

3M™ Steri-Vac™ Sterilizer/Aerator GS Series



Site Planning & Installation Guide



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I. Introduction

This Site Planning and Installation Guide is intended to provide information for prospective and new purchasers of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, in order to help plan for and execute site and installation requirements.

The purchaser is responsible for providing required GS Series sterilizer service requirements to the area where the equipment will be installed. These services include electricity, compressed air, and an ethylene oxide (EO) vent line. A dedicated exhaust system is required for installing the 3M™ Steri-Vac™ Exhaust Hood option.

The purchaser is responsible for installing the GS Series sterilizer and accessory equipment in their permanent location and to connect the required services to the unit(s). The purchaser is also responsible for ensuring that all national, state and local code requirements are met (e.g., EO abatement, state of California seismic bracing, etc.). At the time of installation, 3M Health Care service personnel or authorized 3M service personnel will require written documentation to verify the requirements for room ventilation and non-recirculating ventilations systems are met.

See ANNEX A for a complete listing of symbols, safety warnings and cautions.

Device Safety Compliance

CAUTION

To reduce the risk of injury, always follow the procedures described in this Site Planning and Installation Guide.

The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is an instrument and Class II medical device per the U.S. Food and Drug Administration (FDA) classification definitions. It is a Class IIb medical device per the European Union Medical Device Directive (MDD) and carries a CE mark related to the Medical Device Directive 93/42/EEC as confirmed in the Declaration of Conformity.

The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is listed as Laboratory Electrical Equipment for Use in Health Care Applications and carries the UL mark with adjacent indicators “C” and “US” based on compliance to the standards UL 61010-1 and CAN/CSA 22.2 No. 61010-1.

The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is designed, manufactured, and tested to meet the safety and performance requirement of common safety codes and standards which include applicable portions of the following standards demonstrated by the CB Scheme Certificate and test report issued by Underwriters Laboratories (UL):

- IEC/EN 61010-1. Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- IEC/EN 61010-2-010. Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.
- IEC/EN 61010-2-040. Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for Sterilizer/Aerators and washer-disinfectors used to treat medical devices.
- RoHS Directive, Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

I. Introduction (continued)

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide a reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with this document and the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series Operator Manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the purchaser will be required to correct the interference at their own expense. In addition, operation of this device may accept any interference received, including interference that may cause undesired operation.

EMC Compliance

The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series complies with the following EMC standards as confirmed in the Certificate of Compliance generated by 3M:

- IEC 61326-1. Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.
- EMC requirements of the CE mark EMC Directive 2004/108/EC.
- Australian EMC requirements as confirmed in the Supplier's Declaration of Conformity that is linked to the RCM Mark.
- As a Class A digital apparatus meeting all requirements of the Canadian Interference-Causing Equipment Regulations.

See ANNEX E for a complete list of related compliance standards for the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series.

I. Introduction (continued)

Site planning is a critical aspect for a successful installation process. Site planning includes considerations for: the location, the work flow, the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series service requirements, 3M™ Steri-Gas™ EO Gas Cartridge storage requirements both near the GS Series sterilizer and storage for larger volumes, any connected hardware such as the 3M™ Abator, 3M™ Stacking Rack 1237, ventilation apparatuses, and local code requirements. The purchaser must comply with all state and local regulations affecting the use of ethylene oxide (EO). It is important to have a properly planned and acceptably prepared site to ensure the GS Series sterilizer operates safely and effectively. All site planning and preparation must be completed prior to the scheduled installation date.

Plan and Install

The following describes the tasks for planning and preparing for a successful installation. While each installation site is unique, the following steps are common to all situations:

Step 1 Select the Equipment

3M offers a complete system of products for ethylene oxide (EO) sterilization, including two sizes of 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. Both sizes are available in single door or double door configurations. Use the 3M™ Abator, where applicable, for efficient abatement of exhausted EO and for using supporting accessory equipment. Selecting the size, quantity and configuration of the GS Series sterilizer and the number of 3M™ Abators is the first equipment selection task. Second, select any required auxiliary equipment. Additional detailed equipment technical specification information for the products is available from 3M. Use Table 1 on the following page to document selected equipment.

Step 2 Select a Location

Step 2 recommends a process for analyzing a site and for selecting a suitable location for installing the Sterilizer/Aerator system. This Guide includes sample proposed site plans, with architectural details, for a satisfactory site design. It also includes information on how to design the site. Site Planning and Equipment Location Worksheets are provided in ANNEX B.

Step 3 Prepare the Area and Service Requirements

Critical service requirements must be met before completing and approving the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series Site Readiness Verification Form. These requirements include acceptable room ventilation, connections to electrical power, connections to vent lines, and compressed air lines. Service requirements are detailed in Section III.

The purchaser is responsible for securing and scheduling all contracted services in order to meet installation requirements and for supplying details of the service requirements to the contractors. The final installation support visit will not be scheduled until all equipment installation requirements have been met, verified, and documented on the Site Readiness Verification Form found in ANNEX C.

Sections II and III provide information detailing service specifications and requirements. ANNEX B provides Site Planning and Equipment Location Worksheets. This information can be reproduced and provided to service contractors, as necessary, to complete the required pre-installation work.

Deviations from the Site Plan:

The purchaser should document any deviations from the recommended 3M Site Planning guidance and communicate the deviations to 3M Health Care service personnel or authorized 3M service personnel prior to installation.

Step 4 Install the Equipment

Final equipment hook-up and installation support is performed by 3M Health Care service personnel or authorized 3M service personnel. A final Installation Verification Form is completed at the end of equipment installation.

II. Select the Equipment

Table 1 provides the complete listing of 3M™ Steri-Vac™ Sterilizer/Aerator GS Series products and accessories equipment. This Table provides product descriptions, dimensions and other information that is important to consider in equipment selection. 3M Sales and Service personnel will consult and assist in selecting the appropriate equipment in order to meet specific facility and use requirements.

See Figure 1 for GS5 dimensions and elevations. See Figure 2 for GS8 dimensions and elevations.

Table 1 – 3M™ Steri-Vac™ Product and Accessory Options

Product	Description	Shipping Weight	Operational Weight	Chamber Size		Exterior Dimensions H x W x D	Select	Quantity
				Area	H x W x D			
3M™ Steri-Vac™ Sterilizer/Aerator GS5	Single Door – EO Sterilizer/Aerator	163 kg (359 lbs) Single Door	127 kg (281 lbs) Single Door	136 L (4.8 cubic feet)	38 x 43 x 83 cm (15 x 17 x 32.5 in)	70.9 x 76.2 x 95.0 cm (27.9 x 30.0 x 37.4 in)	<input type="checkbox"/>	
	Double Door – EO Sterilizer/Aerator	169 kg (373 lbs) Double Door	132 kg (290 lbs) Double Door				<input type="checkbox"/>	
3M™ Steri-Vac™ Sterilizer/Aerator GS8	Single Door – EO Sterilizer/Aerator	355 kg (782 lbs) Single Door	261 kg (576 lbs) Single Door	223 L (7.9 cubic feet)	46 x 51 x 97 cm (18 x 20 x 38 in)	179.8 x 94.0 x 109.0 cm (70.8 x 37.0 x 42.9 in)	<input type="checkbox"/>	
	Double Door – EO Sterilizer/Aerator	362 kg (799 lbs) Double Door	267 kg (593 lbs) Double Door				<input type="checkbox"/>	
3M™ Abator Models 50, 50AN, 50AE	Emission Control System	212 kg (469 lbs)	163 kg (360 lbs)	NA		80.0 cm x 82.0 x 105.0 cm (31.0 x 32.0 x 41.0 in)	<input type="checkbox"/>	
3M™ Steri-Vac XL Aerator (outside U.S. only for health care)	Single Door Aerator	147 kg (325 lbs) Single Door	115 kg (253 lbs) Single Door	141.5 L (4.5 cubic feet)	38 x 43 x 83 cm (15 x 17 x 32.5 in)	61.0 x 77.0 x 89.0 cm (24.0 x 30.3 x 35.0 in)	<input type="checkbox"/>	
3M™ Steri-Vac XL Aerator (outside U.S. only for health care)	Double Door Aerator	156 kg (345 lbs) Double Door	124 kg (273 lbs) Double Door				<input type="checkbox"/>	

Product	Part Number	Description	Dimensions H x W x D	Select	Quantity
Extra Baskets GS5 and XL Aerator	78-8055-6040-2	Stainless lower basket	39 x 80 x 18 cm (15.5 x 31.5 x 7 in)	<input type="checkbox"/>	
	78-8055-6039-4	Stainless upper basket	39 x 80 x 18 cm (15.5 x 31.5 x 7 in)	<input type="checkbox"/>	
Extra Baskets GS8	78-8078-8313-3	Stainless steel lower basket	47 x 95 x 20 cm (18.5 x 37.5 x 8 in)	<input type="checkbox"/>	
	78-8078-5399-5	Stainless steel upper half basket	47 x 47 x 20 cm (18.5 x 18.5 x 8 in)	<input type="checkbox"/>	
	78-8078-6251-7	Stainless steel basket cover	Cover fits on top of lower basket	<input type="checkbox"/>	

Note: Equipment may vary in overall exterior dimensions if accessories (e.g. exhaust duct, leveling feet) are added.

Factors to consider in equipment selection:

- Chamber size related to processing volume requirements, including future volume requirements
- Single door or double door configuration based on process flow and available space
- National, state, and local requirements for ethylene oxide (EO) abatement as applicable
- 3M™ Steri-Vac™ EO Gas Cartridge type, volume and storage requirements. A vented liquid flammable storage cabinet is required for EO gas storage. See Section III for additional information.

**Figure 1. 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS5
Single Door Dimensions**

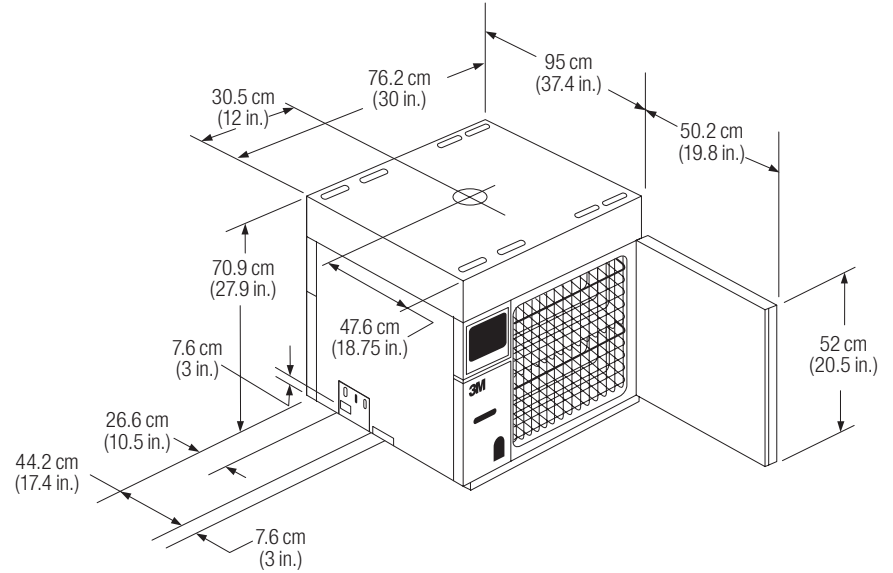
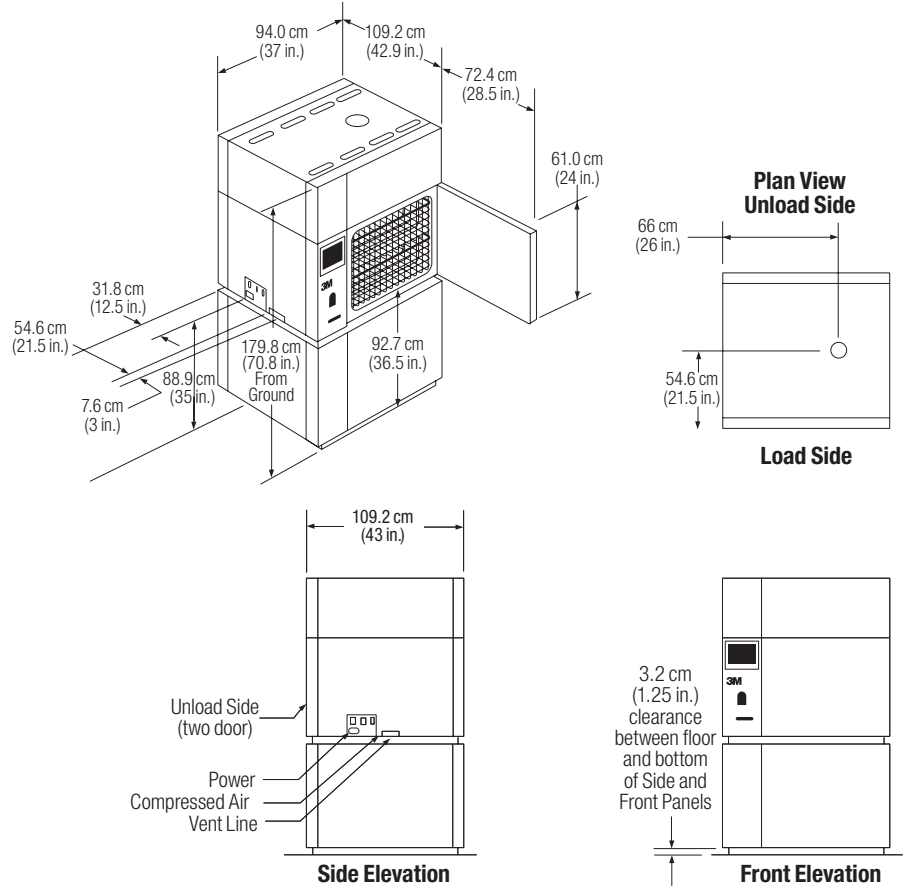


