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 Purge Time - Hours and Minutes

Digital display indicates elapsed time of the purge or **AERATE** cycle up to a maximum of 99 hours and 59 minutes. The timer 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.

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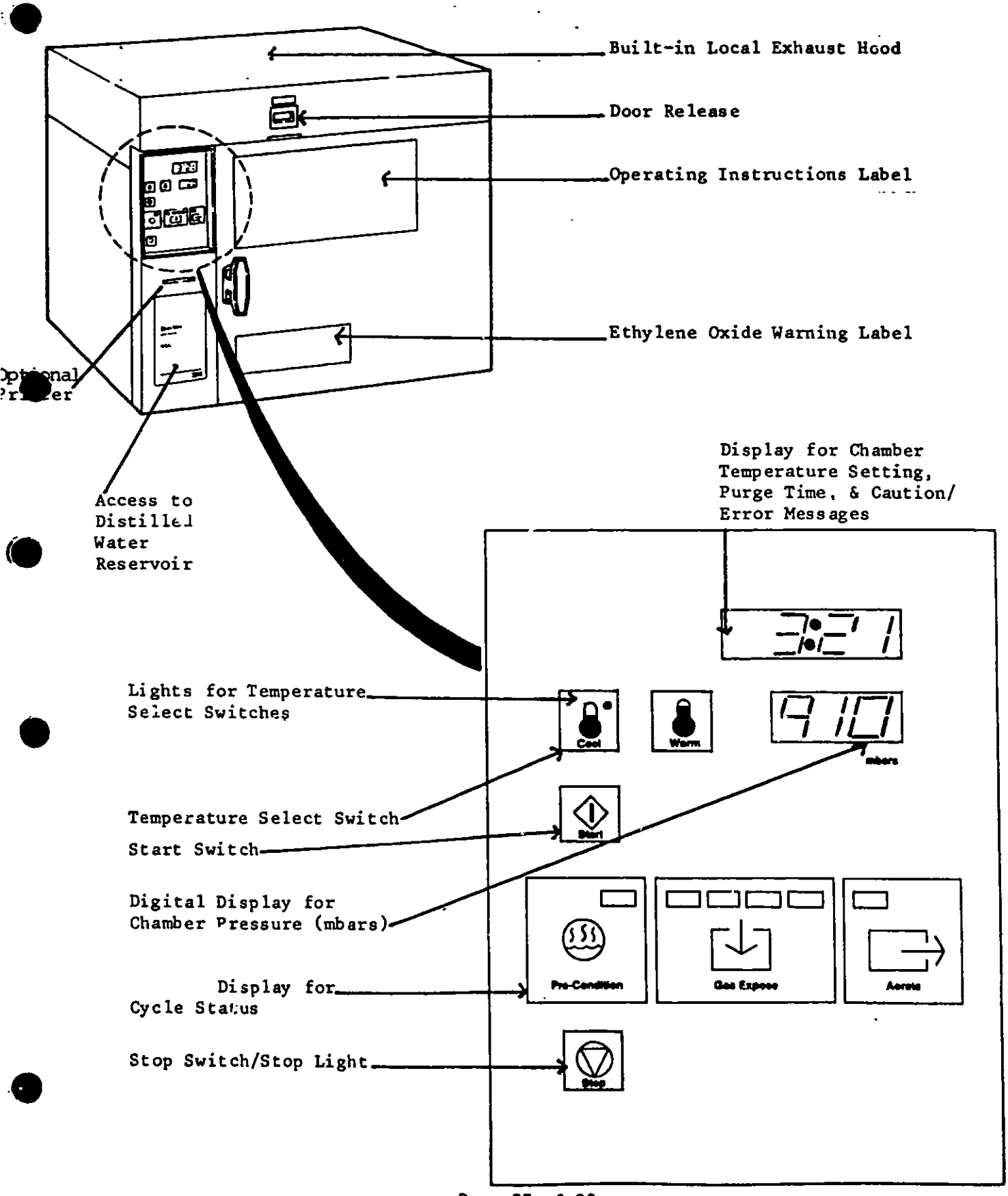
FIGURE 1. STERI-VAC 4XL STERILIZER CONTROLS ON FRONT PANEL



16.2.4 **Lights in Temperature Select Switches**

Indicates that either **WARM** or **COOL** switch was pressed. Remains lighted 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.

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 non-flashing message (e.g. E10) in digital display. Aborts/stops cycle in progress. Operator must check **Section 19** and correct problem to clear code. Cycle status lights are also turned off.

16.2.10.1 Aborts occurring **during electronic self tests in STANDBY or before cartridge puncture** stop the cycle, turn off heaters and vacuum and unlock the door. E1 - E49 abort codes. Operator must open door, press **STOP SWITCH** and take corrective steps indicated.

16.2.10.2 Aborts **E50-69** occurring when gas could be in chamber, turn on STOP indicator, advance through final exhaust vacuum and 15 minute purge, and unlock door. **Constant alarm** after door unlocks. Operator must open door and press STOP switch to stop alarm and take corrective steps.

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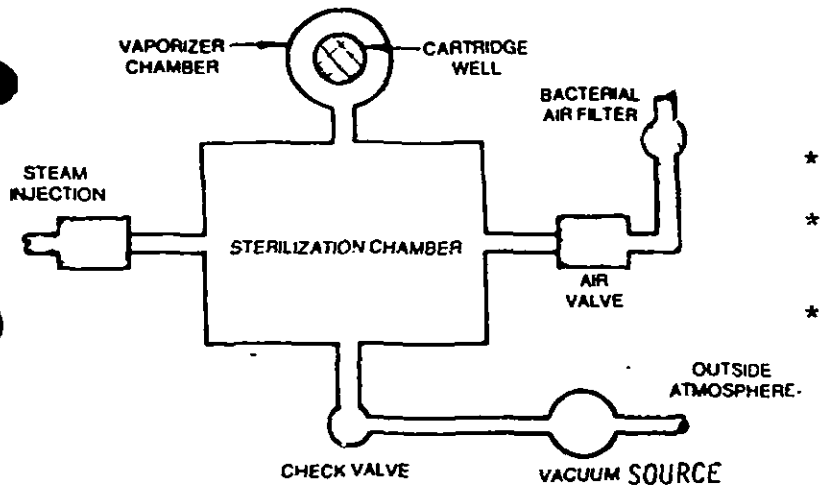
16.?.10.3 Aborts E70-89 occur if sterilizer can not complete final exhaust vacuum and 15 minute air purge. Usually require service call; check Section 19. Sterilizer turns off heaters, vacuum system and cycle status indicators. Door is locked. No alarm. STOP indicator is lighted.

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

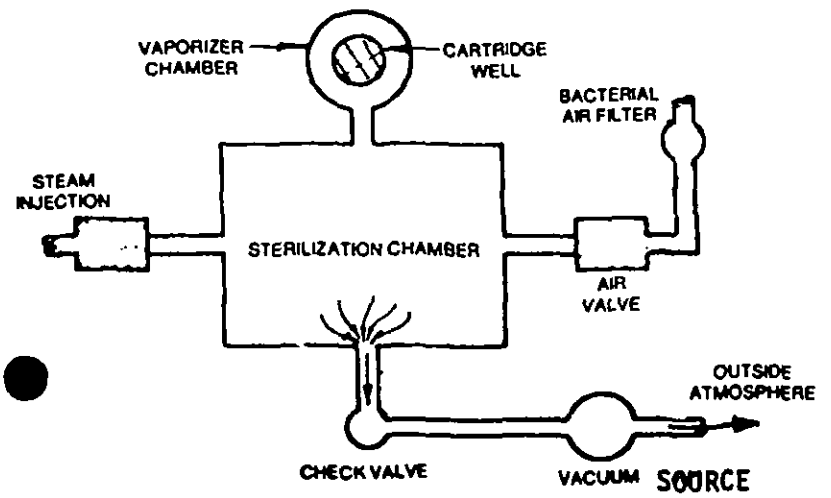
17.1 Standby



* 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 lighted. Other panel lights should be off.
* Door is unlocked.
* Open door, insert cartridge, load chamber, and close door.
* Press either **WARM** or **COOL** Temperature Select switch. Check that light in upper left corner of selected switch is on.

NOTICE
Warning codes for low air flow in exhaust hood (cl) or low water in reservoir may flash in digital display. Use Section 19 of manual to determine corrective steps.

17.2 Initial Vacuum



* Press START switch.
* The door locks and the cycle is now automatic.
* The vacuum pump is on.
* The panel lights marked PRECONDITION illuminates.
* The digital display shows chamber temperature.

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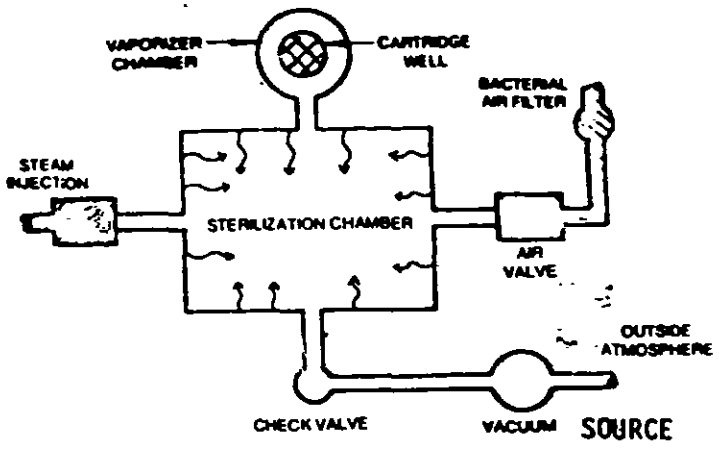
Preheat

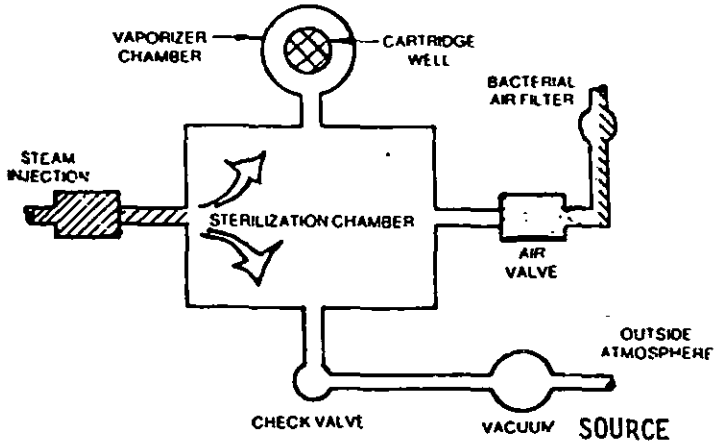


* The chamber simultaneously draws a vacuum and heats to the selected temperature.

* 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 abort explanation in **Section 19.** The chamber pressure must decrease by at least 500 millibars in the first minute the pump is on. Otherwise, the sterilizer issues an error code E21 in the digital display indicating no vacuum.

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

17.4 **Humidification**



* The sterilizer draws an additional two minutes of vacuum and measures to ensure the pressure is below 240 millibars.

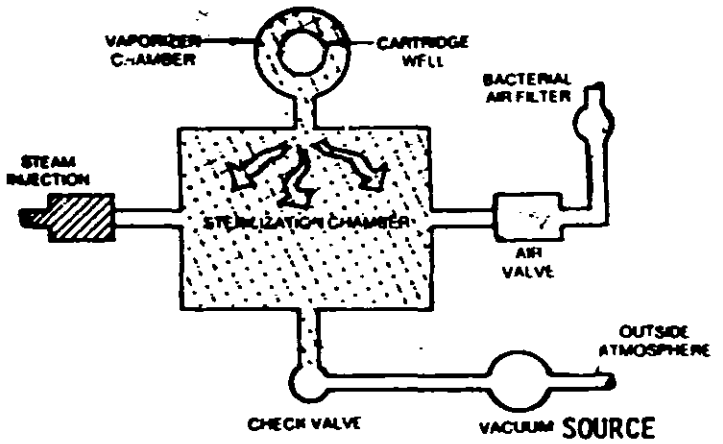
  For higher pressures, the vacuum system will stay on up to eight minutes until reaching adequate vacuum. Otherwise, the E27 abort code will appear.

* 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 a cool cycle. The total humidification time for either cycle is 30 minutes.

* NOTICE
  There is an 18 minute delay after the 4th injection for cold cycles to allow equal time for water to be absorbed.

17.5 Gas Injection



* 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 abort code E31 appears if the vacuum is not reduced below 240 millibars.

* The heaters are turned off.

* The locked door is checked. The E32 abort code appears if the door is unlocked.

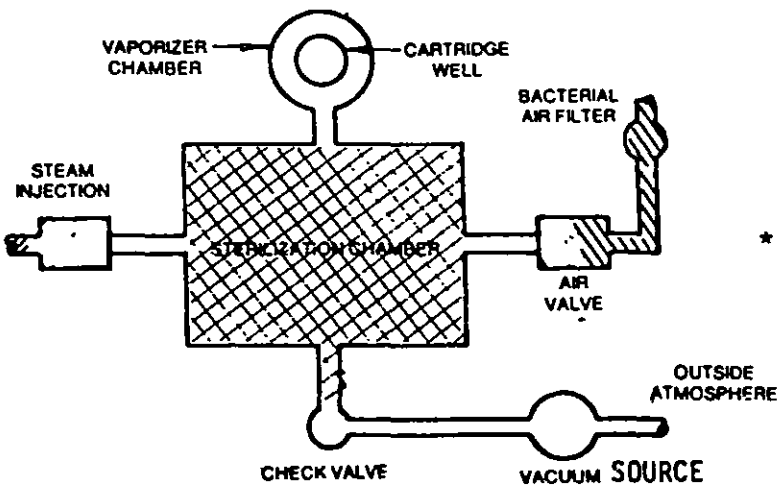
* The temperature and pressure are checked again. One of the following abort codes will appear if there are problems: E29, E30, E31.

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

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

* The pressure is checked two minutes after puncture to ensure it rises by at least 300 millibars. A lower pressure reading indicates that a 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	248

* 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 abort code appears if the vacuum system turns on more than eight times.

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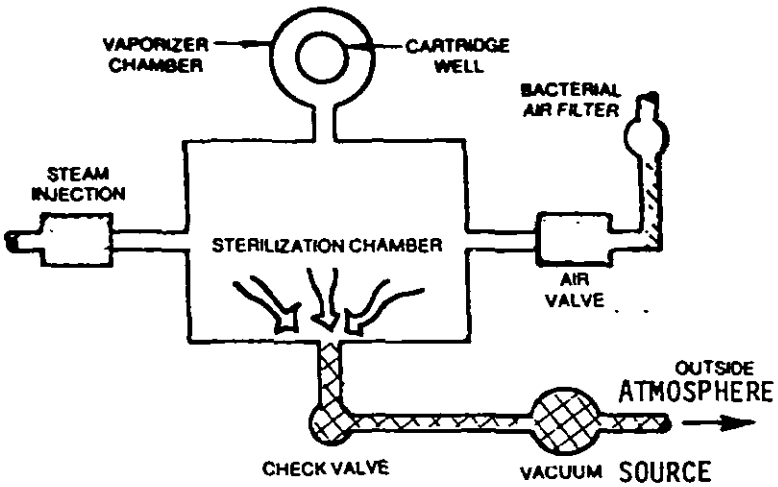
* The temperature is maintained to within + 2°C of that selected. One of the abort codes, E52 or E53, appears if the temperature varies 5°C or more from the set point at any time.

