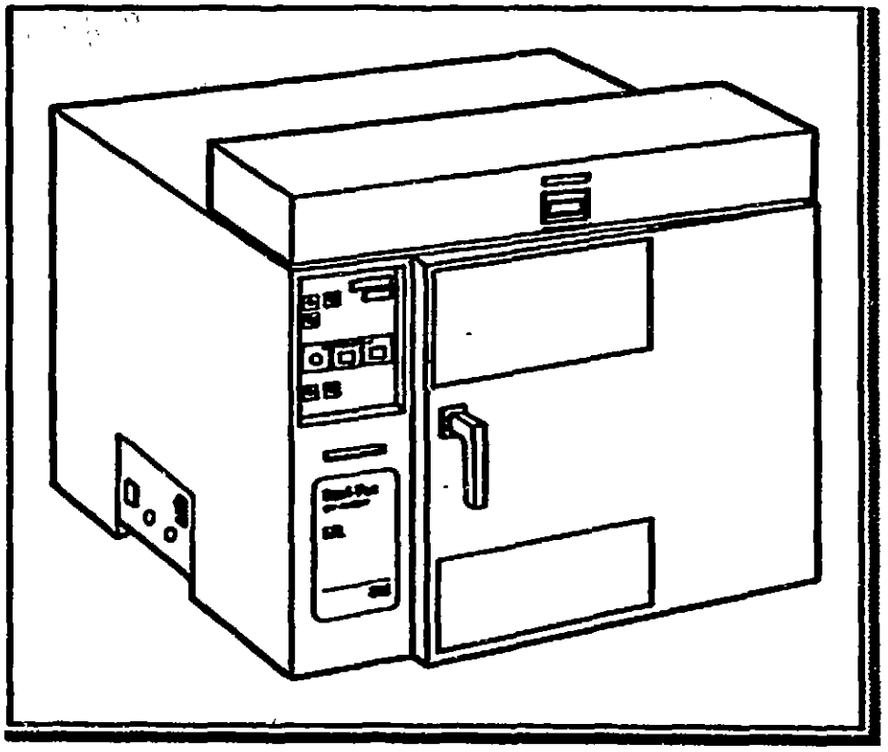
CAUTION!

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

Steri-Vac™

3M

5XL Gas Sterilizer/Aerator



Installation Guide

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WARNING
Due to the potentially hazardous nature of the chemical used in this sterilizer, it is imperative that the Steri-Vac 5XL gas sterilizer/aerator be installed in strict accordance to the installation requirements contained in this guide.

Caution
Hazardous Voltage

Refer installation and servicing to qualified persons.

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2.	3M Service Installation Review and Checkout	4
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1. Planning the Sterilizer Installation

Plan for the installation before the equipment is purchased. Consider such things as location, machine service requirements, Steri-Gas cartridge storage, accessories, and code compliance. Obtain all state and local regulations affecting the use of ethylene oxide (EO). If possible, review the proposed installation with the department manager, facility's engineer, architect, and 3M sales representative.

Ensure that anyone who will be involved with the sterilizer installation receives a copy of this Installation Guide. Contact your local 3M Medical-Surgical sales representative for additional copies. Contact the local 3M service representative if you have any questions about installing the sterilizer. If you need help contacting your local representatives, call your local 3M Medical-Surgical sales branch office or the 3M Medical-Surgical Service Center (612/733-7865).

2. 3M Service Installation Review and Checkout

Contact your local 3M service representative by phone when the sterilizer is installed (i.e., all electrical and mechanical services are connected and functioning). Do not operate the sterilizer without having a 3M service representative check the installation. Complete the Customer Checklist (Section 4) before calling your service representative to review the installation checklist with you and discuss any changes to be made before the checkout visit.

The 3M service representative will schedule the checkout visit to assure that the sterilizer is installed and operating according to 3M specifications. After the checkout, the service representative will:

- request you sign a checkout form
- inservice personnel on the proper operation of the sterilizer
- provide you with information on a Steri-Vac 5XL Gas Sterilizer/Aerator Operator Certification Program
- provide you with a completed Customer Service Order that includes the date the warranty takes effect

3. Optional and Accessory Equipment for the 5XL

These optional machine configurations and accessories should be considered during the planning of the sterilizer/aerator installation.

a. Dual doors for a pass-through installation (clean room concept).
b. Local exhaust hood(s) to allow load transfer into an aerator immediately after the end of the sterilization cycle.
c. Stacking racks for either in-wall or freestanding installations.
d. Installation kit that includes hardware required for proper connection of the sterilizer/aerator to the customer supplied vent and compressed air line.

4. Customer Checklist

Read this entire Installation Guide carefully before installing your Steri-Vac 5XL gas sterilizer/aerator. The following checklist is provided to ensure that you consider all important aspects of the installation. Section numbers are given for your reference. Contact your local 3M service representative or the 3M Medical-Surgical Service Center with any questions.

The completed checklist is to be used when contacting your 3M representative(s) to review your sterilizer installation. Completion will help ensure that 3M installation specifications are met.

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Customer Checklist

General

1. Did you obtain all state and local regulations affecting EO?
   _____Yes _____No

Electrical Supply *(Section 9)*

2. At what current is the sterilizer's electrical supply fused?
   _____AMP
3. What is the supply voltage rating?
   _____VAC
4. What is the voltage at the sterilizer?
   _____VAC
5. What is the lowest voltage the supply line drops to during peak usage periods?
   _____VAC

Vent Line *(Section 10)*

5. Does the vent go from the sterilizer to the outside atmosphere directly without being terminated into any existing ductwork, air flow system, or ventilation system?
   _____Yes _____No
6. What type of material is the vent line made of?
   _____
7. What is the total length of the vent line?
   _____
8. If the answer to the above question is greater than 91 m (300 ft), was the system approved by 3M?
   _____Yes _____No
9. What is the diameter in mm (in) of the vent line?
   _____O.D. _____I.D.
10. Does the vertical travel of the vent line exceed 3 m (10 ft)?
    _____Yes _____No
11. If "yes" to the above question, was a moisture trap installed?
    _____Yes _____No
12. If the vent line run is completely horizontal, how far does it extend outside the building?
    _____
    a. Does it have a downward bend?
       _____Yes _____No
    b. Is the vent outlet located within 7.6 m (25 ft) of any possible sources of ignition or any openings to the building interior (e.g., doors, fresh air, inlets, unsealed windows)?
       _____Yes _____No
13. Have you checked to ensure the vent line is gas-tight?
    _____Yes_____No

Customer Checklist (continued)

14. If the vent line extends through the roof, does it meet 3M installation requirements?
    _____Yes _____No
    a. Is it insulated?
    _____Yes _____No
    b. How far above the roof does it extend?
    _____
    c. Does it have a 180° bend?
    _____Yes _____No
    d. Is there a cupola over the vent line?
    _____Yes _____No

Compressed Air Line *(Section 11)*

15. What is the pressure rating of the compressed air source at the sterilizer at a minimum flow rate of 3.4 liters per second (7 scfm)?
    _____
16. What is the maximum supply line air pressure?
    _____
17. Is the air supply clean, dry and oil free?
    _____Yes _____No
18. If the air supply is not clean, dry and oil free, are proper filters installed?
    _____Yes _____No
19. Does the air enter into the filter through the port marked "IN"?
    _____Yes _____No
20. Are the filters accessible for maintenance?
    _____Yes _____No
21. Has a shutoff been installed upstream from the air filter so that air can be turned off for machine service?
    _____Yes _____No
22. If a dedicated compressor is used to supply air:
    a. What is the tank volume?
    _____
    b. At what pressure is the cut-in switch set?
    _____
23. Has an air pressure gauge been installed between the filters and the air inlet to the sterilizer?
    _____Yes _____No

Unit Location *(Section 8)*

24. Are there 51 cm (20 in) of clearance on the left side panel and the right side panel?
    _____Yes _____No
25. Are there 51 cm (20 in) of clearance on the top?
    _____Yes _____No

Customer Checklist (continued)

25. If either of the two questions above is answered "No," can the unit be moved so that those clearances are possible?
    _____Yes _____No
27. If the question above is answered "Yes":
    a. Has Coboflow™ stainless braided flexible tubing been used on the vent line?
    _____Yes _____No
    b. How long is the Coboflow tubing?
    _____
    c. Is there a flexible line used on the air service so the unit can be moved without disconnecting that service?
    _____Yes _____No
28. Has the unit been installed in a hazardous area where flammable gases or liquids other than EO are present?
    _____Yes _____No
29. What is the air exchange rate in the sterilizer room?
    _____air changes/hour
30. Is the unit located properly with respect to the intake and exhaust of the room's ventilation system?
    _____Yes _____No

Local Exhaust System (*Section 12, only applicable when unit is equipped with local exhaust hood feature*)

31. What volume of air does the local exhaust system provide to the hood?
    _____
32. What is the minimum static pressure in the hood created by the local exhaust system?
    _____
33. Is the ductwork material impervious to EO?
    _____Yes _____No
34. Is the outside diameter of the ductwork connection for the hood 102 mm (4 inches)?
    _____Yes _____No
35. What is the distance between the outside exhaust termination and any sources of building air intake?
    _____
36. Is the exhaust source spark-proof, suitable for continuous operation and protected from adverse weather?
    _____Yes _____No

NOTES:

5. Purchaser's Responsibility

NOTICE
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.

It is the purchaser's responsibility to provide the necessary machine service requirements to the area where the sterilizer is to be installed. These services consist of electricity, compressed air, and vent line. A dedicated exhaust system is required for installation of the local exhaust hood.

Because of varying local codes and labor policies, it is also the responsibility of the purchaser to locate the machine in its permanent location and to connect the services to the machine. For example, the state of California requires that seismic bracing be provided on the sterilizer. It is the purchaser's responsibility to ensure that state and local requirements are met.

NOTICE
Do not attempt to plug the cord into an outlet and operate the sterilizer until a 3M service representative has checked out the installation and inserviced the operators. Costly damage and hazard could result.

6. Sterilizer Listings

The Steri-Vac 5XL gas sterilizer/aerator is listed with 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.

7. Unpacking the Sterilizer

Unpack and inspect your sterilizer as soon as it arrives. Remove the shipping carton from the machine. To do this, cut the tape at each corner around the bottom edge of the carton, unfold the flaps and lift the carton off the machine. Examine the unit for damage and, if necessary, follow the instructions provided below for filing a damage claim.

Shipping Damage
Immediately inspect the sterilizer upon its arrival. Look for damage that may have occurred during transit. Immediately file a damage claim, if necessary, with the transportation company and notify your 3M sales or service representative. The transportation company assumes liability for shipping damage only for a 10-day period starting with the day of delivery. After the 10 days, the purchaser must accept the merchandise as delivered.

8. Locating the Sterilizer

CAUTION
Since ethylene oxide is both flammable and toxic, locate the sterilizer in a well ventilated area. Do not locate the sterilizer unit or the ethylene oxide (EO) cartridges in an area of possible ignition sources.

Select an appropriate site well in advance of purchasing the sterilizer. Contact your building engineering department for help in selecting a site. Keep sterilization/aeration equipment away from main traffic areas.

Locate the machine in its permanent location and level the unit by adjusting the feet. When installed, provide adequate space on both sides of the unit for periodic maintenance and service access. Leave a minimum of 51 cm (20 in) space on each side and the top of unit for service access.

Do not install sterilization equipment in areas where flammable gases or liquids other than EO are present. At the time of the installation checkout, your 3M service representative will request that you certify in writing that this requirement is met. Contact appropriate local regulatory agencies to determine their requirements.

Locate the equipment in a well-ventilated area. Avoid small, inadequately ventilated areas. Locate the equipment in an area with a non-

recirculating ventilation system; the local exhaust hood(s) must be dedicated. Provide an air exchange rate of at least ten room changes per hour.

The location of intake air and exhausts in relation to the sterilization equipment is important. Measure the room air flow to ensure that there are no "dead" air spaces in the immediate sterilizer area and that air moves away from equipment operators. Refer to Figure 1.

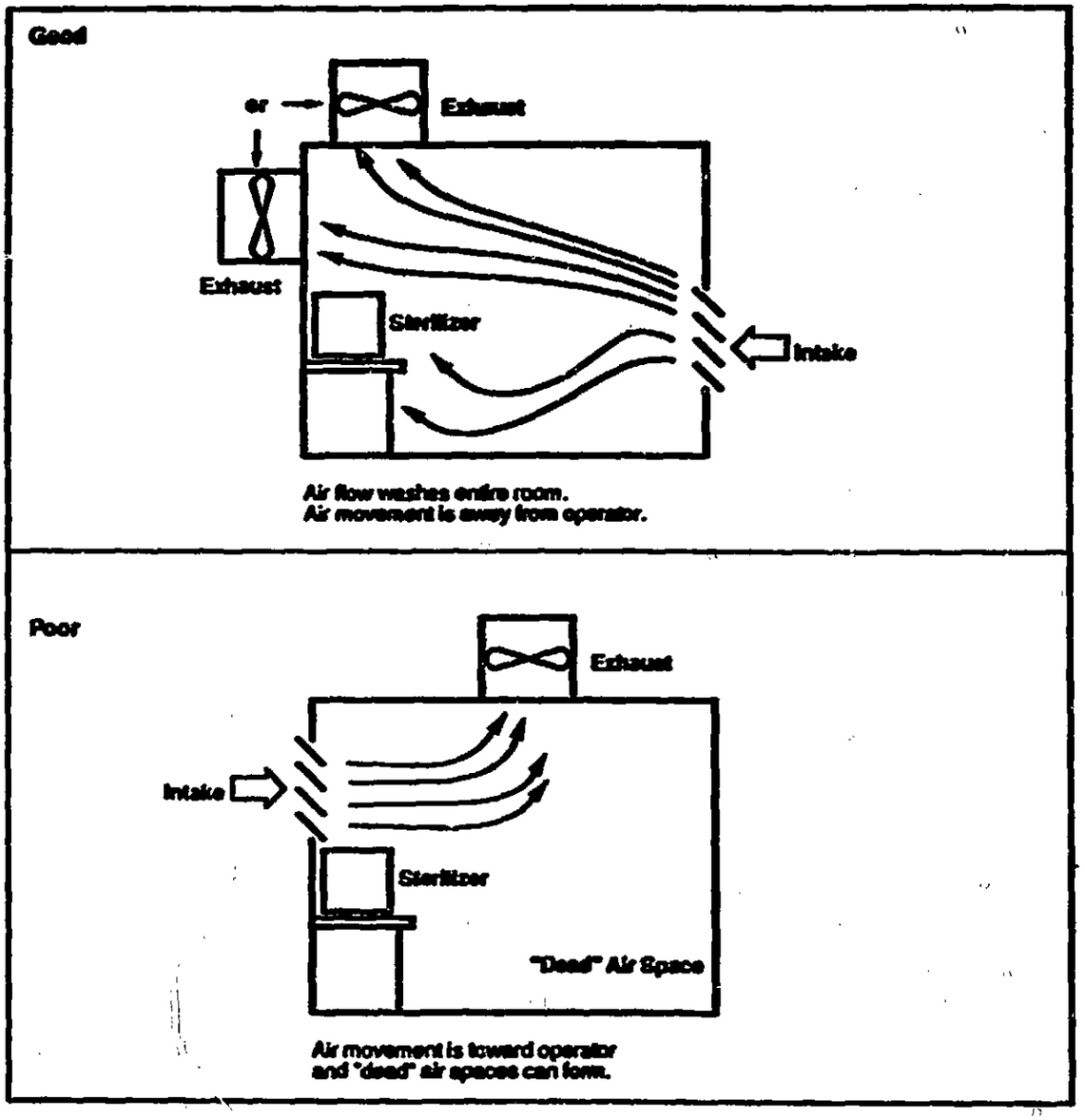

Figure 1. Recommended location of sterilization/aeration equipment relative to room intakes and exhausts.

Your 3M service representative will request that you certify, in writing, that the requirements for the general room ventilation rate and the non-recirculating ventilation system are met when reviewing your installation.

9. Electrical Requirements

Specifications
Voltage: 220 Volts A.C. (220 V~) ±10%
Frequency: 50/60 Hz
Phase: Single (1)
Current: 15 Amp (dedicated)
Power Cord: 220 Volts, 15 Amp NEMA 6-15 plug.
Power cords furnished with sterilizers sold outside the USA will meet local electrical requirements. A circuit breaker is incorporated in the power switch.

NOTICE
UL standards require that the unit must be connected to a UL listed hospital grade receptacle to ensure proper grounding of the equipment.

10. Vent Line Requirements

Connect the sterilizer/aerator to a dedicated vent line to exhaust ethylene oxide to the outside atmosphere or to an emission control system. The following requirements for venting the Steri-Vac 5XL gas sterilizer/aerator must be met.

Multiple combinations of the Steri-Vac gas sterilizer models 5XL, 4XL, 400, 202B and 202 may be vented through a common vent line. Please note, Steri-Vac models 400B and 400C require a separate dedicated vent line for each unit. Ensure the vent line is constructed of straight lengths of copper tubing. Do not extend the length of line beyond 91.5 m (300 ft). The diameter of the vent line depends on the length of the line. Refer to the table below for vent sizes. Use a 3/8 in National Pipe Thread (NPT) connection at the sterilizer.

The vent line contains significant amounts of EO during the final purge phase. Do not terminate the vent line within 7.6 m (25 ft) of any possible source

Recommended Outer Diameter (OD) Vent Sizes for Steri-Vac 5XL Gas Sterilizer/Aerator

Number of Steri-Vac Sterilizers	Length of Vent Line				
	8 meters (25 ft)	15 meters (50 ft)	31 meters (100 ft)	61 meters (200 ft)	91.5 meters (300 ft)
1	1.6 cm (5/8 in)	1.6 cm (5/8 in)	1.6 cm (5/8 in)	1.9 cm (3/4 in)	1.9 cm (3/4 in)
2	1.6 cm (5/8 in)	1.9 cm (3/4 in)	1.9 cm (3/4 in)	1.9 cm (3/4 in)	2.5 cm (1 in)
3	1.9 cm (3/4 in)	2.5 cm (1 in)	3.2 cm (1-1/4 in)	3.2 cm (1-1/4 in)	3.2 cm (1-1/4 in)
4	2.5 cm (1 in)	2.5 cm (1 in)	3.2 cm (1-1/4 in)	3.2 cm (1-1/4 in)	3.8 cm (1-1/2 in)

of ignition or any opening to the building interior such as fresh air inlets, unsealed windows or pedestrian traffic areas.

Install a moisture trap if there are more than three meters (ten feet) of vertical distance in the vent line. Route the vent line so that moisture drains toward the trap. Avoid sags or loops in the vent line to prevent moisture buildup at other points in the line. Ensure that the vent line is gas-tight from the machine to the outside atmosphere. Use flanged or compression fittings at the sterilizer and the moisture trap. Braze or solder all the other vent line fittings. Call or write the 3M Medical-Surgical Service Center (612/733-7865) for a moisture trap available at a nominal charge.

Keep all of the vent line, with the exception of a turned-down extension terminating on the roof top or exterior wall, inside the building. This is to prevent moisture from freezing in the line and blocking the vent. (See the diagram of vent line terminations in Figures 2 and 3).

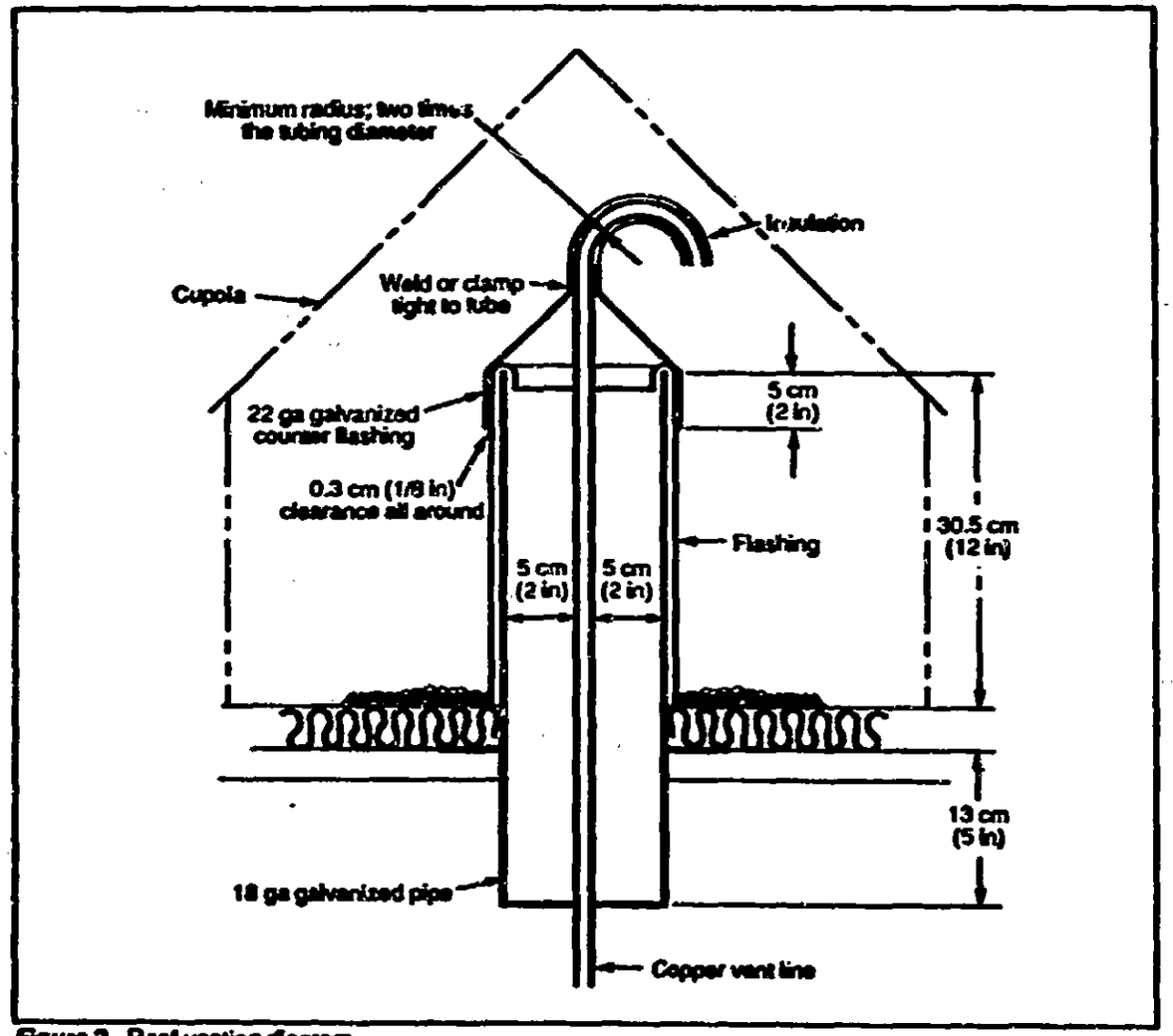

Figure 2. Roof venting diagram.