Figure 2. 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS8 Single Door Dimensions and Elevations



III. Select the Location

⚠ WARNING

To reduce the risk of shock due to hazardous voltage, do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series outside the environmental conditions as stated in this Guide.

⚠ DANGER

To reduce the risks associated with exposure to ethylene oxide:

Ensure a minimum of ten (10) air exchanges per hour (ACHs) for the room in which the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is installed.

Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series outside the environmental conditions as stated in this Guide.

Ensure the instructions detailed in this Guide are followed when planning the ventilation system.

Give careful consideration in selecting the location for the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series and accessories in order to ensure that facility, compliance, and safety requirements are met. This section provides information on requirements that the equipment location must meet related to Recommended Environmental Operating Specifications (Table 2), occupational safety, and work flow aspects. Prior to installation, 3M Health Care service personnel or authorized 3M service personnel will request written verification that the requirements for the general room ventilation rate and the non-recirculating ventilation system, as described in this Guide and documented on the Site Readiness Verification Form, are met (see ANNEX C). At the time of installation, 3M Health Care service personnel or authorized 3M service personnel will require the purchaser's requirements document and verification in writing stating that the requirements for general room ventilation rate, non-recirculation, and dedicated system requirements are met.

Table 2 – Recommended Environmental Operating Specifications

Environmental Condition	Condition Range	Units
Altitude	2500 (max)	Meters
Operating Temperature*	15–35	°C
Humidity	20–80 (non-condensing)	% RH
Voltage Range (Frequency) Single Phase	200–240 (50/60)	VAC (Hz)
Current: GS5	7	A
GS8	12	A
Transient Over Voltages	Category II	N/A
Pollution Degree	2	N/A

* Operating the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series in a temperature environment that is close to the sterilization process temperature set point (e.g. 35°C operating environment and a 38°C sterilization process temperature set point) may result in a temperature fault during the sterilization process.

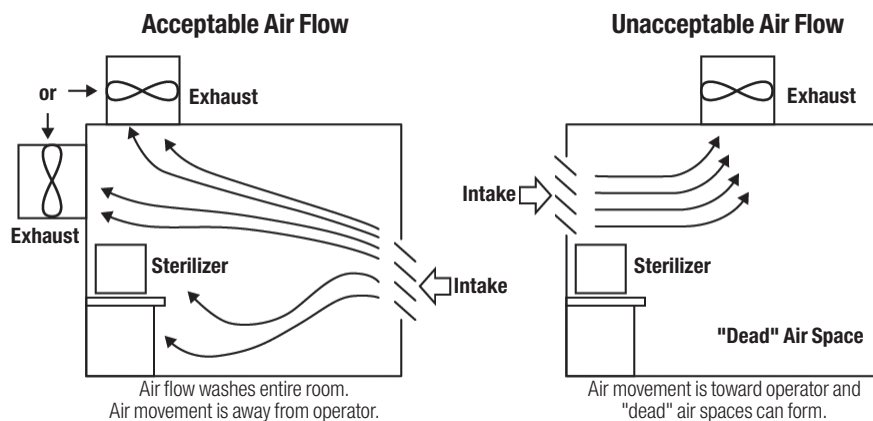
Note: Verify the requirements and follow all applicable national, state, and local environmental regulations concerning proper installation of the GS Series sterilizer and any 3M™ Abator for control of ethylene oxide (EO) emissions. It is important to place the sterilizer in a contained area, with traffic routed around or away from the area, and restricted personnel access. The size of the area should be 30 m³ (1000 ft³), or more, and have a minimum of 10 air exchanges per hour. **Do not** place the sterilizer or 3M™ Steri-Gas™ EO Gas Cartridges in an area of possible ignition sources.

An appropriate selected location must meet all of the following requirements. The location:

- has no flammable gases other than ethylene oxide (EO) present at the location.
- is not a high traffic area.
- is well-ventilated with at least 10 air changes per hour. The flow of air is away from the equipment operator (Figure 3). Recommended room size is a minimum of 28.32 m³ (1,000 ft³).
- has a non-recirculating ventilation system. The exhaust hood, if used, must be connected to an exhaust system that is dedicated to the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series area and supplies air flow >125 cubic feet per minute (CFM) through each vent hood.
- allows 51 cm (20 inches) of clearance space at the top, rear, and sides of the GS Series sterilizer for maintenance and service (Figure 5).
- provides a suitable location for storage of 3M™ Steri-Gas™ EO Gas Cartridges that includes a flammable liquids cabinet vented to the outside.

Appropriate installation of the air handling system is important and should be designed and installed to provide air flow through the entire room and direct air movement away from the GS Series sterilizer and Operator as shown in Figure 3.

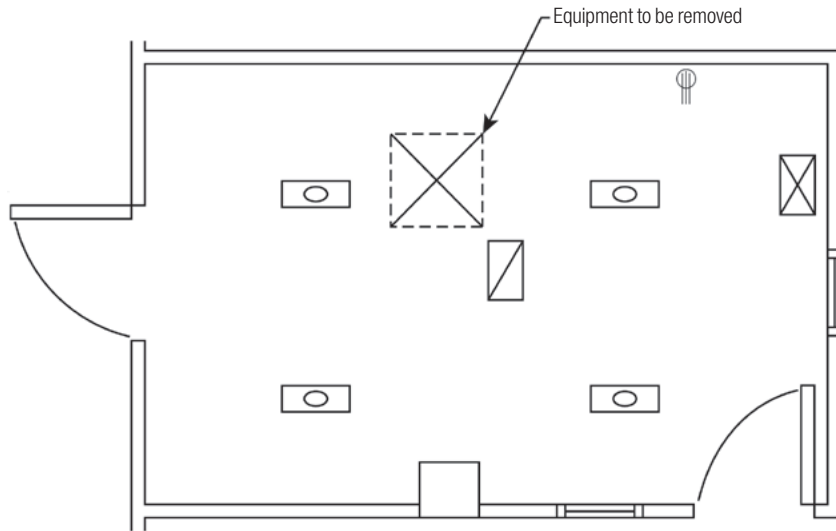
Figure 3. Example of Acceptable and Unacceptable Air Flow



Site Planning Worksheet

It may be helpful to use the provided Site Planning Worksheet (ANNEX B) to sketch the architectural details of the location where the equipment will be installed. Include all details, such as walls, doorways, structural supports, ventilation ducts (intake and exhaust), and electrical outlets (Figure 4). Indicate any equipment that will be removed. The blank worksheet can be duplicated by the purchaser.

Figure 4. Site Planning Example



CAUTION

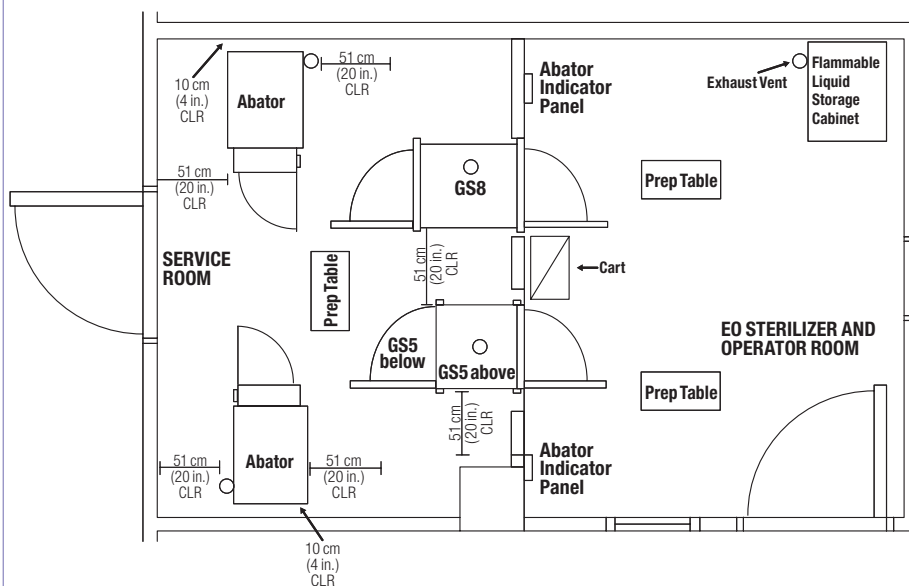
To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures, do not install 3M™ Steri-Vac™ Sterilizer/Aerator GS Series near any device emitting strong electronic magnetic fields (EMFs).

Proposed Location of Equipment

Using the completed sketch on the Site Planning Worksheet, complete an Equipment Location Worksheet (ANNEX B) to show the location and size of each piece of equipment in the work area (Figure 5). Include all other hard good items in the room (e.g. work tables, storage cabinets, etc.), as this will help to assess the work flow.

After placing the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series and any accessory equipment on the Equipment Location Worksheet, indicate on the Worksheet any additional services required for the new equipment. Provide the worksheets and service requirements to any contractors (electrical, ventilation, plumbing, and structural) involved with the project.

Figure 5. Work Area and Equipment Location Example



The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS5 can be installed in-wall or installed and used with a 3M™ Stacking Rack Model 1237 as shown in Figure 6. The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS8 is typically installed in-wall (Figure 7).