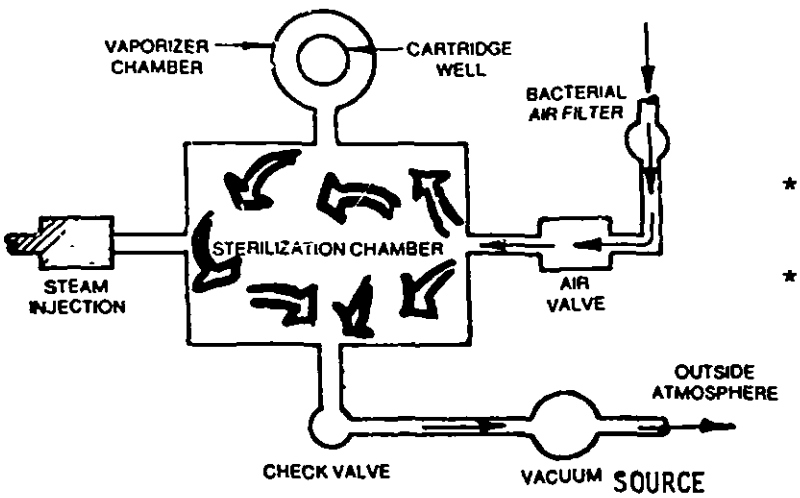
* The GAS EXPOSURE lights show cycle progression.

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 abort code appears if pump down is not complete in 20 minutes.

17.8 15 Minute Air Purge

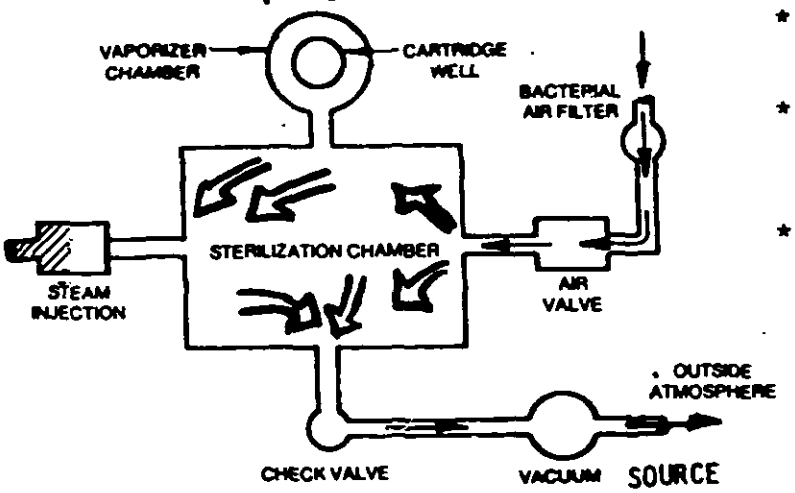


* The air valve opens to draw in bacterial filtered air after the chamber pressure reaches 240 millibars. An E72 abort code appears if the pressure does not rise above 860 millibars in the first six minutes.

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

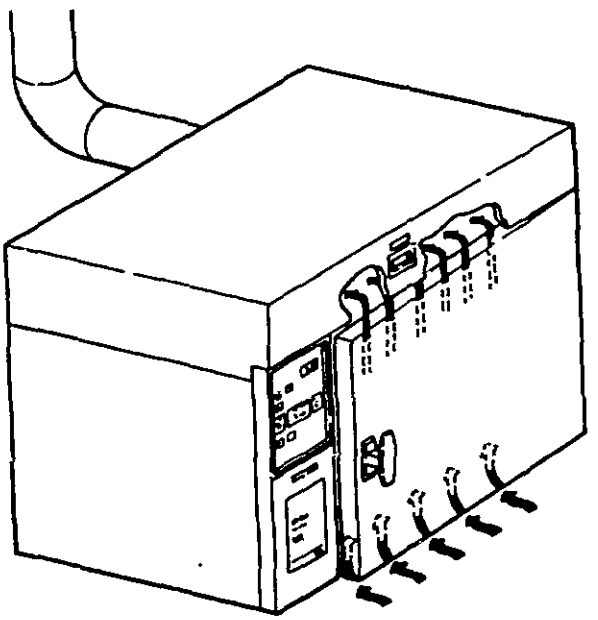
* If the chamber pressure rises to within 40 millibars of atmosphere during the purge the air valve closes until the vacuum drops to 80 millibars below atmospheric pressure.

17.9 Continuous Air Purge/Aerate - Open Door

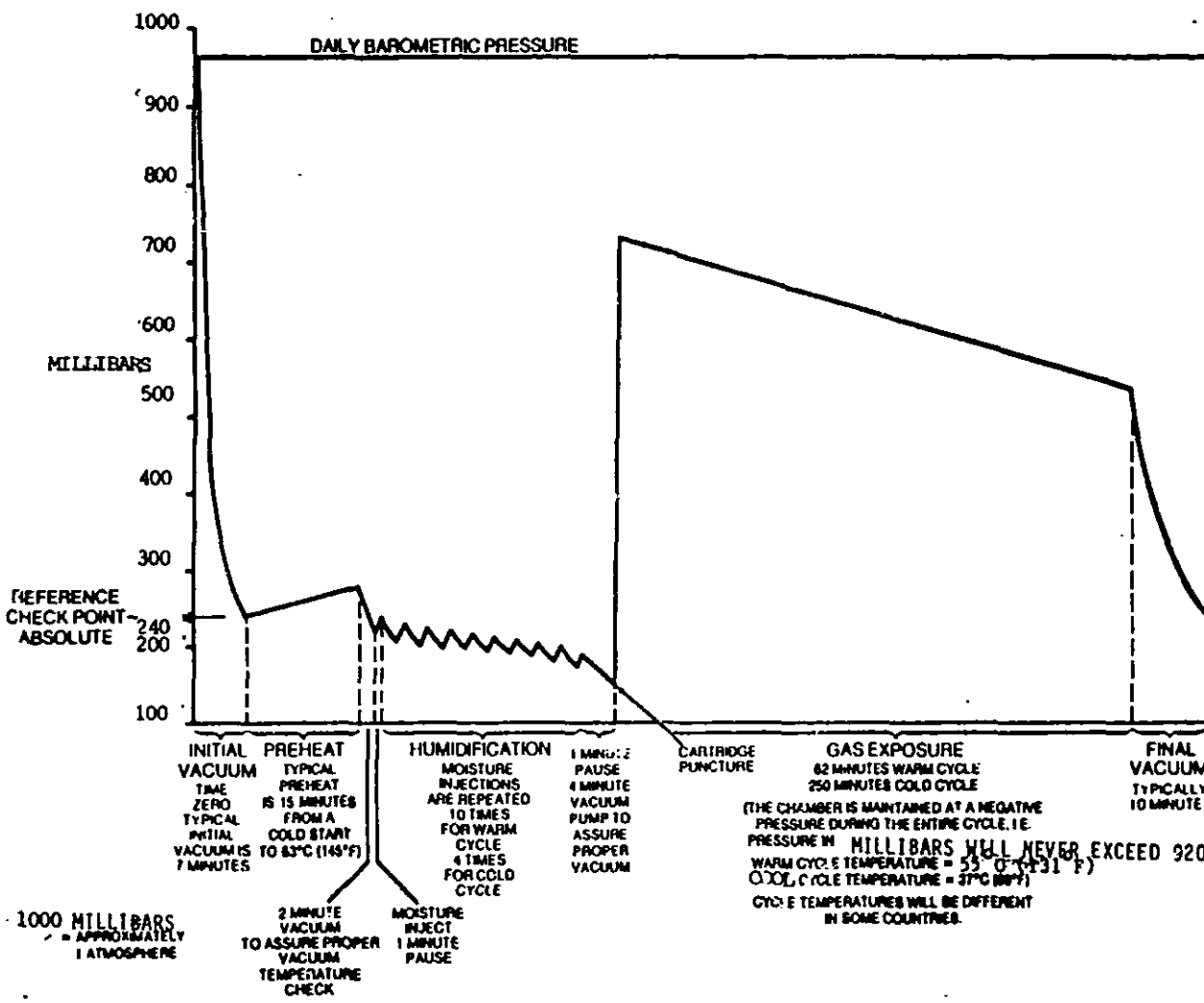


* The AERATE light comes on.
* The door alarm sounds for 15 seconds and the door unlocks.
* Aeration begins. The digital display becomes a clock showing elapsed aeration time.
* Open the door at any time during aeration to remove or transfer items. The time clock stops while the door is open and resumes 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.

17.10 Local Exhaust



* A local exhaust hood is built into the top of the sterilizer. The hood must be connected to a dedicated, customer-supplied exhaust system (e.g. fan, ductwork) that meets 3M specifications.
* When the door is opened to the open-latched position, the hood captures and exhausts ethylene oxide gas that otherwise may escape into the room during basket removal.
* Keep the door in the open-latched position for at least 5 minutes before fully opening the door and removing items.
* A c1 caution message will flash in the digital display if there is insufficient air movement in the exhaust hood.


1000
900
800
700
600
MILLIBARS
500
400
300
REFERENCE CHECK POINT – ABSOLUTE
240
200
100
DAILY BAROMETRIC PRESSURE
INITIAL VACUUM
TIME ZERO TYPICAL INITIAL VACUUM IS 7 MINUTES
PREHEAT
TYPICAL PREHEAT IS 15 MINUTES FROM A COLD START TO 63°C (145°F)
HUMIDIFICATION
MOISTURE INJECTIONS ARE REPEATED 10 TIMES FOR WARM CYCLE 4 TIMES FOR COLD CYCLE
1 MINUTE PAUSE
4 MINUTE VACUUM PUMP TO ASSURE PROPER VACUUM
CARTRIDGE PUNCTURE
GAS EXPOSURE
62 MINUTES WARM CYCLE
250 MINUTES COLD CYCLE
(THE CHAMBER IS MAINTAINED AT A NEGATIVE PRESSURE DURING THE ENTIRE CYCLE, I.E.
PRESSURE IN MILLIBARS WILL NEVER EXCEED 920
WARM CYCLE TEMPERATURE = 55°C (131°F)
COOL CYCLE TEMPERATURE = 37°C (99°F)
CYCLE TEMPERATURES WILL BE DIFFERENT IN SOME COUNTRIES.
FINAL VACUUM
TYPICALLY 10 MINUTE
1000 MILLIBARS = APPROXIMATELY 1 ATMOSPHERE
2 MINUTE VACUUM TO ASSURE PROPER VACUUM TEMPERATURE CHECK
MOISTURE INJECT 1 MINUTE PAUSE

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 non-flashing error messages. The cycle in progress will abort or stop. The cycle status lights will turn off. Follow the steps listed below to correct the problem and clear the code. Contact your 3M Service Representative if you have any questions.

Caution or Error Code	Message	Possible Reasons	Corrective Steps
		<u>Caution Messages - Do Not Stop Cycle</u>	
c1	Low Air in Exhaust Hood	Fan Malfunction	Check Fan and Fan Belts
		Duct Plugged/Disconnected	Check Ductwork
		Airflow Sensor Failure	Call Service Representative
c2	Low Water During Standby	Reservoir Needs Water	Add Water
c3	Power Interruption	Power Outage	Cycle Restarts Automatically
c4	Compressed Air Lost During Aeration	No Compressed Air	Check Compressor, Air Lines
		<u>Self Test Errors Occurring on Power Up or at the Start of a Cycle</u>	
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 Fail	Bad Sensor or Connection	Call Service Representative
E7	Pressure Fail w/Door Open	Bad Sensor or Connection	Call Service Representative

E10	Low Water	Water Resevoir Needs Water	Add Water to Reservoir
		Float Switch Failure	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	No Compressed Air Connection	Check Air Lines & Pressure
		Defective Vacuum Pump	Call Service Representative
E22	Initial Pumpdown Timeout	Defective Vacuum Pump	Call Service Representative
		Improper Air Pressure	Check Air System
		Blockage at Vacuum Port	Clear Pkg. from Chamber Port
E23	Chamber Preheat Timeout	Chamber Too Cold at START	Restart
		Defective Heaters	Call Service Representative
		Defective Sensor	Call Service Representative
		Opened Thermal Cutout	Call Service Representative
		Heater Relay Failure	Call Service Representative
E24	Heatsink Preheat Timeout	Chamber too Cold at START	Restart
		Defective Heater Rod	Call Service Representative
		Defective Sensor	Call Service Representative
		Opened Thermal Cutout	Call Service Representative
		Heatsink Relay Failure	Call Service Representative
E25	Interrogation #1 Over Temp	Heater Relay Failure	Call Service Representative
		Defective Sensor	Call Service Representative
		Defective Controller	Call Service Representative
E26	Interrogation #1 Under Temp	Heater Relay Failure	Call Service Representative
		Defective Sensor	Call Service Representative
		Defective Controller	Call Service Representative
E27	Interrogation #1 Pressure	Leak in Chamber	Call Service Representative
		Defective Pressure Sensor	Call Service Representative
E28	No Water Injected	Resevoir Float Sw. Stuck	Add Water to Reservoir
		Water System Plugged	Call Service Representative
E29	Interrogation #2 Over Temp	Heater Relay Failure	Call Service Representative
		Defective Sensor	Call Service Representative
		Defective Controller	Call Service Representative
E30	Interrogation #2 Under Temp	Heater Relay Failure	Call Service Representative
		Defective Sensor	Call Service Representative
		Defective Controller	Call Service Representative
E32	Door Unlocked	Door Latch Hung up on Bolt	Turn handle completely vertical
		Controller Bd Failure	Call Service Representative
E33	Latching Relay	Latching Relay Failure	Call Service Representative
		Controller Bd Failure	Call Service Representative
		Door Latch Stuck	Call Service Representative
E34	Door Open	Door Not Closed Before Start	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 Loaded	Use new Cartridge
		Puncture Mechanism Failed	Call Service Representative
E51	Chamber Vacuum Leakage	Air Leak in Chamber	Call Service Representative
E52	Under Temp Abort	Heater Relay Failure	Call Service Representative
		Defective Sensor	Call Service Representative
		Defective Controller	Call Service Representative
E53	Over Temp Abort	Heater Relay Failure	Call Service Representative
		Defective Sensor	Call Service Representative
		Defective Controller	Call Service Representative
E54	Extended Power Outage	Could Not Restart After Outage	Restart
E60	User Interruption	User Pressed STOP switch	Restart

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Errors That Leave the Chamber Locked with Gas Possibly 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	Try press START/ Call Service Representative
E73	Pressure Sensor Out of Range	Sensor Failure/ Controller Bd	Call Service Representative
E75	Low Gas Injected	Partially Filled Cartridge Partially punctured	Call Service Representative Call Service Representative
E76	Latching Relay Won't Reset	Latching Relay Failure	Call Service Representative

20. INSTALLATION GUIDE

21. CUSTOMER MAINTENANCE

21.1 Cleaning

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

21.1.1 chamber floor and walls

21.1.2 outer chamber lip

21.1.3 inner door surface

21.1.4 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.

21.2 Servicing Filters, Moisture Trap, and Vent Line

21.2.1 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.

21.2.2 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.

22. 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
(612) 733-7865

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

23. 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 checks of your sterilizer and emergency coverage. Contact your local 3M Service Representative or the Service Center for PMA information. Refer to Section 22 for the Service Center's address.

24. SERVICE MANUAL

A Service Manual for the Steri-Vac 4XL gas sterilizer can be purchased. The manual contains an illustrated parts list, a troubleshooting guide, the details of operation, and an electrical schematic. Request the manual by writing or calling the 3M Service Center at the address listed in **Section 22.** Outside the USA, contact your 3M Medical-Surgical Representative to determine if a manual is available.