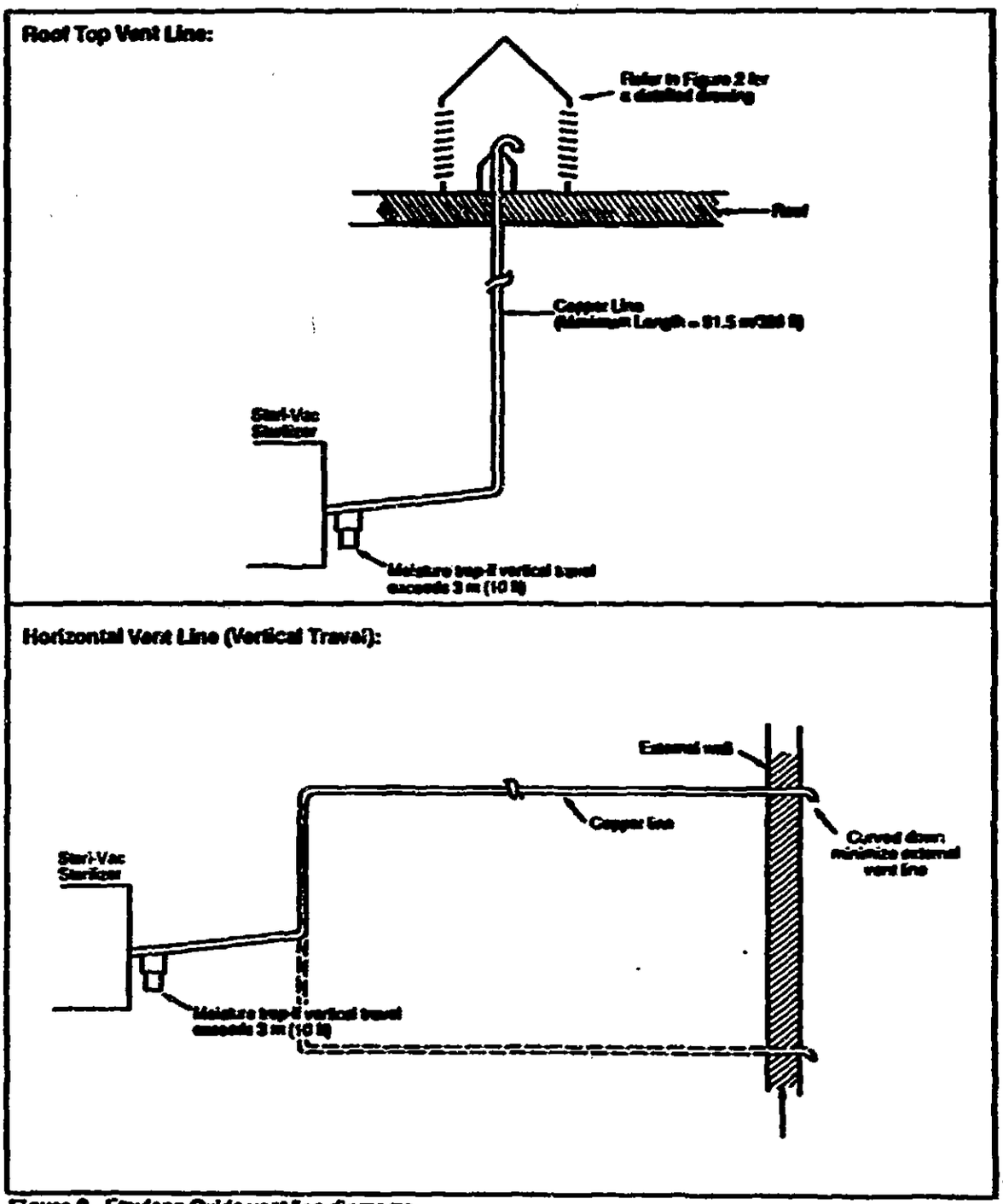

Figure 2. Ethylene Oxide vent line diagrams

Flexible Vent Line Requirements
A flexible, gas-tight line is needed between the sterilizer and the stationary vent line if the sterilizer must be moved for service (e.g., built into a wall). Minimize the amount of flexible tubing used.

Recommended Products
The following are the only types of flexible tubing recommended for this application.

Cobolow stainless braided flexible tubing
1.25 cm (1/2 in) ID, No. 1-8; standard length 2.1 m (7 ft)
Parker-Hannifan tubing
1.25 cm (1/2 in) ID, Series 90

The 3M Medical-Surgical Service Center must approve any other materials used. The Cobolow braided stainless steel tubing can be ordered directly from the Service Center. Order the length of tubing needed. Specify in the order that gas-tight fittings be included. Make the length of tubing at least 1.8 meters (6 feet) to avoid kinking, but short enough to prevent looping or coiling.

11. Compressed Air Requirements

Air Supply Specifications
Pressure: 3.5 kg/cm^2 (50 psig) minimum
10.5 kg/cm^2 (150 psig) maximum.
Flow Rate: 3.4 liters per second
(7.0 scfm) at 3.5 kg/cm^2 (50 psig).

Quality: Clean air supply with a maximum allowable dirt particle size of five microns and free of oil.

Moisture Content: Moisture content less than 10°C (50°F) dewpoint.

⚠ DANGER

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.

NOTICE

3M's Warranty and Preventive Maintenance Agreement does not cover machine failures caused by an improper compressed air source. These are the customer's responsibility.

Filters
3M supplies with each sterilizer an air filter assembly to remove oil and dirt particles from the incoming air. This filter must be installed on the compressed air line at the time of installation. This filter must be drained periodically to remove excess water.

⚠ DANGER

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 supplying a complete air supply meeting such specifications.

Installation and Replacement
Install the prefilter in front of the oil removal filter to remove coarse air contaminants that would otherwise plug the oil filter element. Replace the prefilter element at least every 6 months and the oil filter element at least every 12 months. Change the elements more frequently if the air supply is highly contaminated.

Air Dryer
Excessive water in the compressed air line will not be removed by the filter supplied. A refrigerated air dryer (e.g. Norgren D-10 Series or Arrow A-10) may be required to bring the dewpoint of the incoming air down to the 50°F dewpoint requirement.

Shut-off Valve
Install a shut-off valve in the air line, upstream from any filters, so the compressed air can be turned off during maintenance operations.

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Pressure Gauge

Install a pressure gauge between the filters and the air inlet to the sterilizer. Connect the supply air line to the 1/4 in National Pipe Thread fitting labeled "Compressed Air" at the sterilizer.

Flexible Air Line Connection

Use a flexible air line between the sterilizer and the fixed air line when the sterilizer must be moved for service accessibility. Use the shortest possible length of flexible line which will allow the unit to be moved without disconnecting the air line from the unit. The tubing must be rated to handle the highest pressure that the compressor delivers. Select a tubing diameter which does not cause the pressure to drop below 3.5 kg/cm^2 (50 psig) at the sterilizer.

Tank-Type Compressors

If needed, purchase a tank-type compressor to meet the sterilizer's compressed air requirements.

Specifications

Design: Twin cylinder type

Ratings: Minimum of 5 horsepower, ASME, and complies with state codes in USA

Air Pressure: 3.5 kg/cm^2 (50 psig) to 10.5 kg/cm^2 (150 psig)

Flow Rate: 3.4 liters per second (7.0 scfm) at 3.5 kg/cm^2 (50 psig)

Pressure Switch Setting: Cut in pressure 3.5 kg/cm^2 (50 psig minimum).

Minimum Tank Size: 225 liters (60 gal)

The following manufacturers have compressors that meet or exceed these requirements:

- Campbell Hausfeld
- Sears Craftsman
- Quincy
- Sullair

Compressor Location

Consider electrical power requirements for the compressor. Locate the compressor away from work areas to reduce noise levels around the sterilizer.

Multiple Sterilizer Installations

Each unit requires a minimum of 3.5 kg/cm^2 (50 psig) pressure with a minimum flow rate of 3.4 liters per second (7.0 scfm). Example: Two sterilizers would require 3.5 kg/cm^2 (50 psig) with a 6.8 liters per second (14 scfm) air flow.

12. Optional Local Exhaust System Requirements

Note: Disregard Section 12 if the Steri-Vac 5XL gas sterilizer/aerator is not equipped with the optional local exhaust hood feature.

Function

An optional local exhaust hood can be added to the top panel of the sterilizer. Its purpose is to allow faster access after the sterilization cycle is completed. The hood removes residual ethylene oxide gas (EO) from the sterilizer chamber when the door is in the latched position. The hood must be connected to a dedicated exhaust system supplied by the customer. At the end of the sterilization cycle, the operator opens the sterilizer door to a latched position. While in this position, air is drawn upward from the bottom of the sterilizer door through the hood to the outside or to an emission control system via the exhaust duct. The air stream pulls EO molecules from the front of the sterilizer chamber. Refer to Figure 4.

Units without the local exhaust hood have a mandatory three-hour aeration after the sterilization cycle before the door unlocks. This reduces the airborne EO level sufficiently to allow the operator to remove the baskets.

Specifications

The following requirements should be met to ensure strong air movement through the hood.

Air Flow: Minimum of 2.8 cubic m/min (100 scfm) through the hood, or a minimum of 350 m/min (1150 fpm) in the 102 mm (4 in) line to the hood.

Minimum static pressure of -0.15 cm (-0.06 in) of water at the static pressure port. Measure the static pressure when the sterilizer door is in the open latched position.

Hood Connection: 102 mm (4 in) outside diameter. Design and construct the exhaust system in accordance with state and/or local fire, health and safety codes. Connect the hood to a dedicated exhaust system. Do not connect the hood to an exhaust system that recirculates air into the building.

Ductwork

Use metallic ductwork rated to handle the highest pressure that the system delivers.

Use a minimal amount of flexible, air-tight duct. Flexible duct can introduce significant air flow resistance. Use larger diameter duct to minimize frictional air drag loss. Minimize the number of elbows to reduce the static pressure loss in the system. Seal duct seams and joints with aluminum duct tape or sealant to prevent leaks.

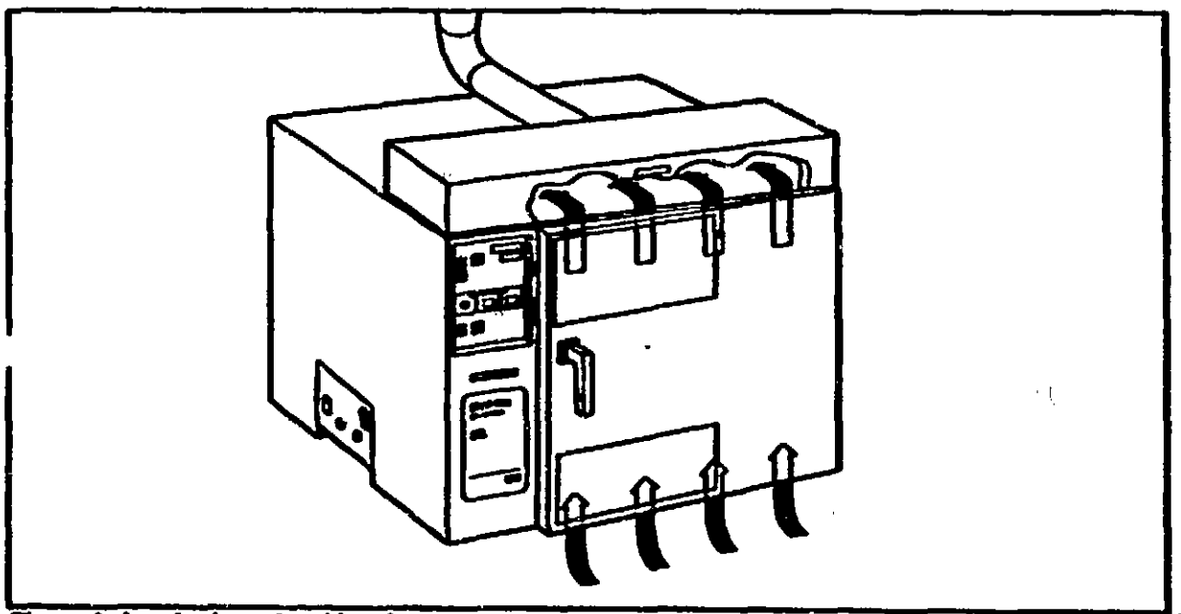

Figure 4. Local exhaust hood function.

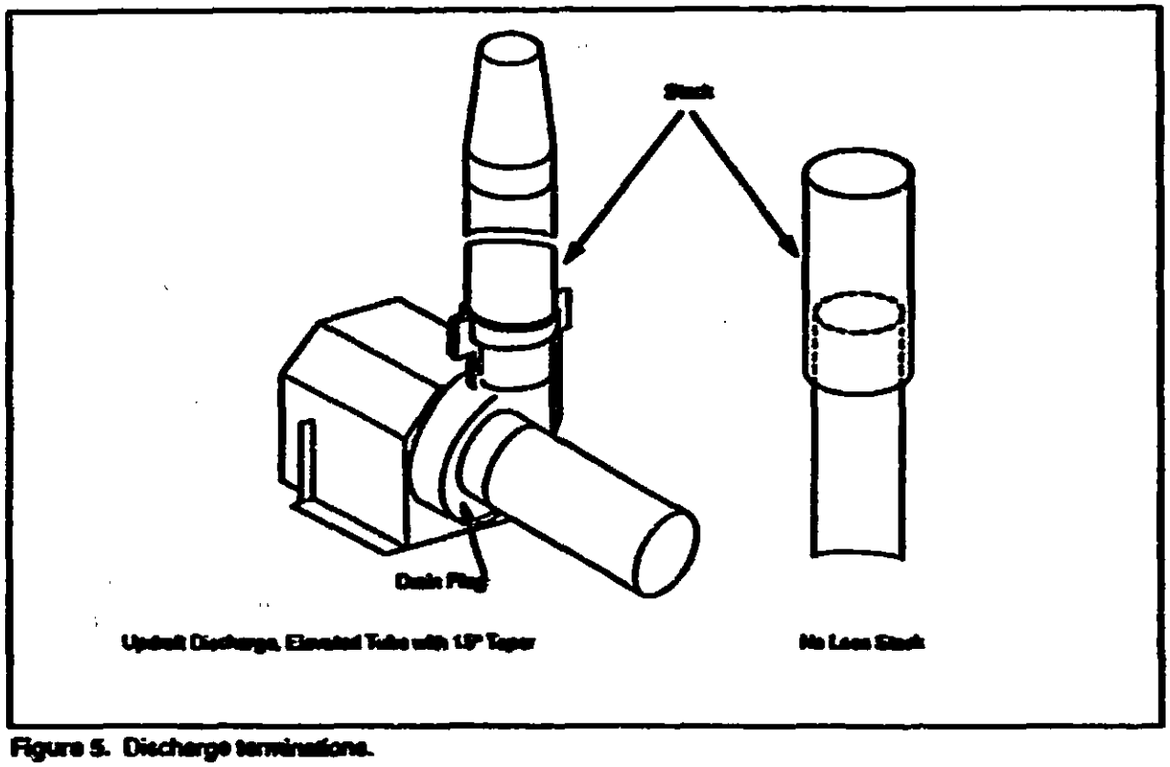

Figure 5. Discharge terminations.

Exhaust Fan

Use a centrifugal fan with backward curved blades designed for continuous operation. This is a high efficiency spark-proof fan with the motor sealed from the exhaust air stream. The impeller and impeller ring around the drive shaft must be nonferrous.

Ventilation Failure Detector

An air flow sensor is installed in the 102 mm (4 in) exhaust opening of the hood. The sensor will activate a flashing error message, cl (low air flow), to alert personnel of ventilation system failure (e.g., fan malfunction). The error message does not stop a cycle in progress. The ventilation problem must be corrected for the sterilizer to clear the message.

Outside Discharge

The ventilation system should exhaust to the outside or to an emission control system. A roof-top discharge should be used. The discharge point should be at least 7.6 m (25 ft) away from any possible sources of ignition, openings to building, or pedestrian traffic ways. Greater distances may be needed in some locations. Use one of the types of discharge terminations illustrated in Figure 5, and use the installation diagrams in Figures 6, 7, 8 and 9 if applicable.

Use an industrial ventilation consultant or ventilation contractor to help design and install the local exhaust system. Contact your 3M medical sales representative for additional copies of the Installation Guide. For technical assistance contact the 3M Medical-Surgical Service Center (612/733-7865).

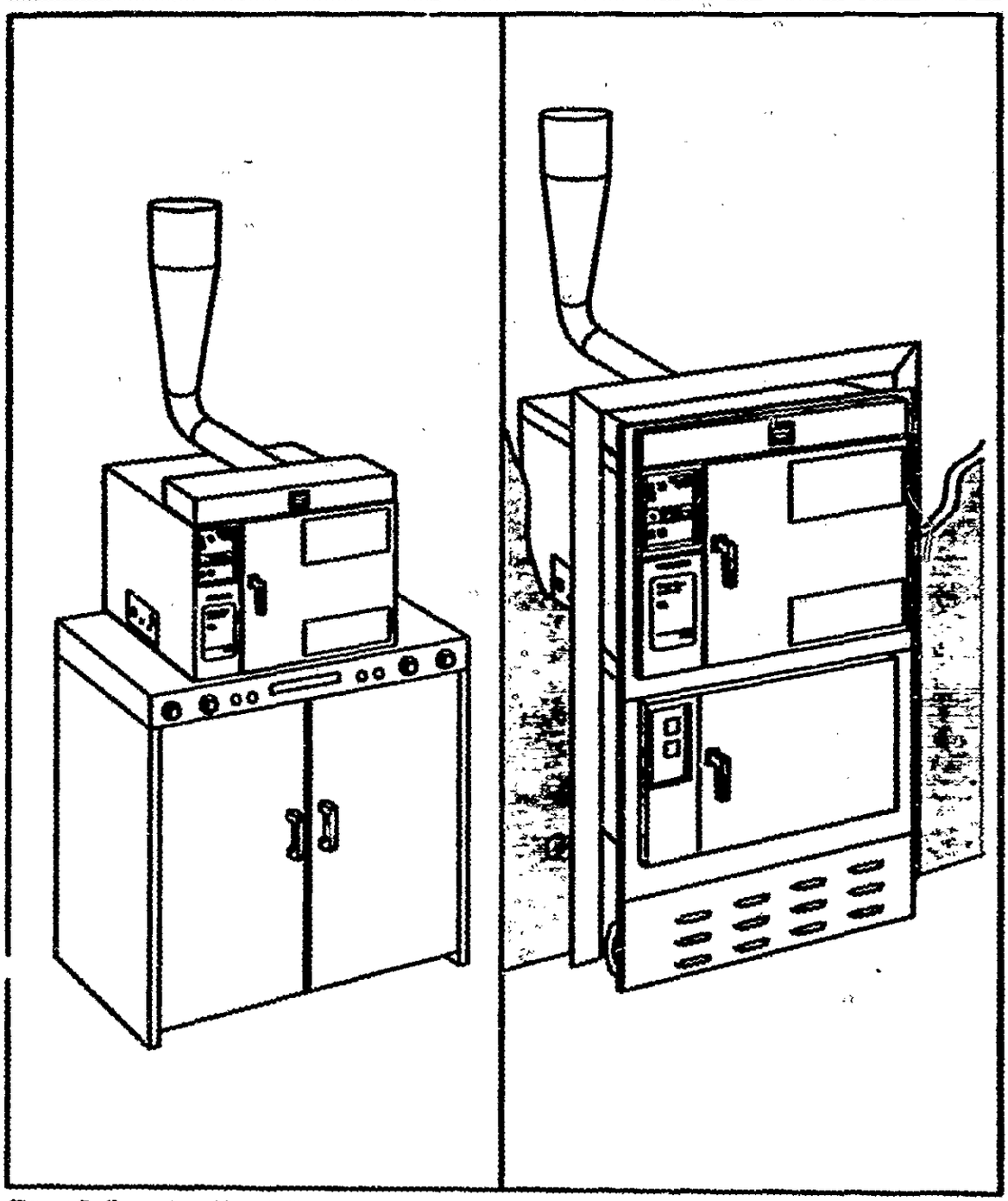

Figure 6. Examples of installations.

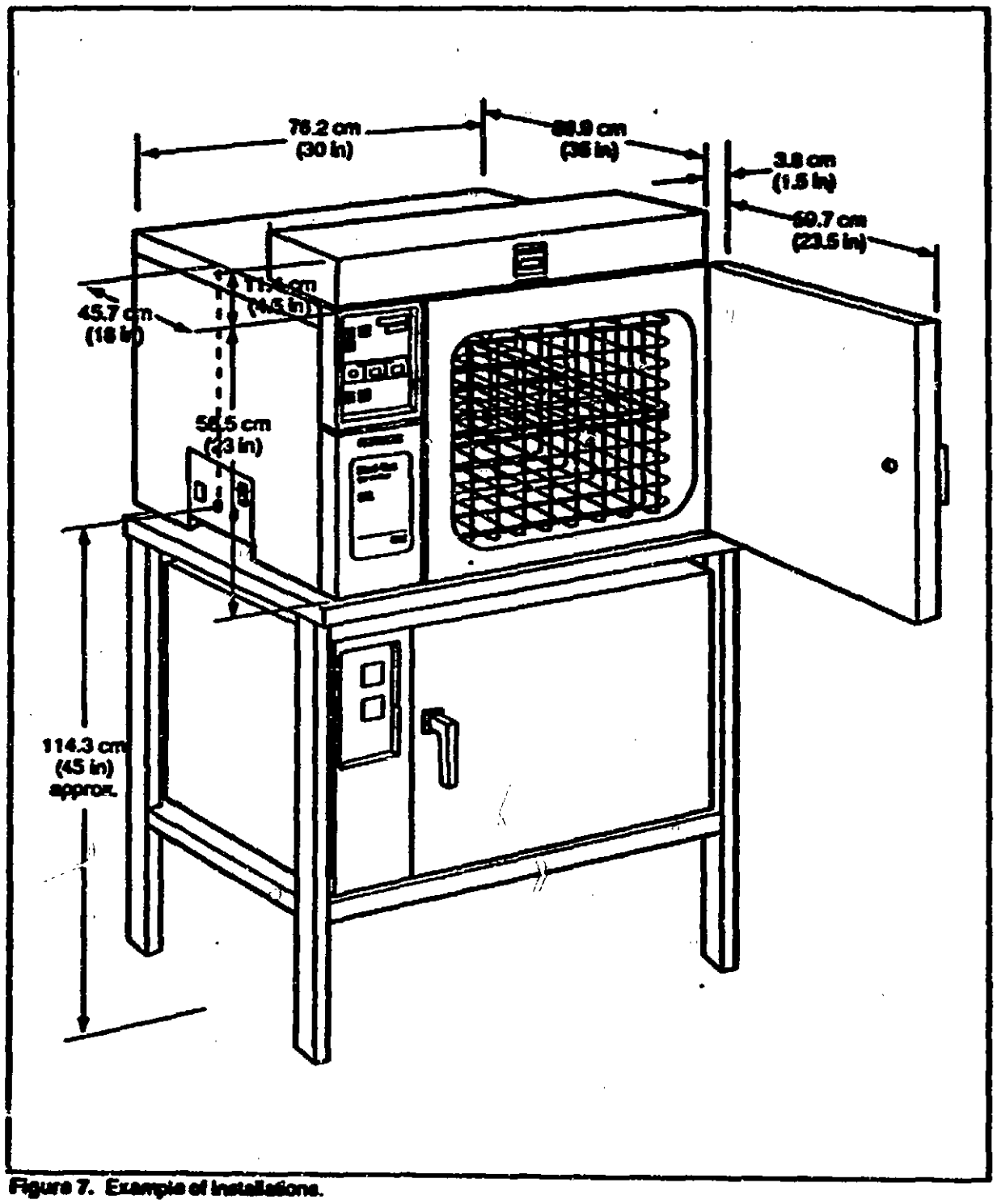

Figure 7. Example of installations.