Figure 6. Typical In-wall Opening Requirements for 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS5

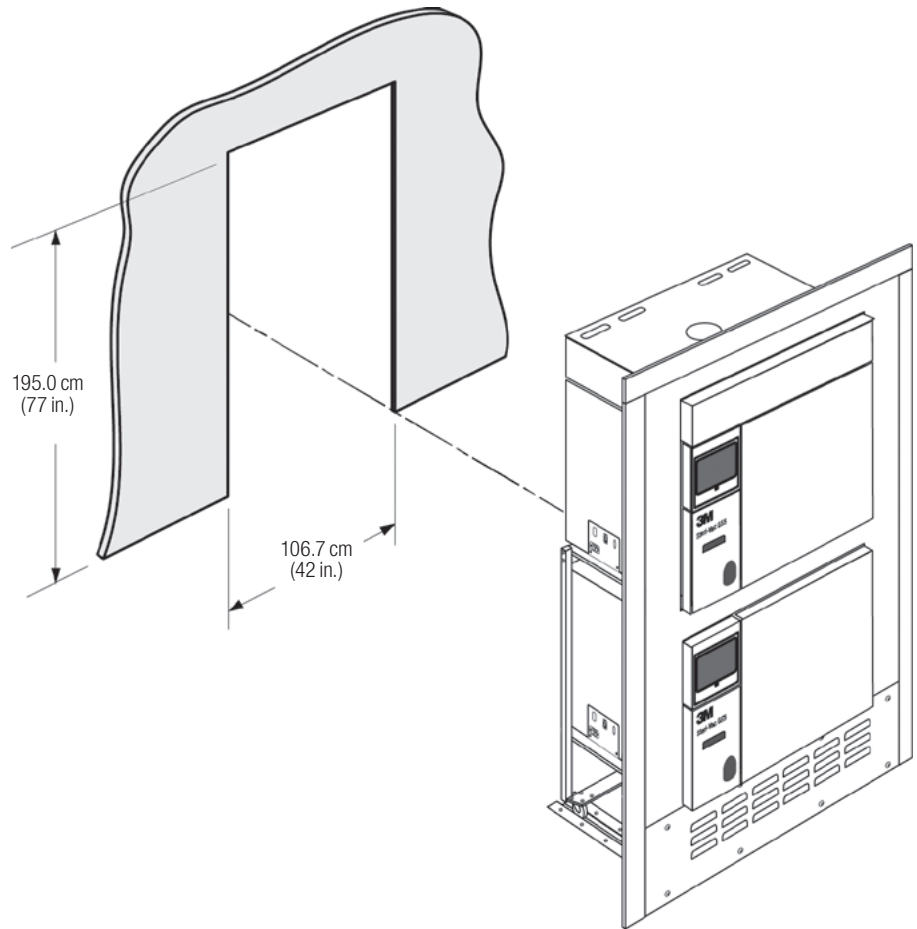
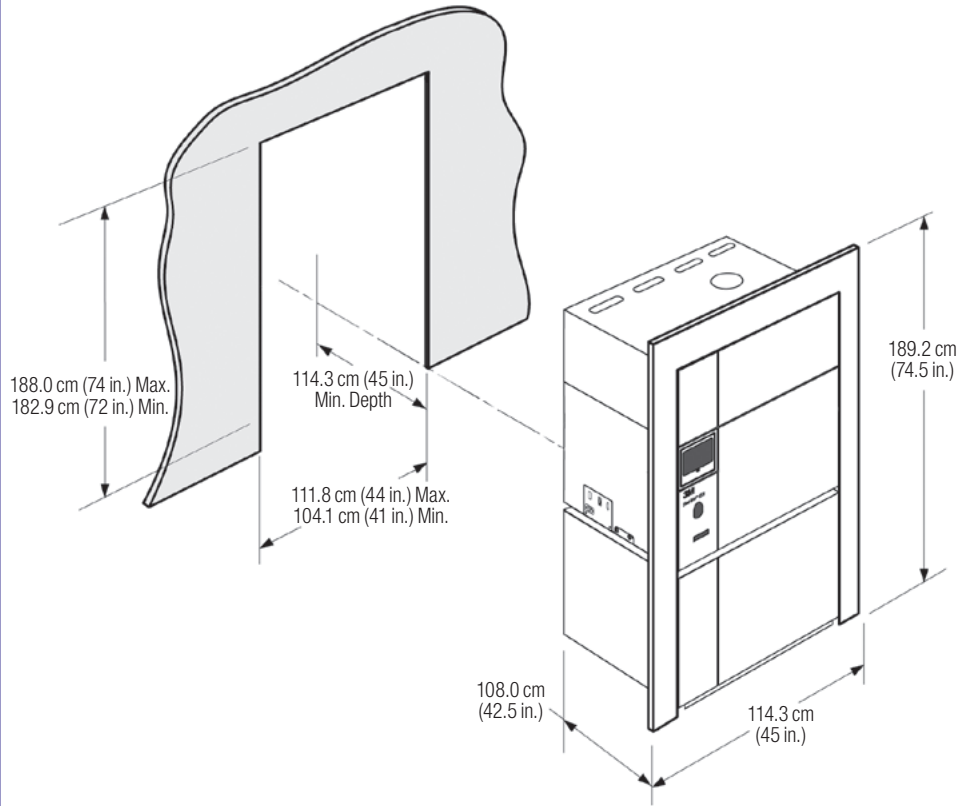


Figure 7. Typical In-Wall Opening Requirements for 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS8



Pre-Installation Visit and Site Readiness Verification

Prior to the installation of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series and any other accessory equipment, the 3M Health Care service personnel or authorized 3M service personnel can be contacted to visit the facility where the equipment will be installed. The proposed Site Planning and Equipment Location Worksheets must be reviewed to discuss the required services, equipment spacing, and any additional considerations. A Site Readiness Verification Form (ANNEX C) must be completed and documented with the purchaser.

IV. Preparing the Area and Service Requirements

Preparing the Selected Area

Once the location is selected and designed, the next step is to prepare the area. This section provides details on the basic service connections required for the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series and accessory equipment. Additional services may be needed for other equipment installed in order to support the GS Series sterilizer equipment.

Note: The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series will remain locked for three (3) hours for mandatory aeration without a connected and operational local exhaust hood.

The following equipment is needed to prepare the area:

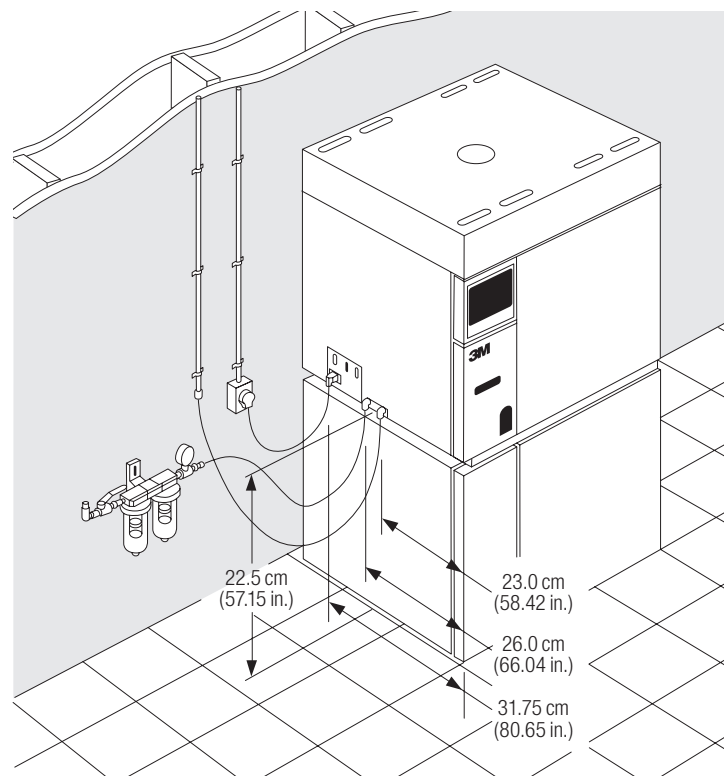
- An air compressor to supply clean, dry, oil-free air for the sterilizer vacuum system.
- A ventilation system connection to local exhaust hoods (as applicable).
- If required by national, state, or local regulations or facility/company policy, an ethylene oxide (EO) emission control system.
- Ethernet connection for service and other electronic interfaces.

Utilities

Consider the placement of utility services required for additional equipment. Obtain documentation from supplier(s) for additional non-3M equipment and understand and implement all applicable installation and service requirements for this equipment.

Table 3 provides detailed information for contractors installing the utilities and services that are required to safely use the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series and accessory equipment. This Guide, or individual pages from this Guide, can be photocopied and provided to contractors involved with the project. The information, figures, and project worksheets are intended to provide examples of before and after installation of the equipment in order to provide contractors with an understanding of the project scope and requirements. Figure 8 shows typical service connections for the GS Series sterilizer.

Figure 8. Typical Service Connections for the GS Series Sterilizer, Model GS8



⚠ WARNING

To reduce the risk of shock due to hazardous voltage, purchaser must provide a properly grounded outlet (an earth ground) for installation, per applicable codes and regulations.

⚠ WARNING

To reduce the risks associated with fire and explosion, purchaser must comply with applicable codes and regulations as they pertain to locating the equipment and providing services to the equipment.

Electrical Service Requirements

The electrical service requirements for the installed 3M equipment are shown in Table 3. Be sure to provide sufficient access to the power disconnect and switch. When planning the electrical service, consider support equipment including: compressors, air dryers, and emission control systems.

Table 3 – Electrical Service Requirements

Requirement	GS5 Sterilizer/Aerator	GS8 Sterilizer/Aerator
Voltage	200–240 Vac	
Frequency	50/60 Hz	
Phase	Single	
Current	15 amp dedicated circuit	
Heat Load	5500 Btu/hr	6150 Btu/hr
Internal Circuit Breaker	7 amp	12 amp
Power Cord	240 volt, 15 amp, NEMA 6-15 plug ²	
Marks	FCC cULus RCM CE0086	FCC cULus RCM CE
Code and Building Regulation Compliance	Due to variation in local regulations, the purchaser is responsible for complying with applicable codes and regulations as they pertain to locating the equipment and providing services to the equipment.	
Seismic Bracing	Seismic Bracing kits for 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Models GS5 and GS8 units are available from 3M. For information on the State of California pre-approved seismic bracing certificates, contact 3M.	

UL listed to U.S. and Canadian Safety Standards
 RCM Compliant with all applicable regulatory arrangements (RCM)
 FCC (Federal Communication Commission)
 Conformity to European Directives

⚠ DANGER

To reduce the risks associated with exposure to ethylene oxide, ensure compressed air supply is clean, with a maximum allowable dirt particle size of 0.5 microns, and oil-free. Ensure air filters on compressed air supply contain a water trap and are cleaned and maintained properly.

Compressed Air Requirements

Compressed air is used to operate a venturi vacuum generator and to operate the air-controlled pistons that both lock and unlock the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series door. Table 4 provides the compressed air requirements. The vacuum operates during the sterilization cycle to remove air and ethylene oxide (EO) from the GS Series sterilizer chamber. The vacuum also operates during the Aeration stage, which may last in excess of 12 hours.

Moisture in the compressed air line will not be removed by the supplied filter. A refrigerated air dryer may be needed to meet the dew point requirement in Table 4 and should be a non-cycling hermetic type compatible with the flow and pressure of the selected compressor. The air dryer should be capable of accepting saturated air and drying it to 10°C (50°F) dew point at 38°C (100°F) ambient. The air dryer would typically have an automatic drain trap and be wired from the compressor controller.

Table 4 – Compressed Air Specifications

Specifications	Value/Range
Pressure	7.0 kg/cm ² (100 psig) minimum 10.5 kg/cm ² (150 psig) maximum
Flow Rate	2.2 liters per second at 5.6 kg/cm ² (4.7 cubic feet per minute at 80 psig) per Sterilizer/Aerator based on 100% duty cycle compressor
Quality	Clean air supply with a maximum allowable dirt particle size of 0.5 microns and free of oil
Moisture Content	Less than 10°C (50°F) dew point

If the compressed air source does not meet the specifications, it can cause early equipment failures. The GS Series sterilizer warranty and preventive maintenance agreements do not cover equipment failures caused by an improper compressed air source. Contact the 3M Health Care Service Center or your local 3M office for additional information regarding warranty and preventative maintenance plans.

The following refrigerated air dryer is an example of equipment that may be used:

Model: Arrow F-10
Supplier: Arrow Dryers
Website: www.arrowpneumaticdryers.com
Telephone (U.S.): 1-800-761-4298

Compressor System

The following recommended compressor manufacturer can provide additional information about compatible compressor systems:

Supplier: Powerex
Website: www.powerexcompressors.com
Telephone (U.S.): 1-800-761-4298

Outside of the U.S., contact your local 3M Health Care service personnel or authorized 3M service personnel for local suppliers of equipment that meets the required specification.

Filters

A 3M air line filter kit is needed and supplied with each 3M™ Steri-Vac™ Sterilizer/Aerator GS Series to remove dirt and mist particles from the incoming air. This filter must be installed on the compressed air line at the time of equipment installation and must be drained periodically by the purchaser in order to remove excess water. These filters are replaced at each recommended six month preventative maintenance service procedure.

The installation includes installing the 0.3 micron filter element (mist separator) in front of the 0.1 micron filter element (micro mist separator) in order to remove coarse air contaminants that would otherwise plug the micro-mist element. The elements may need to be changed more frequently than six month intervals if the air supply is highly contaminated.