ACCESSORY EQUIPMENT

25. BASKETS

26. PRINTER

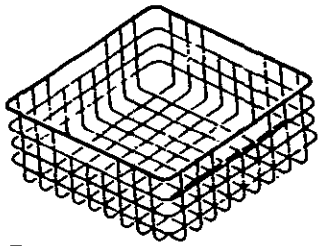
STERILANT

27. Steri-Gas cartridge CONSUMER PRODUCT PROFILE

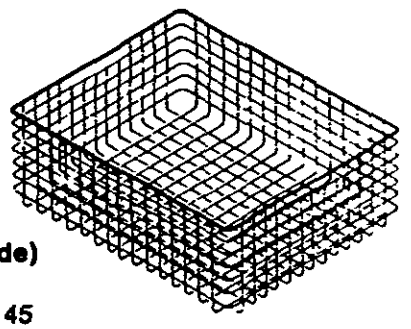
Steri-Gas, Steri-Vac, Indox and Attest are registered trademarks of 3M.

Tyvek is a registered trademark of DuPont.

Steri-Vac Accessory Baskets for Gas Sterilization Equipment

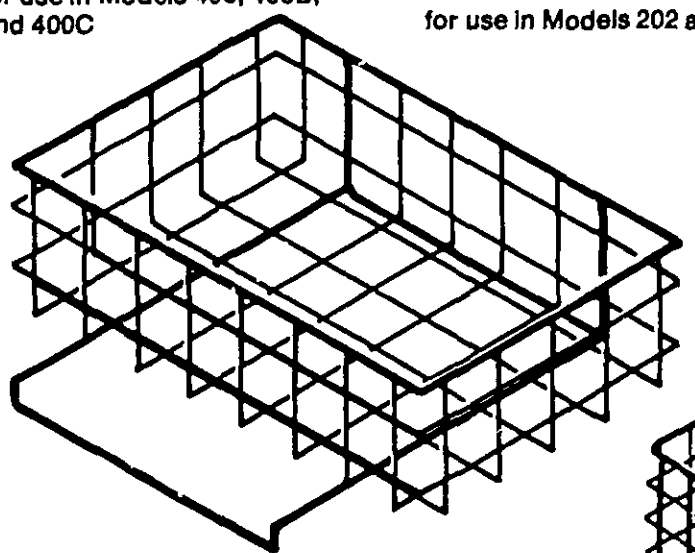


Chrome
12-2376-1127-7
for use in Model 22

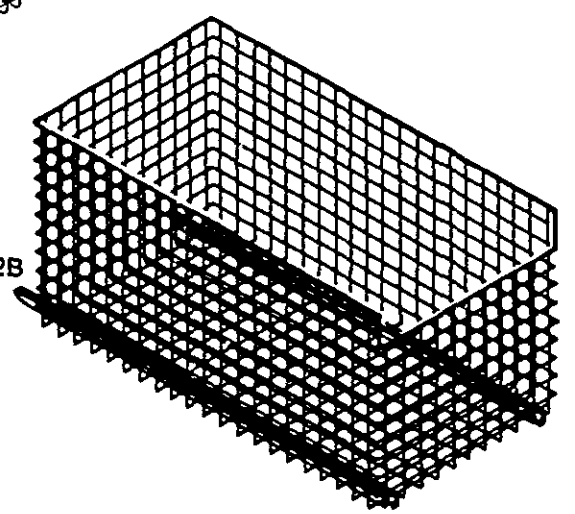


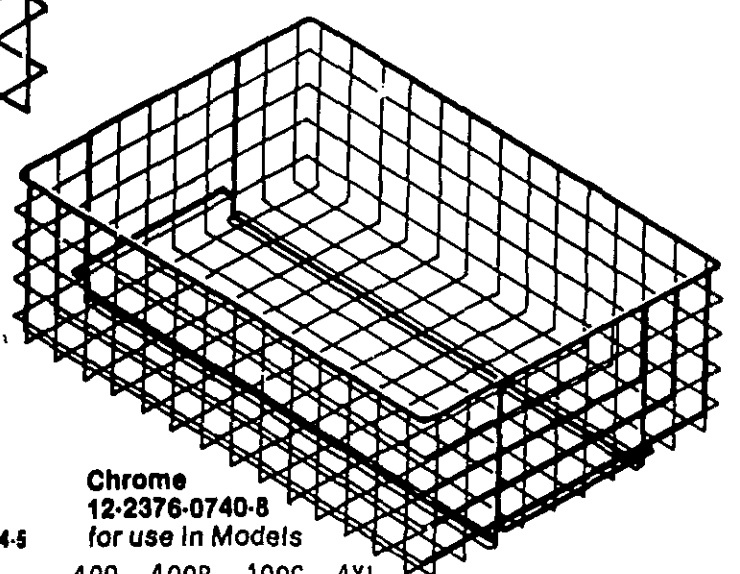
Chrome (10" wide)
12-2376-2926-1
for use in Model 45

Upper Basket
Chrome
12-2376-0472-8
for use in Models 400, 400B, and 400C



Chrome
12-2376-2256-3
for use in Models 202 and 202B





Nylon basket runners are included on new baskets if required.

RUNNER KITS AVAILABLE
Models 202 and 202B—basket rail P/N 12-2376-2255-5
Models 400, 400B, 400C, 33, 33B and 20—basket rail P/N 12-2376-1454-5
(2 required—no mounting hardware necessary)

Chrome
12-2376-0740-8
for use in Models
400, 400B, 400C, 4XL, 33, 33B and 20.

c 3M Co., July 1986

(87-2)R LITHO IN U.S.A.

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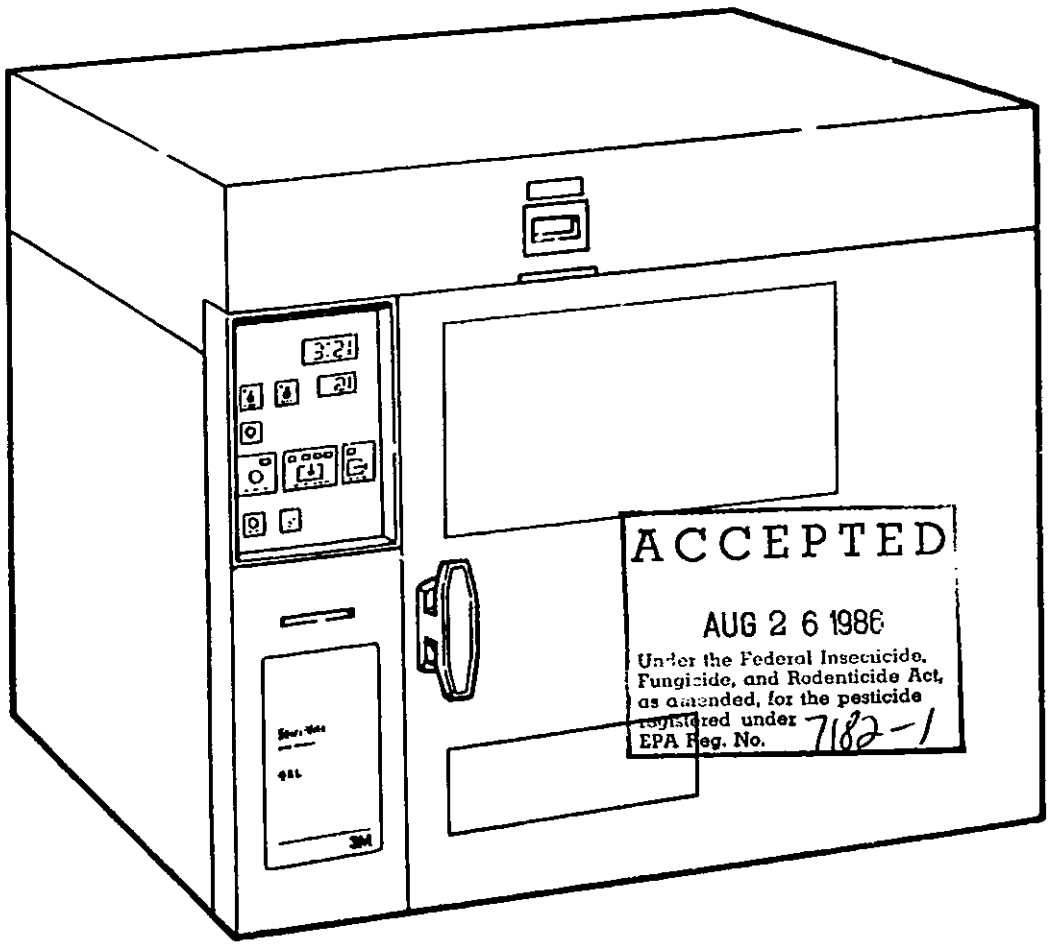
Date of Draft: June 11, 1986

Reason to Issue: 1) Provide labeling relevant to OSHA classification of ethylene oxide; 2) specify use of the Steri-Gas 4-100 cartridge in the newly designated Steri-Vac model change from 400C to 4XL; 3) revise certain precautionary, transportation and user handling information; 4) specify U.S. and O.U.S. electrical listings approvals; 5) move certain editorial and label format improvements; 6) add certain hazard symbols.

- -

Steri-Vac®
4XL Gas Sterilizer 3M

Installation
Guide



Medical-Surgical Division/3M
St. Paul, MN 55144-1000

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STERI-VAC 4XL GAS STERILIZER

INSTALLATION GUIDE

Table of Contents

STERILIZER LABELING

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

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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. 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 may cause severe irritation and burns to the gastro-intestinal 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.

12-2376-9529-6

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

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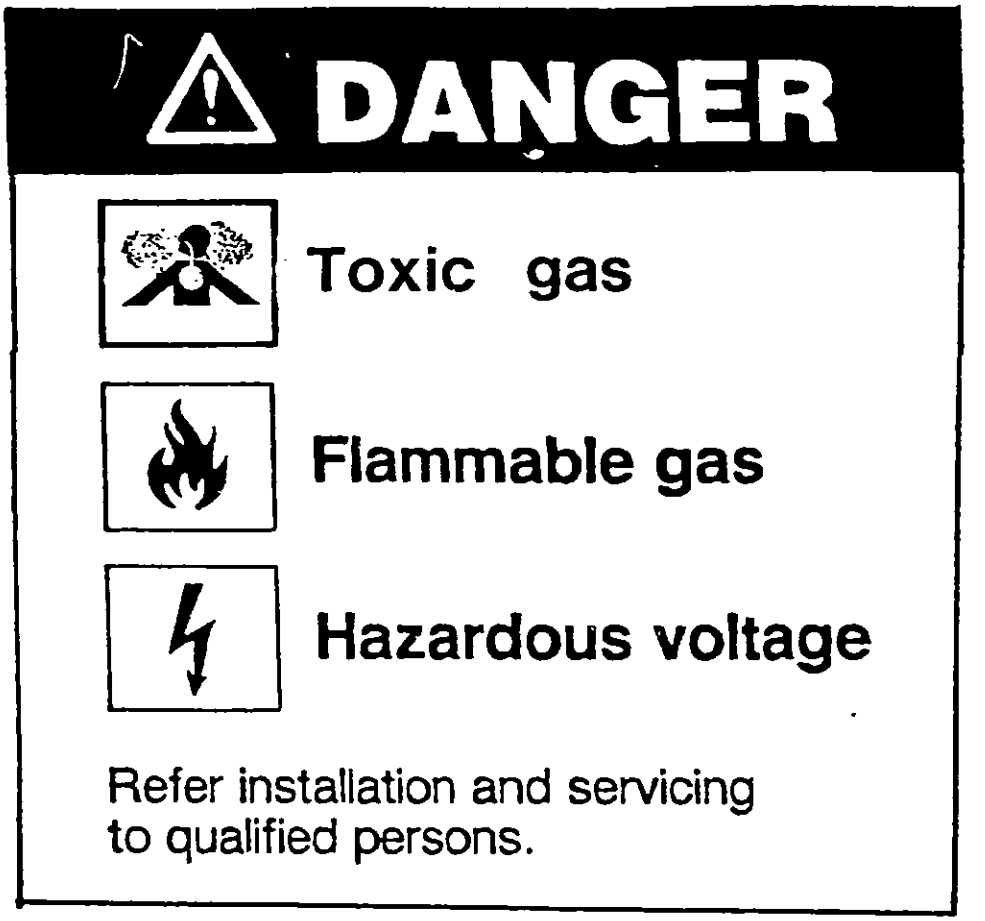

Affixed to back panel of Steri-Vac 4XL gas sterilizer.
3M part no. 12-2376-9490-1

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READ INSTALLATION GUIDE AND OPERATING INSTRUCTIONS CAREFULLY.

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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	APPROXIMATE 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 instructions. (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 sterilizer is in standby.
3. Turn handle counter-clockwise while lifting DOOR RELEASE to open door.
4. Insert Steri-Gas cartridge 4-100 into 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 initiate 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

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CAUTION/ ERROR MESSAGE CHART

Use the chart below to determine the steps to take 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. 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 Messages - Will Not Stop Cycle

c1	Low Air in Exhaust Hood	External Fan Malfunction	Check Fan and Fan Belts
		Airflow Sensor Failure	Call Service Representative
c2	Low Water During Standby	Reservoir Needs Water	Add Water
c3	Power Interruption	Power Outage	Cycle Restarts Automatically
c4	Compressed Air Lost During Aeration	No Compressed Air	Check Compressor, Air Lines

Errors That are Detected Before Puncture

E10	Low Water	Water Resevoir Needs Water	Add Water to Reservoir
		Float Switch Failure	Call Service Representative
E20	Chamber Needs to Cool Down	Tried to Run COOL Cycle too Soo ı After WARM Cycle	Open Door, let Chamber Cool
E21	No Vacuum	Blockage at Vacuum Port	Clear Pkg. from Chamber Port
		No Compressed Air Connection	Check Air Lines & Pressure
		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	Chamber Too Cold at START	Restart
		Defective Temperature Control	Call Service Representative
E24	Heatsink Preheat Timeout	Chamber too Cold at START	Restart
		Defective Temperature Control	Call Service Representative
E28	No Water Injected	Resevoir Float Sw. Stuck	Add Water to Reservoir
		Water System Plugged	Call Service Representative
E32	Door Unlocked	Door Latch Hung up on Bolt	Turn handle completely vertical
		Control Error	Call Service Representative
E34	Door Open	Door Not Closed Before Start	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 Loaded	Use new Cartridge
		Puncture Mechanism Failed	Call Service Representative
E54	Extended Power Outage	Could Not Restart After Outage	Restart
E60	User Interruption	User Pressed STOP switch	Restart

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	Try press START/ Call Service Representative

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

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AIR LINE

Maximum air inlet pressure shall not exceed 150 psig

Located on back panel of 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.

Located on back panel of Steri-Vac 4XL gas sterilizer. 3M part no. 12-2376-9415-8.

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

Located on back panel of Steri-Vac 4XL gas sterilizer. 3M part no. 12-2376-9709-4.

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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.

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, air flow 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 completely 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 openings 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? _____

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 service? _____ Yes _____ No

2.3.8 If a compressor is used to supply air:

2.3.8.1 A. What is the tank size? _____ gallons

2.3.8.2 B. 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

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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 rooms 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 outside between the exhaust termination and any sources of building air intake? _____Yes _____No

2.5.6 Is the exhaust source spark-proof, suitable for continuous operation and protected from adverse weather? _____Yes _____No

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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 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), 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.