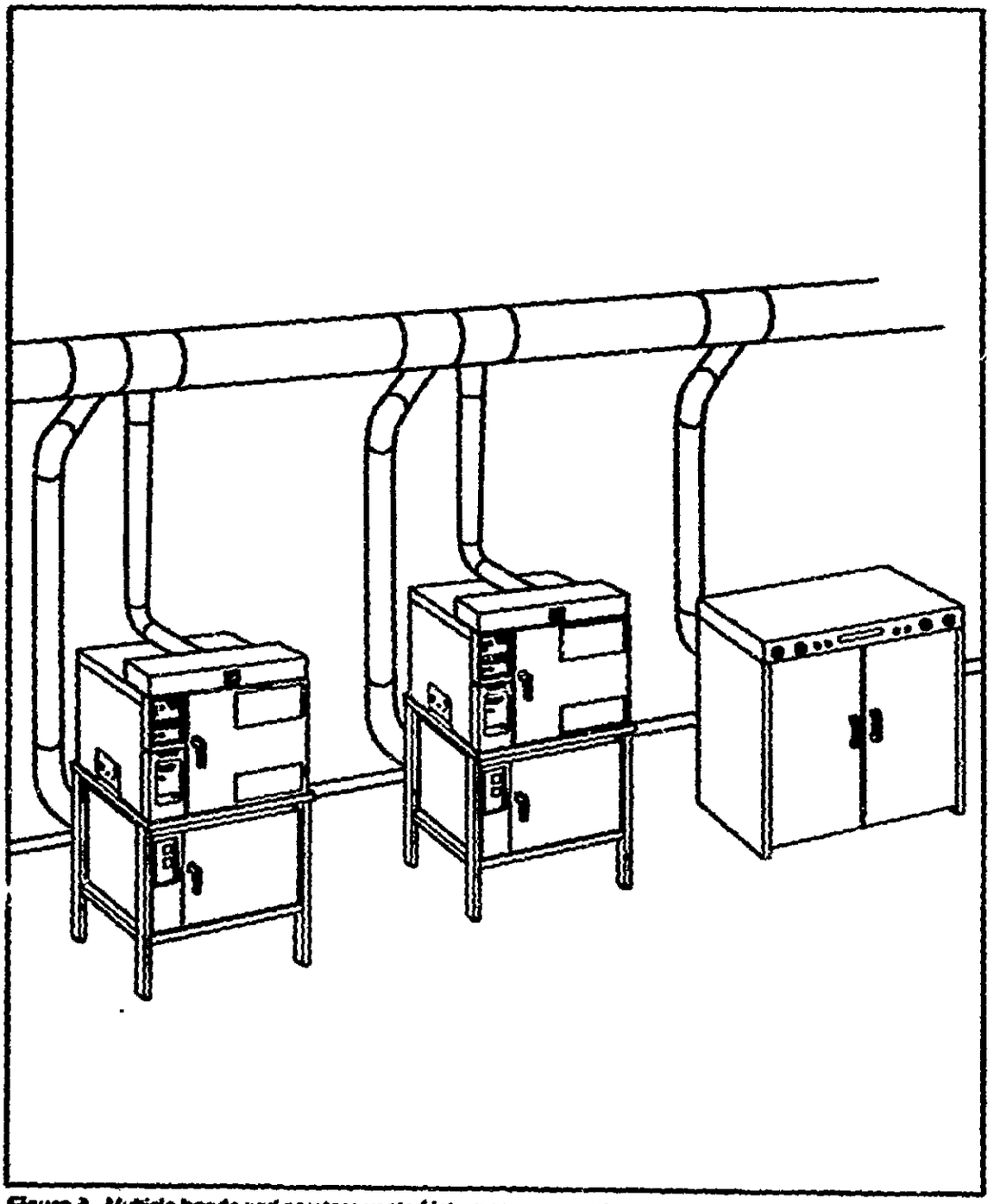

Figure 8. Multiple hoods and aerators vented into a common system.

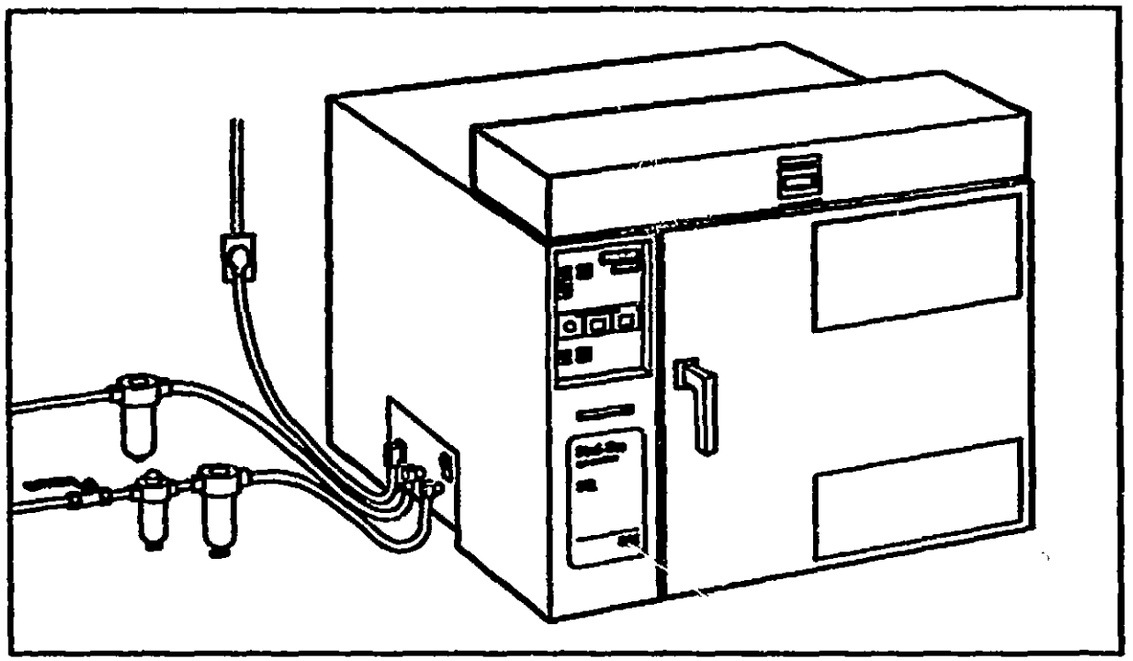

Figure 9. Example of Service Connections

For further reference, please consult the following:

1) EPA, "Sterilant Use of EtO in Hospitals & Health Care Facilities," Appendix A, Table VII; OSHA EtO Standard: 29 CFR 1910: Occupational Exposure to Ethylene Oxide.
2) Dept. Health Education and Welfare, DHEW Publ. No. HRA-74-400. "Minimum Requirements of Construction & Equipment for Hospital & Medical Facilities," HEW, PHS, Health Resources Adm., Div. of Facilities & Utilization, Rockville, MD 20852, 1974, p. 27.
3) Industrial Ventilation, Committee on Industrial Ventilation, P.O. Box 16153, Lansing, MI 48902.
4) American Society of Heating, Refrigeration & Air Conditioning Engineers, ASHRAE, Applications Volume 1982, Chapter 7.

Ventilation Design Steps

Determine the air flow required, size, length and number of elbows needed in the ductwork. Note that each elbow introduces losses in air flow. Calculate the total air flow required for each branch.

Calculate the static pressure for the entire system using standard industrial ventilation techniques, and add a 10% safety factor to the air flow and the previously calculated static pressure. Select an exhaust fan to meet these requirements.

Determine if a new exhaust system is needed or if an existing system can be used. Ensure that the existing system is capable of meeting Steri-Vac equipment specifications. The diagrams in Figures 6, 7, 8 and 9 depict a number of local exhaust systems. Consider them in planning your installation.

13. Additional Information

The Occupational Safety and Health Administration (OSHA) requires that you monitor your employee exposure to ethylene oxide after sterilizer installation to establish base lines for the Permissible Exposure Level (PEL) of 1 ppm/8-hour TWA and the Excursion Limit (EL) of 5 ppm averaged over a 15-minute sampling period.

Material Safety Data Sheets or additional information on installation, accessories, Preventive Maintenance Agreements, etc., can be obtained by writing or calling the 3M Medical-Surgical Service Center.

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

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

3M Canada, Inc.
P.O. Box 5757
London, Ontario, N6A4T1
1-800-268-9696

14. Installation Parts and Part Numbers

Part No.	Description
12-2376-5158-8	Braided stainless steel tubing 2.1 m (7 ft), vent line
12-2376-1209-3	Moisture trap, vent line
12-2376-7969-6	Installation kit, Steri-Vac 5XL gas sterilizer

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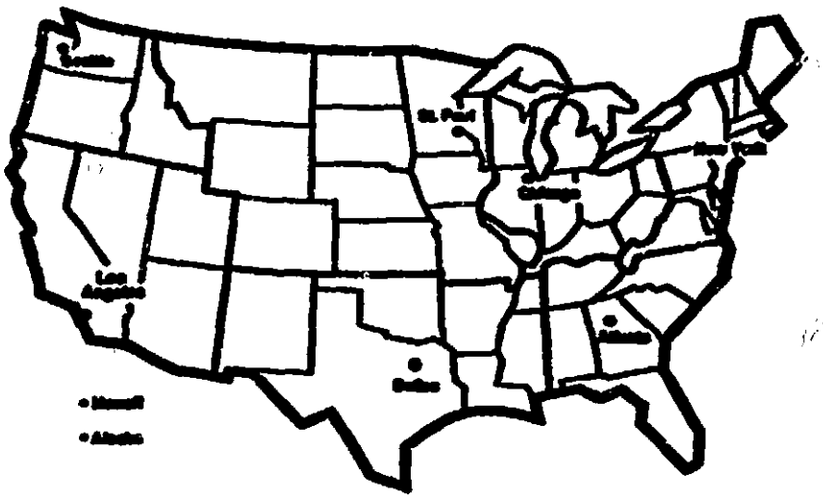

Cities:	To contact your sales representative:	To order Steri-Vac equipment:
3M Atlanta	2860 Bankers Industrial Drive Atlanta, GA 30360-2764 (404) 447-7007	3M Medical-Surgical Service Center 3M Center Building 582-1E-02 St. Paul, MN 55144-1000 612/733-7865
3M Chicago	6850 South Harlem Avenue Bedford Park (Argo), IL 60501-0902 (312) 496-6500	
3M Dallas	2121 Santa Anna Avenue Dallas, TX 75228-0158 (214) 324-6100	
3M Los Angeles	6023 South Garfield Avenue Los Angeles, CA 90040 (213) 726-6300	
3M New York	15 Henderson Drive West Caldwell, NJ 07006-6689 (201) 575-2000	
3M Seattle	100 Andover Park West Seattle, WA 98188 (206) 244-7200	
3M Twin Cities	3130 Lexington Avenue South Eagan, MN 55121 (612) 733-3300	
3M Alaska	11151 Calaska Circle Anchorage, AK 99515 (907) 522-5200	
3M Hawaii	4443 Malaai Street Honolulu, HI 96818 (808) 422-2721	

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Medical-Surgical Division
3M Health Care
3M Center Building 225-5S-01
St. Paul, MN 55144-1000

3M

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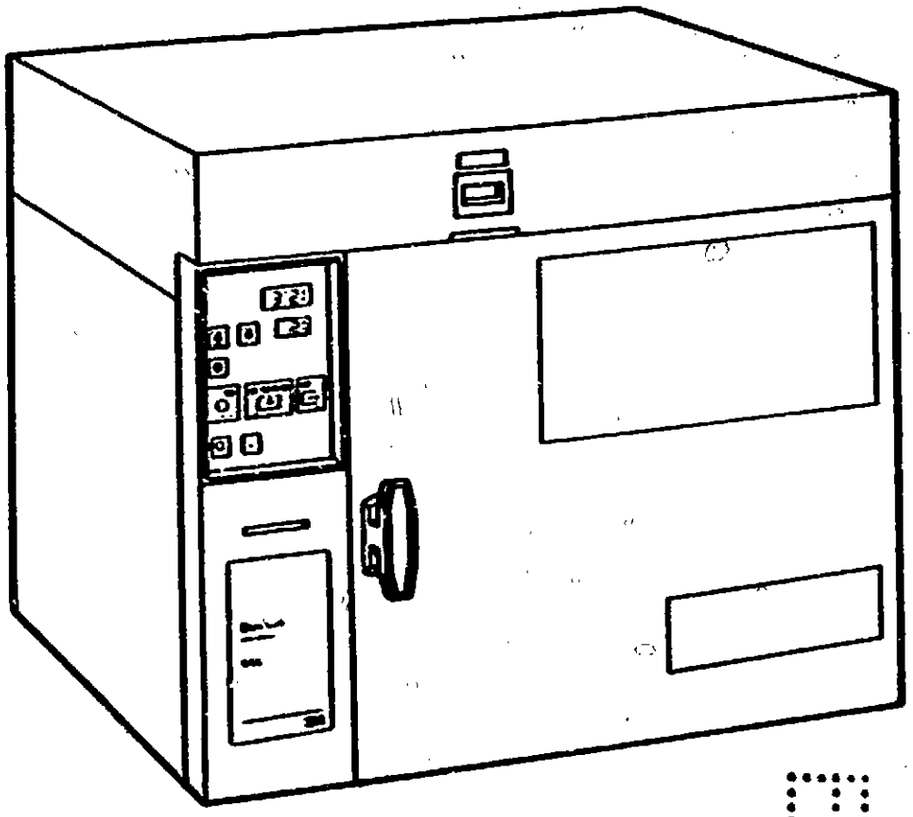
Steri-Vac™

4XL

Gas Sterilizer



Installation Guide

ST-4119

STERI-VAC™ 4XL GAS STERILIZER INSTALLATION GUIDE

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1. STERILIZER LABELING

READ SAFETY LABELS CAREFULLY

Carefully read all warning labels on the front and back of the sterilizer to avoid hazards.

Front Door Hazard Label

⚠ DANGER

ETHYLENE OXIDE

FLAMMABILITY

Flammable in concentrations from 3% (30,000 ppm) to 100%.

Keep all sources of ignition such as matches, lit 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. Repeated overexposure may result in olfactory fatigue (i.e. increasingly difficult to smell ethylene oxide).

Chronic inhalation. The Occupational Safety and Health Administration (OSHA) classifies ethylene oxide (EO) as a cancer and reproductive hazard.

7182-1

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 maycause 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.

STATEMENT OF PRACTICAL TREATMENT/FIRST AID

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

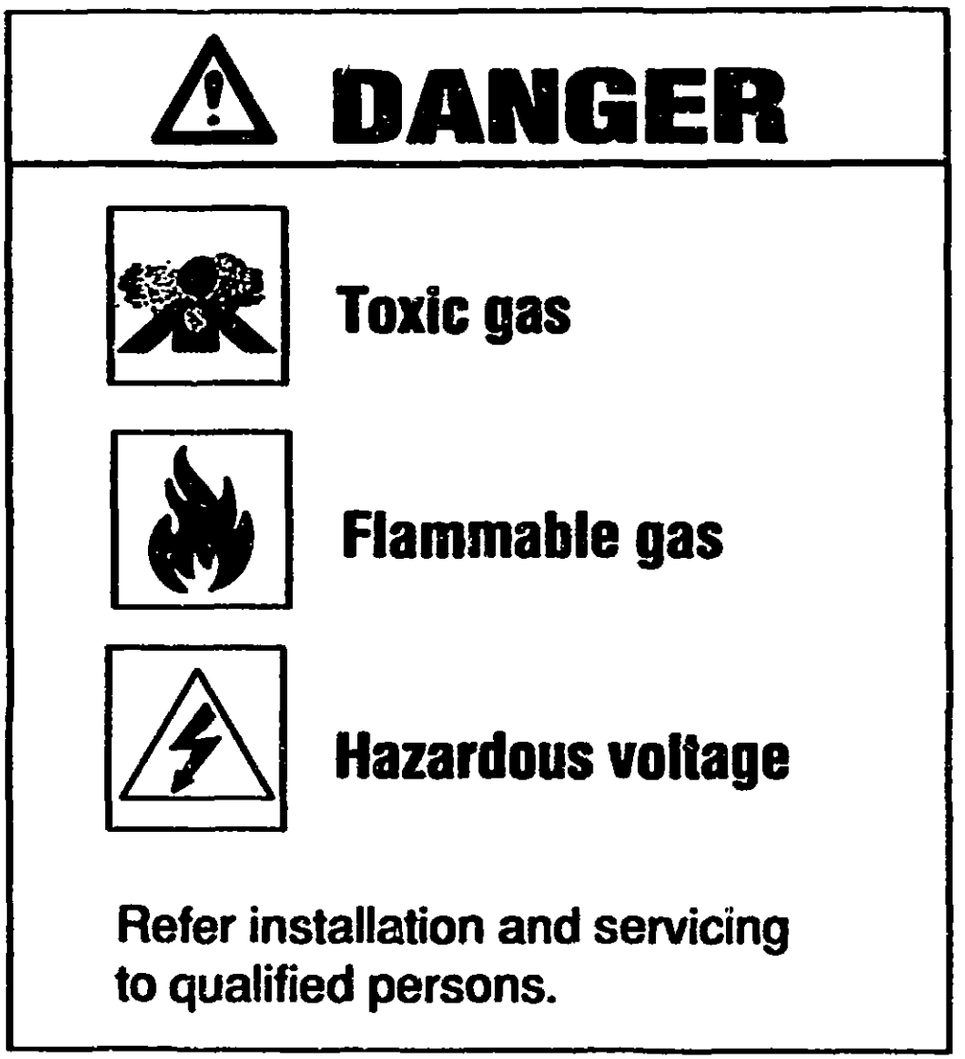
Eye Contact. For liquid EO or high concentrations of gas, immediately flush the eyes with water for at least 10 minutes. Contact a physician immediately.

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.

Affixed to the front panel of the Steri-Vac 4XL gas sterilizer.

Back Panel Danger Label



Affixed to the front panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-9490-1

READ INSTALLATION GUIDE AND OPERATING INSTRUCTIONS CAREFULLY

Front Panel Label

OPERATING INSTRUCTIONS

I. USER RESPONSIBILITY

Know the information in the Steri-Vac™ 4XL gas sterilizer Operator's Manual before using this product. 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.

II. GENERAL USE INFORMATION

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.
2. Standard cycle parameters:

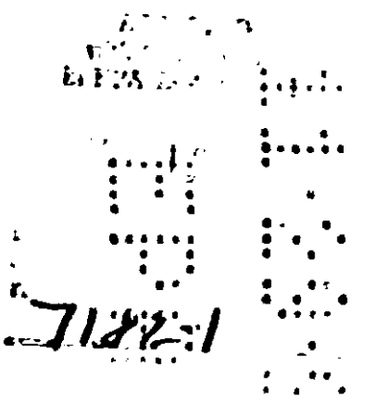
Cycle	Temperature	Approx. Sterilization Time
WARM	55°C	2.5 hours
COOL	37°C	5.5 hours

3. Clean, precondition and package, as needed, all articles to be sterilized. (Refer to Sections 10, 11 and 12 in Operator's Manual.)
4. For routine sterilization monitoring, place a test pack containing a biological indicator (BI) in the center of the load. Remove the test pack and process the biological indicator according to the manufacturer's instruction. (Refer to Section 14 in the Operator's Manual.)
5. Aerate all gas sterilized items (excluding unpackaged metal and glass) before handling. Follow the instructions from the device manufacturer.
6. Remove the empty Steri-Gas™ cartridge from the holder and place it on top of the load to be aerated. A cartridge that has aerated in its sterilizer holder for 2 hours or more needs no further aeration.

III. STERILIZER OPERATING INSTRUCTIONS

A normal sterilization cycle consists of the following sequence of operator steps:

1. Load basket loosely and orderly.
2. Check that the sterilizer is in standby.
3. Turn handle counter-clockwise while lifting DOOR RELEASE to open door.
4. Insert Steri-Gas cartridge 4-100 into the holder. (Green label on cartridge matches green ring of holder.)
5. Add basket to chamber and shut door. Turn door handle clockwise to vertical position.
6. Press WARM or COOL cycle switch.
7. Press START switch.
   - *Cycle continues automatically until completion.*
   - *Sterilization cycle is complete when AERATE indicator is lit and timer is on.*
8. Use STOP switch to interrupt the sterilization cycle.
9. To interrupt aeration:
   a. Turn handle counter-clockwise.
   b. Wait approximately 30 seconds.
   c. Open door to latched position.
   d. Keep door in the open latched position for at least 5 minutes.
   e. Fully open door while lifting DOOR RELEASE.
   f. Remove sterile items.
   g. Close door and turn handle clockwise to resume aeration.
10. To terminate aeration:
    a. Turn handle counter-clockwise.
    b. Wait approximately 30 seconds.
    c. Open door to latched position.
    d. Keep door in the open-latched position for at least 5 minutes.
    e. Fully open door while lifting DOOR RELEASE.
    f. Remove basket.
    g. Press STOP switch.
       - *Machine will go to standby.*
    h. Close door.



Affixed to the front panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-9339-0

60-4119

Front Panel Label

CAUTION/ERROR MESSAGE CHART

Use the chart below to determine the reasons for a caution/error message appearing in the digital display. This chart lists the messages most likely to appear. Refer to Section 19 of the Operator's Manual for the complete chart and more details. Follow the steps designated. Call your 3M Service Representative when: (1) indicated, (2) a code appears that is not listed, or (3) you have any questions.

Be alert to any codes appearing. This indicates a problem or potential problem that requires corrective action. Refer to Section 18 for an explanation of the sterilizer controls associated with these codes.

Caution Messages — Will not stop cycle	Possible Causes	What To Do
c1 Low Air in Exhaust Head	External Fan Malfunction Airflow Sensor Failure	Check Fan and Fan Belts 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, Airlines

Errors that are detected before puncture

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 Plug from Chamber Port Check Airlines and Pressure Call Service Representative
E22 Initial Pumpdown Timeout	Improper Air Pressure Defective Vacuum Pump	Check Air System Call Service Representative
E23 Chamber Preheat Timeout	Chamber Too Cold Defective Temperature Control	Rerun Cycle Call Service Representative
E24 Heatsink Preheat Timeout	Chamber Too Cold Defective Temperature Control	Rerun Cycle Call Service Representative
E28 No Water Injected	Reservoir Float Switch Stuck Water System Plugged	Add Water To Reservoir Call Service Representative
E32 Door Unlocked	Door Latch Hung Up on Bolt Control Error	Turn Handle Completely Vertical 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

Erros found during gas exposure

E50 mpty Cartridge	Empty Cartridge Loaded Puncture Mechanism Failed	Use New Cartridge Call Service Representative
E54 Extended Power Outage	Could Not Resume Cycle After Outage	Rerun Cycle
E60 User Interruption	User Pressed STOP Switch	Rerun Cycle

Errors that leave the chamber locked with gas possible in the chamber

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

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.