The purchaser is solely responsible for providing a dry, oil-free air supply (to a dew point of 10°C/50°F). Filters are provided for precautionary purposes only, and not as a replacement for a clean air supply. A contaminated air supply can quickly reduce the effectiveness of the filter element, resulting in early equipment failure.

Multiple Sterilizer/Aerator Installations

Each 3M Steri-Vac GS Series sterilizer requires a minimum flow rate of 2.2 liters per second (4.7 scfm) at 5.6 kg/cm² (80 psig) pressure. Two sterilizers would require a flow rate of 4.4 liters per second (9.4 scfm) air flow at 5.6 kg/cm² (80 psig).

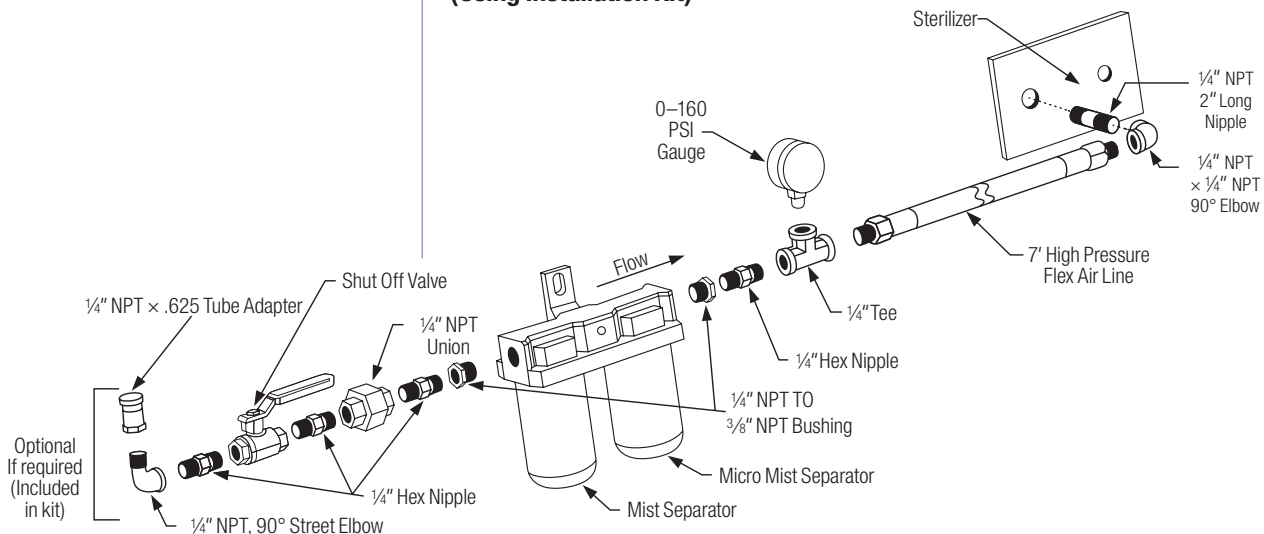
Compressed Air Line Installation Kit

The Compressed Air Line Installation Kit, supplied with each GS Series sterilizer, is installed between the sterilizer and the compressed air services as shown in Figure 9. The purchaser is responsible for providing compressed air services.

Compressor Location

The compressor should be located away from work areas in order to reduce noise levels around the GS Series sterilizer. Make sure the compressor manufacturer's electrical power requirements are met.

Figure 9. Compressed Air Line Connection Details (Using Installation Kit)



⚠ DANGER
To reduce the risks associated with exposure to ethylene oxide:
a connection must be made from the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series to a dedicated vent line to exhaust ethylene oxide (EO) to the outside atmosphere or to the 3M™ Abator emission control system.
ensure the vent line is gas tight from the GS Series sterilizer to the outside atmosphere.
do not terminate vent line into exhaust system that recirculates air into the building.
the vent line should terminate away from areas where people walk or work. The vent line should be located at least 7.6 m (25 ft) away from the building air intake source.
vent line must be labeled to indicate EO.
ensure no blockages in vent line exist.
ensure the instructions detailed in this Guide are followed when planning and installing the ethylene oxide vent line.

Ethylene Oxide Vent Line Requirements

A connection must be made from the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series to a dedicated vent line in order to exhaust ethylene oxide (EO) to the outside atmosphere or to the 3M™ Abator emission control system. The requirements for venting the GS Series sterilizer must be met (Table 5).

Table 5. Vent Line Requirements for GS Series

Number of Sterilizer per Abator	Length and Diameter of Vent Line			
	1	Length	≤ 31.0 m (100 ft.)	31.1 m to ≤ 61.0 m (200 ft.)
Diameter		2.54 cm (1 in.)	2.54 cm (1 in.)	2.54 cm (1 in.)
2	Length	≤ 31.0 m (100 ft.)	31.1 m to ≤ 61.0 m (200 ft.)	61.1 m to ≤ 91.5 m (300 ft.)
	Diameter	2.54 cm (1 in.)	3.8 cm (1.5 in.)	3.8 cm (1.5 in.)

The 3M EO Abator can be used with the GS Series sterilizer with a maximum of two GS Series sterilizers and up to a maximum of two 3M Aerator models XL or XLS connected to a single EO Abator unit. Sterilizer models 5XL and 8XL cannot be combined with a GS Series sterilizer when connecting to an EO Abator. The EO Abator interfaces with GS Series sterilizers to start and stop automatically.

The diameter of the vent line used for the EO inlet and safety vent depends on the combined length of the two vent lines. The size of the copper tubing to connect sterilizer discharge to the EO Abator system EO inlet should be between 2.5 cm (1.0 in) and 3.8 cm (1.5 in). The size of the National Pipe Thread (NPT) connection at the EO Abator system should be 1.9 cm (3/4 in.). Reference Table 5 for required line diameters.

The maximum length of the vent line from the GS Series sterilizer port is 91.5 meters (300 feet). Do not exceed this specification. The use of Type K hard drawn copper tubing is recommended.

The vent system should be constructed of straight lengths of copper tubing using a minimum number of long radius elbows. Short radius elbows and T fittings cause an excessive amount of back pressure and should not be used. Include a threaded fitting to termination of the run with which to facilitate the pressure test of the system.

The vent line should be designed to avoid sags or loops in order to prevent moisture buildup at other points within the vent line. The vent line must be gas tight from the sterilizer to the outside atmosphere and be brazed or soldered in accordance with local fire codes.

The vent line, with the exception of a turned-down extension terminating on the roof top or exterior wall, should be inside the building in order to prevent moisture from freezing in the vent line and blocking the vent (Figures 10, 11 and 12).

3M Abator (Emission Control Devices)

3M Abators (Models 50AN, 50AE or 50AJ) can be connected to and are compatible with the 3M Steri-Vac Sterilizer/Aerator GS Series. Consult the 3M Abator Operation and Installation Manual for further information.

Vent Line Labeling and Install Considerations

The vent line contains significant amounts of EO during the Gas Removal and Flushing stages. Ensure the vent line is gas tight from the GS Series sterilizer to the outside atmosphere and is labeled to indicate EO. A separate vent line to the outside is required. The vent line should terminate away from areas where people walk or work and should be located at least 7.6 m (25 ft) away from the building air intake source.¹

Do not terminate the vent line within 7.6 m (25 ft) of any possible source of ignition or any opening to the building interior such as fresh air inlets, unsealed windows, or pedestrian traffic areas. The inlet assembly, from the Vent Line Installation Kit, must be installed within 91.44 cm (3 ft) of the sterilizer's EO port in a position that is accessible to 3M Health Care service personnel (Figure 10). The single vent line is run directly to the exterior or to the 3M Abator using the appropriate connection fittings. When the 3M Abator is installed, run the vent line from the vent outlet port on the 3M Abator to the outside. Shut off valves in the vent line are not recommended.

1. AAMI/ANSI ST41 (2009) Ethylene oxide in health care facilities: Safety and effectiveness

Figure 10. Ethylene Oxide Vent Line Connection Details (Using an Installation Kit)

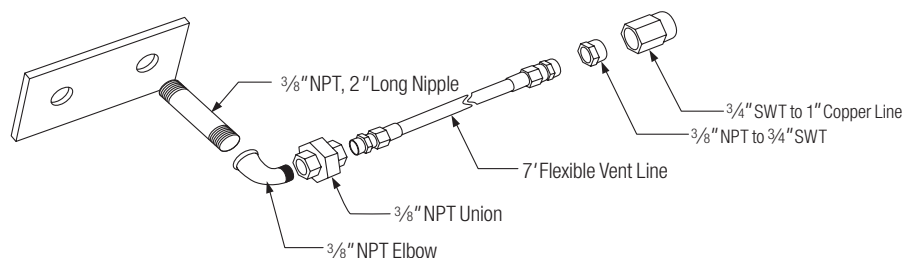


Figure 11. Ethylene Oxide Horizontal Vent Line Installation Example

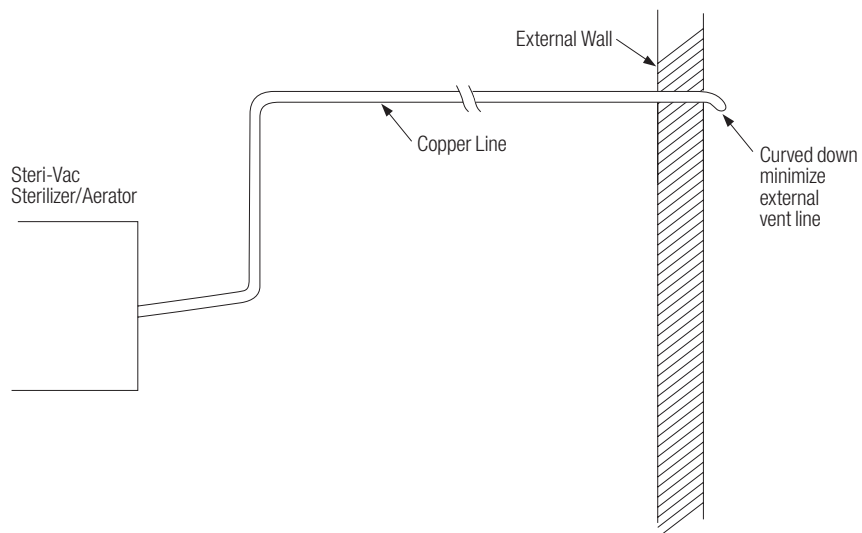
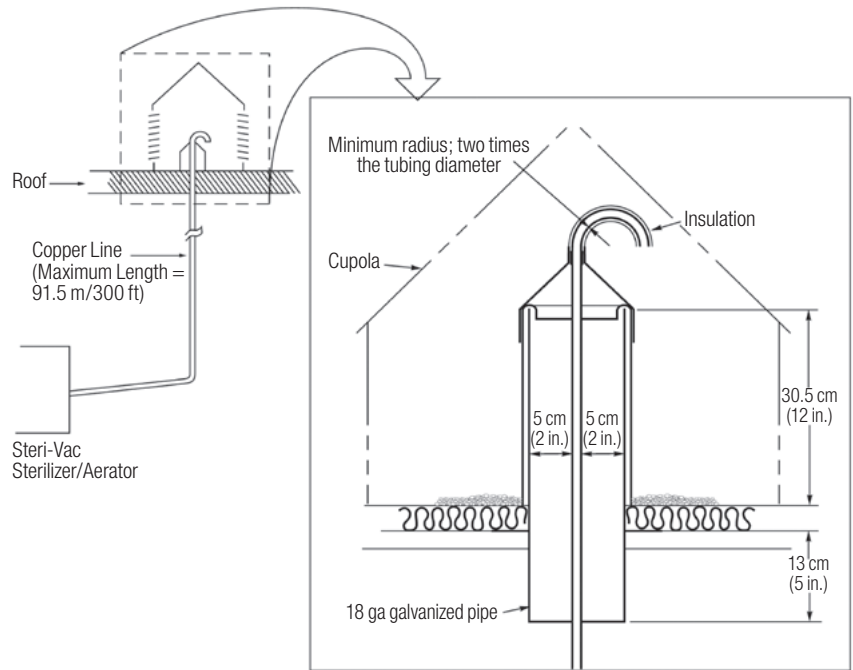


Figure 12. Ethylene Oxide Vertical Vent Line Installation Example

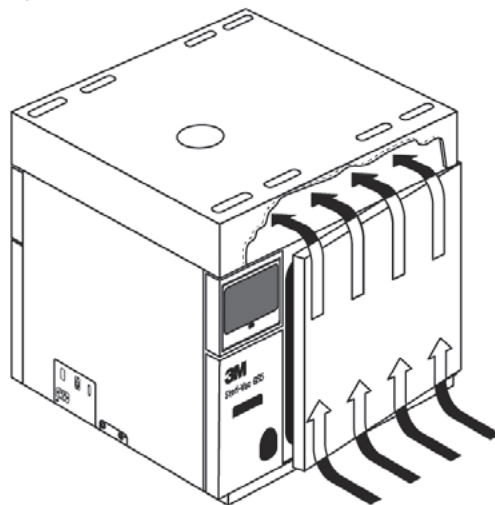


Local Exhaust Hood Requirements

The 3M™ Steri-Vac™ Exhaust Hood is an over-the-door exhaust (e.g. vent) hood that supplements the room's directional air flow, and is designed to draw air away from the Operator removing the load from the chamber. The exhaust hood is connected by 3M Health Care service personnel or authorized 3M service personnel to a purchaser-supplied dedicated exhaust system during installation.