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 claim.

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 holes which hold the shipping board to the frame. The feet must be installed for proper air flow 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

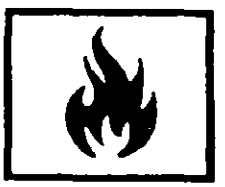
Immediately inspect the sterilizer upon its arrival. Look for damage that may have occurred during transit. Immediately file a damage claim, if necessary, with the transportation company and notify your 3M Sales or Service Representative. The transportation company assumes liability for shipping damage 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 lighted cigarettes, sparks and static discharge away from the sterilizer and cartridges.

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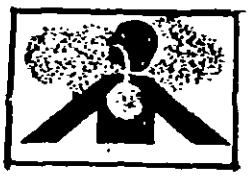
7.2 Toxicity



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.

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7.4.4 Ingestion. Call a physician or Poison Control Center. Drink or 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 cartidge 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 Sales Branch Office or the Medical-Surgical Service Center if you need help contacting your local representatives. Refer to **Section 20** for phone numbers.

9. LOCATION OF THE STERILIZER

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.

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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. (V~) ± 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 & Medial 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.

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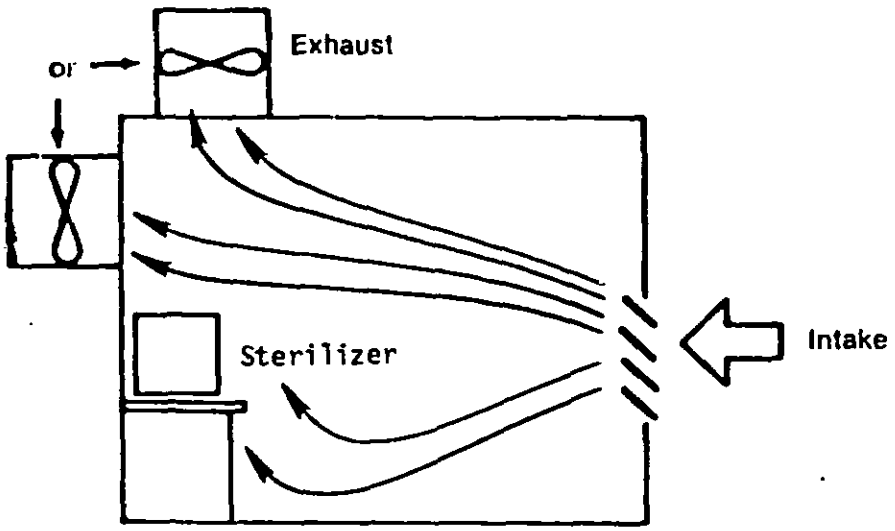
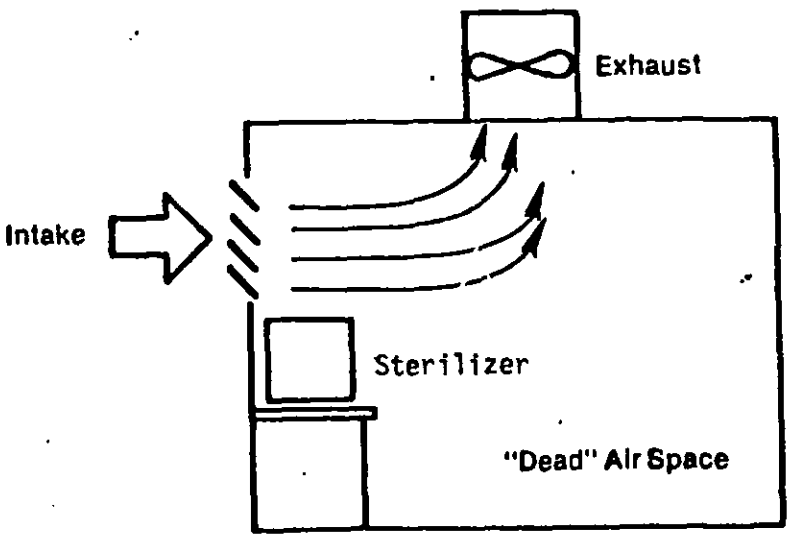
FIGURE 1:
RECOMMENDED LOCATION OF STERILIZATION/AERATION EQUIPMENT RELATIVE TO ROOM INTAKES AND EXHAUSTS

GOOD



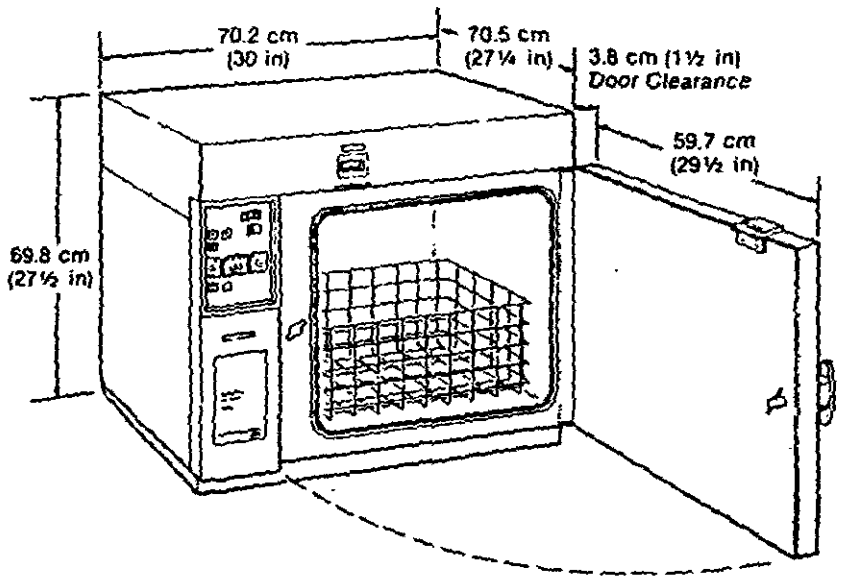
Air flow washes entire room.
Air movement is away from operator.

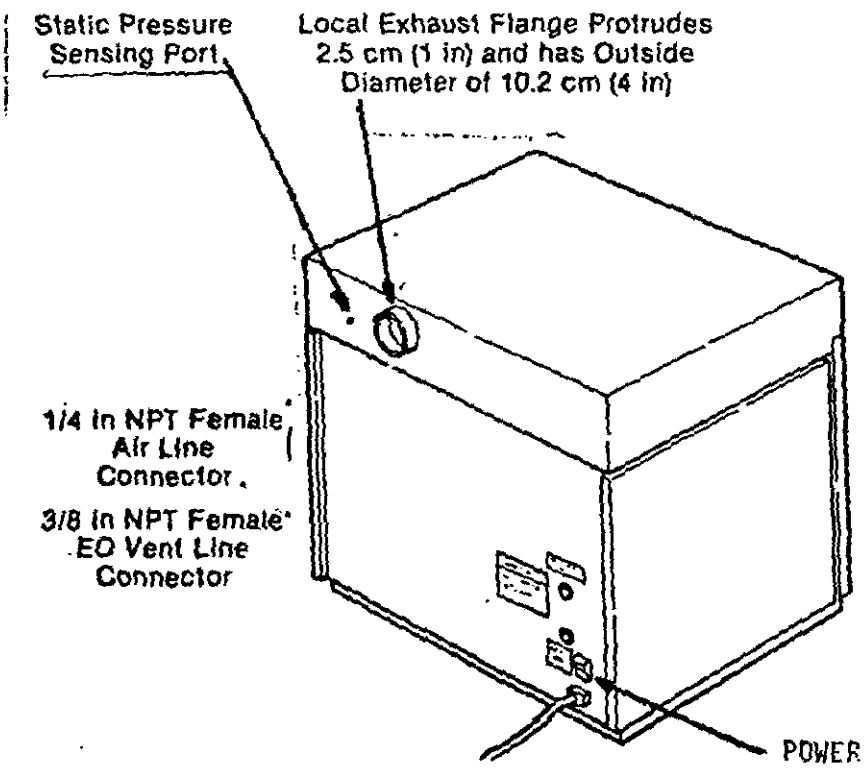
Poor



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

Figure 2: Dimensions, Model 4XL





Notes: 1. Leveling feet must be installed and base of unit must not be blocked so unit can circulate air properly over the electrical components and out 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.

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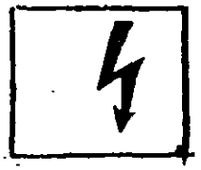
11.2 **Connection to sterilizer**



⚠ 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 inserviced 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 temper.

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 a 0.95 cm** (3/8 in.) **National Pipe Thread (NPT) connection at the sterilizer.**

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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	1.6 cm (5/8 in)	1.6 cm	1.6 cm	1.6 cm	1.9 cm (3/4 in)	1.9 cm	1.9 cm	1.9 cm
2	1.6 cm (5/8 in)	1.9 cm (3/4 in)	1.9 cm	1.9 cm	1.9 cm	1.9 cm	1.9 cm	2.5 cm (1 in)
3	1.9 cm (3/4 in)	2.5 cm (1 in)	2.5 cm	3.2 cm (1-1/4 in)	3.2 cm	3.2 cm	3.2 cm	3.2 cm
4	2.5 cm (1 in)	2.5 cm	3.2 cm (1-/4 in)	3.2 cm	3.2 cm	3.2 cm	3.2 cm	3.8 cm (1-1/2 in)
5	2.5 cm (1 in)	3.2 cm (1-1/4 in)	3.2 cm	3.2 cm	3.8 cm (1-1/2 in)	3.8 cm	3.8 cm	3.8 cm
6	3.2 cm (1-1/4 in)	3.2 cm	3.8 cm (1-1/2 in)	3.8 cm	3.8 cm	3.8 cm	3.8 cm	4.1 cm (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 distances 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.

12.6 **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.

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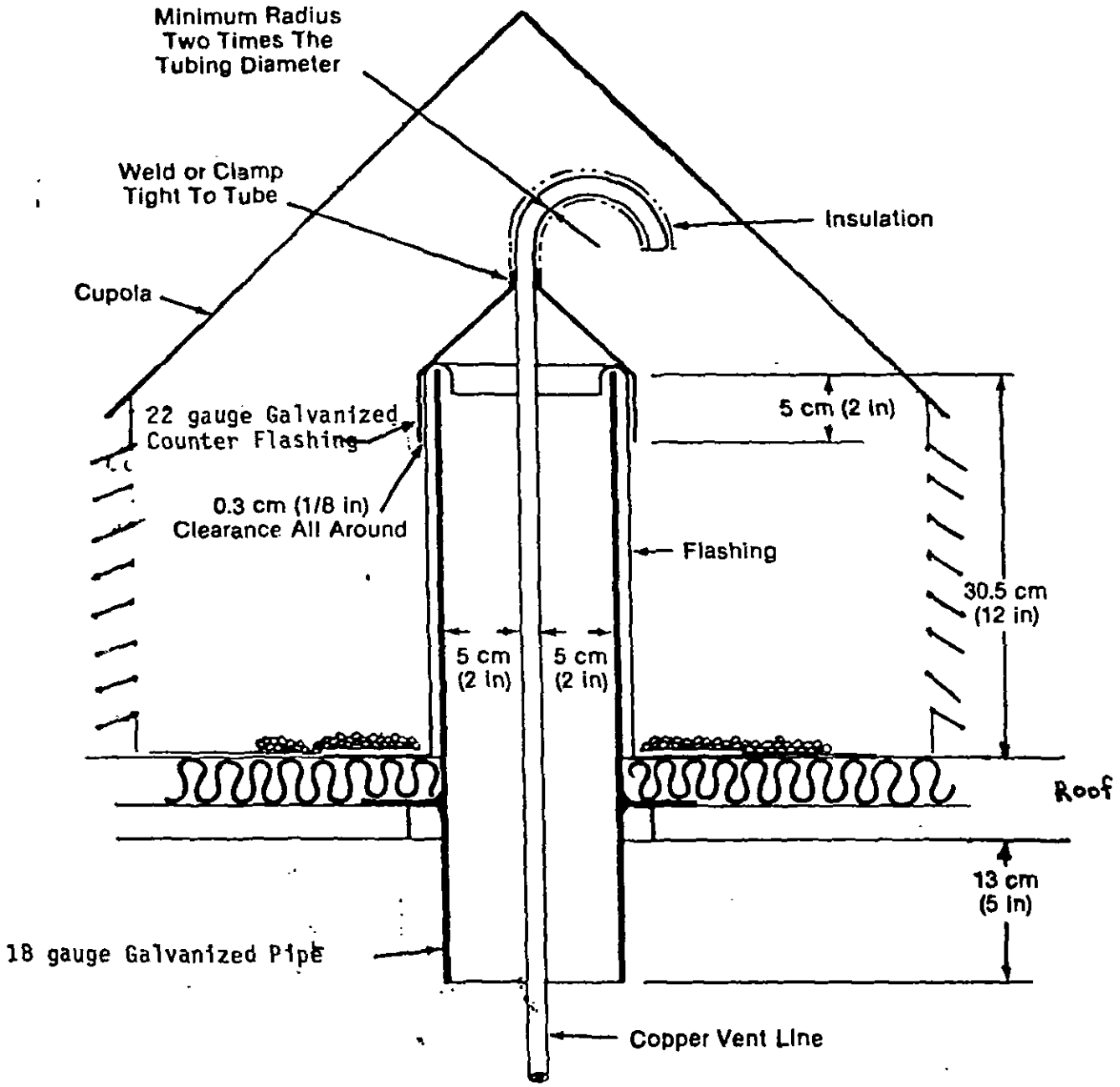
Figure 3 Roof Venting Diagram

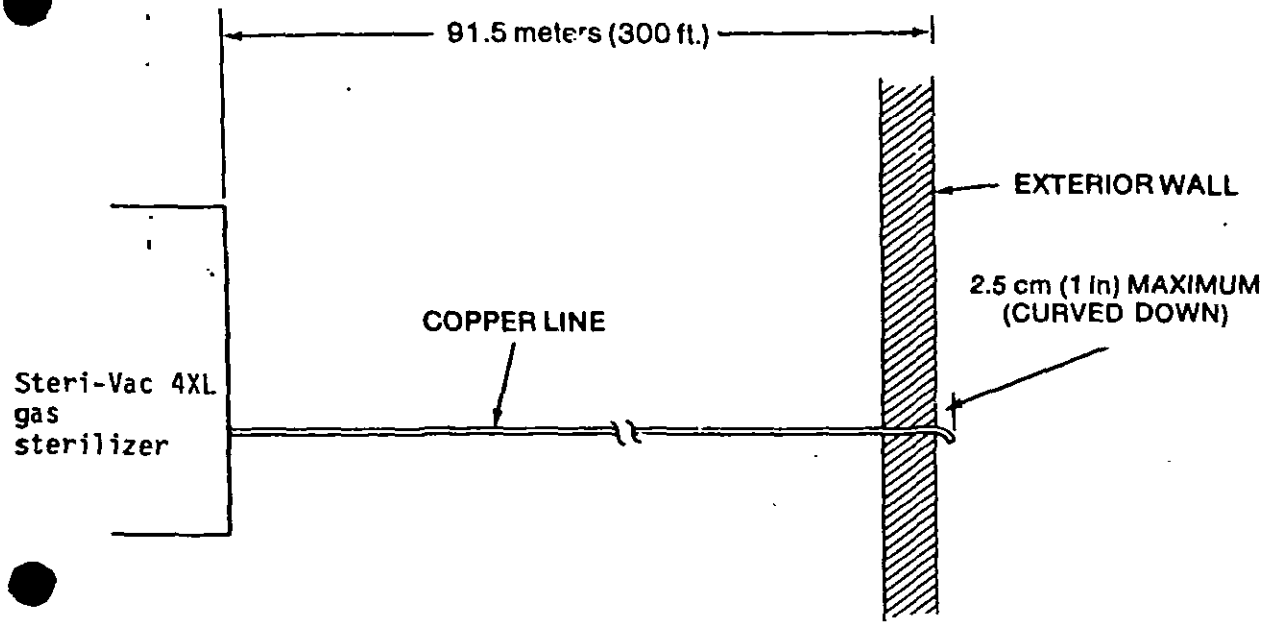


Note: The unit must be vented to the outside atmosphere, using the specified diameter copper tubing for the required vent line length. Vertical travel and restrictions, such as elbows, sharp bends and contractions should be kept to a minimum. The vent line should be a maximum of 91.5 meters (300 feet) 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.