Affixed to the front panel of the Steri-Vac 4XL gas sterilizer.
3M Part No.

1147 172

6394114

AIR LINE

Maximum air inlet pressure shall not exceed 150 psig

Affixed to the back panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-3271-1

Power On/Off Switch and Circuit Breaker

To reset, turn switch to "On" position.

Affixed to the back panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-9415-8

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Grounding reliability can only be achieved when equipment is connected to equivalent receptacle marked "Hospital Only" or "Hospital Grade".

Affixed to the back panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-9709-4

STERI-VAC 4XL GAS STERILIZER
INSTALLATION GUIDE

2. CUSTOMER CHECKLIST

Read this entire Installation Guide carefully before installing your Steri-Vac 4XL gas sterilizer. Contact your local 3M Service Representative or the 3M Medical-Surgical Service Center with any questions.

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As indicated in Section 16, complete the following checklist before contacting your 3M representative(s) to review your sterilizer installation. Completion will help ensure that 3M installation specifications are met.

2.1 Electrical Supply

2.1.1 At what current is the sterilizer's electrical supply fused? _____ AMP

2.1.2 What is the supply voltage rating? _____ VAC

2.1.3 What is the voltage reading at the sterilizer? _____ VAC

2.1.4 What is the lowest VAC to which the supply voltage drops during peak usage periods? _____ VAC

2.2 Vent Line

2.2.1 Does the vent go from the sterilizer to the outside atmosphere directly - without being terminated into any existing duct work, airflow system, or ventilation system? _____ Yes _____ No

2.2.2 What type of material is the vent line made of? _____

2.2.3 What is the diameter in inches of the vent line? _____ O.D. _____ I.D.

2.2.4 What is the total length of the vent line? _____ ft.

2.2.5 If the answer to the above question is greater than 300 ft., was the system approved by 3M? _____ Yes _____ No

2.2.6 Does the vertical travel of the vent line exceed 10 ft.? _____ Yes _____ No

2.2.7 If "yes" to the above question, was a moisture trap installed? _____ Yes _____ No

2.2.8 If the vent line run is horizontal, how far does it extend outside the building? _____ ft.

2.2.8.1 Does it have a downward bend? _____ Yes _____ No

2.2.8.2 Is the vent outlet located within 25 ft. of any possible sources of ignition or any opening to the building interior (e.g., doors, fresh air inlets, unsealed windows)? _____ Yes _____ No

2.2.9 Have you checked to ensure the vent line is gas-tight? _____ Yes _____ No

2.2.10 If the vent line extends through the roof, does it meet 3M installation requirements? _____ Yes _____ No

2.2.10.1 Is it insulated? _____ Yes _____ No

2.2.10.2 How far above the roof does it extend? _____ ft.

2.2.10.3 Does it have a 180° bend? _____ Yes _____ No

2.2.10.4 Is there a cupola over the vent line? _____ Yes _____ No

2.3 Compressed Air Line

2.3.1 What is the psi rating of the compressed air source at the sterilizer at a flow rate of 7 scfm? _____ psi

2.3.2 What is the maximum supply line air pressure? _____ psi

2.3.3 Is the air supply clean, dry and oil free? _____ Yes _____ No

2.3.4 If the air supply is not clean, dry and oil free, are proper filters installed? _____ Yes _____ No

2.3.5 Does the air enter into the filter through the port marked "in"? _____ Yes _____ No

2.3.6 Are the filters accessible for maintenance? _____ Yes _____ No

2.3.7 Has a shutoff been installed upstream from the air filter so that air can be turned off for machine/filter service? _____ Yes _____ No

2.3.8 If a dedicated compressor is used to supply air:
2.3.8.1 What is the tank size? _____ gallons
2.3.8.2 At what pressure is the switch cut-in set? _____ psig

2.3.9 Has an air pressure gauge been installed between the filters and the air inlet to the sterilizer? _____ Yes _____ No

2.4 Unit Location

2.4.1 Is there 20 inches of clearance on the left side panel and the right side panel? _____ Yes _____ No

2.4.2 Is there 20 inches of clearance on the top? _____ Yes _____ No

2.4.3 If either of the two questions above is answered "No", can the unit be moved so that those clearances are possible? _____ Yes _____ No

2.4.4 If the question above is answered "Yes":

2.4.4.1 Has Coboflow® stainless braided flexible tubing been used on the vent line? _____ Yes _____ No

2.4.4.2 How long is the Coboflow tubing? _____

2.4.4.3 Is there a flexible line used on the air service so the unit can be moved without disconnecting that service? _____ Yes _____ No

2.4.5 Has the unit been installed in a hazardous area where flammable gases or liquids other than EO are present? _____ Yes _____ No

2.4.6 What is the air exchange rate in the sterilizer room? _____ air changes/hour

2.4.7 Is the unit located properly with respect to the intake and exhaust of the room's ventilation system? (See diagram in Installation Guide.) _____ Yes _____ No

2.5 Local Exhaust System

2.5.1 How many cubic feet per minute (cfm) of air does the local exhaust system provide to the hood? _____ cfm

2.5.2 What is the minimum static pressure in the hood created by the local exhaust system? _____ inches of water

2.5.3 Is the ductwork material impervious to EO? _____ Yes _____ No

2.5.4 What is the outside diameter of the ductwork connection for the hood? _____ inches

2.5.5 What is the distance between the outside exhaust termination and any sources of building air intake? _____

2.5.6 Is the exhaust source spark-proof, suitable for continuous operation and protected from adverse weather? _____ Yes _____ No

Notes:

_____

_____

_____

_____

_____

3. PURCHASER'S RESPONSIBILITY

3.1 It is the purchaser's responsibility to provide the necessary machine service requirements to the area where the sterilizer is to be installed. These services consist of electricity, compressed air, a vent line and a dedicated exhaust system. Because of varying local codes and labor policies, it is also the responsibility of the purchaser to locate the machine in its permanent location and to connect the services to the machine. The State of California requires that seismic bracing be provided on the sterilizer. It is the purchaser's responsibility to ensure that state and local requirements are met.

⚠ WARNING

3.2 This product is limited to use by medical professionals or appropriately trained personnel in medical and industrial use areas. 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. Personnel must be familiar with its labeling. Personnel must be familiar with information contained on the sterilizer's labeling and in the Operator's Manual prior to using this product. Do not attempt to operate the unit until 3M service personnel have checked out the installation. Costly damage and hazards could occur.

4. STERILIZER LISTINGS

The Steri-Vac 4XL gas sterilizer is listed with Underwriters Laboratories, Inc. (UL) and the West German Technischer Uberwachngs-Verein (TUV). These are iernationally recognized laboratories that inspected and evaluated the Steri-Vac system. Their labels are located on or near the serial plate of your sterilizer.

5. UNPACKING THE STERILIZER

5.1 Unpack and inspect your sterilizer as soon as it arrives.

5.2 Remove the shipping carton from the machine. To do this, cut the tape at each corner around the bottom edge of the carton, unfold the flaps and lift the carton off the machine. Examine the unit for damage and if necessary, follow the instructions provided in Section 6 for filing a damage

5 3 Remove the plywood shipping board by removing the four bolts holding it to the machine base. Do not rest the full weight of the machine on its sheet metal panels when tipping for access to the bolts. This, could damage the panels.

5.4 Open the door and remove the feet which are packed in a bag inside the chamber. Install the feet in the same holdes which hold the shipping board to the frame. The feet must be installed for proper airflow through the bottom of the unit.

5.5 Locate the machine in its permanent location and level the unit by adjusting the feet. When installed, provide adequate space on both sides of the unit for periodic maintenance and service access. Leave a minimum of 50 cm (20 in) space on each side and the top of unit for service access.

6. SHIPPING DAMAGE

Immediately inspect the sterilizer upon its arrival. Look for damage that may have occurred during transit. Immediately file a damage claim, if necessary, with the transportation company and notify your 3M sales or service representative. The transportation company assumes liability for shipping damage only for a ten-day period starting with the day of delivery. After the ten days, the purchaser must accept the merchandise as delivered.

7. HEALTH AND SAFETY INFORMATION

The Steri-Vac 4XL gas sterilizer uses the Steri-Gas™ cartridge 4-100 containing 100% ethylene oxide which is flammable and toxic. It is important that Steri-Vac sterilizer users understand the chemical's hazards and the necessary precautions. Contact your local 3M sales or service representative to obtain a copy of a Steri-Gas Material Safety Data Sheet which contains detailed health and safety information.

⚠ DANGER

7.1 Flammability

Small unit dose cartridges containing the sterilant, ethylene oxide (EO), are used in the sterilizer. EO is flammable when present in concentrations from 3% (30,000 ppm) to 100%. Keep all sources of ignition including lit cigarettes, sparks and static discharge away from the sterilizer and cartridges.

7.2 Toxicity

7.2.1 Acute inhalation 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 ethylene oxide).

7.2.2 Chronic inhalation. The results of animal toxicity and human epidemiology studies indicate that long term exposures 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.

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

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

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

7.3 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. Direct contact with ethylene oxide as a liquid or in solutions must be prevented.

7.4 Statement of Practical Treatment/First Aid

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

7.4.2 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.

7.4.3 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.

7.4.4 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.

8. PLANNING THE STERILIZER INSTALLATION

Plan for the installation before the equipment is purchased. Consider such things as location, machine service requirements, ordering a Steri-Gas cartridge 4-100 supply, accessories, and code compliance. If possible, review the proposed installation with the department manager, the facility's engineer (and architect, if appropriate) and the 3M sales representative.

Ensure that anyone who will be involved with the sterilizer installation receives a copy of this Installation Guide. Contact your local 3M medical sales representative for additional copies. Contact the local 3M service representative if you have any questions about installing the sterilizer. Call your local 3M Medical-Surgical sales branch office or the Medical-Surgical Service Center if you need help contacting your local representatives. Refer to Section 20 for phone numbers.

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9. LOCATION OF THE STERILIZER

⚠ DANGER

Since ethylene oxide is both flammable and toxic, locate the sterilizer in a well-ventilated area. Keep all sources of ignition away from the sterilizer and ethylene oxide cartridges. Avoid contact with gaseous or liquid ethylene oxide. Refer to Section 7 for Health and Safety Information.

9.1 Select an appropriate site well in advance of purchasing the sterilizer. Contact your building engineering department for help in selecting a site.

9.2 Locate the equipment in a well-ventilated area. See Section 10 for General Room Ventilation requirements. Avoid small, inadequately ventilated areas.

9.3 Keep sterilization/aeration equipment away from the main traffic areas of personnel.

9.4 Do not install sterilization equipment in areas where flammable gases or liquids other than EO are present. At the time of installation checkout, your 3M service representative will request that you certify in writing that this requirement is met.

9.5 Provide at least 50 cm (20 in.) on both sides and at the top of sterilizer for service access.

9.6 Contact appropriate local regulatory agencies to determine their requirements.

10. GENERAL ROOM VENTILATION

10.1 Locate the sterilization equipment in a well-ventilated area. Avoid small, inadequately ventilated areas.

10.2 Locate the equipment in an area with a non-recirculating ventilation system; the ventilation exhaust(s) must be dedicated.[1]

10.3 Provide an air exchange rate of at least ten (10) room changes per hour.[2]

10.4 The location of air intakes and exhausts in relation to the sterilization equipment is important. Measure the room air flow to ensure that there are no "dead" air spaces in the immediate sterilizer area and that air moves away from equipment operators.[3,4] Refer to Figure 1.

10.5 Your 3M service representative will request that you certify, in writing, that the requirements for the general room ventilation rate and the non-recirculating ventilation system are met when he reviews your installation.

11. ELECTRICAL REQUIREMENTS

11.1 Specifications

Voltage: 220 volts A.C. ± 10%
Frequency: 50/60 Hz
Phase: Single (1)
Current: 15 Ampere (Dedicated)

Power Cord: 220 volts,
15 Amp, NEMA 6-15, plug and an IEC 320/CEE-22 "Hot" (120° C), 250 Volt, 10 Amp receptacle to connect to the machine.

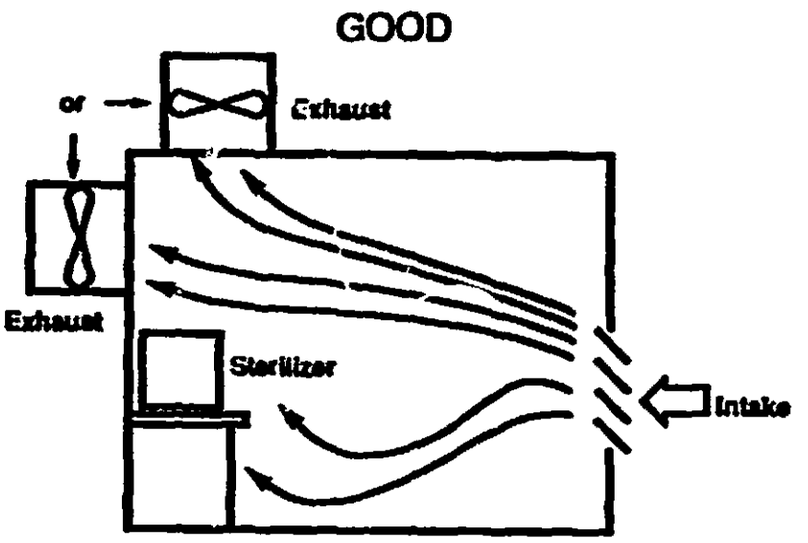
For machines sold outside the U.S.A., the 3M subsidiary will supply a power cord meeting local electrical requirements.

[1] EPA's Recommendations, "Sterilant Use of EtO in Hospitals & Health Care Facilities", Appendix A, VII. OSHA's EtO Standard 29 CFR 1910.1047, Federal Register, Volume 49, No. 122, June 22, 1984, p. 25802.

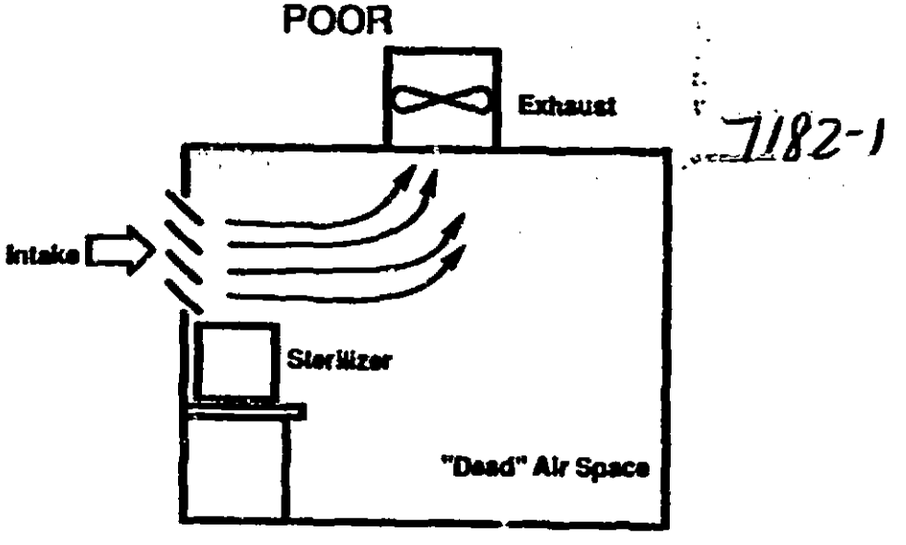
[2] Dept. Health Education and Welfare, DHEW Publ. No. HRA-74-400. "Minimum Requirements of Construction & Equipment for Hospital & Medical Facilities", HEW, PHS, Health Resources Adm., Div. of Facilities & Utilization, Rockville, MD 20852, 1974, p.27.

[3] Industrial Ventilation, A Manual of Recommended Practice, Committee on Industrial Ventilation, P. O. Box 16153, Lansing, MI 48902.

[4] ASHRAE, American Society of Heating, Refrigeration & Air Conditioning Engineers, Applications Volume, 1982, Chapter 7

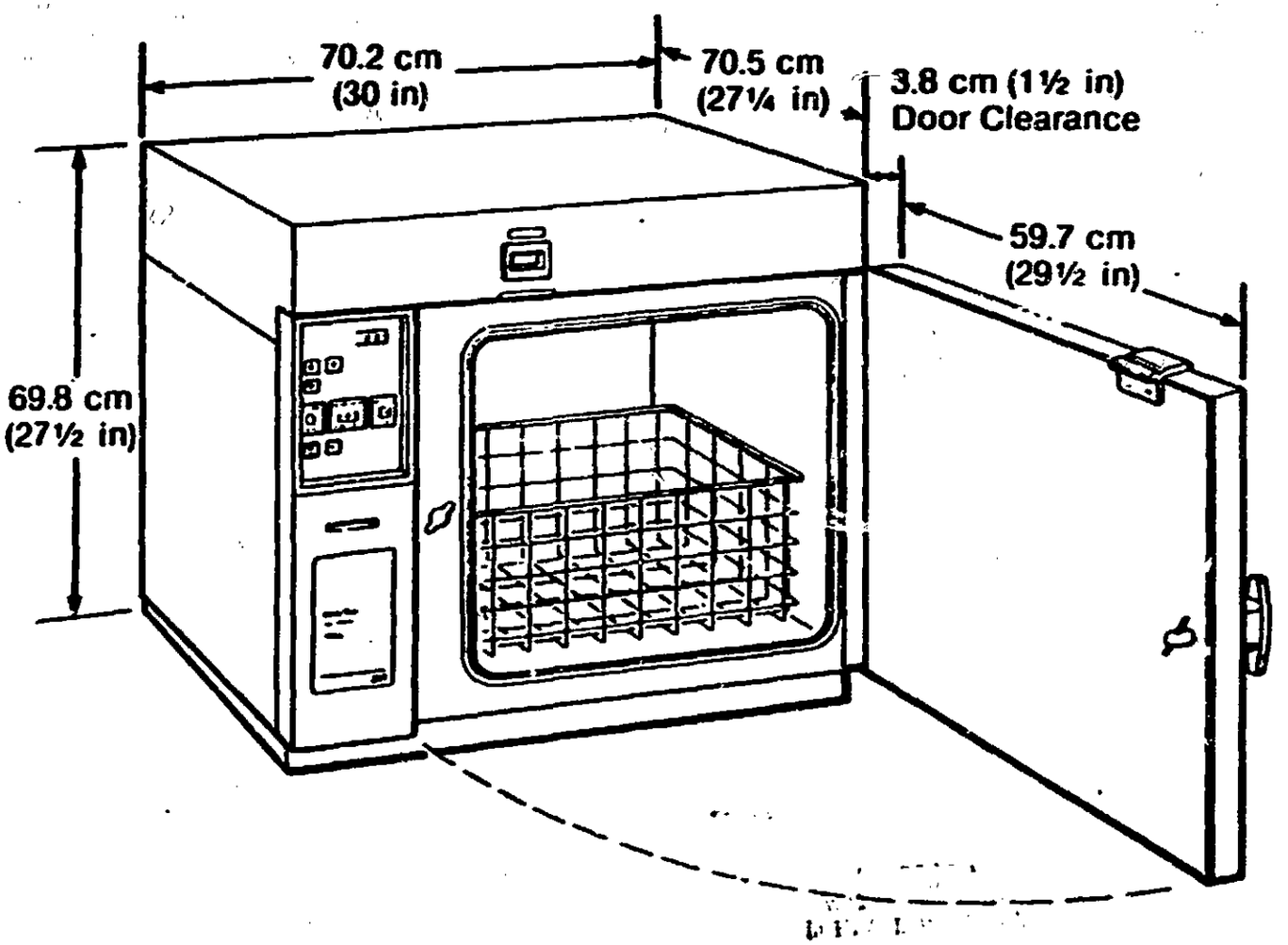


Air flow washes entire room.
Air movement is away from operator.



Air movement is toward operator
and "Dead" air spaces can form.

Figure 1:
RECOMMENDED LOCATION OF STERILIZATION/AERATION EQUIPMENT RELATIVE TO ROOM INTAKES AND EXHAUSTS



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Notes: 1. Leveling feet must be installed and base of unit must not be blocked so unit can circulate air over the electrical components drawing air in through the base of the cabinet.

2. Leave a minimum of 50 cm (20 in.) space on each side and top of the unit for service access.

Figure 2: Dimensions, Model 4XL

11.2 Connection to sterilizer

⚠ WARNING

Do not attempt to plug the cord into an outlet and operate the sterilizer until a 3M Service Representative has checked out the installation and completed inservice training of the operators. Costly damage and hazard could result.

12. VENT LINE REQUIREMENTS

Connect the sterilizer to a dedicated vent line to exhaust ethylene oxide to the outside atmosphere or to an emission control system. Meet the following requirements for venting the Steri-Vac 4XL gas sterilizer.

12.1 Multiple units of the Steri-Vac gas sterilizer models 4XL, 400, 202B and 202 may be vented through a common vent line. Each Steri-Vac 400B and 400C sterilizer requires a separate dedicated vent line

12.2 Ensure the vent line is constructed of straight lengths of copper tubing available in hard or soft temp

12.3 Do not extend the length of line beyond 91.5 m (300 feet). Label and/or color code the line. The diameter of the vent line depends on the length of the line. Refer to the table below for vent sizes. Use 0.95 cm (3/8 in.) National Pipe Thread (NPT) connection at the sterilizer.