Monitor the exhaust hood for appropriate air flow (Figure 13). If the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series detects the air flow is too low (<125 CFM) through the exhaust hood (or either of the exhaust hoods if using a double door unit), the GS Series sterilizer door will remain locked until a minimum three hours of aeration is complete. See the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series Operator Manual for additional set-up information.

Figure 13. Air Flow to the Exhaust Hood



Exhaust Ventilation System Planning and Design

The following requirements must be met for planning and designing the ventilation system:

- Determine the required air flow and the size, length and number of elbows needed for the ductwork. Take into consideration that each elbow introduces losses in air flow.
- Calculate the total air flow required for each branch.
- Calculate the static pressure for the entire system using standard industrial ventilation techniques, and add a 10% safety factor to the air flow and the static pressure to determine the final air flow target.
- Select an exhaust fan to meet the defined requirements.
- Determine if a new exhaust system is needed or if an existing system can be used. If using an existing system, make sure the existing system meets the GS Series sterilizer equipment specifications. The diagrams in Figures 14 and 15 show installation options for consideration in planning for the installation.
- Design and construct the exhaust system in accordance with national, state and/or local fire, health, and safety codes.

Connect the hood to a dedicated exhaust system. The hood should not be connected to an exhaust system that re-circulates air into the building.

Exhaust Ventilation System Specifications

The following ventilation system requirements must be met to ensure maximum air movement through the hood.

Air flow

Single Door Unit: Minimum of 3.5 cubic m/min (125 scfm) to the exhaust hood connection, or a minimum of 350 m/min (1435 ft/min) in the 102 mm (4 in) line to the exhaust hood connection. Maximum air flow through the hood is 7.0 cubic m/min (250 scfm).

Double Door Unit: Minimum of 7.0 cubic m/min (250 scfm) to the exhaust hood connection, or a minimum of 700 m/min (2870 ft/min) in the 102 mm (4 in) line to the exhaust hood connection. Maximum air flow to the exhaust hood connection is 14.0 cubic m/min (500 scfm).

Hood connection 102 mm (4 in) outside diameter

Ductwork

- Use metallic ductwork rated to handle the highest pressure that the system delivers. Use a minimal amount of flexible, air-tight duct. A flexible duct can introduce significant air flow resistance.
- Use a larger diameter flexible duct to minimize frictional air drag loss.
- Minimize the number of elbows to reduce the static pressure loss in the system.
- Seal duct seams and joints with aluminum duct tape or sealant to prevent leaks. The duct does not have to be gas tight.
- Ensure the ductwork material is impervious to ethylene oxide (EO).

Exhaust Fan

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

Ventilation Failure Detector

An air flow sensor is installed in the exhaust opening of the hood as standard equipment. The sensor detects low air flow in the exhaust hood and activates a **Caution** message (E501 - Exhaust Hood Air Flow) to alert personnel of ventilation system failure. This **Caution** message does not stop the sterilization cycle in progress, but will cause the performance of an automatic three-hour locked, mandatory aeration. The ventilation problem must be corrected in order to clear the **Caution** message.

Figure 14. Exhaust Connection

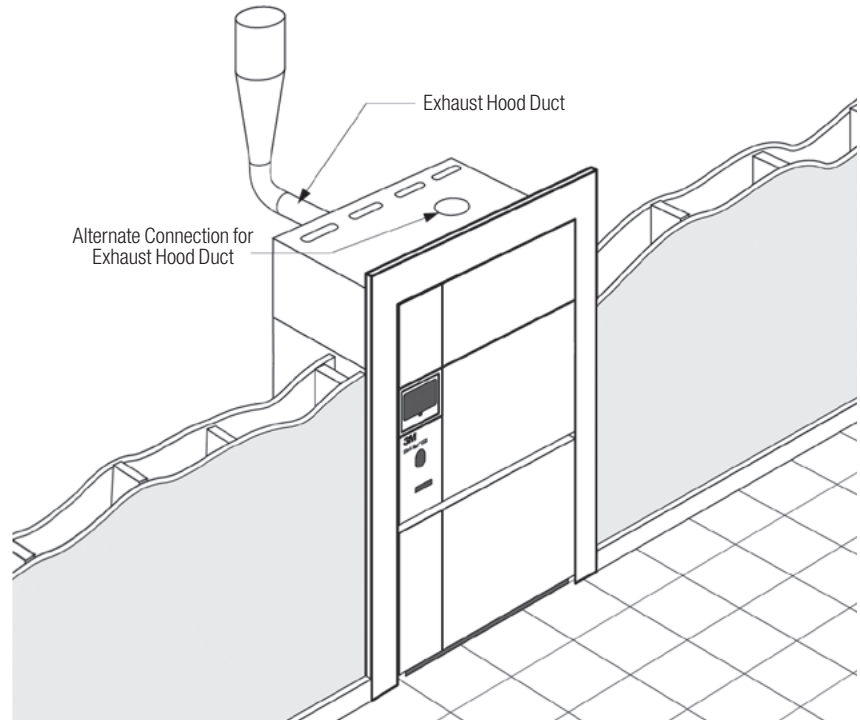
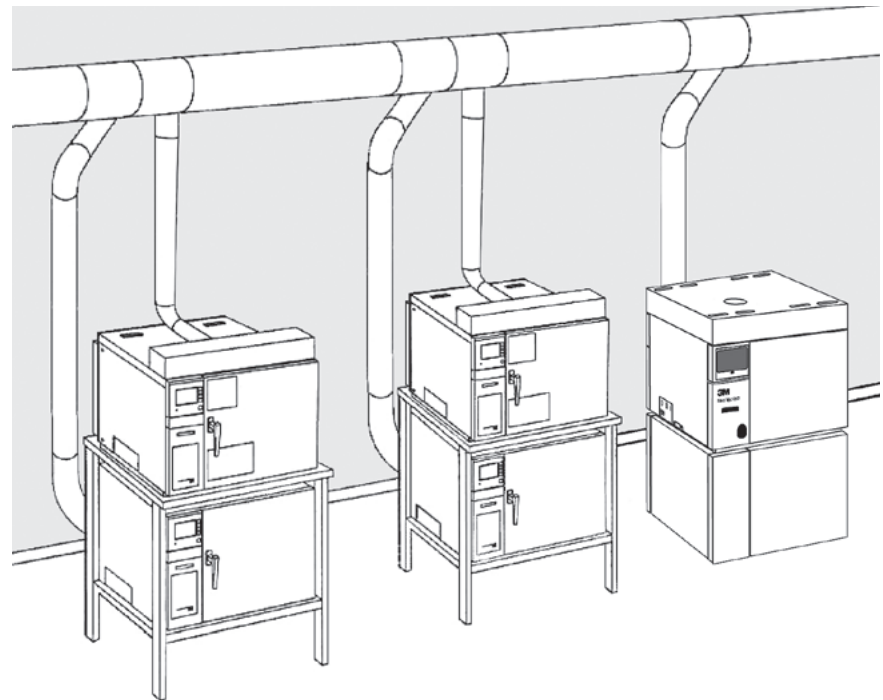


Figure 15. Multiple Exhaust Hoods Vented into a Dedicated Ventilation System



 **DANGER**

To reduce the risks associated with exposure to ethylene oxide:

Only use 3M™ Steri-Gas™ 100% Ethylene Oxide (EO) Gas Cartridges as listed in this Guide. Do not use other brands or types of sterilant cartridges.

Do not use damaged 3M™ Steri-Gas™ EO Gas Cartridges.

 **WARNING**

To reduce the risks associated with fire and explosion:

3M™ Steri-Gas™ EO Gas Cartridges contain 100% Ethylene Oxide (EO), which is an extremely flammable gas and liquid under pressure. Do not use near flame, electrical spark, hot surfaces, or allow sources of ignition near the cartridges. Do not puncture cartridge outside the sterilization chamber. Do not incinerate cartridges. Exposure to temperatures above 150°F (65.5°C) may cause cartridge to burst.

Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. Operators should not service the sterilizer as there are no user serviceable parts.

First Aid: Exposure to Ethylene Oxide (EO)

Inhalation:

Move the person to fresh air and seek medical attention.

Skin or Clothing Contact:

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, seek medical attention.

Eye Contact:

Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do so. Continue rinsing. Immediately seek medical attention.

If Swallowed:

Rinse mouth. DO NOT INDUCE VOMITING. Immediately seek medical attention.

Hazard Statements of Ethylene Oxide (EO):

- Extremely flammable gas
- Contains gas under pressure, may explode if heated
- Toxic if inhaled
- Causes serious eye irritation
- May cause drowsiness or dizziness
- Suspected of damaging fertility or an unborn child
- May cause cancer
- May cause genetic defects

Ethylene Oxide Storage

For additional information, go to www.3M.com to obtain the 3M™ Steri-Gas™ EO Gas Cartridge Safety Data Sheet (SDS). Follow specific storage requirements for storing Steri-Gas EO Gas Cartridges. Check national, state and local regulatory requirements, including fire protection codes, for storing EO.

Store Steri-Gas EO Gas Cartridges in an approved flammable liquid storage cabinet that vents to the outside, through a non-recirculating, continuously operating, dedicated exhaust system, or in an area suitable for storage of flammable liquids that appropriately vents to the outside. Keep all sources of ignition (e.g. matches, lit cigarettes, sparks and static discharge) away from the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series and 3M™ Steri-Gas™ EO Gas Cartridges.

One (1) box of twelve (12) Steri-Gas EO Gas Cartridges can be stored at least two meters (6.5 ft) from the Operator desk or work station that is designed and verified with 10 air exchanges per hour. Amounts greater than one box of Steri-Gas EO Gas Cartridges must be stored in a flammable liquid storage cabinet as described. Follow all national, state and local regulations for ethylene oxide storage.

Requirements for a Vented Cabinet

The following are requirements for ethylene oxide (EO) gas cartridge storage:

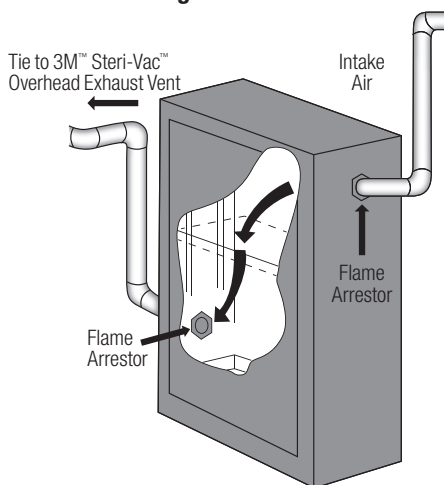
- Flammable storage cabinet has venting capability. Size of cabinet is based on the amount of planned and stored EO – typically one to two months supply.
- SECURALL® cabinets are one type of cabinet that can be used for storing EO. These types of cabinets can be purchased through Grainger, a vendor with international access. Product information is available at: www.grainger.com.
- Use metal tubing, which can be flexible tubing with stainless steel foil for use outside of a wall; or, use rigid metal tubing for use within a wall.
- A centrifugal fan, with backward curved blades designed for continuous operation, is required to exhaust the cabinet in a dedicated exhaust system. The fan must be a high efficiency spark-proof fan with the motor sealed from the exhaust air stream. The impeller and impeller ring around the drive shaft must be nonferrous. The fan size is based on cabinet size, length of run, and air flow requirements. The fan size should be determined by the facility's heating, ventilation, and air conditioning experts and should be capable of providing 10 air exchanges per hour inside the cabinet.