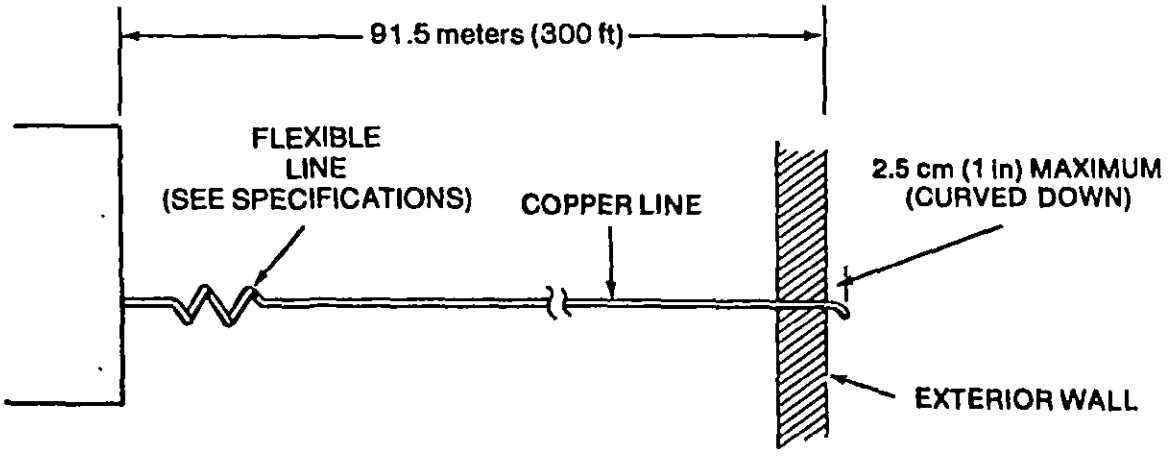
95/111

FIGURE 4: ETHYLENE OXIDE VENT LINE DIAGRAMS MODEL 4XL (CON'T)

HORIZONTAL VENT LINE:



FLEXIBLE TO SOLID VENT LINE:



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

../111 7182-1 PM 31

Date of Draft: June 11, 1986

PRE-REGISTRATION LABEL DRAFT

Reason To Issue: 1) To update Storage and Disposal statements in line with PR Notice 83-3, 2) to change registrant address of record to Medical-Surgical Division/3M, and 3) to specify the use of Steri-Gas 4-100 cartridge in the newly designated Steri-Vac® gas sterilizer model change from 400C to 4XL.

INSERT THIS END

Steri-Gas®

3M

Cartridge 4-100

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

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

DANGER—EXTREMELY FLAMMABLE
DO NOT USE NEAR FIRE OR FLAME
N.Y.F.D.C. of A. No. 933
USE ONLY IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS IN STERI-VAC MODEL 400C & 4XL
ETHYLENE OXIDE VAPOR HARMFUL • MAY CAUSE BURNS
Keep Container Closed — Avoid Breathing Vapor. Avoid inhalation and contact with skin or eyes. In case of contact remove contaminated clothing and flush skin or eyes with plenty of water, for eyes get medical attention. Avoid contact with oxidizing materials.
The product is limited to use by medical professionals or appropriately-trained personnel in medical and industrial use areas.

Medical-Surgical Division/3M
St. Paul, MN 55144 Made in U.S.A.
681160

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

ACCEPTED
AUG 2 6 1986
Under the [illegible] Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 7182-1

2/111.

Date of Draft: June 11, 1986

PRE-REGISTRATION LABEL DRAFT

Reason To Issue: 1) To update Storage and Disposal statements in line with PR Notice 83-3, 2) to change registrant address of record to Medical-Surgical Division/3M, and 3) to delete the use of the Steri-Gas® cartridge 2-67 with the Steri-Vac® 200 gas sterilizer.

INSERT THIS END

Steri-Gas® **3M**

Cartridge 2-67

Active Ingredient: Ethylene Oxide 100%
Net Wt 67 gms (2 37 oz)

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

DANGER—EXTREMELY FLAMMABLE
DO NOT USE NEAR FIRE OR FLAME

N.Y.F.D.C. of A. No. 933
USE ONLY IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS IN STERI-VAC MODEL 202 and 2028
ETHYLENE OXIDE VAPOR HARMFUL • MAY CAUSE BURNS

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

Medical-Surgical Division/3M
St. Paul, MN 55144 Made in U.S.A.
681160

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

ACCEPTED

AUG 2 6 1986

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

3/11

Date of Draft: June 11, 1986

PRE REGISTRATION LABEL DRAFT

Reason To Issue: 1) To update Storage and Disposal statements in line with PR Notice 83-3.

INSERT THIS END

Steri-Gas®

3M

Cartridge 4-134

Active Ingredient: Ethylene Oxide 100% • Net Wt 127 gms (4.50 oz.)

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

DANGER—EXTREMELY FLAMMABLE
DO NOT USE NEAR FIRE OR FLAME
N.Y.F.D.C. of A. No. 933
USE ONLY IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS IN STERI-VAC MODELS 400 OR 400B
ETHYLENE OXIDE VAPOR HARMFUL • MAY CAUSE BURNS

Keep Container Closed — Avoid Breathing Vapor. Avoid inhalation and contact with skin or eyes. In case of contact remove contaminated clothing and flush skin or eyes with plenty of water; for eyes get medical attention. Avoid contact with oxidizing materials. *The product is limited to use by medical professionals or appropriately-trained personnel in medical and industrial use areas.*

Medical-Surgical Division/3M
St. Paul, MN 55144 Made in U.S.A.
681160

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

ACCEPTED

AUG 2 6 1986

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

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PRE-REGISTRATION LABEL DRAFT

Date of Draft: 6-11-86

REASON TO ISSUE: 1) provide labeling relevant to OSHA classification of ethylene oxide; 2) revise precautionary and user handling statements; 3) reflect label symbols recommended by ANSI; 4) delete references to the obsolete Steri-Gas cartridges 1-30 and GS-10; 5) make certain editorial and format changes; 6) specify use of the Steri-Gas 4-100 cartridge in the newly designated model change from Steri-Vac 400C to 4XL.

- -

STERI-GAS® CARTRIDGES - PACKAGE INSERT
EPA REG. NO. 7182-1

DANGER: ETHYLENE OXIDE
Flammability

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

Toxicity

Acute inhalation. Overexposure 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 EO).

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

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

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

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

ACCEPTED
AUG 2 6 1986
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 7182-1

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OSHA LIMITS (29 CFR 1910.1047)

A worker's exposure to EO must not exceed OSHA's Permissible Exposure Limit of 1 ppm (one part per million) measured as an 8-hour time-weighted average. Direct contact with EO as a liquid or in solutions must be prevented.

Statement of Practical Treatment/First Aid

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

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

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. Contact a physician as soon as possible.

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.

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

Steri-Gas cartridge No.	Gas Sterilizer
2-67	Steri-Vac gas sterilizer Models 202 or 202B
4-134	Steri-Vac gas sterilizer Models 400 and 400B
4-100	Steri-Vac gas sterilizer Models 400C and 4XL

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

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

Medical-Surgical Division/3M
St. Paul, Minnesota 55144-1000

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

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PRE-REGISTRATION LABEL DRAFT

Date of Draft: June 11,1986

Reason to Issue: 1) Provide labeling relevant to OSHA classification of ethylene oxide; 2) specify use of the Steri-Gas 4-100 cartridge in the newly designated Steri-Vac model change from 400C to 4XL; 3) revise certain precautionary, transportation and user handling information; 4) specify U.S. and O.U.S. electrical listings approvals; 5) make certain editorial and label format improvements; 6) add certain hazard symbols recommended.

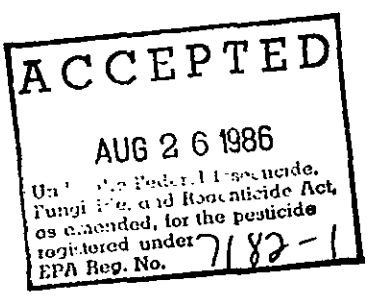
- -

Consumer Product Profile

Steri-Gas®
cartridges
EPA Reg. No. 7182-1

(Pictures of 3 Steri-Gas cartridges)

2-67
4-100
4-134



Medical-Surgical Division/3M
St. Paul, Minnesota 55144-1000

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1. INTRODUCTION

For over twenty years, unit dose quantities of ethylene oxide have been supplied to 3M Steri-Vac® gas sterilizers in Steri-Gas cartridges. More than eighteen hundred health care facilities have found the system to be a reliable and cost-effective method for sterilizing medical devices.

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

2. FEATURES AND BENEFITS

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

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

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

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

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

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

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

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

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

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

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3. STERI-GAS CARTRIDGE APPLICATIONS

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

Steri-Gas cartridges	Steri-Vac sterilizer models
2-67	202 & 202B
4-100	400C & 4XL
4-134	400 & 400B

4. STERI-GAS PRODUCT SPECIFICATIONS

4.1 Cartridge Contents

Steri-Gas cartridges contain one hundred percent **liquid** ethylene oxide. The liquid becomes a gas when released from the cartridge into the sterilization chamber. The major physical characteristics of ethylene oxide are:

Boiling Point	10.7°C (51.3°F)
Vapor Pressure	1094 mm Hg at 20°C $\left(\frac{457\ g}{sq\ cm\ gauge}\right)$
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

4.2 Shelf Life

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

4.3 Cartridge Weights

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

Steri-Gas cartridge	Minimum Gross Weight in Grams
2-67	89
4-100	131
4-134	157

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4.4 Cartridge Construction

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

4.5 Gasket Material

The gasket material for Steri-Gas cartridges was selected because of its capability to swell and form a tight seal when in contact with ethylene oxide. The swelling, referred to as **gasket oozing**, may result in two normal and observable phenomena:

4.5.1 The gasket may swell out from under the cartridge cap, and/or

4.5.2 An oily residue may appear on the body of the cartridge.

5. CARTRIDGE REGISTRATION AND LISTINGS

5.1 EPA Registration

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

5.2 Listing With Underwriters Laboratories, Inc.

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

5.3 International Listings

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

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[2] CSA Standards C22.0, Nos. 0, 04 and 151 and CAN3-2314.1 - M84.

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AUG 26 1986
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5.4 Factory Mutual Systems Listing

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

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

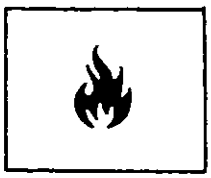
Factory Mutual Systems is an internationally recognized testing laboratory similar to Underwriters Laboratories. Its tests include both electrical and mechanical tests and end-of-cycle gas concentration measurements. 3M participated with Factory Mutual in a program of periodic factory inspections and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

6. HEALTH AND SAFETY INFORMATION

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

⚠ **DANGER**

6.1 Flammability



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

6.2 Toxicity

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

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

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

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

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

6.3 OSHA LIMITS (29 CFR 1910.1047)

A worker's exposure to ethylene oxide must not exceed OSHA's Permissible Exposure Limit of 1 ppm (one part per million) measured as an 8-hour time-weighted average. Direct contact with ethylene oxide as a liquid or in solutions must be prevented.

6.4 **STATEMENT OF PRACTICAL TREATMENT/FIRST AID**

6.4.1 **Inhalation.** Immediately get fresh air for overexposures to ethylene oxide gas. Contact a physician as soon as possible.

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

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

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

7. STORAGE OF STERI-GAS CARTRIDGES

7.1 National Fire Protection Association (NFPA) Codes

NFPA Article No. 30, Section 4450 outlines storage requirements for Class I flammable liquids in Office, Education and Institutional Occupancies. The requirements pertain to Steri-Gas cartridges containing 100% ethylene oxide. Subparagraph (b) of this section states: "Not more than 10 gallons of Class I and Class II liquids combined shall be stored outside of a storage cabinet or storage room, except in safety cans." Ten (10) gallons of ethylene oxide is approximately equivalent to 245 of the largest Steri-Gas cartridges (No. 4-134).

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AUG 2 6 1986

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

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7.2 3M RECOMMENDATIONS

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

⚠ **DANGER**

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

7.2.2 Store cartridges at room temperature.

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

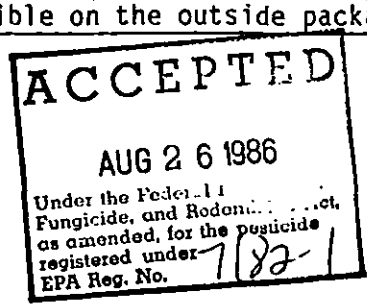
7.2.4 Store 13-48 cartridges (2-4 boxes) in an area away from the sterilizer(s) and ignition sources.

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

8. CARTRIDGE SHIPPING

It is the customer's responsibility to ship according to local, state and federal transportation requirements. Steri-Gas cartridges must be stored and transported in the original shipping case or intermediate package, both of which are Department of Transportation (DOT) approved shipping containers. The following must be clearly visible on the outside packaging for transportation.

8.1 Red Flammable Liquid Label
8.2 UN-1040
8.3 ETHYLENE OXIDE



9. CARTRIDGE HANDLING AND DISPOSAL

9.1 Used Cartridges

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

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

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

9.2 **Unused Cartridges**

Unused cartridges are pesticide wastes which are toxic. Improper disposal is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Contact your local 3M Medical-Surgical representative for additional information.

10. ETHYLENE OXIDE LEAKS OR SPILLS

10.1 **Characteristics of a Leak or Spill**

Do not confuse gasket oozing or an oily residue, described in Section 4.5, with ethylene oxide leakage. The following indicate Steri-Gas cartridge leakage:

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

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

10.1.3 cartridge weight loss.

10.2 Emergency Plan and Procedures

10.2.1 OSHA Requirements

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

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OSHA requires an audible or visible alarm system to alert personnel of a spill or leak in areas with more than ten (10) employees. A public address system, a call to the switchboard for an intercom announcement, and lights are examples of acceptable systems. The alarm can be either manually or automatically activated. An alarm connected to an air sampling system is **not** required. OSHA has specific requirements for installing, testing, and maintaining alarms. Direct voice communication can be used as an alarm in areas with ten or fewer employees. Consult OSHA's standards on ethylene oxide (29 CFR 1910.1047), employee emergency plans (29 CFR 1910.28), and alarm systems (29 CFR 1910.165) for more detailed information.