Recommended Outer Diameter (OD) Vent Sizes for Steri-Vac 4XL gas sterilizer

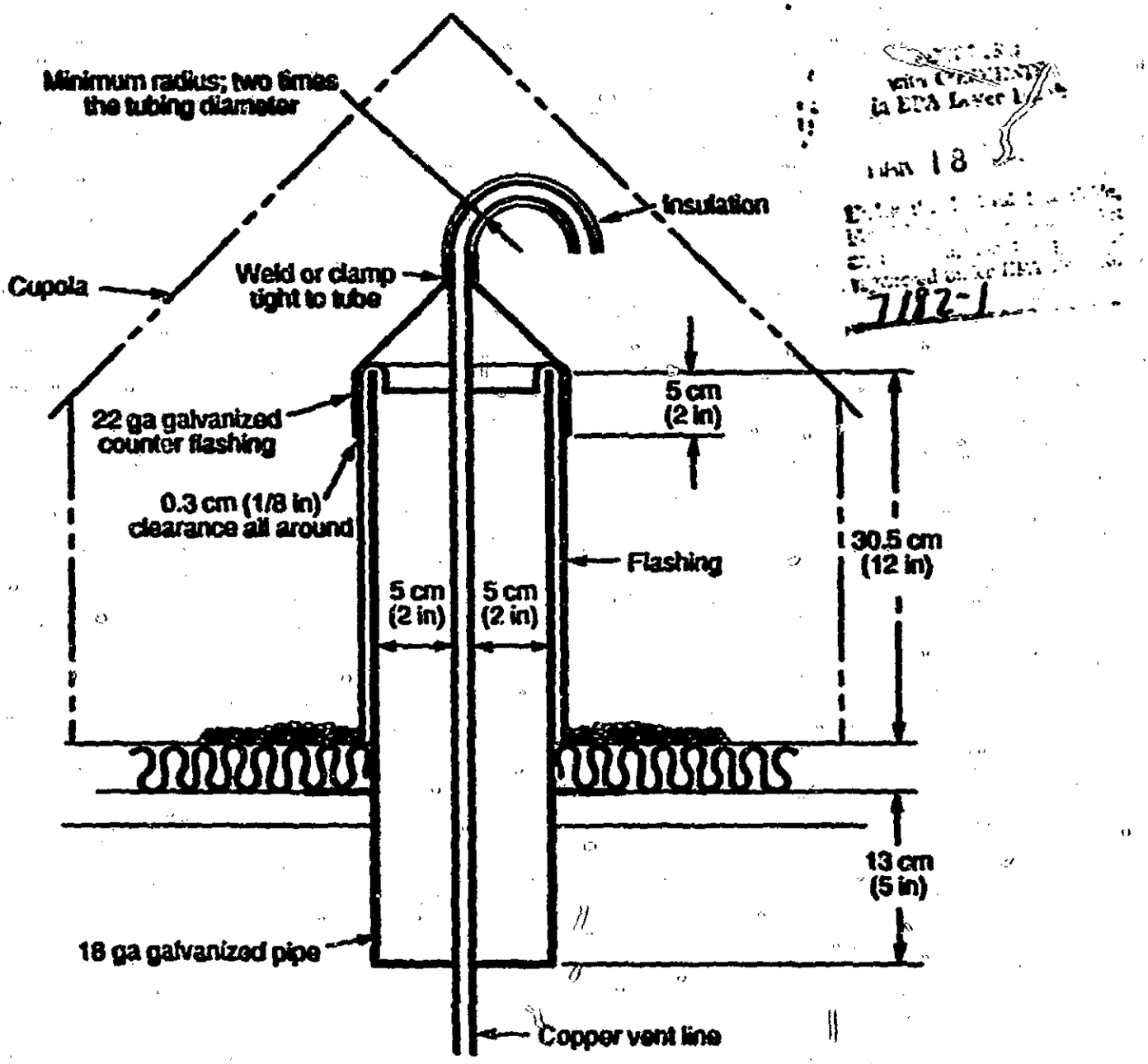
Number of Steri-Vac Sterilizers	Length of Vent Line 8 meters (25 ft)	15 meters (50 ft)	23 meters (75 ft)	31 meters (100 ft)	46 meters (150 ft)	61 meters (200 ft)	76 meters (250 ft)	91.5 meters (300 ft)
1	1.6cm (5/8 in)	1.6cm	1.6cm	1.6cm	1.9cm (3.4 in)	1.9cm	1.9cm	1.9cm
2	1.6cm (5/8 in)	1.9cm (3/4 in)	1.9cm	1.9cm	1.9cm	1.9cm	1.9cm	2.5cm (1 in)
3	1.9cm (3/4 in)	2.5cm (1 in)	2.5cm	3.2cm (1-1/4 in)	3.2cm	3.2cm	3.2cm	3.2cm
4	2.5cm (1 in)	2.5cm	3.2cm (1-1/4 in)	3.2cm	3.2cm	3.2cm	3.2cm	3.8cm (1-1/2 in)
5	2.5cm (1 in)	3.2cm (1-1/4 in)	3.2cm	3.2cm	3.8cm (1-1/2 in)	3.8cm	3.8cm	3.8cm
6	3.2cm (1-1/4 in)	3.2cm	3.8cm (1-1/2 in)	3.8cm	3.8cm	3.8cm	3.8cm	4.1cm (1-5/8 in)

12.4 The vent line will contain significant amounts of EO during the sterilization cycle. Do not terminate the vent line within 7.6 meters (25 ft) of any possible source of ignition or any opening to the building interior such as fresh air inlets, unsealed windows and pedestrian traffic areas. Greater distance may be needed in some cases; consider wind directions and the location of buildings in selecting the discharge point.

12.5 Install a moisture trap if there are more than 3 meters (10 feet) of vertical distance in the vent line. Route the vent line so that moisture drains toward the trap. Avoid sags or loops in the vent line to prevent moisture buildup at other points in the line. Call or write the 3M Medical-Surgical Service Center for a

moisture trap (3M Part No. 12-2376-1209-3) available at a nominal charge. Refer to Section 20 for the address and phone number of the Service Center.

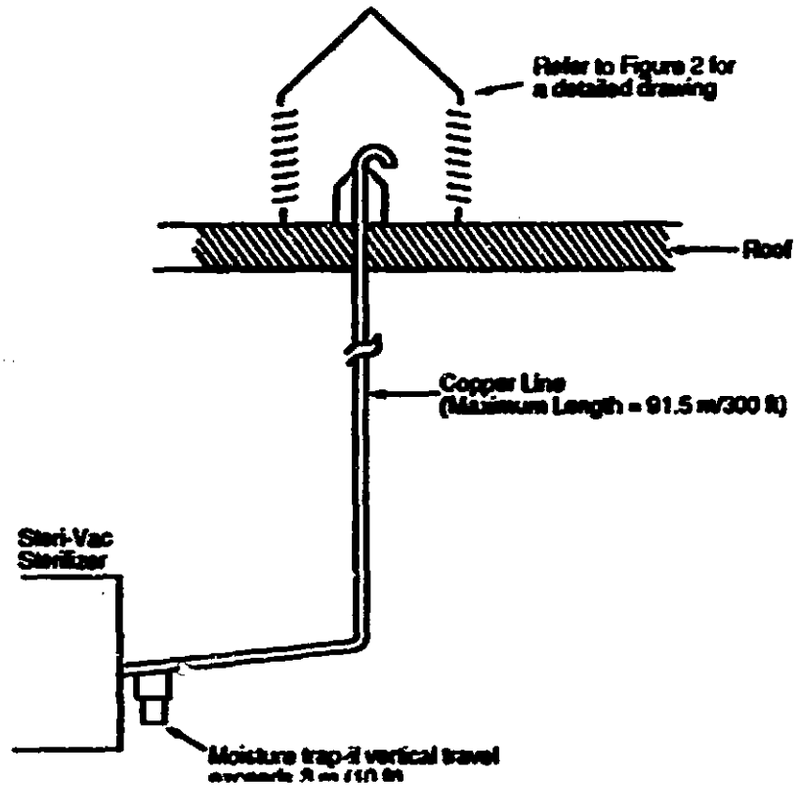
6 Ensure that the vent line is gas-tight from the machine to the outside atmosphere. Use flanged or compression fittings at the sterilizer and the moisture trap. Braze or solder all the other vent line fittings



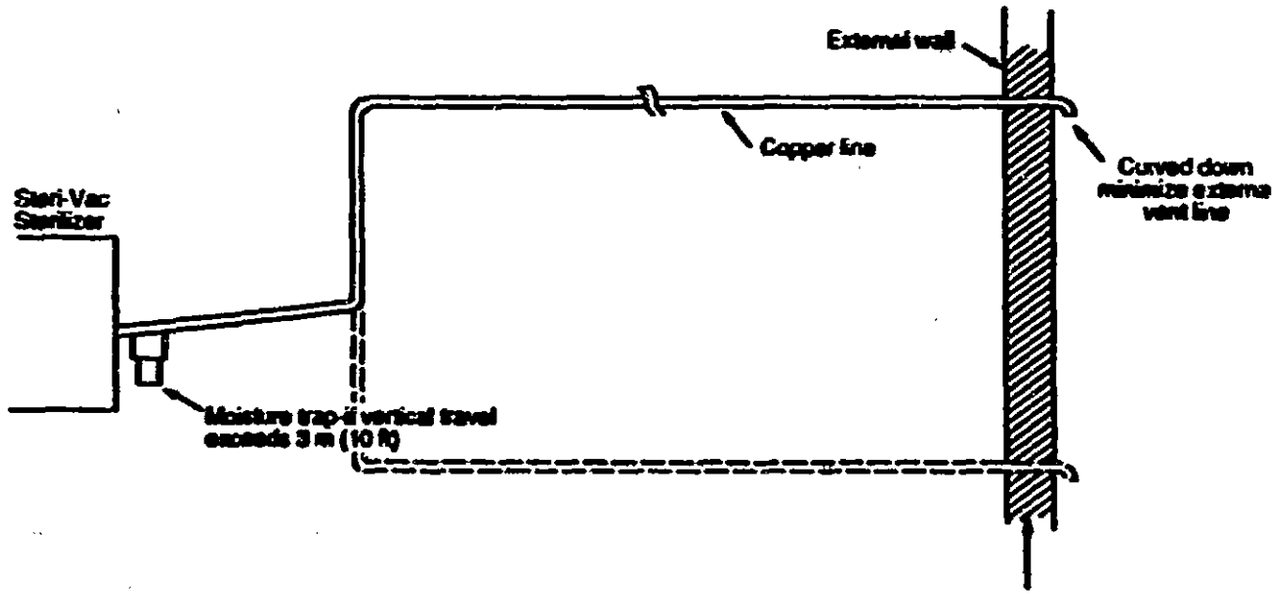
Note: The unit must be vented to the outside atmosphere, using the specified diameter copper tubing for the required vent line length. Vertical travel and restrictions, such as elbows, sharp bends and contractions should be kept to a minimum. The vent line should be a maximum of 91.5 meters (300 feet) and vertical travel held to a minimum. Be certain the termination point of the vent line is not located within 7.6 meters (25 feet) of any possible source of ignition or opening to a building. In northern climates, remove snow around the roof vent.

Figure 3: Roof Venting Diagram

Roof Top Vent Line



Horizontal Vent Line (Vertical Travel)



Note: Flanged or compression fittings should be utilized at vent line and moisture trap fittings.

Figure 4: Ethylene Oxide Vent Line Diagrams - Model 4XL

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12.7 Keep all of vent line, with the exception of a turned-down extension terminating on the roof top or exterior wall, inside the building. This is to prevent moisture from freezing in the line and blocking the vent
(See the diagram of vent line terminations in Figures 3 and 4.)

12.8 Refer to Figure 5 for diagrams of vent line connections.

12.9 Flexible vent line requirements.
A flexible, gas-tight line is needed between the sterilizer and the stationary vent line if the sterilizer must be moved for service (e.g., built into a wall).

12.9.1 Minimize the amount of flexible tubing used.

12.9.2 Recommended Products. The following are the only products tested and recommended for this application. The 3M Medical-Surgical Service Center must approve any other materials used. Call or write the service center (See Section 20) to order the Coboflow tubing.

12.9.2.1 COBOFLOW® Stainless Braided Flexible Tubing
1.25cm (1/2" ID) No. 1-8
Cobon Plastic Corp.
Newark, NJ
(201)624-4200

3M Part No. 12-2376-5158-8 available in 7 ft. pieces; longer lengths available on special request.

12.9.2.2 Parker-Hannifan
1.25cm (1/2" ID), Series 90
Parker-Hannifan Hose
Wickliffe, OH 44092
(216)943-5700

12.9.3 Order the length of tubing needed. Specify in the order that gas-tight fittings be included. Make the length of tubing at least 1.8 meters (6 feet) to avoid kinking but short enough to prevent looping or coiling.

12.9.4 Refer to Figure 5 for a diagram of flexible tubing connection to a sterilizer.

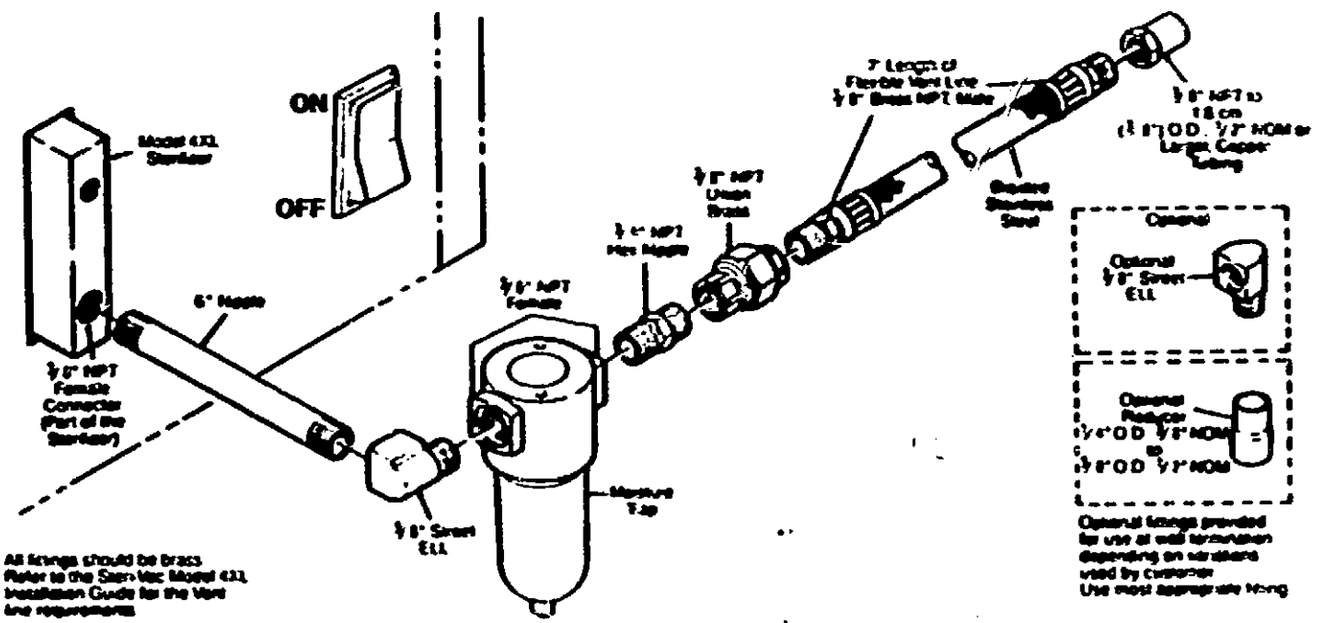

Figure 5: Suggested Vent Line Connection

13. COMPRESSED AIR REQUIREMENTS

13.1 Air Supply Specifications

Pressure: 3.5 Kg/cm^2 (50 psig) minimum; 10.5 Kg/cm^2 (150 psig) maximum.

Flow Rate: A flow rate of 3.4 liters per second (7.0 scfm) at 3.5 Kg/cm^2 (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.

13.2

⚠ DANGER

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.

Notice

3M's Warranty and Preventive Maintenance Agreement does not cover machine failures caused by an improper compressed air source. These are the customer's responsibility.

13.3 Filters

13.3.1 3M has the following filters available for the air supply:

Prefilter:	Filters dirt particles that are larger than 3 microns. Part No. Prefilter Assembly 26-1004-0633-4 Prefilter Elements 26-1004-0634-2
Oil Removal Filter Assembly:	Removes oil and filters dirt particles that are larger than 0.5 microns. Part No. Oil Removal Filter Elements 26-1003-4221-6 Oil Removal Filter Assembly 26-1003-4223-2

⚠ DANGER

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 supplying a complete air supply me_ting such specifications.

13.3.2 **Installation and Replacement**

Install the prefilter in front of the oil removal filter to remove coarse air contaminants that would otherwise plug the oil filter element. Replace the prefilter element at least every 6 months and the oil filter element at least every 12 months. Change the elements more frequently if the air supply is highly contaminated.

13.4 Air Dryer

Install a refrigerated air dryer (e.g., Norgren D-10 Series) at the air service if the dry air specification cannot be met.

13.5 Connections to Sterilizer

13.5.1 Shut-off Valve
Install a shut-off valve in the airline, upstream from any filters, so the compressed air can be turned off during maintenance operations.

13.5.2 Pressure Gauge
Install a pressure gauge between the filters and the air inlet to the sterilizer.

13.5.3 Connect the supply airline to the 1/4 in. National Pipe Thread fitting labeled "Airline" at the sterilizer. Refer to Figure 6 illustrating both stationary and flexible airline connections.

13.5.4 Flexible Airline Connections
Use a flexible airline between the sterilizer and the fixed airline when the sterilizer must be moved for service accessibility. Use the shortest possible length of flexible line which will allow the unit to be moved without disconnecting the airline from the unit. The tubing must be rated to handle the highest pressure that the compressor delivers. Select a tubing diameter which does not cause the pressure to drop below 3.5 Kg/cm^2 (50 psig) at the sterilizer.

13.6 Tank-Type Compressors

Purchase a low cost, tank-type compressor if needed to meet the sterilizer's compressed air requirements.

13.6.1 Specifications
Design: Twin Cylinder Type
Ratings: Minimum of 5 horsepower, ASME, and complies with state codes in U.S.A.
Air Pressure: 3.5 Kg/cm^2 (50 psig) to 10.5 Kg/cm^2 (150 psig)
Flow Rate: 3.4 liters per second (7.0 scfm) at 3.5 Kg/cm^2 (50 psig)
Pressure Switch Setting: Cut in pressure 3.5 Kg/cm^2 (50 psig minimum)
Tank Size: 60 gallon minimum

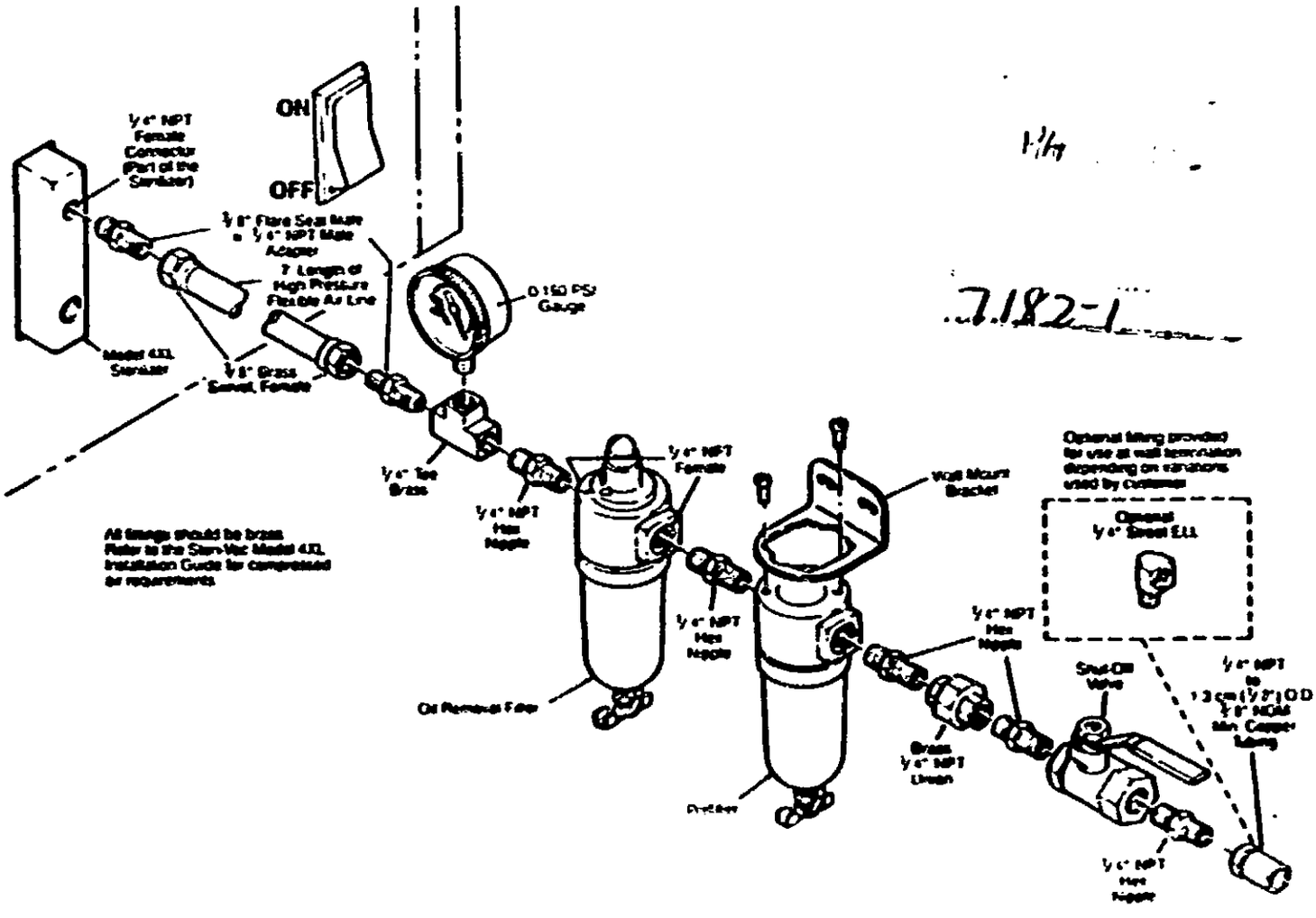

Figure 6: Compressed Air Connection

13.6.2 Compresssor Location

Consider electrical power requirements for the compressor. Locate the compressor away from work areas to reduce noise levels around the sterilizer.

13.6.3 Multiple Sterilizer Installations

Each unit requires a minimum of 3.5 Kg/cm^2 (50 psig) pressure with a minimum flow rate of 3.4 liters per second (7.0 scfm). Example: Two sterilizers would require 3.5 Kg/cm^2 (50 psig) with a 5.8 liters per second (14 scfm) air flow.

13.6.4 Suggested Compressors

The following units meet or exceed the compressed air requirements. The catalogue/model numbers may change.

Manufacturer	Horsepower	Size of Horizontal Tank in Gallons	Catalogue/ Model No.
Campbell Hausfeld	2	20	FL 3507
	2	20	VT 6102
	2	20	VT 6103
	3	30	VT 6104
	3	30	VT 6116
Sears	2	20	9GT 17432N
	4	20	9GT 17754N
	5	30	9GT 17755N
Quincy	2	60	F216
	3	80	F230
	5	80	F240
Sullair	2	60	210S 2A605
	3	60	210S 3A605
	5	60	23S 560S

14. LOCAL EXHAUST SYSTEM REQUIREMENTS

14.1 Function

An exhaust hood is built into the top panel of the sterilizer. Its purpose is to remove residual ethylene oxide gas (EO) from the sterilizer chamber when the door is opened at cycle completion. The hood must be connected to a dedicated exhaust system supplied by the customer. At the end of the sterilization cycle, the operator opens the sterilizer door to a latched position. While in this position, air is drawn upward from the bottom of the sterilizer door through the hood to the outside or to an emission control system via the exhaust duct. The air stream vacuums EO molecules from the front of the sterilizer chamber. Refer to Figure 7.