Connect EO Storage Cabinet to GS Series Sterilizer Dedicated Exhaust

The vent for the storage cabinet can be connected into the overhead exhaust that is dedicated to the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series exhaust as a non-recirculating system. With this configuration, no additional fan is needed. Connecting the cabinet to the system should follow these steps (Figure 16):

- Remove both metal bungs from the sides of the cabinet and replace flame arrestor screens (normally these come with the cabinets) into the openings.
- Connect the bottom opening to the GS Series sterilizer exhaust vent (or separate exhaust fan) using metal tubing. Tubing must have an inner diameter no less than that of the opening.
- The piping should be sealed and is not required to be gas tight. Weld the seams for rigid metal tubing. For flexible tubing, seal with aluminum duct tape or sealant. The length of tubing should be verified in order to allow a minimum of 10 air exchanges per hour in the cabinet.
- The top opening shall serve as the fresh air inlet. The make-up air should be supplied to the fresh air inlet in tubing similar to that used for the exhaust.
- The discharge point for the outside exhaust should be at least 7.6 m (25 ft) away from any possible sources of ignition, openings to buildings, or pedestrian traffic ways.

Figure 16. Vented EO Storage Cabinet Connection to Dedicated Exhaust



Disposal of 3M™ Steri-Gas™ EO Gas Cartridges

Empty 3M™ Steri-Gas™ EO Gas Cartridges should be aerated for a minimum of two (2) hours before disposal. The empty cartridge can aerate while located inside the GS Series sterilizer chamber cartridge holder during a normal aeration cycle. After aeration is complete, remove the cartridge from the holder and dispose of it in non-incinerated waste or recycle per your facility's requirement.

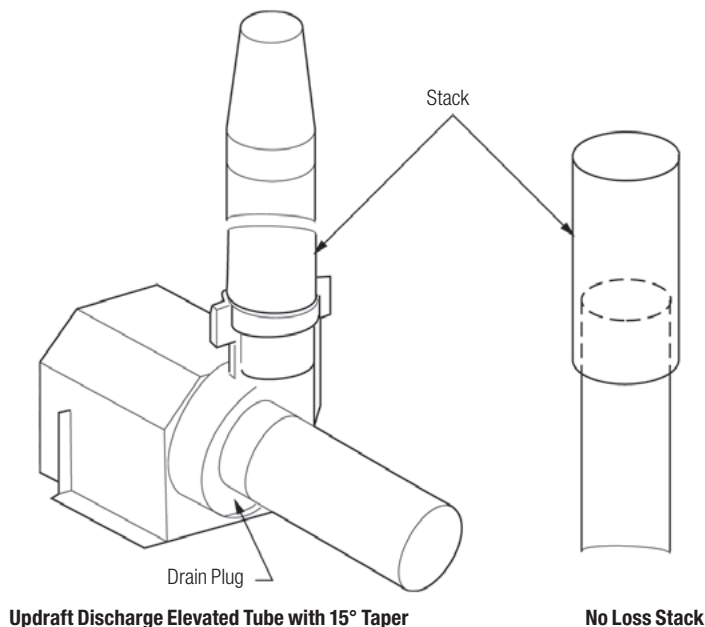
See ANNEX E for additional information related to the proper handling of ethylene oxide (EO).

Outside Discharge

The ventilation system should exhaust to the outside. Use a roof-top discharge. The discharge point should be at least 7.6 m (25 ft) away from any possible sources of ignition, openings to building, or pedestrian traffic ways. Greater distances may be needed in some locations. Use one of the types of discharge terminations illustrated in Figure 17.

It may be helpful to work with an industrial ventilation consultant or ventilation contractor to help design and install the local exhaust system.

Figure 17. Recommended Outside Ventilation Stack Design



V. Final Installation and Support

WARNING

To reduce the risks associated with fire and explosion, do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. Operators should not service the sterilizer as there are no user serviceable parts.

WARNING

To reduce the risk of shock due to hazardous voltage:

Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. Operators should not service the sterilizer as there are no user serviceable parts.

Use only trained 3M Health Care or authorized 3M service personnel for installation support and maintenance.

Do not modify any part of 3M Steri-Vac Sterilizer/Aerator GS Series.

Use only 3M designated replacement parts.

DANGER

To reduce the risks associated with exposure to ethylene oxide (EO):

Vent line must be labeled to indicate EO.

3M Health Care service personnel or authorized 3M service personnel must verify that final installation checks are completed.

Only qualified service personnel should install and service this equipment. Do not plug the cord into an outlet or operate the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series until 3M Health Care service personnel or authorized 3M service personnel have completed final installation support activities, including an in-service training and the safe handling of ethylene oxide (EO) training for Operators.

Site Readiness Verification

A Site Readiness Verification must be conducted by 3M Health Care service personnel or authorized 3M service personnel with the purchasing facility.

The purchaser of the GS Series sterilizer and any accessory equipment should complete the Site Readiness Verification Form (ANNEX C) and provide the form to the designated 3M Health Care service personnel or authorized 3M service personnel to review **prior to** the scheduled installation date. During this review, the 3M service personnel will discuss any changes required before final installation support and verification can be completed by 3M.

Unpacking the GS Series Sterilizer

The purchaser will unpack and inspect the GS Series sterilizer as follows:

1. Remove all shipping material from the sterilizer.
2. Examine the sterilizer for damage. If any shipping damage is found when unpacking the sterilizer, immediately file a damage claim with the transportation company and notify your 3M sales or service representative. Typically, a transportation company assumes liability for shipping damage for a 10-day period starting with the day of delivery. After the 10 days, the purchaser must accept the merchandise as delivered.
3. Discard packaging per 3M recommendations; reference ANNEX F for details.
4. Position the sterilizer in its permanent location and level the unit by adjusting the sterilizer feet. The position of the sterilizer must allow a minimum of 51 cm (20 in) on each side and on top of the unit for service access.

Once the GS Series sterilizer is in place and is connected to the required electrical and mechanical services, it is ready for final installation support by 3M Health Care service personnel or authorized 3M service personnel.

 **DANGER**

To reduce the risks associated with exposure to ethylene oxide:

It is the user's facility management's responsibility to ensure that all personnel working with toxic chemicals, gases, and vapors are given comprehensive instruction in the process. This instruction includes information on relevant health hazards; national, state and local regulations methods for safe use; and methods to detect escape of the agent.

It is the user's facility management's responsibility to ensure regular training of all personnel concerned with the operation and maintenance of the equipment, including emergency procedures for any toxic, flammable, or explosive material released into the environment. Records of attendance at training are maintained, and evidence of understanding demonstrated.

System Checkout and In-Service Training

3M Health Care service personnel or authorized 3M service personnel will provide installation support and assure that the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is installed and operating according to 3M specifications. At final installation, the 3M Health Care service personnel or authorized 3M service personnel will:

- complete the final Installation Verification Form and request signature by the purchaser's authorized personnel.
- provide a completed Customer Service Order that includes the date the warranty takes effect.
- provide in-service training for purchaser facility personnel on the proper operation of the GS Series sterilizer and any accessory equipment.
- provide in-service training on the safe handling of ethylene oxide (EO) and information on a 3M™ Steri-Vac™ Gas EO Sterilization Operator Certification Program.
- review ANNEX A for first aid information related to EO exposure.

VI: Install Guide for 3M™ In-Wall Mounting Unit

Note: All figures for this section are located at the end of Section VI for reference.

General Information

The 3M™ In-Wall Mounting Unit 1238 is a kit that contains the 3M™ Stacking Rack 1237 along with a stainless wall bezel and front trim for flush mount installation as shown in Figure 18. The Stacking Rack is a two level apparatus that holds two 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS5 or one GS Series sterilizer, Model GS5 and one 3M™ XL Aerator.

The purchaser should understand and comply with all national, state and local regulations related to installing the In-Wall Mounting Unit 1238.

To begin the installation process, remove the Stacking Rack 1237 from its shipping carton.

Be sure to check for any shipping damage and report any damage immediately to the shipping company. Inspect the major components as depicted in Figure 20.

To prepare the In-Wall Mounting Unit 1238 for installation, remove the feet from the bottom of the Stacking Rack 1237 and install the supplied casters using $\frac{5}{16} \times 1$ inch bolts, nuts and washers. Turn the Stacking Rack over so it is sitting on the casters and locate the upper frame and joining tabs. Attach the joining tabs to the upper frame with $\frac{5}{16} \times 1$ inch bolts. Remove two of the plastic caps from the front of the Stacking Rack and install the upper frame as shown in Figure 19.

General Specifications

The **Access Area** is the space into which the In-Wall Mounting Unit 1238 is placed. The access area must be well ventilated:

- to maintain an ambient temperature of **not greater** than 35°C (100°F). Higher ambient temperatures may impact the Sterilizer/Aerator 38°C cycle temperature or cause 38°C cycle to abort.
- by having a minimum of 10 air exchanges per hour.

Finished Installation

- Figure 18 provides a diagram of a completed installation. This example shows a GS Series sterilizer, Model GS5 on the top shelf and a second GS Series sterilizer, Model GS5 on the bottom shelf.
- Figure 21 shows the dimensions of the door frame opening required for the In-Wall Mounting Unit.
- Figure 22 shows the wall preparation for a double door GS Series sterilizer pass-through configuration.

Finished Wall Specifications

A finished wall opening should meet the following dimensions:

Height: 195.58 cm +1.27/- 0 cm (77 in. + 1/2 /-0 in.)

Width: 106.68 cm +1.27/- 0 cm (42 in. + 1/2 /-0 in.)

Depth: Minimum of 106.68 cm (42 in.)

The finished walls must be plumb. If a side wall is in front of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, there must be a distance of 50.8 cm (20 in.) between such a wall and the 3M™ In-Wall Mounting Unit 1238 to allow for service access when the unit is rolled out of the access area.

Floor Preparation

The floor finish in the area housing the unit must be the same height (i.e. on the same plane) as the work area in front of the unit for ease of movement for unit service and repair. The floor finish area should be flat and level with dimensions of:

Width: 106.68 cm minimum (42 in.)

Depth: 106.68 cm minimum (42 in.)

The GS Series sterilizer must be available for fitting onto the unit at the time of installation since some adjustments may be necessary when attaching the front panels.

Installing Permanent Floor Channels

Reference Figure 23.

Use of the template:

- A blueprint marked "TEMPLATE, Model 1238" is included with the 3M™ In-Wall Mounting Unit Model 1238.
- Lay the TEMPLATE in the access area with the front aligned with the front wall of the DOOR FRAME.
- If the TEMPLATE does not fit properly, check the DOOR FRAME width for uniformity, top-to bottom, and shim as needed.
- Tape the TEMPLATE down, being careful to obtain as much surface contact of the TEMPLATE to the floor as possible.
- Mark and drill at least four (4) holes per the FLOOR CHANNEL.
- Remove the TEMPLATE.
- Anchor the FLOOR CHANNELS to the floor using suitable concrete anchors. Do not over tighten the bolts at this time, as it may be necessary to adjust the FLOOR CHANNELS later in the installation.
- Attach the STOP BRACKET as illustrated in Figure 24. Temporarily adjust the STOP BRACKET to its farthest rear position. It will be readjusted later in the installation.

Placement of 3M™ Steri-Vac™ Sterilizer/Aerators onto the Stacking Rack

- Roll the STACKING RACK onto the permanently mounted FLOOR CHANNELS.
- Attach the EXTENSION TRACKS to the FLOOR CHANNELS.
- Roll the STACKING RACK forward onto the EXTENSION channels as illustrated in Figure 26.
- Position the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series onto the top tray of the STACKING RACK. Position the front of the GS Series sterilizer as illustrated in Figure 27. **CAUTION:** Due to the weight of the Sterilizer/Aerator, this procedure will normally require at least three (3) individuals.
- Secure the GS Series sterilizer to the top tray by means of the provided $\frac{5}{16} \times 1\frac{1}{2}$ in. bolts, washers, and nuts.
- Follow the same procedure for mounting the Aerator to the bottom tray of the STACKING RACK. Observe the same precautions.
- Adjustments: The front plane of both GS Series sterilizers must be approximately parallel with the front plane of the STACKING RACK. If adjustments are needed, use the ADJUSTABLE NYLON FEET for this purpose.