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

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

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

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

Doc. No. AAMI EO-VRSU 3/81

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

10.2.2 **3M Recommendations for a Gas Leak or Spill Response**

10.2.2.1 Avoid direct contact with liquid ethylene oxide.

10.2.2.2 Evacuate personnel from the immediate department.

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

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

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

10.2.2.6 Re-enter the department only after a qualified health and/or safety personnel has determined that re-entry is safe (e.g., air sampling or calculating the amount of time needed for the ventilation system to remove ethylene oxide).

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

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

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11. PRECAUTIONS

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

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

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

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

11.5 In accordance with the OSHA ethylene oxide standard, develop a written emergency plan for leaks or spills. Ensure your personnel are trained in the emergency procedures. Refer to the OSHA standard, 29 CFR 1910.1047, and Section 10 of this Product Profile for detailed information.

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APPENDIX A

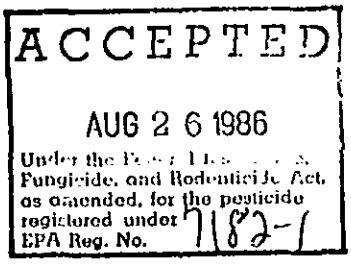
June 10, 1986

Review of Modifications in the STERI-VAC Sterilizer as the Basis for Changing the Model Designation from 400C to 4XL

The basis for the change in brand name designation from STERI-GAS 400C to 4XL, is to provide improved electronics and unit design resulting in a more aesthetic "user friendly" device. It is emphasized at the outset of this comparison that the design and electronic modifications have not altered the performance parameters of the Steri-Vac sterilizer unit. The performance parameters were previously identified in the efficacy data submitted in support of the Steri-Vac 400C sterilizer, and assigned EPA Accession No. 245866. The fact that these parameters have not changed is demonstrated in Figure 1 and 2 by comparing the "CYCLE EXPLANATION TIME AND PRESSURE DIAGRAM." Thus the method of application and the conditions necessary for achieving efficacy has not changed. A point-by-point comparison of each of these parameters is presented in the table below.

STERILIZATION CYCLE PARAMETER	STERILIZER MODEL	
	Steri-Vac 400C Sterilizer	Steri-Vac 4XL Sterilizer
Cycle Time		
i) warm cycle	62 min.	62 min.
ii) cold cycle	250 min.	250 min.
Temperature		
i) warm cycle	55°C or 63°C	55°C
ii) cold cycle	37°C	37°C
Moisture (injections)		
i) warm cycle	10x10 cc water	10x10 cc water
ii) cold cycle	4x10 cc water	4x10 cc water
Ethylene oxide concentration	$100g/4ft^3$	$100g/4ft^3$

The modifications to the Steri-Vac 400C gas sterilizer that are embodied in the proposed Steri-Vac 4XL gas sterilizer are intended to accomplish three basic objectives:



1) To incorporate a local exhaust ventilation system into the design of the machine. This was an optional feature of the Steri-Vac 400C sterilizer.

2) To modify the electronics in the machine resulting in more simplified and modern circuitry.

3) To reduce the complexity of the design making the machine more user friendly (i.e. easier to operate and service).

With regards to 1) above, the built-in exhaust hood located in the top panel of the 4XL sterilizer allows the customer to achieve maximal air flow through a dedicated exhaust system. As noted, by design, the installation of this exhaust system is not optional with the 4XL unit, thereby further minimizing inadvertent exposure to the user of the ethylene oxide.

The electronic modifications noted in 2) above have been made in accordance with specifications set by Underwriters Laboratories, Inc. (UL Standard 544) and the West German laboratory TECHNISCHER UBERWACHUNGS-VEREIN (TUV). The most significant modifications were to separate the "low voltage" circuit from circuit boards containing the "high voltage" (±30 RMSV) circuit; to further update the solid state electronics and reduce the number of components. The steam generating heated block in the 400C sterilizer was replaced with a steam generator.

Finally, relevant to further simplifying the design of the Steri-Vac unit as noted in 3) above, we refer to Figures 3 and 4. Figure 3 is a representation of the front panel of a Steri-Vac 400C gas sterilizer and Figure 4 is a corresponding diagram of the front panel of a Steri-Vac 4XL gas sterilizer. Notable changes involve the combination of the "END PURGE" switch and the "MANUAL ABORT" switch into one "STOP" switch. The "OPEN DOOR" switch on the 400C sterilizer has been incorporated into the door handle on the 4XL sterilizer. The "CYCLE PROGRESS" LEDs on the 4XL sterilizer have been modified, but still provide the user with information on the status of the sterilization cycle. The "TEMPERATURE SELECTION" switches have been changed from one switch to two on the 4XL sterilizer. The ON/OFF switch on the 4XL sterilizer has been moved to the back panel of the machine and the sterilizer is intended to be left on in a "STANDBY" mode. The 4XL sterilizer also has built into the electronic design the ability to display error messages. The same electronics existed in the 400C sterilizer but there was no means available for displaying such messages.

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FIGURE 1: Steri-Vac^{R} 400C gas sterilizer CYCLE EXPLANATION TIME/PRESSURE DIAGRAM

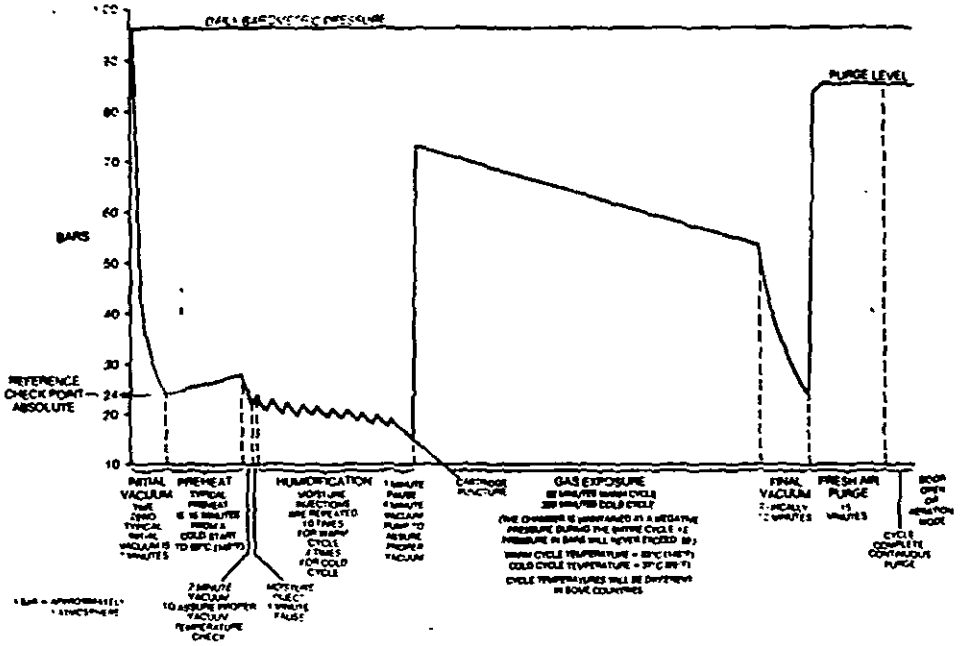


FIGURE 2: Steri-Vac 4XL gas sterilizer CYCLE EXPLANATION TIME/PRESSURE DIAGRAM

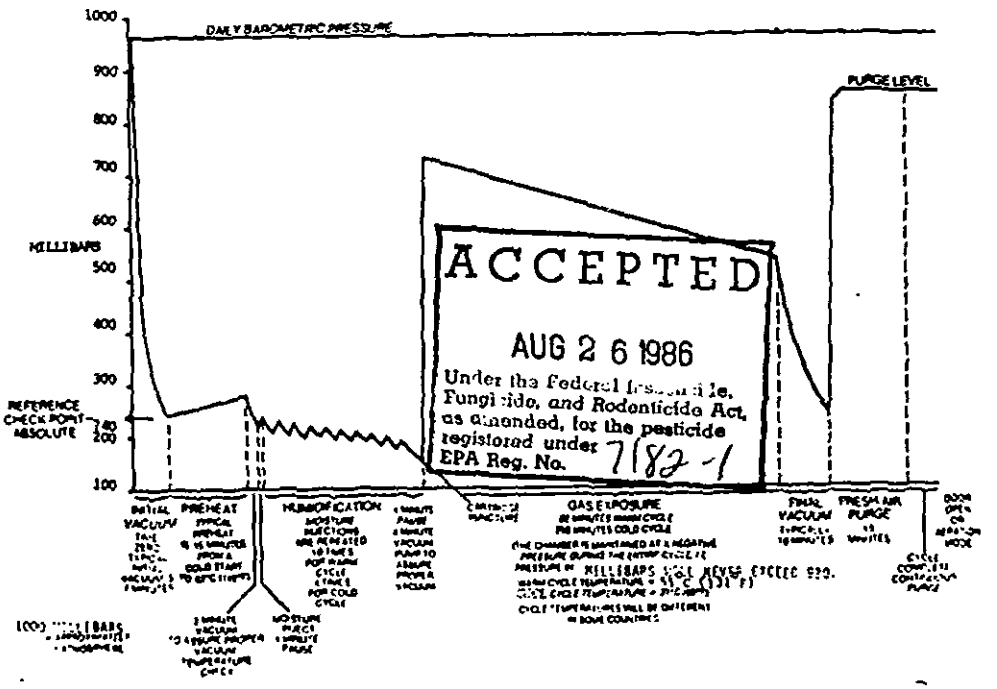
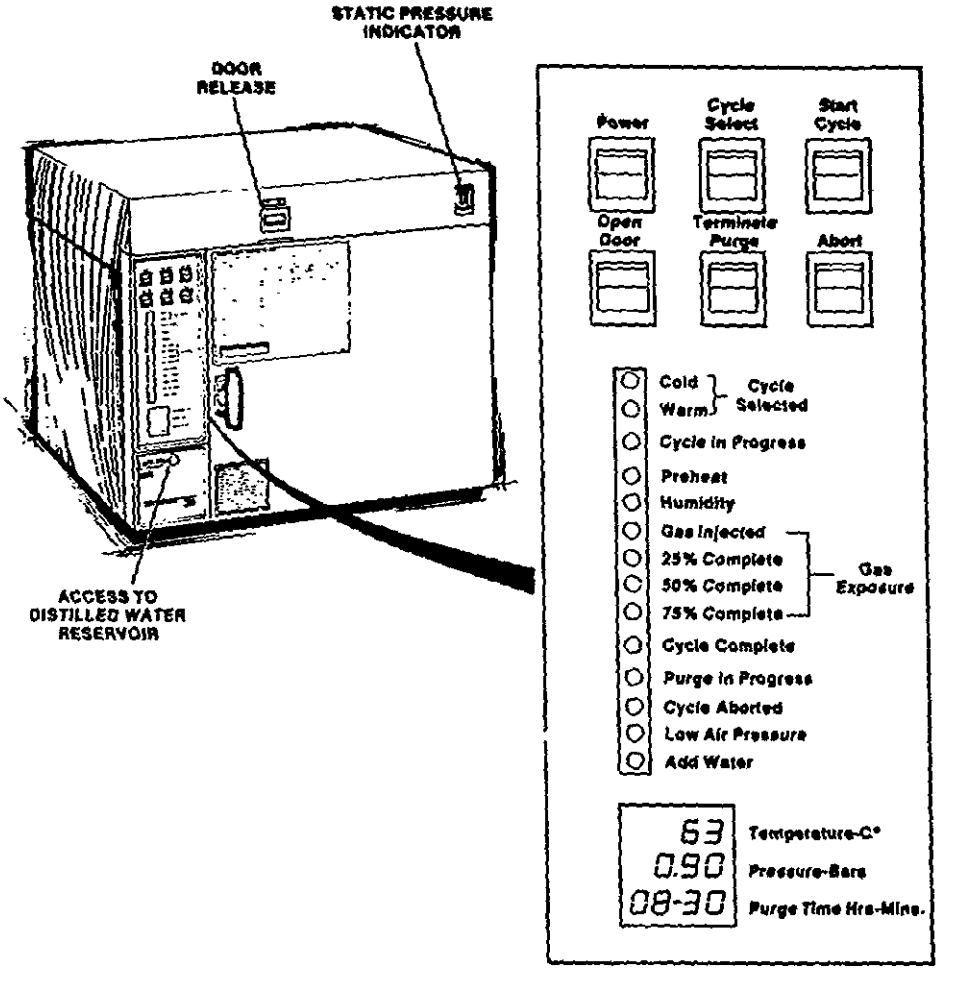


FIGURE 3: Steri-Vac^{R} 400C gas sterilizer



FRONT PANEL

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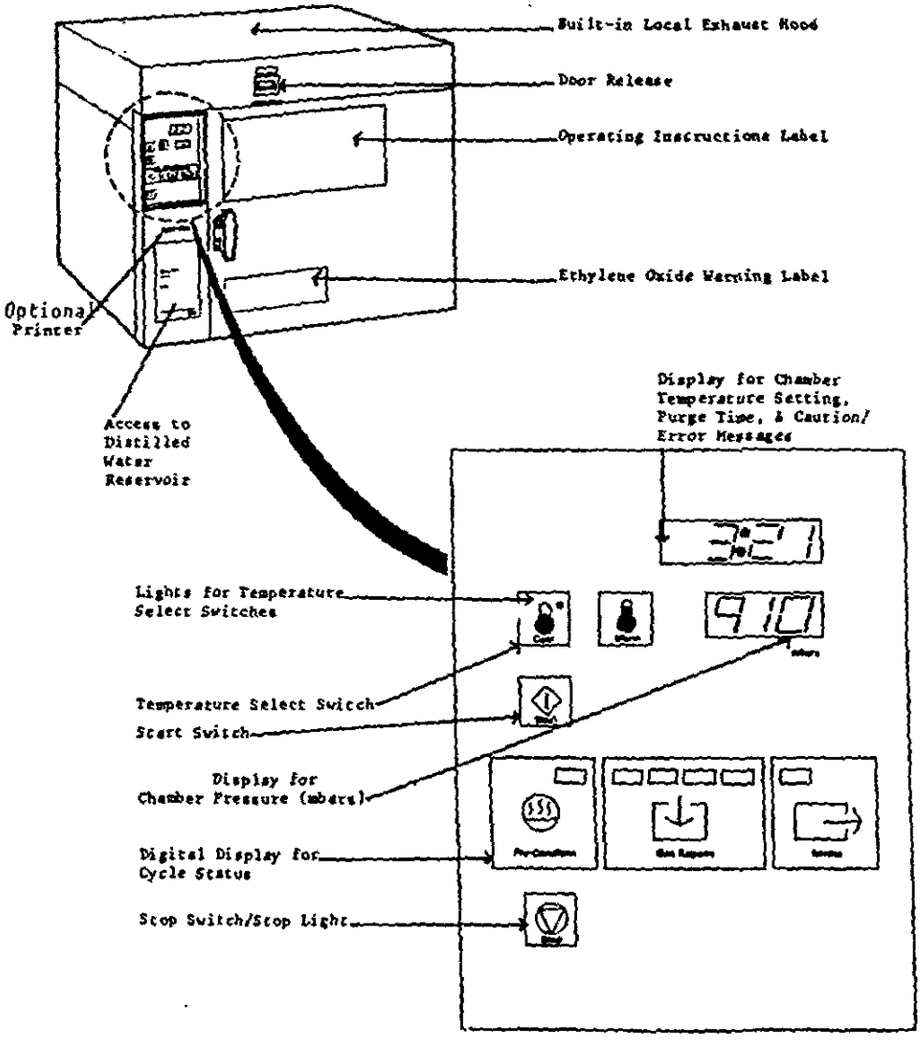
FIGURE 4: Steri-Vac® 4XL gas sterilizer



FRONT PANEL

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READ SAFETY LABELS CAREFULLY.