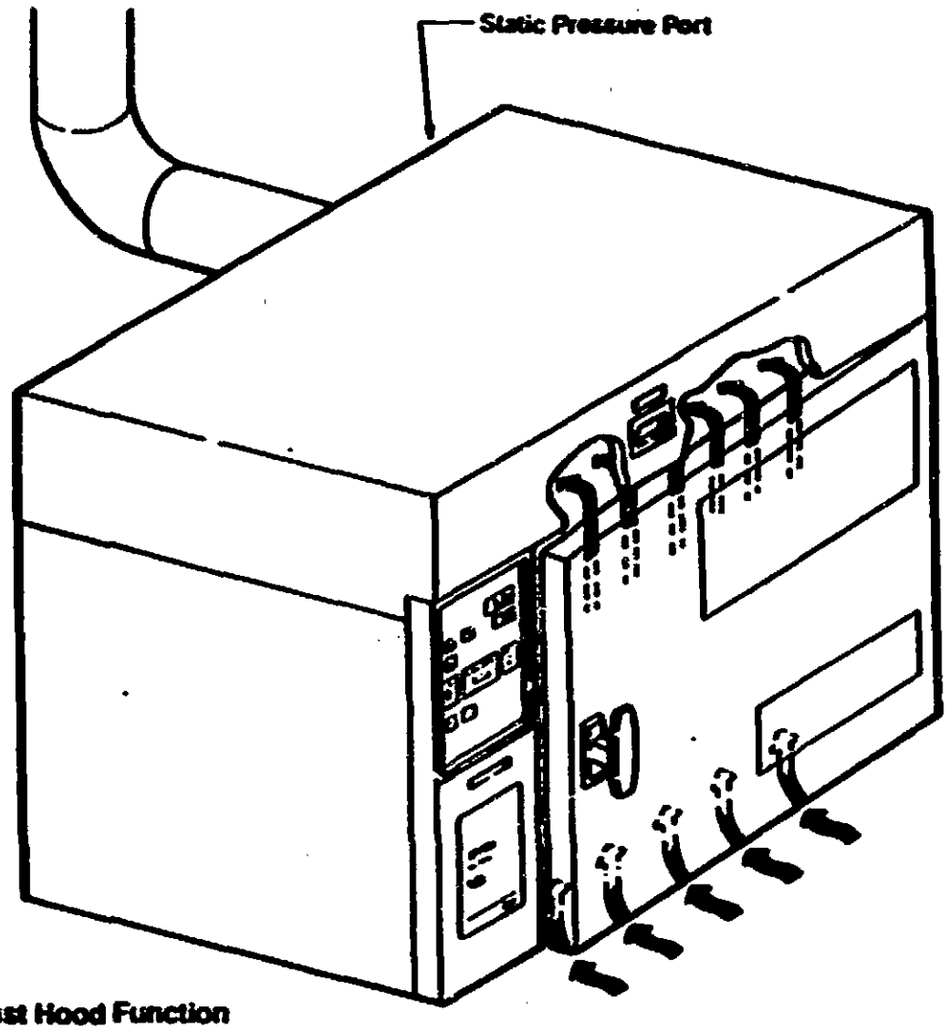

Figure 7: Local Exhaust Hood Function

14.2 Precaution

Inform department head(s) and sterilizer operators before a local exhaust system will be shut down because of repairs, maintenance, etc.

14.3 Specifications

Meet the following requirements to ensure strong air movement through the hood.

⚠ DANGER

14.3.1 Ethylene oxide is both flammable and toxic. Design and construct the exhaust system in accordance with state and/or local fire, health and safety codes.

14.3.2 Connect the hood to a dedicated exhaust system. Do not connect the hood to an exhaust system that recirculates air into the building.

14.3.3 Air Flow: Minimum of 2.8 cubic meters/min. (100 standard cubic ft./min.) through the hood.

Minimum of 350 meters/min. (1150 feet/min.) in the 4 in. line to the hood.

Minimum static pressure of -0.15cm (-0.06 in of water) at the static pressure port (See Figure 7). Measure the static pressure when the sterilizer door is in the open latched position.

14.3.4 Hood Connection: 10.2 cm (4 in.) outside diameter.

14.3.5 Duct Work

14.3.5.1 Use metallic duct work rated to handle the highest pressure that the system delivers. Do not use plastic tubing.

14.3.5.2 Use a minimal amount of flexible, air-tight duct. Flexible ducts can introduce significant air flow resistance.

14.3.5.3 Use larger diameter ducts to minimize frictional air drag losses.

14.3.5.4 Minimize the number of elbows to reduce the static pressure in system.

14.3.5.5 Seal duct seams and joints with impervious (aluminum) duct tape or sealant to prevent leaks.

14.3.6 Exhaust Fan

Use a centrifugal fan with backward curved blades designed for continuous operation. This fan has a high efficiency and is spark-proof with the motor sealed from the exhausted air stream. The impeller and the ring around the impeller drive shaft must be nonferrous.

14.3.7 Ventilation Failure Detector

An air flow sensor is installed in the 10.2 cm (4 in.) opening at the back of the hood. The sensor will activate a flashing error message, c1 (low air flow), to alert personnel of ventilation system failure (e.g., fan malfunction). The error message does not stop a cycle in progress. The ventilation problem must be corrected for the sterilizer to clear the message.

14.3.8 Outside Discharge

14.3.8.1 Exhaust the ventilation system to the outside or to an emission control system. Use a roof-top discharge if possible.

14.3.8.2 Elevate the fan and motor in areas likely to have snow accumulations to prevent corrosion and blockage.

14.3.8.3 Ensure the discharge point is at least 7.6 meters (25 feet) away from any possible sources of ignition, openings to buildings, or pedestrian traffic ways. Greater distances may be needed in some locations.

14.3.8.4 Use one of the types of discharge terminations illustrated in Figure 8.

14.4 Planning the Installation

Good planning is the key to a successful local exhaust system. Follow these steps.

14.4.1 Regulatory and Technical Information

⚠ DANGER

14.4.1.1 EO is both flammable and toxic. Design and construct the local exhaust system in accordance with state and/or local fire, safety and health codes. Contact the appropriate regulatory agencies for their requirements.

14.4.1.2 Use an industrial ventilation consultant or ventilation contractor to help design and install the local exhaust system. Ensure that any person involved in the installation receives a copy of this Installation Guide. Contact your 3M Medical sales representative

for additional copies. Sales Branch locations and phone numbers are listed in Section 20.

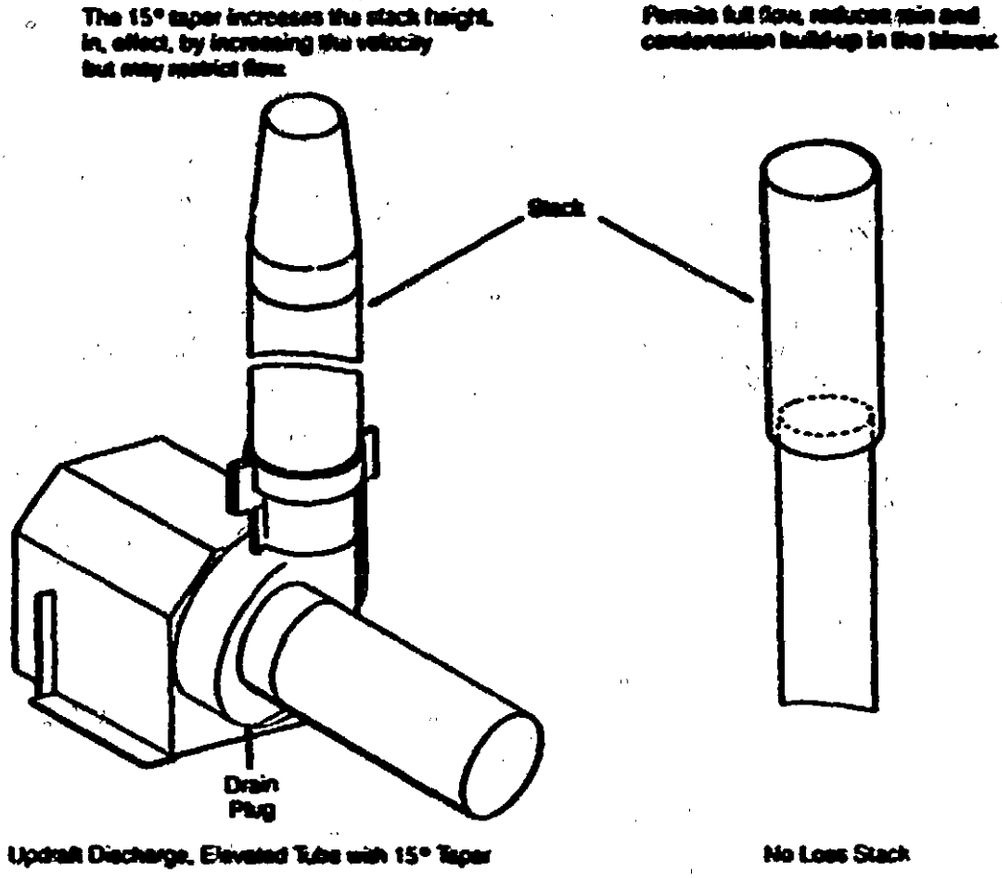

Figure 8: Discharge Terminations

14.4.1.3 Use the installation diagrams in Figures 9, 10, and 11 if applicable.

14.4.1.4 Contact the Medical-Surgical Service Center for technical assistance (612/733-78

14.4.1.5 **Additional References**

Industrial Ventilation, A Manual of Recommended Practice, Committee on Industri Ventilation, P.O. Box 16153, Lansing, MI 48902.

ASHRAE, Applications Volume, American Society of Heating, Refrigeration and Ai Conditioning Engineers, 1982, Chapter 7.

14.4.2 **Design Steps**

14.4.2.1 Know how the state and/or local fire, health and safety codes apply to EO gas sterilization.

14.4.2.2 Determine where the sterilizer will be located. Ensure the location conforms with t requirements listed in Section 9.

14.4.2.3 Identify the point outside the building, preferably on the roof, where the fan and ex will be located. Position the exhaust discharge at least 7.6 cm (25 ft.) from any ign source, openings to buildings and pedestrian traffic ways. Greater distances may b required in some locations. Consider wind directions and building locations. Prote fan from the elements but ensure that there is good air flow around the motor for cooling.

14.4.2.5 Determine the size, length and number of elbows needed in the duct work leading fr the sterilizer to the discharge point. Note that each elbow introduces losses in the system.

14.4.2.6 Calculate the total air flow required for the entire system.

14.4.2.7 Determine the static pressure required for each branch of the system.

14.4.2.8 Calculate the static pressure for the entire system using standard industrial ventilatio techniques.

14.4.2.9 Add a 10% safety factor to the air flow and the static pressure calculated in steps 13.4.2.6 and 13.4.2.8, respectively.

14.4.2.10 Determine if a new dedicated exhaust system is needed or if an existing dedicated exhaust system can be used. Ensure that the existing system, if used, is capable of meeting Steri-Vac equipment specifications.

14.4.2.11 Select an exhaust fan meeting or exceeding the air flow and static pressure requirements calculated in step 14.4.2.9.

14.4.2.12 Consider the inlet and outlet conditions of the fan. Prevent EO reentry, turbulence a back pressure on the fan.

14.4.3 Installation Diagrams

The diagrams in Figures 9 and 10 depict a number of local exhaust systems, one of which ma be applicable to your needs. Use them, if applicable, in planning your installation.

15. AERATION CABINET SPECIFICATIONS

Venting aeration cabinets into the same system which serves the sterilizer local exhaust hood may be advantageous in many situations. You will need to know the air exhaust flow from the aerators to size the appropriate exhaust fan. Contact the aerator manufacturer for their air flow specifications if non-3M aeration cabinets are to be vented. The 3M Steri-Vac aeration cabinet specifications are listed in the following table.

AERATION CAB INET AIR FLOW SPECIFICATIONS

Steri-Vac Aeration Cabinet Model	AIR EXHAUST FLOW Liters Per Second	Cubic Feet Per Minute	Duct Outside Diameter at Connection Point
33B	5	10	7.6 cm (3 in.)
20	15	30	10.2 cm (4 in.)

16. 3M SERVICE TELEPHONE REVIEW

Contact your local 3M Service Representative by phone when the sterilizer is installed (i.e., all electrical and mechanical services are connected and functioning). **Do not operate the sterilizer without having a 3M service representative check the installation.** Complete the Customer Checklist in Section 2 before calling your Service Representative who will review the installation with you. He will point out any changes to be made before his checkout visit.

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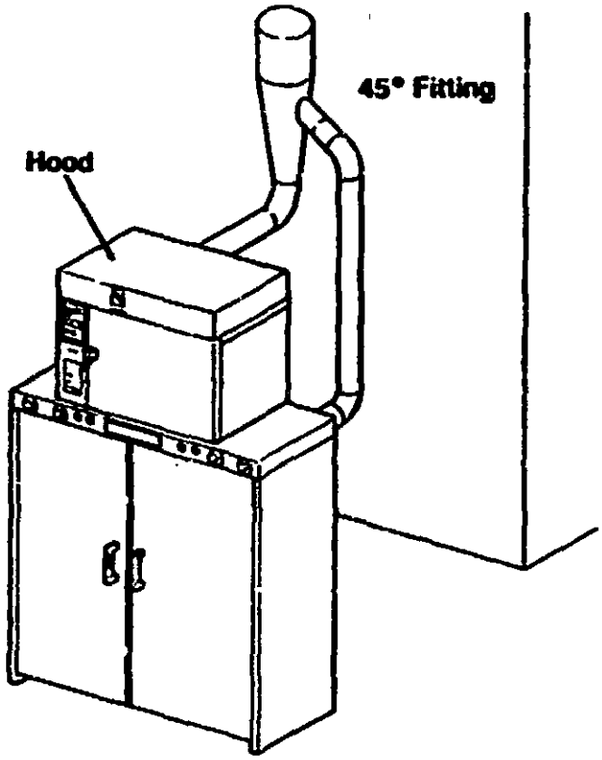
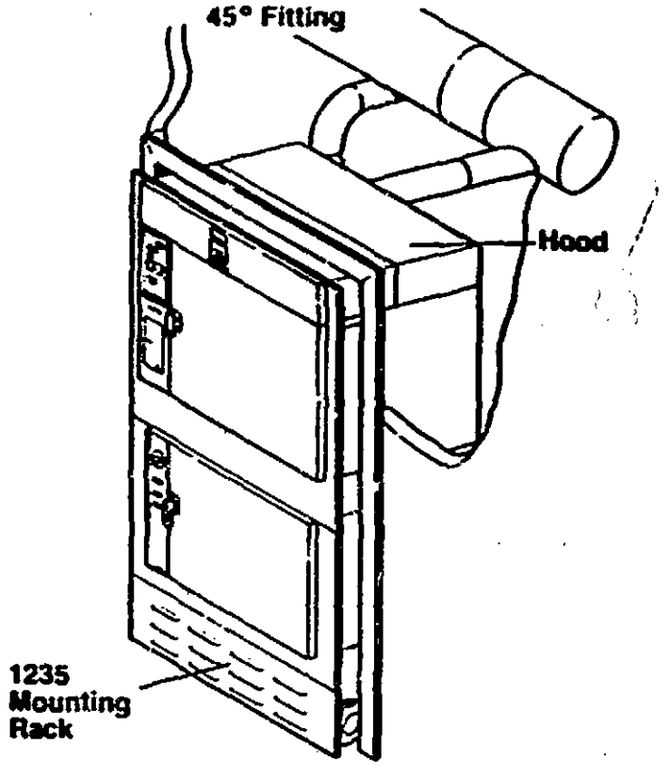
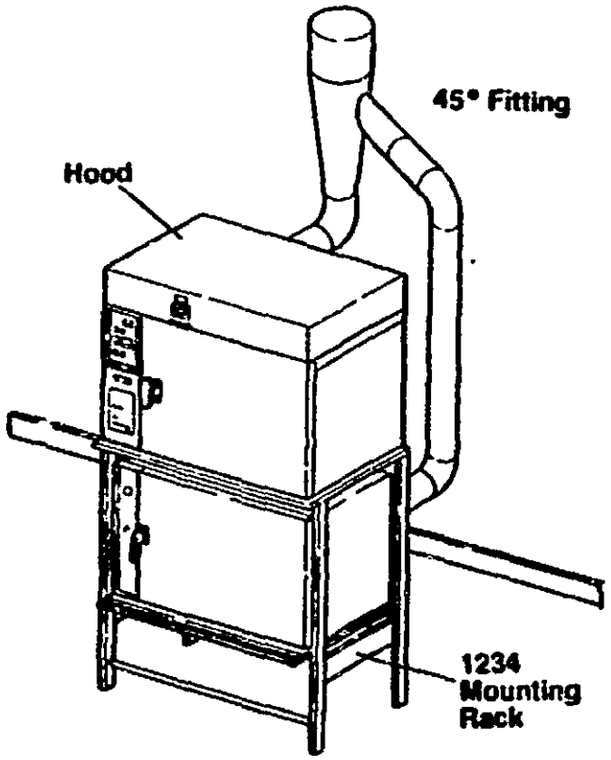
Figure 9: Examples of Installations



Sterilizer Mounted on Top of Model 20 aerator with Hood and Aerator Vented into a Common Hood.



Wall Mounted Sterilizer and Aerator with Hood and Aerator Vented into a Common System.



Stacking Rack Arrangement, with Local Exhaust Hood and Aerator Vented into a Common Exhaust System.

Figure 9: Examples of Installations

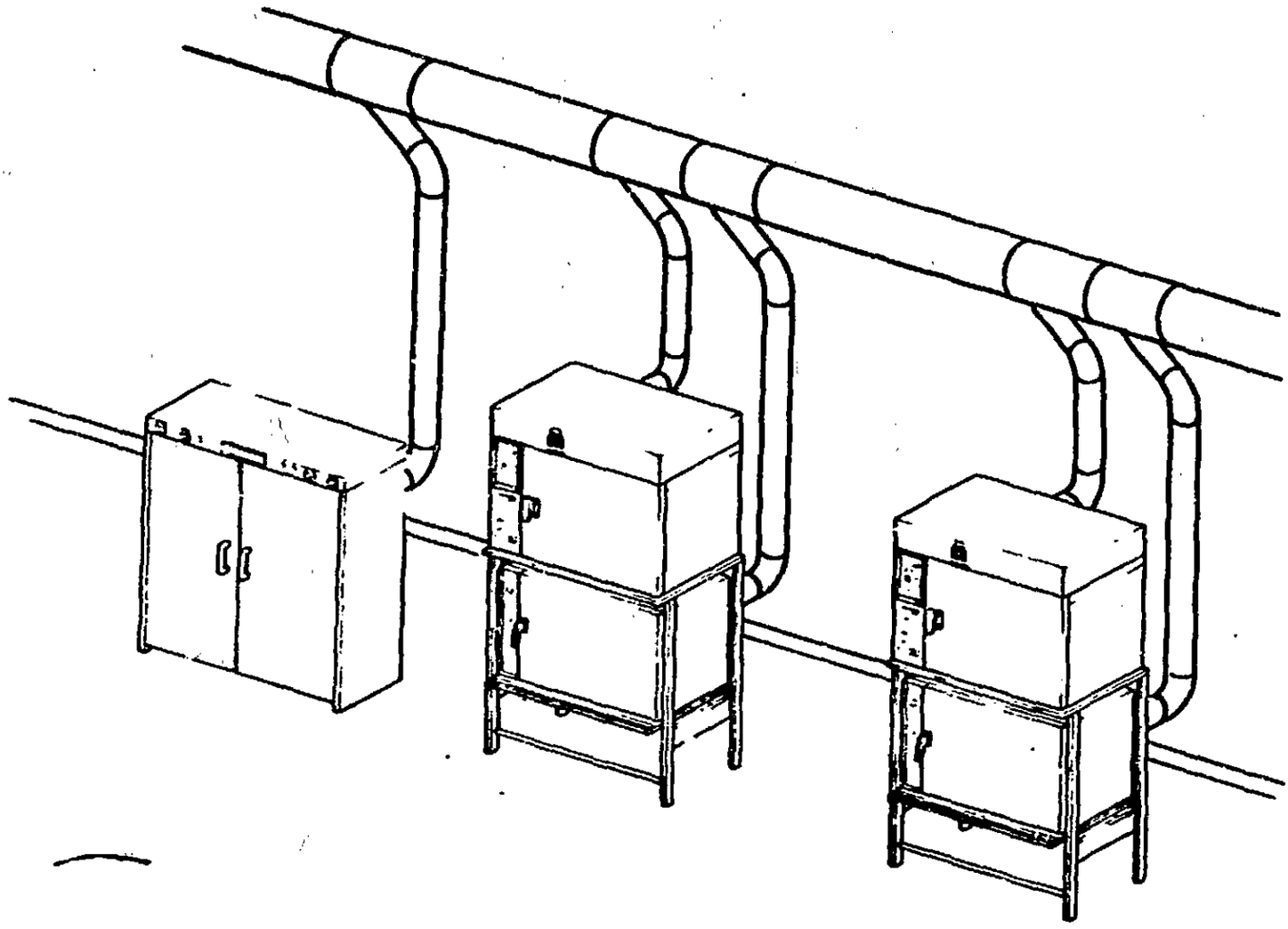


Figure 10: Multiple Hoods and Aerators Vented into aCommon System.

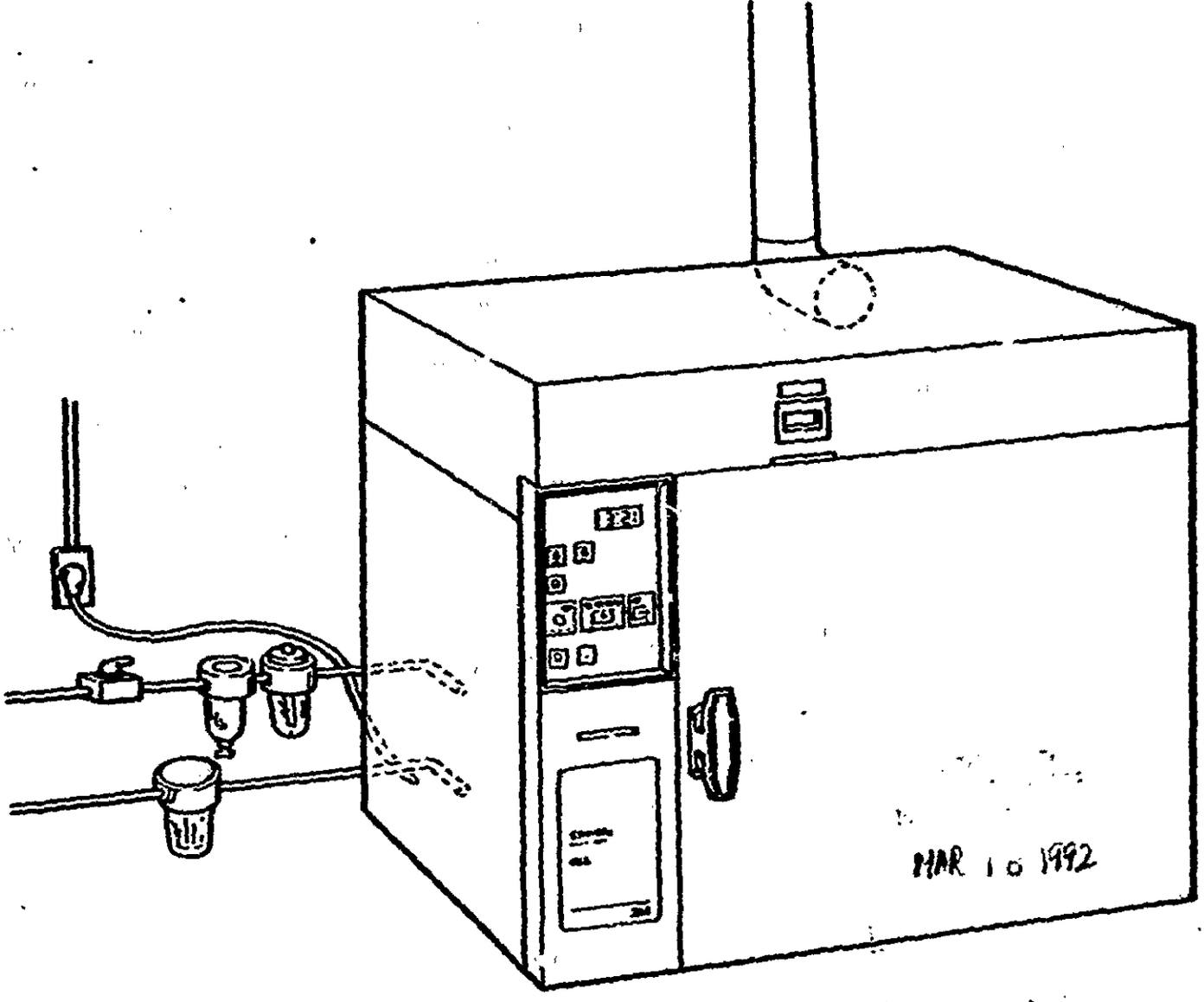


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Figure 11: Example of Installation

17. 3M INSTALLATION CHECKOUT

The service representative will schedule a visit to assure that the sterilizer is installed according to 3M specifications. After checkout the service representative will:

17.1 request the customer to sign a checkout form,

17.2 complete inservice training of personnel on the proper operation of the sterilizer,

17.3 provide you with information on a Steri-Vac sterilizer Operator Certification Program, and

17.4 provide you with a completed Customer Service Order that includes the date at which the 6-month warranty takes effect.