Access Area

Figure 28 is a generalized drawing of the service connections at the rear of the installation. As previously described, flexible lines are required between the GS Series sterilizer and the stationary services. The connections need not be made until installation is complete.

Installation of Stainless Steel Panels

Reference Figure 29.

- Remove the protective adhesive-backed paper from the PANELS prior to installation. During installation, use care so as to not scratch the stainless steel surfaces.
- Beginning with the TOP PANEL, attach the top and lower PANELS to the STACKING RACK by means of the Phillips-head STAINLESS SCREWS. Leave all of the screws loose at this time.
- Do not attempt to install the LOUVERED PANEL at this time.
- Slide the left and right doors frames in behind the STAINLESS STEEL PANELS and tighten the screws.
- Slide the top door frame in behind the top STAINLESS STEEL panel. Align the door frames and tighten all of the panel screws. Install the nut and washer on either end of the top door frame.
- Locate the adhesive backed foam and place it around the back side of the door frame at the outer edge (Figure 25).
- Gently roll the STACKING RACK back into the access area until the DOOR FRAME meets the wall.

Stop and Hook Adjustment

Reference Figure 24.

- The purpose of the STOP is to keep the STACKING RACK/STAINLESS STEEL PANELS from damaging the flange on the DOOR FRAME when returning the unit to the access area after service and maintenance.
- Remove the STOP from the right FLOOR CHANNEL. Apply a liberal coating of petroleum jelly to both the bottom of the STOP and the floor area beneath the STOP.
- Reattach the STOP loosely to the FLOOR CHANNEL, this time in its forward-most position.
- Gently roll the unit back into the access area until contact is barely made between the STAINLESS STEEL PANELS and the flange on the DOOR FRAME.
- Carefully roll the unit forward, again, and tighten the STOP. Be careful not to move the unit forward or rearward during this process.
- The purpose of the HOOK is to keep the unit from rolling forward as operators open and close Sterilizer/Aerator doors.
- Attach the HOOK on the bracket on the lower left corner of the STACKING RACK. Attach the shoulder bolt and three washers on the outside of the left FLOOR CHANNEL (Figure 20).
- With the unit tight against the STOP, adjust the HOOK so that firm contact is made between the HOOK and SHOULDER BOLT (Figure 24).
- Tighten the nut on the shaft of the HOOK to maintain the HOOK position.

Flexible Connections

- Connect all electro-mechanical services to the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series (e.g. compressed air, vent line, exhaust hood and electrical).
- Observe all flexible connections while rolling the unit back into the access area. Make sure that none of these lines fall down into the FLOOR CHANNELS where they might become damaged by the wheels on the STACKING RACK.

Installing the Louvered Panel

Reference Figure 30.

- Roll the unit back into the access area and secure the HOOK.
- Remove the EXTENSION TRACKS and store them beneath the unit.
- Attach the LOUVERED PANEL.
- Installation is now complete.

Figure References for Section VI

Figure 18. Installation Print No. 1: In-Wall Mounting Unit 1238 Showing Stacking Rack

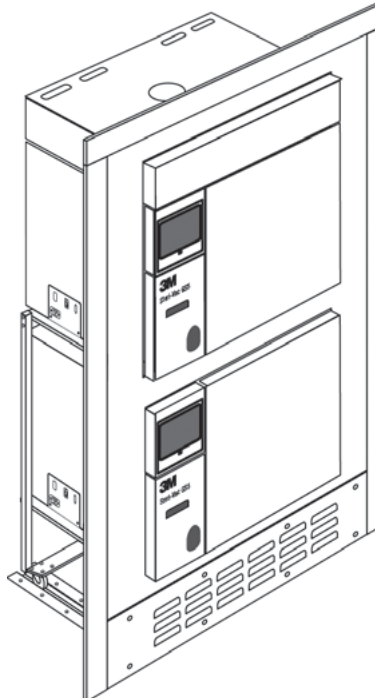
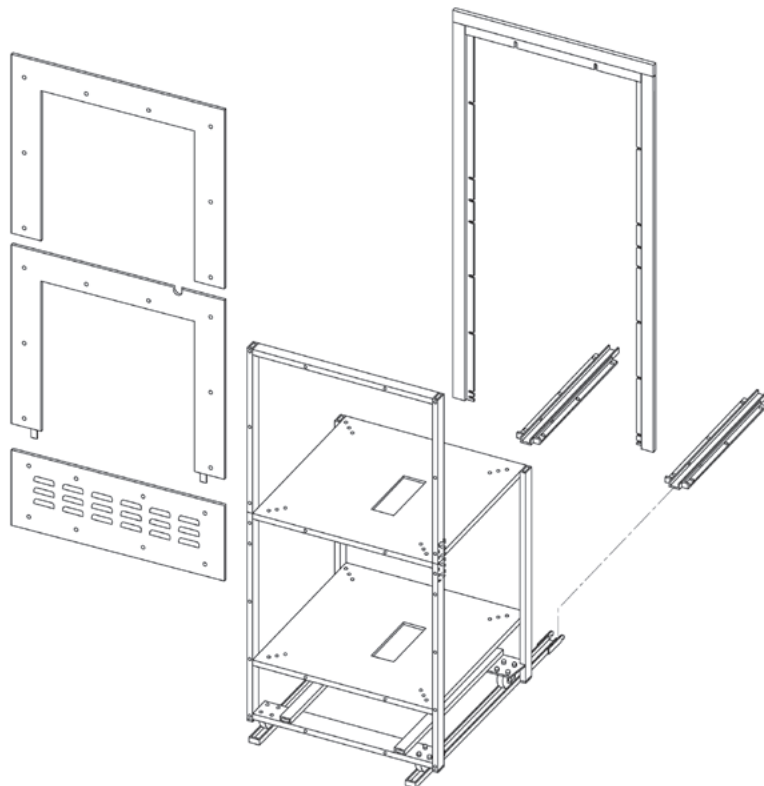
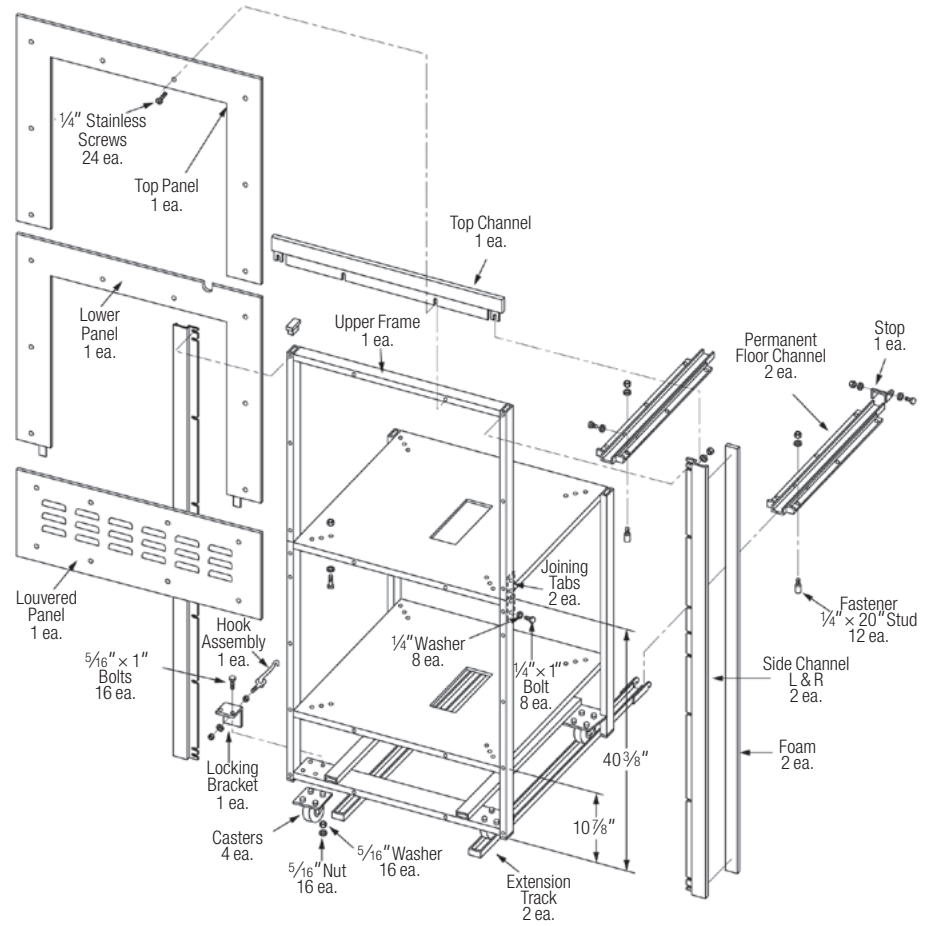


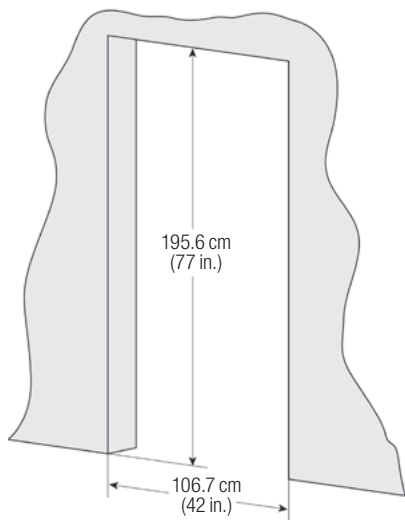
Figure 19. 3M™ In-Wall Mounting Unit 1238 Components



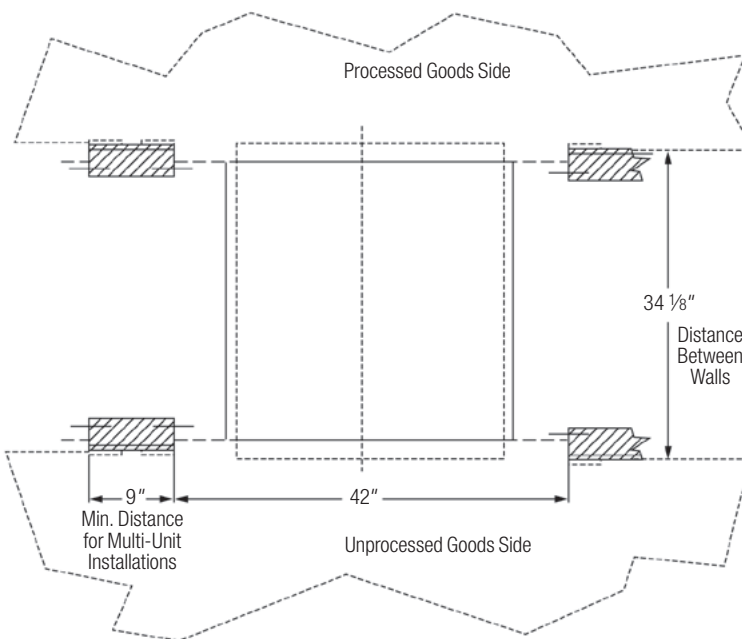
**Figure 20. Installation Print No. 2: 3M™ In-Wall Mounting Unit Model 1238
 Illustrated Parts List**