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

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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. 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 may cause severe irritation and burns to the gastro-intestinal 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.

12-2376-9529-6

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

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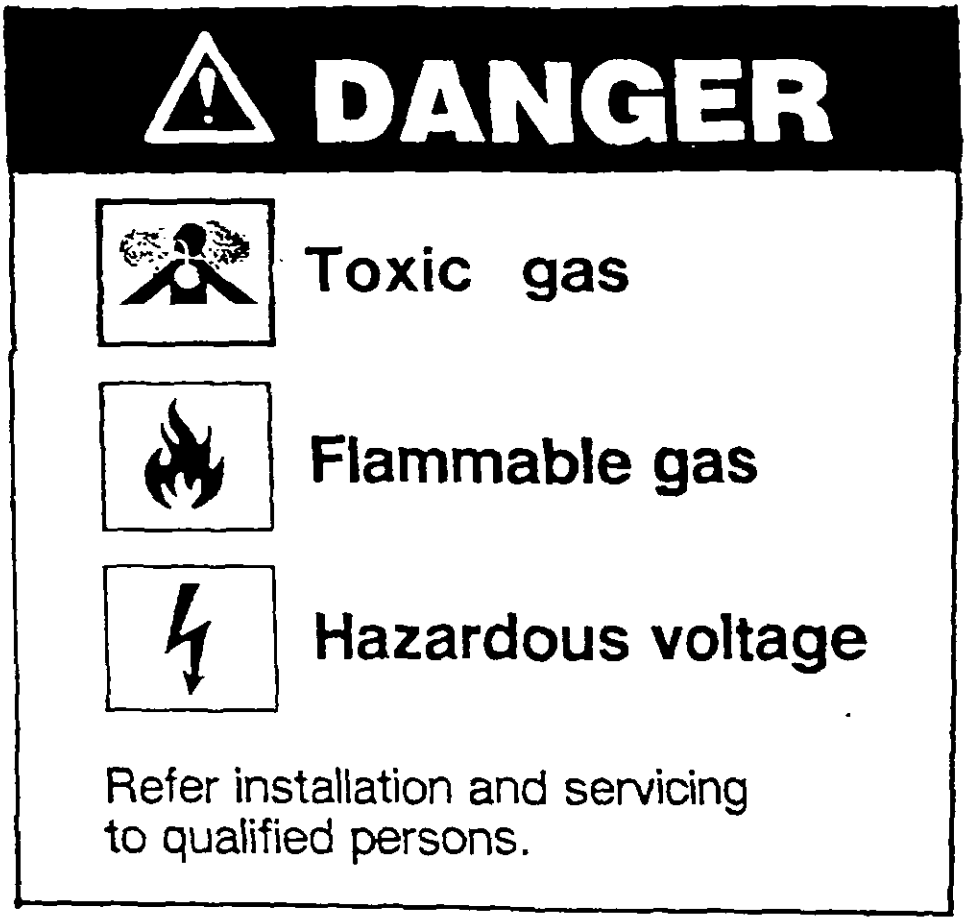

Affixed to back panel of Steri-Vac 4XL gas sterilizer.
3M part no. 12-2376-9490-1

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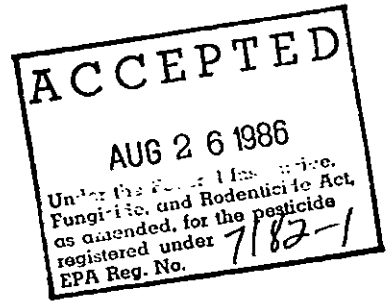
READ INSTALLATION GUIDE AND OPERATING INSTRUCTIONS CAREFULLY.



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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	APPROXIMATE 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 instructions. (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 sterilizer is in standby.
3. Turn handle counter-clockwise while lifting DOOR RELEASE to open door.
4. Insert Steri-Gas cartridge 4-100 into 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

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CAUTION/ ERROR MESSAGE CHART

Use the chart below to determine the steps to take 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. 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.

<u>Caution Messages - Will Not Stop Cycle</u>

c1	Low Air in Exhaust Hood	External Fan Malfunction	Check Fan and Fan Belts
		Airflow Sensor Failure	Call Service Representative
c2	Low Water During Standby	Reservoir Needs Water	Add Water
c3	Power Interruption	Power Outage	Cycle Restarts Automatically
c4	Compressed Air Lost During Aeration	No Compressed Air	Check Compressor, Air Lines

<u>Errors That are Detected Before Puncture</u>

E10	Low Water	Water Resevoir Needs Water	Add Water to Reservoir
		Float Switch Failure	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	Clear Pkg. from Chamber Port
		No Compressed Air Connection	Check Air Lines & Pressure
		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	Chamber Too Cold at START	Restart
		Defective Temperature Control	Call Service Representative
E24	Heatsink Preheat Timeout	Chamber too Cold at START	Restart
		Defective Temperature Control	Call Service Representative
E28	No Water Injected	Resevoir Float Sw. Stuck	Add Water to Reservoir
		Water System Plugged	Call Service Representative
E32	Door Unlocked	Door Latch Hung up on Bolt	Turn handle completely vertical
		Control Error	Call Service Representative
E34	Door Open	Door Not Closed Before Start	Close Door - Restart
		Defective Switch	Call Service [illegible]presentative
E40	User Interruption	User Pressed STOP switch	Restart

<u>Errors Found During Gas Exposure</u>

E50	Empty Cartridge	Empty Cartridge Loaded	Use new Cartridge
		Puncture Mechanism Failed	Call Service Representative
E54	Extended Power Outage	Could Not Restart After Outage	Restart
E60	User Interruption	User Pressed STOP switch	Restart

<u>Errors That Leave the Chamber Locked with Gas Possibly in the Chamber</u>

E71	Final Pumpdown Timeout	Compressed Air Problem	Correct and press Start
		Vacuum System Failure	Call Service Representative
E72	Obstructed Air Inlet	Bacterial Filter Plugged	Try press START/ Call Service Representative

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AUG 26 1986
[illegible] as amended, for the [illegible] registered under EPA Reg. No. 7182-1

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

AIR LINE

Maximum air inlet pressure shall not exceed 150 psig

Located on back panel of 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.

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Located on back panel of Steri-Vac 4XL gas sterilizer. 3M part no. 12-2376-9415-8.

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

Located on back panel of Steri-Vac 4XL gas sterilizer. 3M part no. 12-2376-9709-4.

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PRE-REGISTRATION LABEL DRAFT

Date of Draft: June 11, 1986

Reason to Issue: To provide instructions and information regarding "FIRE AND EXPLOSION HAZARD DATA" not indicated on other Steri-Gas/Steri-Vac labeling. NOTE: All other text found on this MSDS labeling is also reflected on Steri-Gas/Steri-Vac labeling. This MSDS labeling does not accompany the product, but is available upon customer request.

- -

MATERIAL SAFETY DATA SHEET (MSDS)
FOR
STERI-GAS® CARTRIDGES, EPA REG. NO. 7182-1

ACCEPTED

AUG 2 6 1986

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3M

MATERIAL SAFETY
DATA SHEET

3M
3M CENTER
ST. PAUL, MINNESOTA
55144-1000
612/733-1110 Duns No.: 00-617-3082

DIVISION: MEDICAL-SURGICAL DIVISION
TRADE NAME: STERI-GAS BRAND CARTRIDGES 4-100, 4-134 AND 2-67
3M I.D. NUMBER: 70-2004-5709-4 70-2004-6706-9 70-2004-7521-1

ISSUED: JUNE 5, 1986
SUPERSEDES: MAY 12, 1986
DOCUMENT: 10-3495-8

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
ETHYLENE OXIDE (EO)	75-21-8	100.0	1 PPM	2

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

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2. PHYSICAL DATA

BOILING POINT:	10.7C (51.3F)	SOLUBILITY IN WATER:	COMPLETE
VAPOR PRESSURE:	1094MM HG @ 20C	SP. GRAVITY (WATER=1):	0.8711 @ 20/20 C
VAPOR DENSITY (AIR=1):	1.49	PERCENT VOLATILE:	100%
EVAPORATION RATE (=1):	(N/A)	VISCOSITY:	N/A
APPEARANCE AND ODOR:	COLORLESS GAS IN NORMAL USE. SWEET ODOR AT 500-750 PPM	pH:	N/A

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (): < 0 DEG F
FLAMMABLE LIMITS - LEL: 3% UEL: 100%

EXTINGUISHING MEDIA:
CARBON DIOXIDE FOR SMALL FIRES. POLYMER OR ALCOHOL FOAMS FOR LARGER FIRES.
SPECIAL FIRE FIGHTING PROCEDURES:

DILUTION OF ETHYLENE OXIDE WITH 23 VOLUMES OF WATER RENDERS IT NONFLAMMABLE.

UNUSUAL FIRE AND EXPLOSION HAZARDS:
VAPORS OF EO WILL BURN WITHOUT PRESENCE OF AIR OR OTHER OXIDIZERS.

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
ALKALINES AND ACIDS. DECOMPOSES VIOLENTLY AT TEMPERATURES ABOVE 800 DEG F. WILL POLYMERIZE VIOLENTLY IF CONTAMINATED WITH AQUEOUS ALKALINES, AMINES, MINERAL ACIDS, METAL CHLORIDES AND METAL OXIDES.

HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

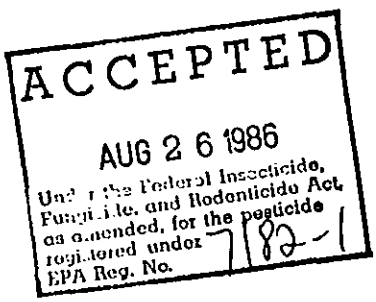
HAZARDOUS DECOMPOSITION PRODUCTS:
CARBON MONOXIDE AND CARBON DIOXIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. EXTINGUISH ALL IGNITION SOURCES. EVACUATE AREA IMMEDIATELY. VENTILATE AREAS. RE-ENTER ONLY WHEN WEARING A GOVERNMENT APPROVED RESPIRATOR FOR EO OR AFTER THE VENTILATION SYSTEM HAS REDUCED THE EO CONCENTRATIONS BELOW AN 8-HOUR TWA OF 1 PPM.

RECOMMENDED DISPOSAL:
USED CARTRIDGES. AERATE AN EMPTY CARTRIDGE AFTER A STERILIZATION CYCLE. DISPOSE OF EMPTY CARTRIDGES WITH NORMAL, NON-INCINERATED WASTE (SANITARY LANDFILL). UNUSED CARTRIDGES: PESTICIDE WASTES ARE TOXIC. IMPROPER DISPOSAL OF EXCESS PESTICIDE IS A VIOLATION OF FEDERAL LAW. IF THESE WASTES CANNOT BE DISPOSED OF ACCORDING TO LABEL INSTRUCTIONS, CONTACT YOUR STATE PESTICIDE OR ENVIRONMENTAL CONTROL AGENCY, OR THE HAZARDOUS WASTE REPRESENTATIVE AT THE NEAREST EPA REGIONAL OFFICE FOR GUIDANCE. CONTACT YOUR LOCAL 3M MEDICAL-SURGICAL REPRESENTATIVE FOR ADDITIONAL INFORMATION.

ENVIRONMENTAL DATA:
N/D



6. SUGGESTED FIRST AID

EYE CONTACT:
FOR LIQUID EO OR HIGH CONCENTRATIONS OF EO GAS, IMMEDIATELY FLUSH THE EYES WITH WATER FOR AT LEAST 10 MINUTES. CONTACT A PHYSICIAN AT ONCE.

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.

INHALATION:
IMMEDIATELY GET FRESH AIR FOR OVEREXPOSURES TO EO GAS. CONTACT A PHYSICIAN AS SOON AS POSSIBLE.

IF SWALLOWED:
CALL A PHYSICIAN OR POISON CONTROL CENTER. DRINK 1 OR 2 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.

7. PRECAUTIONARY INFORMATION

FLAMMABILITY: 1) KEEP ALL SOURCES OF IGNITION SUCH AS MATCHES, LIGHTED CIGARETTES, SPARKS AND STATIC DISCHARGE AWAY FROM EO. 2) STORE 49 OR MORE STERI-GAS CARTRIDGES IN AN APPROVED FLAMMABLE LIQUID STORAGE CABINET OR AN AREA SUITABLE FOR STORING CLASS I FLAMMABLE LIQUIDS IN ACCORDANCE WITH THE NATIONAL FIRE PROTECTION ASSOCIATION CODE, ARTICLE NO. 30, SECTION 4450. 3M RECOMMENDS THAT NO MORE THAN 12 CARTRIDGES BE KEPT IN THE IMMEDIATE STERILIZER AREA. SPILLS/LEAKS: 3) THE OSHA EO STANDARD (29 CFR 1910.1047) REQUIRES A WRITTEN EMERGENCY PLAN FOR SPILLS OR LEAKS. THE PLAN MUST INCLUDE PROCEDURES FOR ALERTING, EVACUATING, RESCUING, TRAINING, AND MEDICALLY TREATING PERSONNEL OVERCOME BY EO. PROCEDURES FOR REPORTING AN EMERGENCY TO APPROPRIATE AUTHORITIES AND DETERMINING WHEN IT IS SAFE TO RE-ENTER A SPILL AREA MUST BE INCLUDED. DO NOT CONFUSE EO LEAKAGE WITH SWELLING OF THE GASKET MATERIAL UNDER THE CARTRIDGE CAP OR AN OILY RESIDUE THAT SOMETIMES APPEARS ON THE CARTRIDGE. 4) WEAR NEOPRENE GLOVES, NEOPRENE APRON/IMPERVIOUS CLOTHING, AND A FULL-FACE RESPIRATOR APPROVED FOR PROTECTION WHENEVER CONTACT WITH LIQUID EO IS POSSIBLE. 5) DO NOT PLACE A LEAKING CARTRIDGE IN AN AERATION CABINET. LEAVE THE CARTRIDGE IN THE STERILIZER AND RUN A CYCLE TO EVACUATE THE EO. 6) DC NOT PUNCTURE THE CARTRIDGE BY ANY OTHER MEANS THAN IN THE STERILIZER. DISPOSAL; 7) DO NOT INCINERATE EMPTY OR FULL STERI-GAS CARTRIDGES.

ACCEPTED
AUG 2 6 1986
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide ... registered under 7182-1

8. HEALTH HAZARD DATA

ACUTE INHALATION: OVEREXPOSURE MAY CAUSE IRRITATION OF THE RESPIRATORY TRACT, DIZZINESS, WEAKNESS, NAUSEA AND VOMITING (IMMEDIATE OR DELAYED), CHEST PAIN, AND NEUROTOXIC EFFECTS. REPEATED OVEREXPOSURE MAY RESULT IN OLFACTORY FATIGUE (I.E. INCREASINGLY DIFFICULT TO SMELL EO).

CHRONIC INHALATION: THE RESULTS OF ANIMAL TOXICITY AND HUMAN EPIDEMIOLOGY STUDIES INDICATE THAT LONG TERM EXPOSURE TO INHALED EO MAY BE HAZARDOUS TO HUMANS. THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA) CLASSIFIES EO AS A CANCER AND REPRODUCTIVE HAZARD. FOR PROTECTION AGAINST THESE EFFECTS, OSHA ESTABLISHED A PERMISSIBLE EXPOSURE LIMIT OF 1 PPM MEASURED AS AN 8-HOUR TIME WEIGHTED AVERAGE. IN ADDITION, THE 3M EXPOSURE GUIDELINE FOR A 15-MINUTE TIME WEIGHTED AVERAGE IS 5 PPM.