18. ETHYLENE OXIDE MONITORING

The Occupational Safety and Health Administration (OSHA) requires that you monitor your employee exposures to ethylene oxide after sterilizer installation (29 CFR 1910.1047[d]. Repeat air sampling at a frequency that not only satisfies the OSHA requirements but also provides you and your personnel with confidence. Changes in sterilization equipment, ventilation, or work practices should prompt immediate surveys.

RB4/19

19. ADDITIONAL INFORMATION

Material Safety Data Sheets or additional information on installation, accessories, Preventive Maintenance Agreements, etc., can be obtained by writing or calling the 3M Medical-Surgical Service Center.

20. 3M Medical Products Service Center
Building 582, Dock 1
St. Paul, MN 55144-1000
612/733-7885

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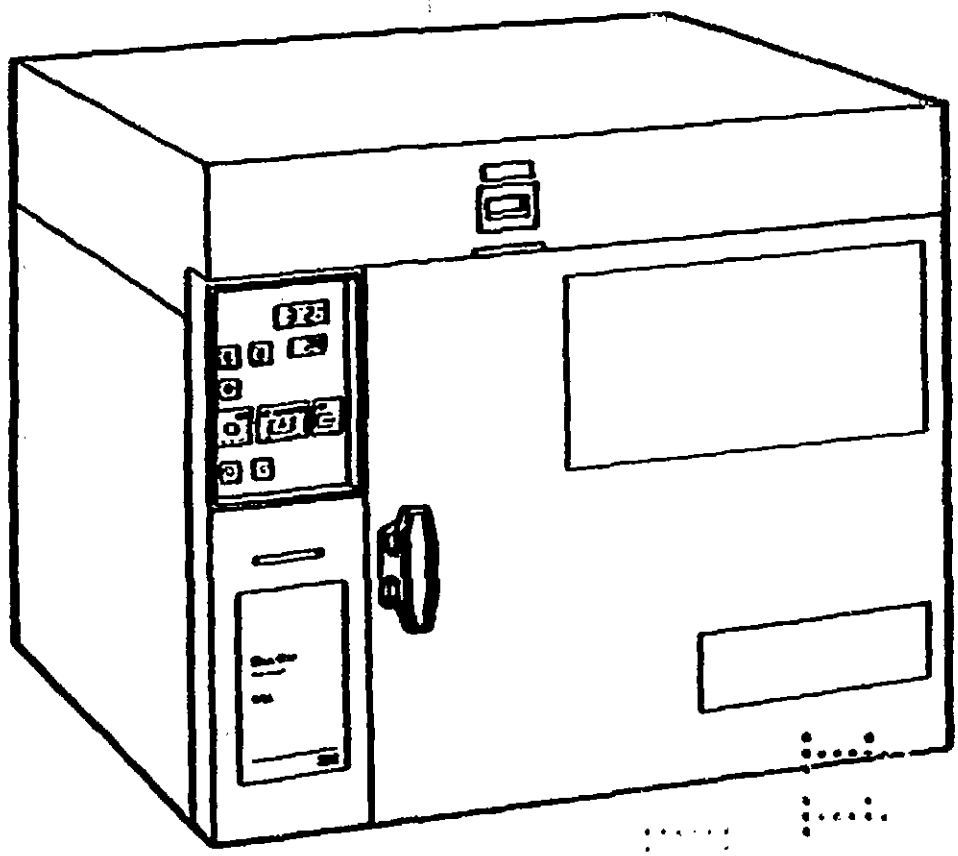
4XL

Gas Sterilizer

EPA Reg. No. 7182-1



Operator's Manual

OPERATOR'S MANUAL
STERI-VAC™ 4XL GAS STERILIZER

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1. STERILIZER LABELING

READ SAFETY LABELS CAREFULLY

Carefully read all warning labels on the front and back of the sterilizer to avoid hazards.

Front Door Hazard Label

⚠ DANGER

ETHYLENE OXIDE

FLAMMABILITY

Flammable in concentrations from 3% (30,000 ppm) to 100%.

Keep all sources of ignition such as matches, lit 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. Repeated overexposure may result in olfactory fatigue (i.e. increasingly difficult to smell ethylene oxide).

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 maycause 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.

STATEMENT OF PRACTICAL TREATMENT/FIRST AID

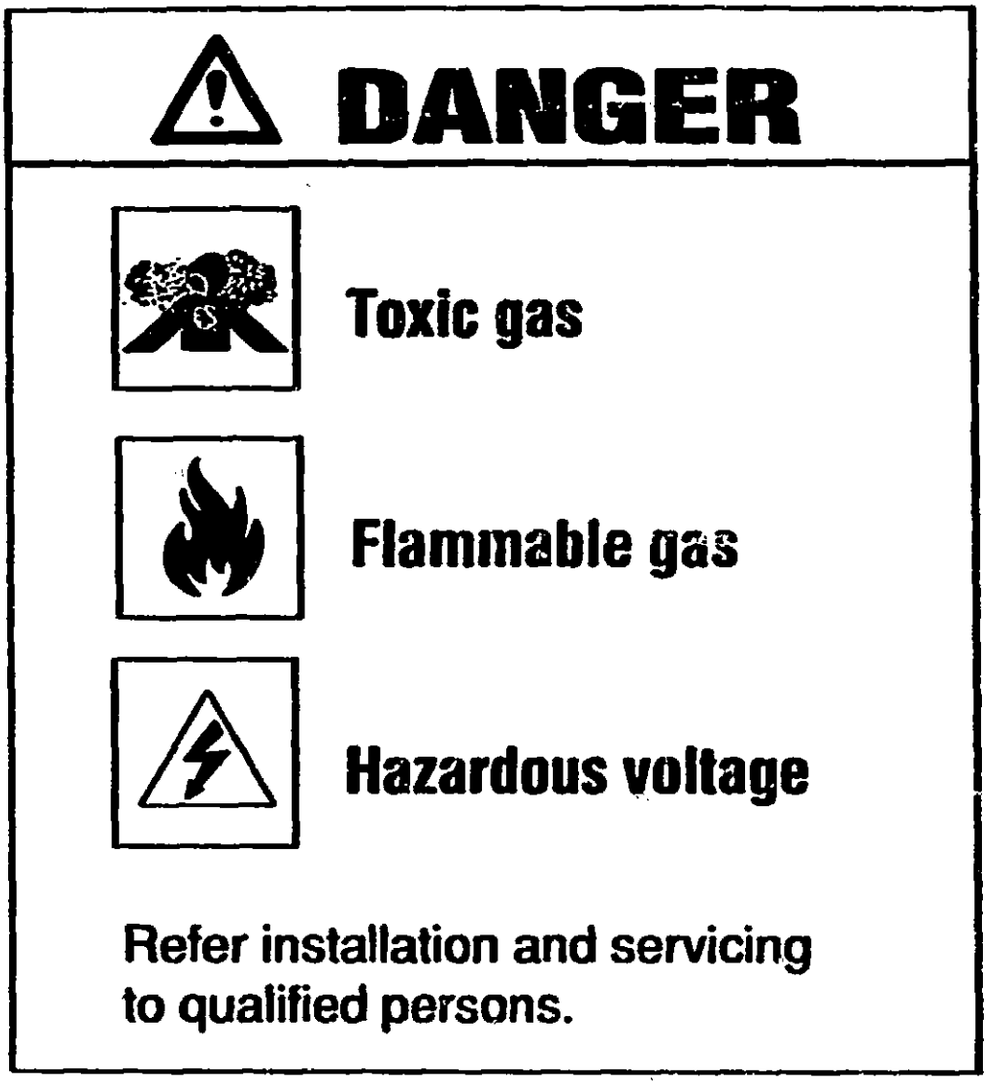
Inhalation. Immediately get fresh air for overexposures to EO gas. Contact a physician as soon as possible.

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

Back Panel Danger Label



Affixed to the front panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-9490-1

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READ INSTALLATION GUIDE AND OPERATING INSTRUCTIONS CAREFULLY

Front Panel Label

OPERATING INSTRUCTIONS

I. USER RESPONSIBILITY

Know the information in the Steri-Vac™ 4XL gas sterilizer Operator's Manual before using this product. 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.

II. GENERAL USE INFORMATION

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.
2. Standard cycle parameters:

Cycle	Temperature	Approx. Sterilization Time
WARM	55°C	2.5 hours
COOL	37°C	5.5 hours

3. Clean, precondition and package, as needed, all articles to be sterilized. (Refer to Sections 10, 11 and 12 in Operator's Manual.)
4. For routine sterilization monitoring, place a test pack containing a biological indicator (BI) in the center of the load. Remove the test pack and process the biological indicator according to the manufacturer's instruction. (Refer to Section 14 in the Operator's Manual.)
5. Aerate all gas sterilized items (excluding unpackaged metal and glass) before handling. Follow the instructions from the device manufacturer.
6. Remove the empty Steri-Gas™ cartridge from the holder and place it on top of the load to be aerated. A cartridge that has aerated in its sterilizer holder for 2 hours or more needs no further aeration.

III. STERILIZER OPERATING INSTRUCTIONS

A normal sterilization cycle consists of the following sequence of operator steps:

1. Load basket loosely and orderly.
2. Check that the sterilizer is in standby.
3. Turn handle counter-clockwise while lifting DOOR RELEASE to open door.
4. Insert Steri-Gas cartridge 4-100 into the holder. (Green label on cartridge matches green ring of holder.)
5. Add basket to chamber and shut door. Turn door handle clockwise to vertical position.
6. Press WARM or COOL cycle switch.
7. Press START switch.
   - *Cycle continues automatically until completion.*
   - *Sterilization cycle is complete when AERATE indicator is lit and timer is on.*
8. Use STOP switch to interrupt the sterilization cycle.
9. To interrupt aeration:
   a. Turn handle counter-clockwise.
   b. Wait approximately 30 seconds.
   c. Open door to latched position.
   d. Keep door in the open latched position for at least 5 minutes.
   e. Fully open door while lifting DOOR RELEASE.
   f. Remove sterile items.
   g. Close door and turn handle clockwise to resume aeration.
10. To terminate aeration:
    a. Turn handle counter-clockwise.
    b. Wait approximately 30 seconds.
    c. Open door to latched position.
    d. Keep door in the open latched position for at least 5 minutes.
    e. Fully open door while lifting DOOR RELEASE.
    f. Remove basket.
    g. Press STOP switch.
       - *Machine will go to standby.*
    h. Close door.

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Affixed to the front panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-9333-9

Front Panel Label

CAUTION/ERROR MESSAGE CHART

Use the chart below to determine the reasons for a caution/error message appearing in the digital display. This chart lists the messages most likely to appear. Refer to Section 18 of the Operator's Manual for the complete chart and more details. Follow the steps designated. Call your 3M Service Representative when: (1) indicated, (2) a code appears that is not listed, or (3) you have any questions.

Be alert to any codes appearing. This indicates 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 Messages — Will not stop cycle	Possible Causes	What To Do
c1 Low Air in Exhaust Hood	External Fan Malfunction Airflow Sensor Failure	Check Fan and Fan Belts 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, Airlines

Errors that are detected before puncture

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 Airlines and Pressure Call Service Representative
E22 Initial Pumpdown Timeout	Improper Air Pressure Defective Vacuum Pump	Check Air System Call Service Representative
E23 Chamber Preheat Timeout	Chamber Too Cold Defective Temperature Control	Rerun Cycle Call Service Representative
E24 Heatsink Preheat Timeout	Chamber Too Cold Defective Temperature Control	Rerun Cycle Call Service Representative
E28 No Water Injected	Reservoir Float Switch Stuck Water System Plugged	Add Water To Reservoir Call Service Representative
E32 Door Unlocked	Door Latch Hung Up on Bolt Control Error	Turn Handle Completely Vertical 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

Erros found during gas exposure

E50 mpty Cartridge	Empty Cartridge Loaded Puncture Mechanism Failed	Use New Cartridge Call Service Representative
E54 Extended Power Outage	Could Not Resume Cycle After Outage	Rerun Cycle
E60 User Interruption	User Pressed STOP Switch	Rerun Cycle

Errors that leave the chamber locked with gas possible in the chamber

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

Error code clearing procedure

When machine is showing an error code it is necessary to return to the sta [illegible]

[illegible]

[illegible] to the front panel of the Steri-Vac [illegible]

AIR LINE

Maximum air inlet pressure shall not exceed 150 psig

Affixed to the back panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-3271-1

Power On/Off Switch and Circuit Breaker

To reset, turn switch to "On" position.

Affixed to the back panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-3415-8

Grounding reliability can only be achieved when equipment is connected to equivalent receptacle marked "Hospital Only" or "Hospital Grade".

Affixed to the back panel of the Steri-Vac 4XL gas sterilizer.
3M Part No. 12-2376-9709-4

INTRODUCTION

2. ETHYLENE OXIDE STERILIZATION AND AERATION

2.1 Sterilization

Health care facilities throughout the world have found 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.

2.1.1 All microorganisms, including resistant spores, are killed by ethylene oxide's chemical action.
2.1.2 Materials can be prepackaged, then sterilized and maintained sterile for use.
2.1.3 Ethylene oxide is relatively noncorrocive to plastic, metal, or rubber materials.
2.1.4 Ethylene oxide can penetrate and sterilize irregularly shaped items.
2.1.5 Biological (e.g. Attest™ monitors) and chemical (e.g. Indox™ tape) systems can be used to ensure that sterilization parameters are met and to distinguish processed from unprocessed materials.
2.1.6 Ethylene oxide can be used to sterilize those materials that cannot be immersed in liquid disinfectants.

2.2 Aeration

Many items retain large amounts of ethylene oxide (EO) during gas sterilization. These devices must be properly aerated before hospital personnel and patient use to reduce the residues of EO and its chemical by-products to safe levels. Aeration is the process of subjecting EO-sterilized items to airflow, generally heated and filtered air, to enhance the diffusion of residual EO from the sterilized items. It is essential for the health protection of patients and personnel handling the devices.

All packaged items should be aerated before handling. It is the responsibility of the individual device manufacturer to provide specific information on the use and processing of reusable devices. The manufacturer should provide sterilization and aeration parameters in writing to health care facilities. Device manufacturers are in the best position to: (1) identify the maximum temperature that the item can withstand, and (2) evaluate the effects that changes in raw materials, processing or configuration can have on aeration times.

3. FEATURES AND BENEFITS OF THE 4XL STERILIZER

The Steri-Vac 4XL gas sterilizer is a compact unit with a four (4) cubic foot chamber. The sterilizer can be installed in a wall, in a specially designed rack, on an open shelf, or on a counter top.

The sterilizer offers a fully automatic system of controls to ensure that proper conditions for sterilization are met and to protect operators from flammable or toxic concentrations of ethylene oxide gas. The following are the major features and benefits of the system.

3.1 The solid state electronic design provides accuracy and dependability.
3.2 The air venturi vacuum pump has no moving parts for maximum reliability.
3.3 Because of the door interlock, the chamber door must be closed before a cycle can be started.
3.4 Once a cycle is started, the door is locked.
3.5 The chamber temperature and vacuum are monitored continuously during the sterilization cycle. The electronic controller automatically stops the cycle if errors are detected.
3.6 Multiple pulses of low temperature steam, referred to as dynamic humidification, assure proper humidification.
3.7 A unit dose cartridge of ethylene oxide is punctured automatically inside the chamber.
3.8 Heaters on all six chamber sides, including the door, provide uniform heat and eliminate cold spots on which moisture can condense.
3.9 The lights on the front panel of the sterilizer show cycle status.
3.10 A printer (optional) can be installed in the front panel of the sterilizer to permanently record time, temperature, pressure, cycle status, and aeration time (see Accessory section).
3.11 By pressing the STOP button, an operator can manually abort a cycle at any time that there is a need to open the sterilizer. The final vacuum system, air purge and aeration will operate but the door is unlocked if the cartridge was punctured.

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 Uberwachungs-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 115 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.

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5.7 Compressed Air Requirements:

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

⚠ DANGER

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.

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

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 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 - 750 ppm

8. HEALTH & SAFETY INFORMATION

⚠ DANGER

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 Emegency 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 bo 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 6.

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

⚠ WARNING

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)[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].

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 ina test pack that is representative of the load and creates the greatest challenge. Another option is to a 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

⚠ DANGER

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.

⚠ DANGER

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

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15.5 Stopping a Sterilization Cycle

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

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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 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.

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.

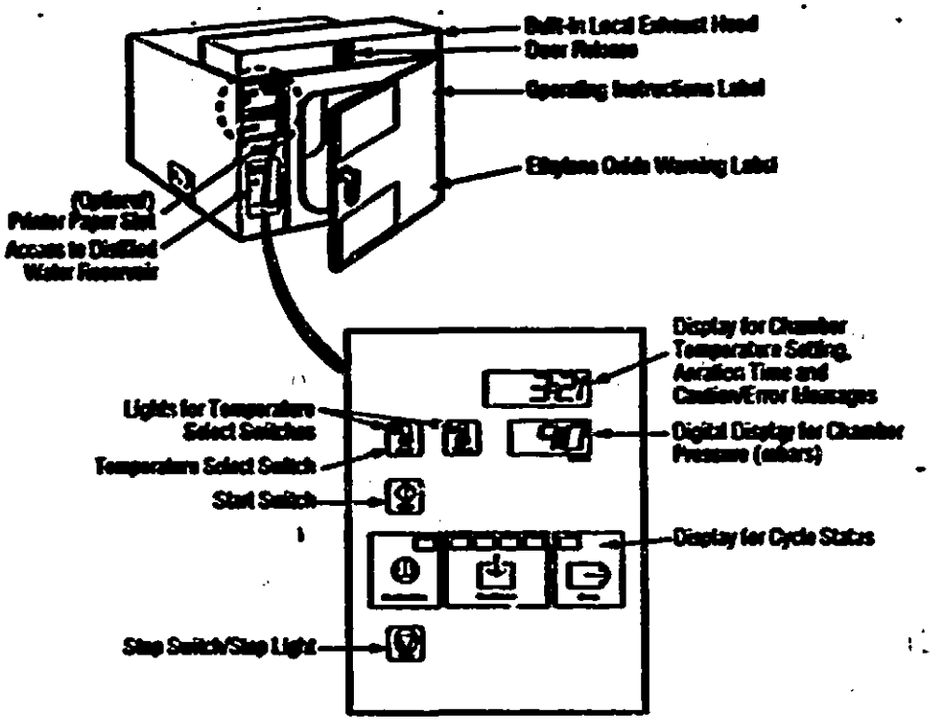

Figure 1: Steri-Vac 4XL Sterilizer Operator Control Panel

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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.

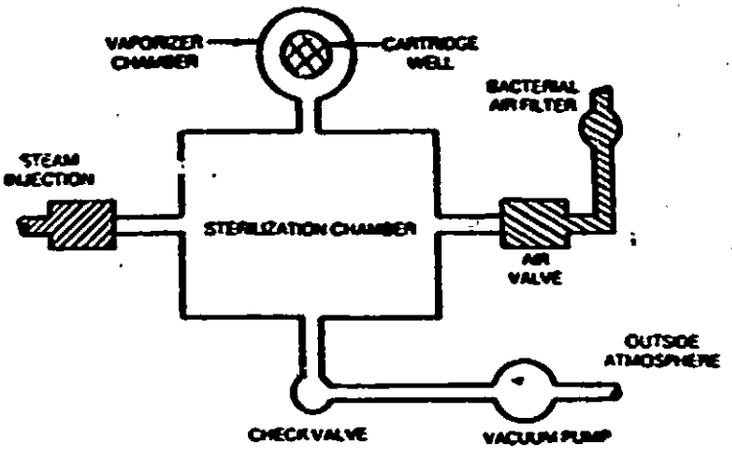
16.2.10.3 Codes E70-89: These occur if sterilizer cannot complete final exhaust vacuum and 15 minute air purge. Usually requires service call; check Section 19. Door is locked. No alarm. STOP indicator is lit.

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



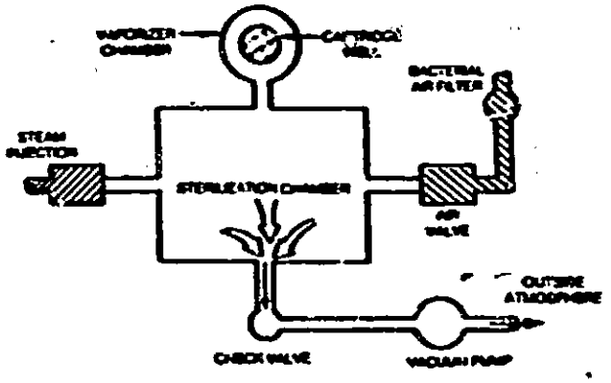
*Leave the POWER SWITCH (located at the back of the sterilizer) on at all times. An indicator in one of the TEMPERATURE SELECT switches should be lit. Other panel lights should be off.

* 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.

17.2 Initial Vacuum



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.

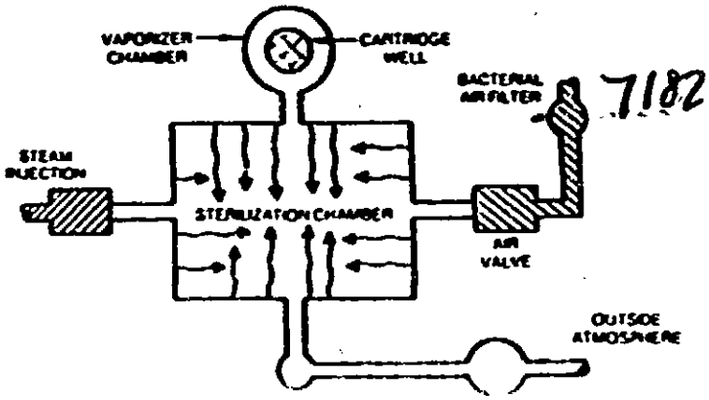
* The door locks and the cycle is now automatic.

* The vacuum pump is on.

* The panel light marked PRECONDITION illuminates.

* The digital display shows chamber temperature.

17.3 Preheat



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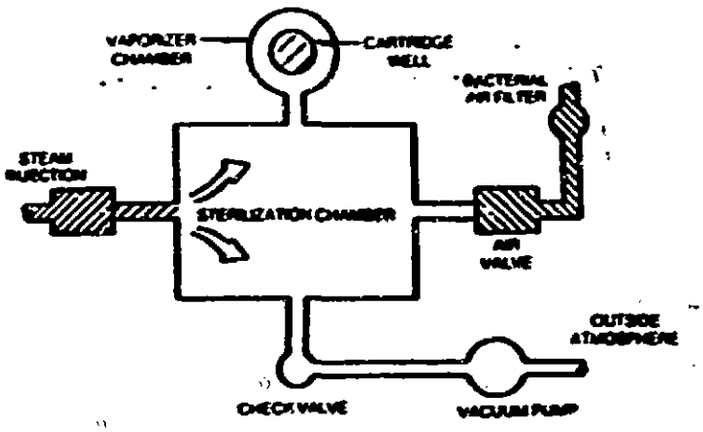
* The chamber simultaneously draws a vacuum and heats to the selected temperature.

* 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

17.4 Humidification

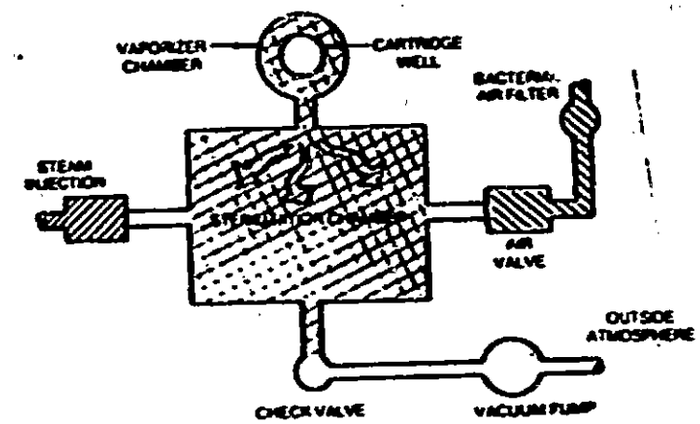


* The sterilizer draws an additional two minutes of vacuum and measures to ensure the pressure is below 240 millibars. For higher pressures, the vacuum system will stay on up to eight minutes until reaching adequate vacuum. Otherwise, the E27 error code will appear.

* 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 18 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 240 millibars.

* The heaters are turned off.

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

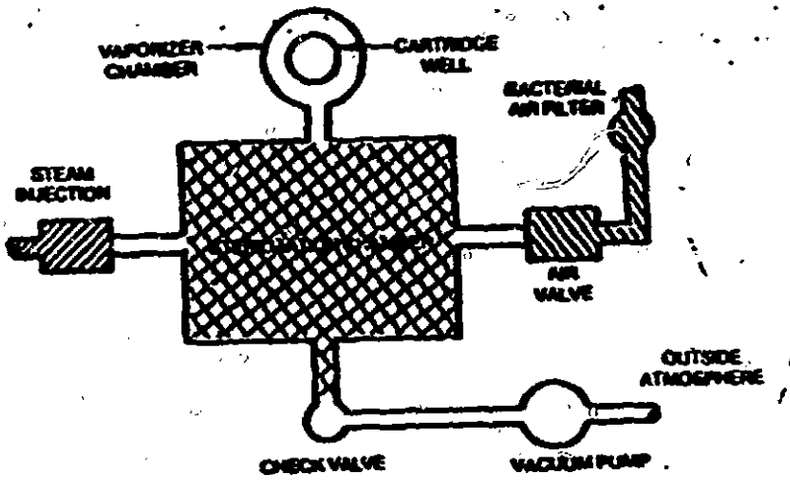
* The temperature and pressure are checked again. One of the following error codes will appear if there are problems: E29, E30, E31.

* 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 cartridge is either empty or missing (E50) or not completely full or punctured (E75).

17.6 Gas Exposure



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

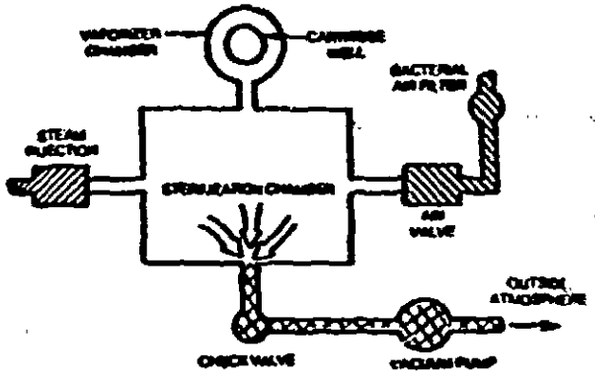
Cycle	Time in Minutes
WARM	62
COOL	250

* 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°C of that selected. One of the error codes, E52 or E53, appears if the temperature varies 4°C or more from the set point at any time.

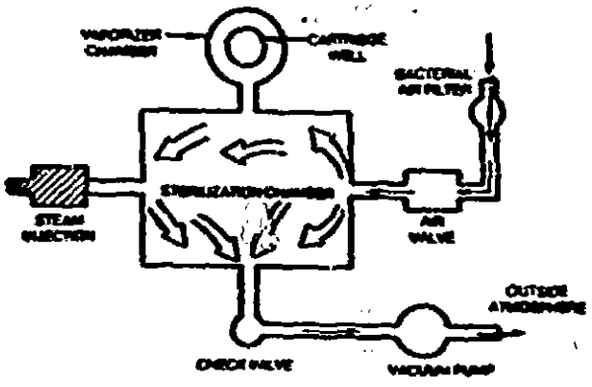
* The GAS EXPOSURE lights show cycle progression.

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

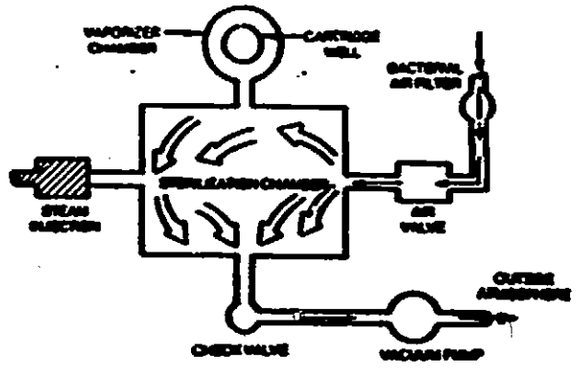


* The air valve opens to draw in bacterial filtered air *after the chamber pressure reaches 240 millibars. An E72 abort code appears if the pressure does not rise above 860 millibars in the first six minutes.*

* Fresh air continues to purge the chamber for15 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



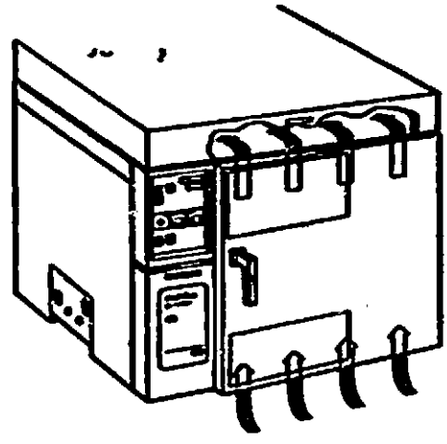
*The *AERATE* light comes on.

*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.

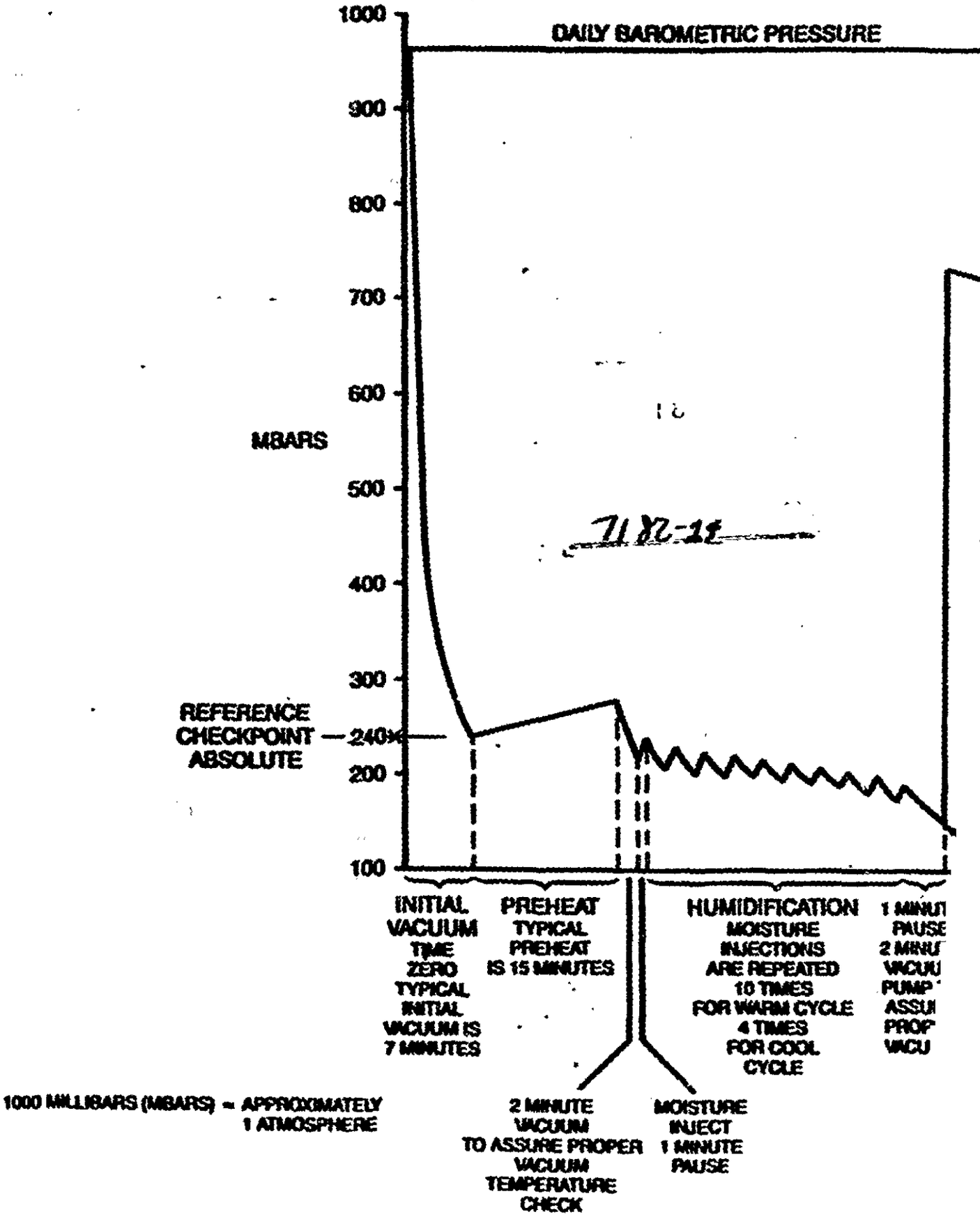
*When the door is opened to the open-latched position, the hood captures and exhausts ethylene oxide gas that otherwise may escape into the room during basket removal.

*Keep the door in the open-latched position for at least 5 minutes before fully openign 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.

18 CYCLE EXPLANATION TIME AND PRESSURE DIAGRAM

D MODEL 4XL CYCLE EXPLANATION
TIME/PRESSURE DIAGRAM



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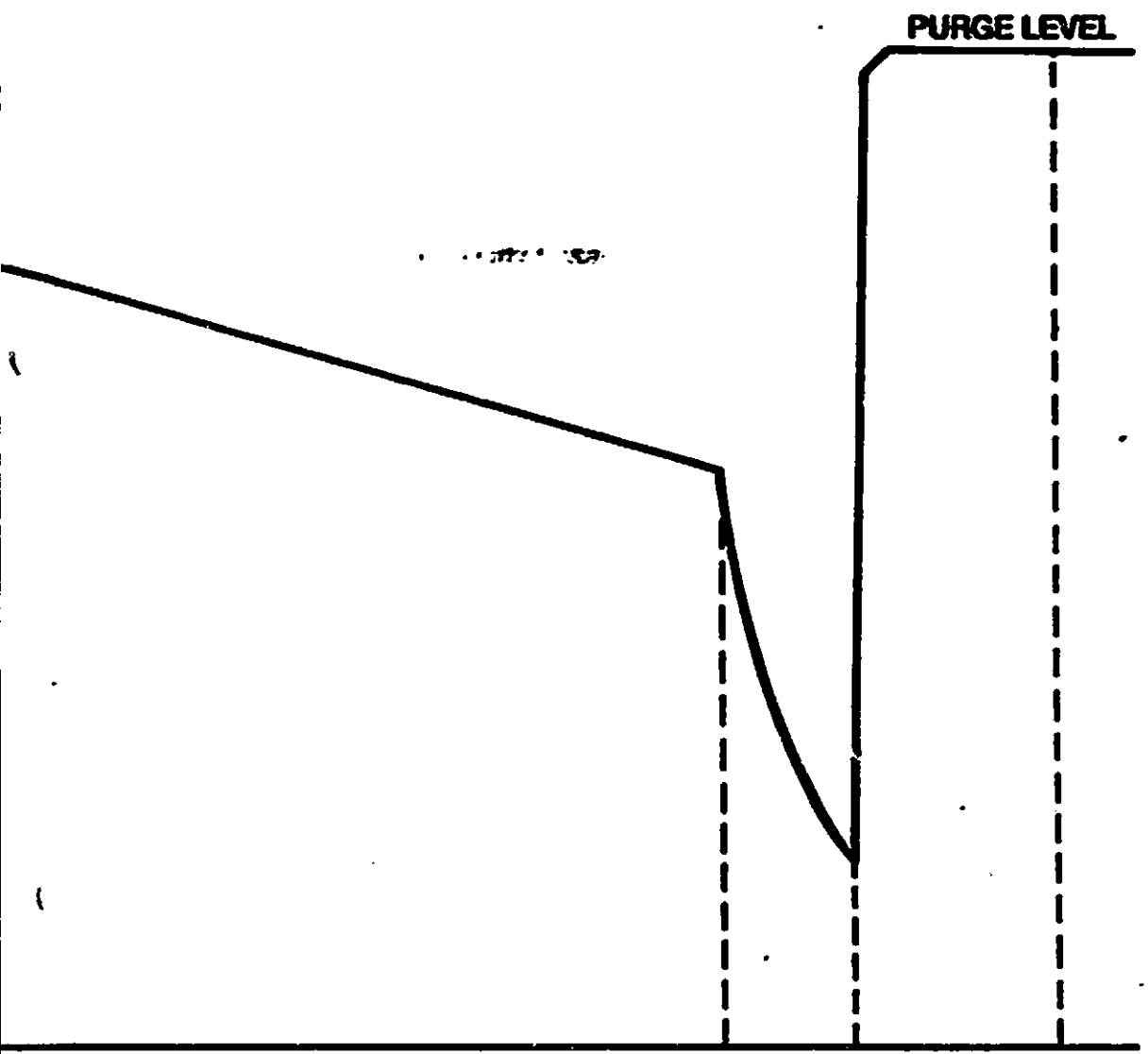

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19. CAUTION/ERROR MESSAGE EXPLANATION

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
		Caution Messages - Do Not Stop Cycle	
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
		Self Test Errors Occurring on Power Up or at the Start of a Cycle	
E1	Processor Memory Failure	Controller Board	Call Service Representative
E2	Program Memory Failure	Controller Board	Call Service Representative
E3	E^2ROM 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

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

Caution or Error Code	Message	Possible Reasons	Corrective Steps
	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	Sensor Failure/Controller Board	Call Service Representative
E75	Low Gas Injected	Partially Filled Cartridge	Call Service Representative
		Partially Punctured	Call Service Representative
E76	Latching Relay Won't Reset	Latching Relay Failure	Call Service Representative
		Door Handle Binding	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.

CUSTOMER MAINTENANCE

20.1 Cleaning

Clean the following parts of your Steri-Vac 4XL gas sterilizer at least [illegible], 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

⚠ DANGER

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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.

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.

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).

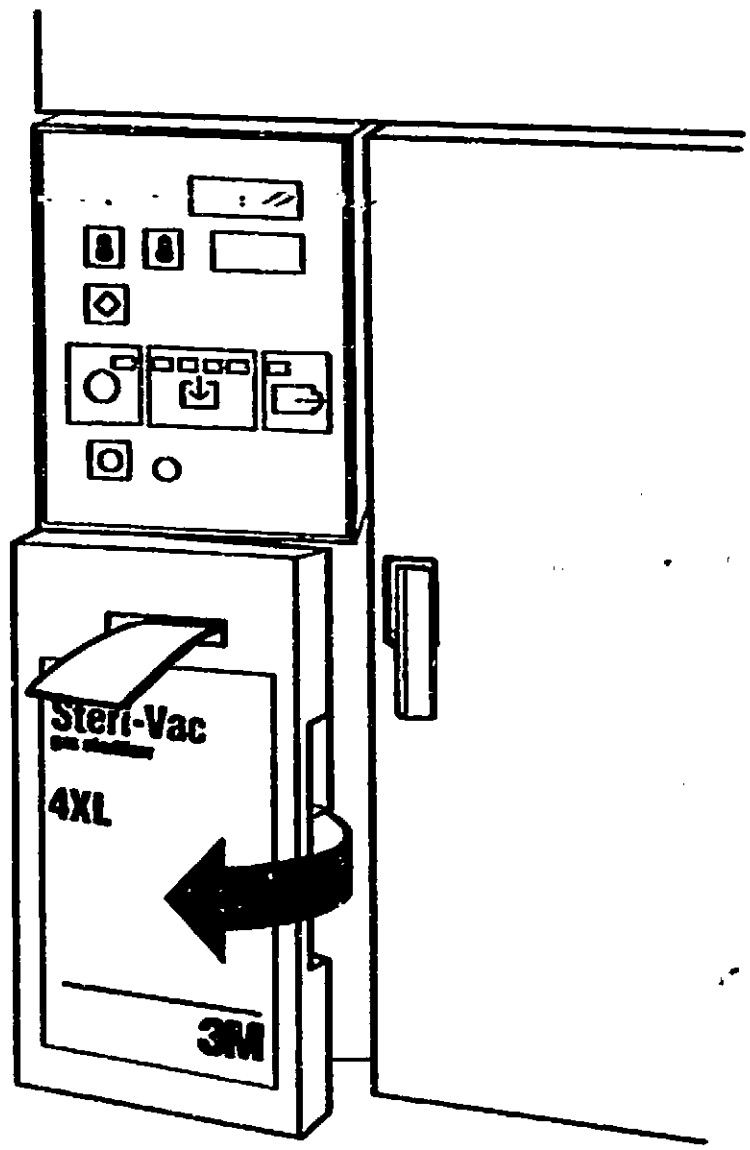

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Fig. 1. Location of Model 412 Printer

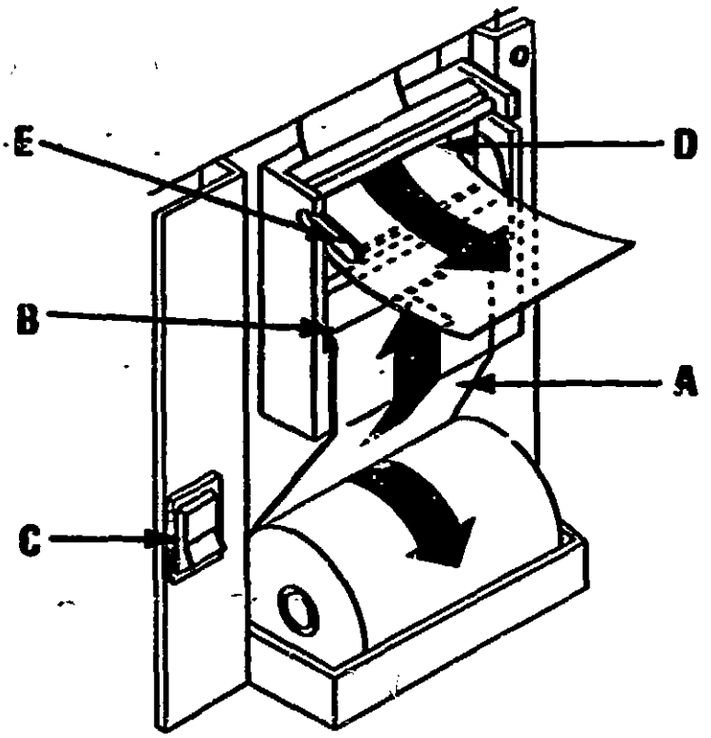

Fig. 2. Paper Loading

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.

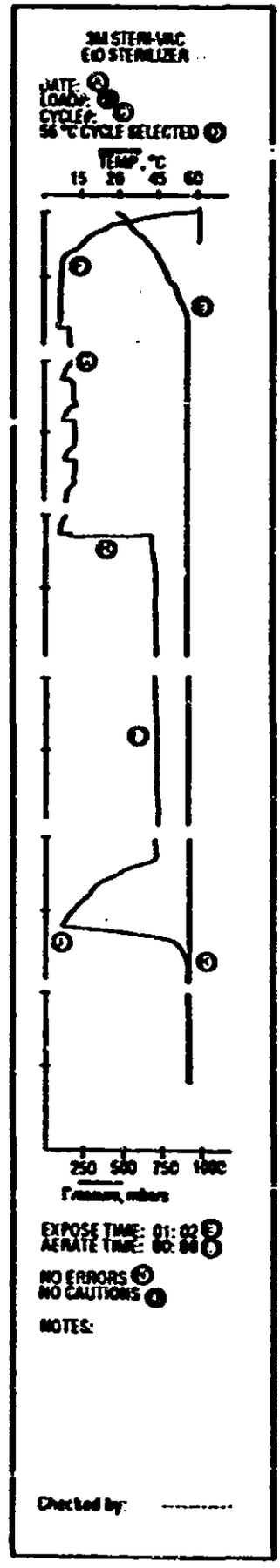

Fig. 3. Print-out

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.

70-2009-1439-6

Litho in U.S.A.

Medical-Surgical Division/3M

St. Paul, MN 55144-1000

3M