EYE CONTACT: LIQUID EO SPLASHED IN THE EYES MAY CAUSE SEVERE INJURY. HIGH CONCENTRATIONS OF EO GAS MAY CAUSE SEVERE EYE IRRITATION AND INJURY.

SKIN CONTACT: LIQUID EO IN CONTACT WITH THE SKIN MAY CAUSE IRRITATION, DERMATITIS, AND CHEMICAL BLISTERS. INGESTION: A HIGHLY UNLIKELY ROUTE OF EXPOSURE. LIQUID EO UPON INGESTION IS CAUSTIC AND MAY CAUSE SEVERE IRRITATION AND BURNS TO THE GASTROINTESTINAL MUCOSA.

ACCEPTED

AUG 2 6 1986

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

The information on this Data Sheet represents our current data and best opinion as to the proper use in handling of this product under normal conditions. Any use of the product which is not in conformance with this Data Sheet or which involves using the product in combination with any other product or any other process is the responsibility of the user.

Reason to Issue: 1) Provide labeling relevant to OSHA classification of ethyle oxide; 2) specify use of the Steri-Gas 4-100 cartridge in the newly designated Steri-Vac model change from 400C to 4XL; 3) revise certain precautionary, transportation and user handling information; 4) specify U.S. and O.U.S. electr listings approvals; 5) make certain editorial and label format improvements, anc add certain hazard symbols.

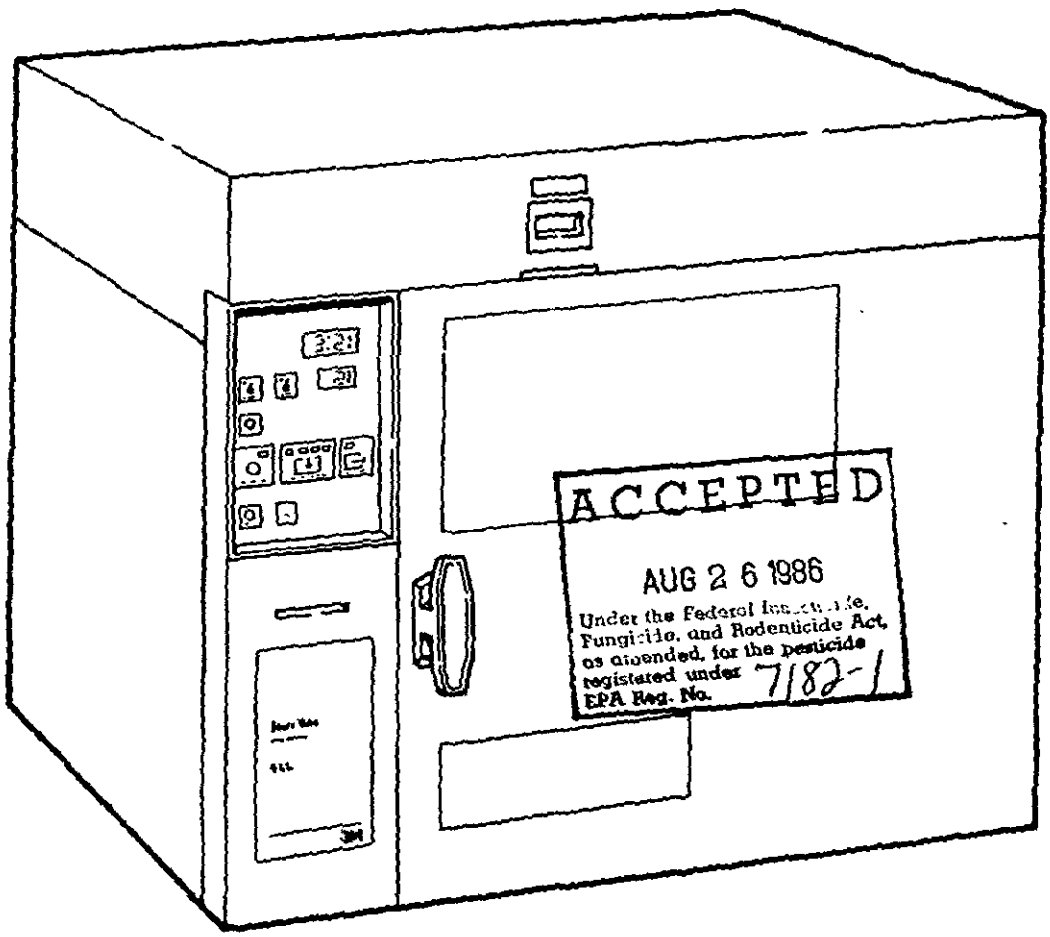
- -

STERI-VAC®

Date of Draft: June 11,1

4XL Gas Sterilizer
EPA Reg. No. 7182-1

OPERATOR'S MANUAL



Medical-Surgical Division/3M
3M Center, St. Paul, MN 55144

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OPERATOR'S MANUAL

STERI-VAC 4XL GAS STERILIZER

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1. STERILIZER LABELING

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READ SAFETY LABELS CAREFULLY.

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

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. 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 may cause severe irritation and burns to the gastro-intestinal 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.

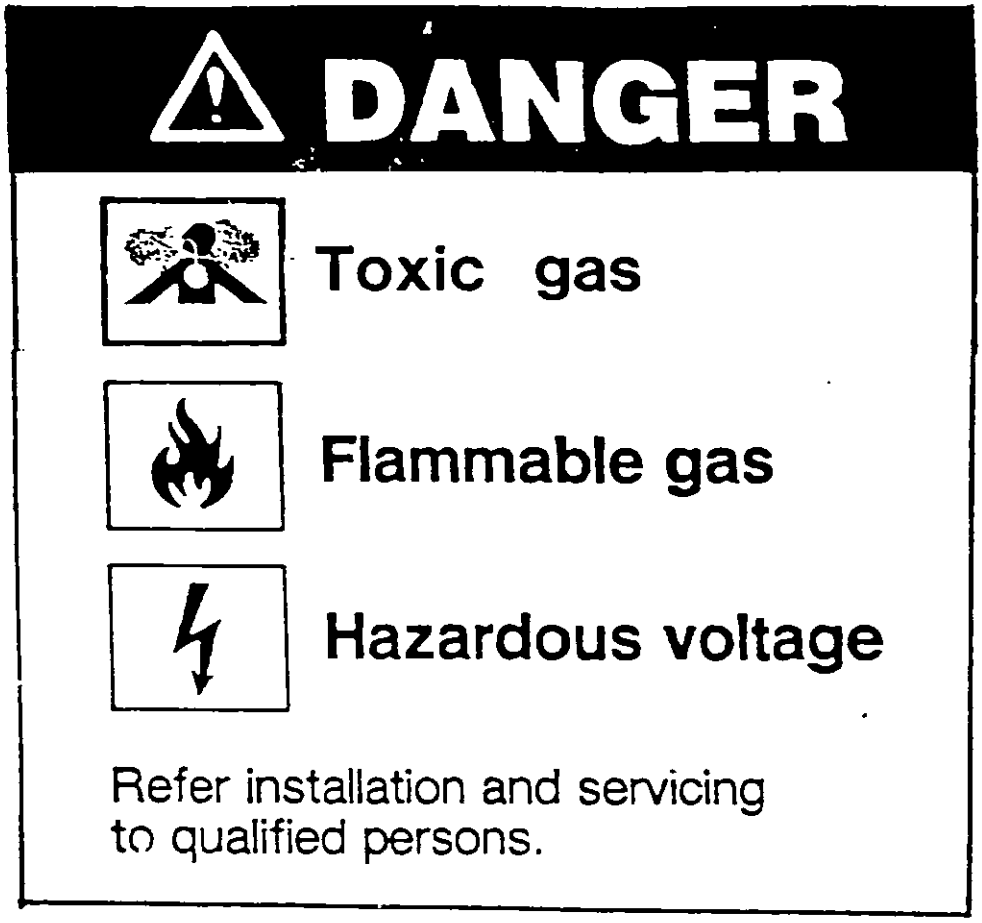
Eye Contact. For liquid EO or high concentrations of gas, immediately flush the eyes with water for at least 10 minutes. Contact a physician immediately.

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.

12-2376-9529-6

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



Affixed to back panel of Steri-Vac 4XL gas sterilizer.
3M part no. 12-2376-9490-1

READ INSTALLATION GUIDE AND OPERATING INSTRUCTIONS CAREFULLY.

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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	APPROXIMATE 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 instructions. (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 sterilizer is in standby.
3. Turn handle counter-clockwise while lifting DOOR RELEASE to open door.
4. Insert Steri-Gas cartridge 4-100 into 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

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CAUTION/ ERROR MESSAGE CHART

Use the chart below to determine the steps to take 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 lised, 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 Messages - Will Not Stop Cycle

c1	Low Air in Exhaust Hood	External Fan Malfunction	Check Fan and Fan Belts
		Airflow Sensor Failure	Call Service Representative
c2	Low Water During Standby	Reservoir Needs Water	Add Water
c3	Power Interruption	Power Outage	Cycle Restarts Automatically
c4	Compressed Air Lost During Aeration	No Compressed Air	Check Compressor, Air Lines

Errors That are Detected Before Puncture

E10	Low Water	Water Resevoir Needs Water	Add Water to Reservoir
		Float Switch Failure	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	Clear Pkg. from Chamber Port
		No Compressed Air Connection	Check Air Lines & Pressure
		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	Chamber Too Cold at START	Restart
		Defective Temperature Control	Call Service Representative
E24	Heatsink Preheat Timeout	Chamber too Cold at START	Restart
		Defective Temperature Control	Call Service Representative
E28	No Water Injected	Resevoir Float Sw. Stuck	Add Water to Reservoir
		Water System Plugged	Call Service Representative
E32	Door Unlocked	Door Latch Hung up on Bolt	Turn handle completely vertical
		Control Error	Call Service Representative
E34	Door Open	Door Not Closed Before Start	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 Loaded	Use new Cartridge
		Puncture Mechanism Failed	Call Service Representative
E54	Extended Power Outage	Could Not Restart After Outage	Restart
E60	User Interruption	User Pressed STOP switch	Restart

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	Try press START/ Call Service Representative

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

AIR LINE

Maximum air inlet pressure shall not exceed 150 psig

Located on back panel of 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.

Located on back panel of Steri-Vac 4XL gas sterilizer. 3M part no. 12-2376-9415-8.

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

Located on back panel of 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 noncorrosive 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 both electronically and physically by compressed air.

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 and cycle status.

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 and air purge will operate before the door is unlocked if the cartridge was punctured.

3.12 An **audible alarm** will sound for approximately 15 seconds at the end of a normal cycle.

3.13 A **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 and 0.5 ppm Action Level.

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), the Canadian Standards Association (CSA) 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)	---
Shelf/Table Space Required	102 cm* (40 in)	73 cm	---	---
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)	---

* Includes service space needed. Actual shelf space occupied is 81 cm (32 in).

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 (V~), ± 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 receptable. Power cords furnished with sterilizers sold outside the USA will meet local electrical requirements.

5.7 **Compressed Air Requirements:**

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

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

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 **Exhaust Hood Requirements:**

An exhaust hood is built into the top panel of the sterilizer. Its function is to remove residual ethylene oxide gas from the front of 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 4-100.** The retainer ring of the cartridge holder is color coded **green** to match the **green label** on the Steri-Gas cartridge 4-100. **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 Section 27** for detailed information.

6.2 Steri-Gas Cartridge Specifications

6.2.1 Shelf Life & Cartridge Weight

The minimum shelf life for Steri-Gas cartridges is twenty-four (24) months from the date stamped on the bottom of each cartridge and on the label of each Steri-Gas box. Weigh cartridges older than 24 months before use. Use Steri-Gas cartridges 4-100 with gross weights of 131 grams or more in the Steri-Vac 4XL gas Sterilizer. Follow the instructions listed in the STERI-GAS Consumer Product Profile, Section 27, for handling underweight cartridges.

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 Registration

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

7. GENERAL ETHYLENE OXIDE DATA

Boiling Point:	10.7°C (51.3°F)
Vapor Pressure:	1094 mm Hg at 20°C $\left(\frac{457\ g}{sq\ cm\ gauge}\right)$
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.** Liquid ethylene oxide splashed in the eyes may cause severe injury. High concentrations of ethylene oxide gas may cause severe irritation and 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** (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.

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

8.4.1 **Inhalation.** Immediately get fresh air for overexposures 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 1 or 2 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 (Section 27), with ethylene oxide leakage. The following indicate Steri-Gas leakage:

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

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

9.1.3 cartridge weight loss.

9.2 Emergency Plan and Procedures

9.2.1 OSHA Requirements

The Occupational Safety and Health Administration (OSHA) requires facilities using ethylene oxide to have a written emergency plan for spills or leaks. Procedures for training, alerting, evacuating, rescuing, and, if necessary, medically treating personnel must be included in the plan. Procedures for reporting an emergency to appropriate authorities and for determining when it is safe to re-enter the spill area must also be specified. Responsibilities must be clearly defined in the plan. Consult OSHA's standards on ethylene oxide (29 CFR 1910.1047), employee emergency plans (29 CFR 1910.38), and alarm systems (29 CFR 1910.165) for more detailed information. Refer to the **Steri-Gas cartridge Consumer Product Profile (Section 27)** 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.

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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 barriers 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 Routine Test Pack

3M recommends the use of the following test pack for routine sterilization monitoring.

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Place a biological indicator inside a disposable plastic or glass 20cc syringe (cap toward needle) with the plunger in place and needle removed. Place this syringe in a peel-pouch and seal. Place the test pack in the center of the sterilizer load. Process as usual. Remove, activate, and incubate the biological indicator according to the manufacturer's instructions after sterilization. Return the packaging material and syringe to the load for aeration according to hospital policy.

AAMI[1] recommends adding one clean surgical towel (woven, 100% cotton, huck back) to the peel-pouch. The towel is included, though towels are not ordinarily sterilized by ethylene oxide, to simulate heat and moisture absorption by the pack.

1 AAMI, "Good Hospital Practice: Performance Evaluation of Ethylene Oxide Sterilizers - Ethylene Oxide Test Packs", Doc. No. AAMI EOTP - 2/85.

2 AHA, "Guidelines for Hospital Central Service Department", 1978.

3 AORN, "Recommended Practices for In-Hospital Sterilization", 1980.

4 U.S. Army, Army Regulations (AR40-19), 1972.

5 Veterans Administration, VA Manual MP-2, Change 107, July 21, 1975.

STERILIZER OPERATING PROCEDURE

15. OPERATING INSTRUCTIONS

15.1 User Responsibility

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 Section 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.

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 right 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 front panel.

The following panel lights indicate the progression of the cycle.

PRECONDITION

GAS EXPOSE

AERATE

15.5 **Stopping a Sterilization Cycle**

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

15.6 **End of Cycle**

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

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

15.7 **Aeration**

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

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

15.8 **Aerating in the Sterilizer**

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

15.8.2 Open the door at any time during aeration to remove or transfer aerated items. Follow the instructions in **Section 15.8.** 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.

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15.9 Door Opening

15.9.1 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.**

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

NOTICE

Put the door in the latched position within 2 minutes of turning the handle. Otherwise the handle must be turned counterclockwise again.

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.