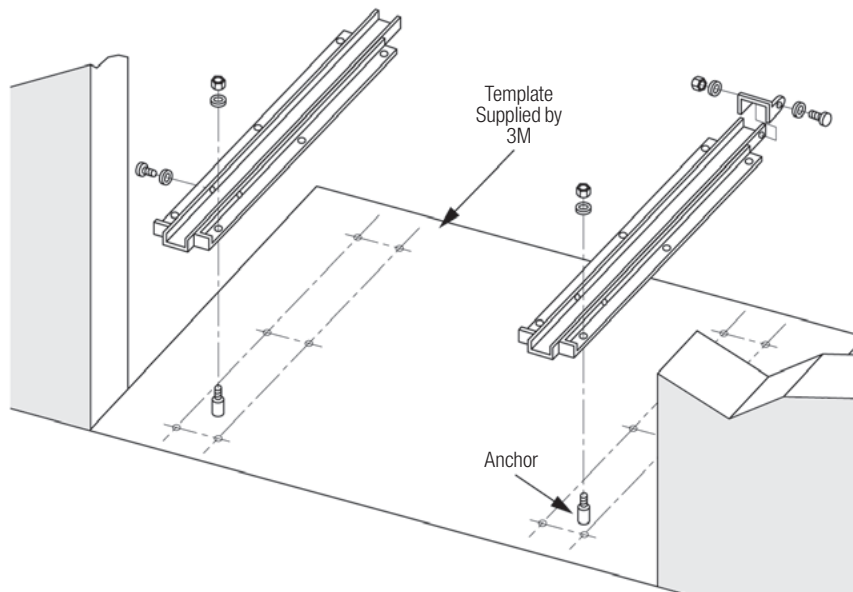
**Figure 21. Installation Print No. 3:
 3M™ In-Wall Mounting Unit Model 1238
 Door Frame Opening**



**Figure 22. Installation Print No. 11: Model 1238 Pass Through
 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS5 Installation**



**Figure 23. Installation Print No. 5: Model 1238 Fastening Permanent
 Floor Channels (Track)**



**Figure 24. Installation Print No. 10: 3M™ In-Wall Mounting Unit Model 1238
Stop and Hook Adjustment**

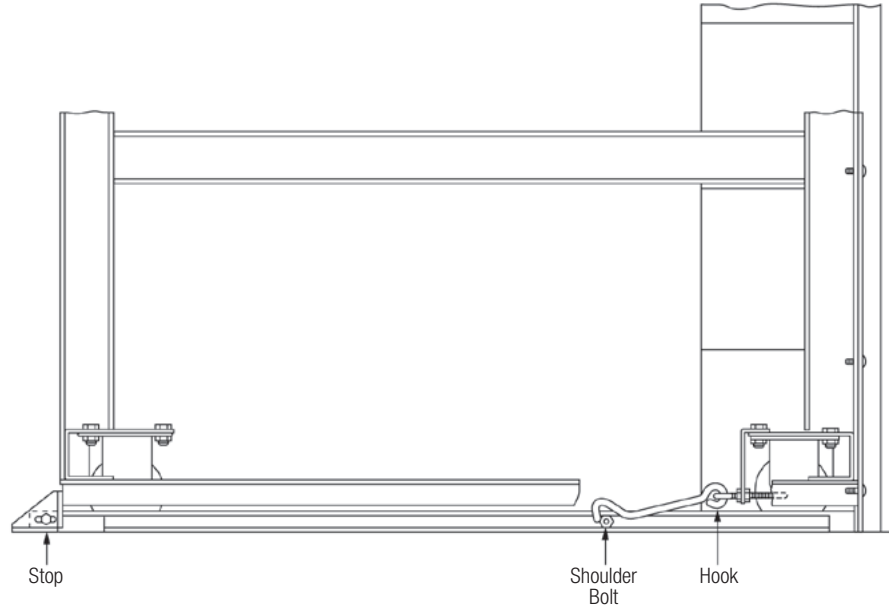
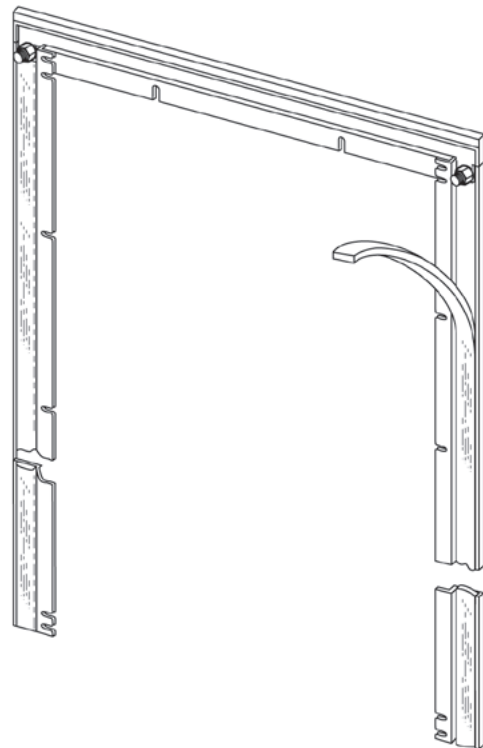


Figure 25. Installation Print No. 4: Model 1238 Mounting Door Frame In-Wall



**Figure 26. Installation Print No. 6: 3M™ In-Wall Mounting Unit Model 1238
Mounting Extension Tracks and Cart**

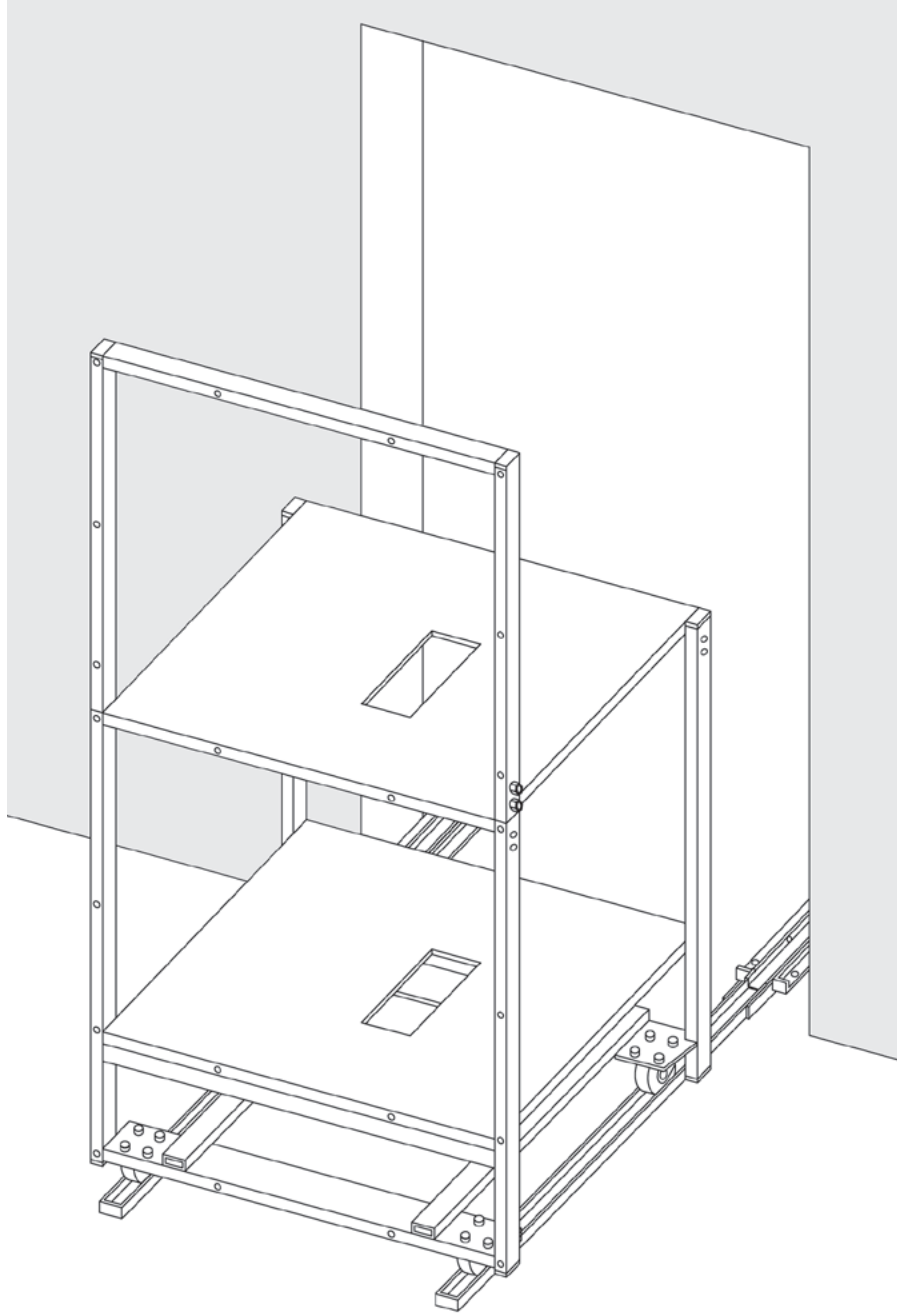
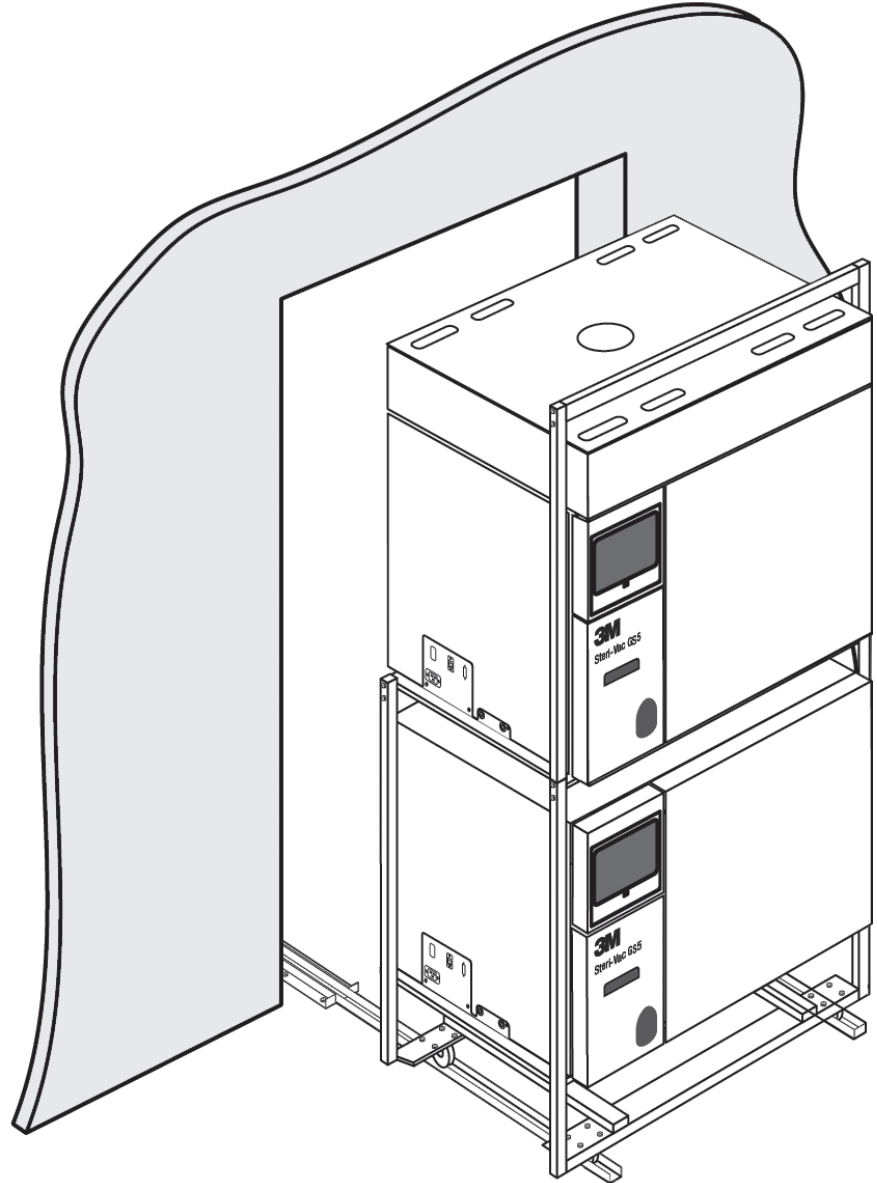


Figure 27. Installation Print No. 7: 3M™ In-Wall Mounting Unit Model 1238
Mounting Units to Cart



Note: Figure 28 shows a 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Model GS5 on the top shelf and a 3M™ Steri-Vac™ XL Aerator on the bottom. Service hookups will vary based on configurations. Refer to the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series and 3M™ Steri-Vac™ XL Aerator Installation Guides for specific requirements.

Figure 28. Installation Print No. 8: 3M™ In-Wall Mounting Unit Model 1238 Unit Rear Hookups

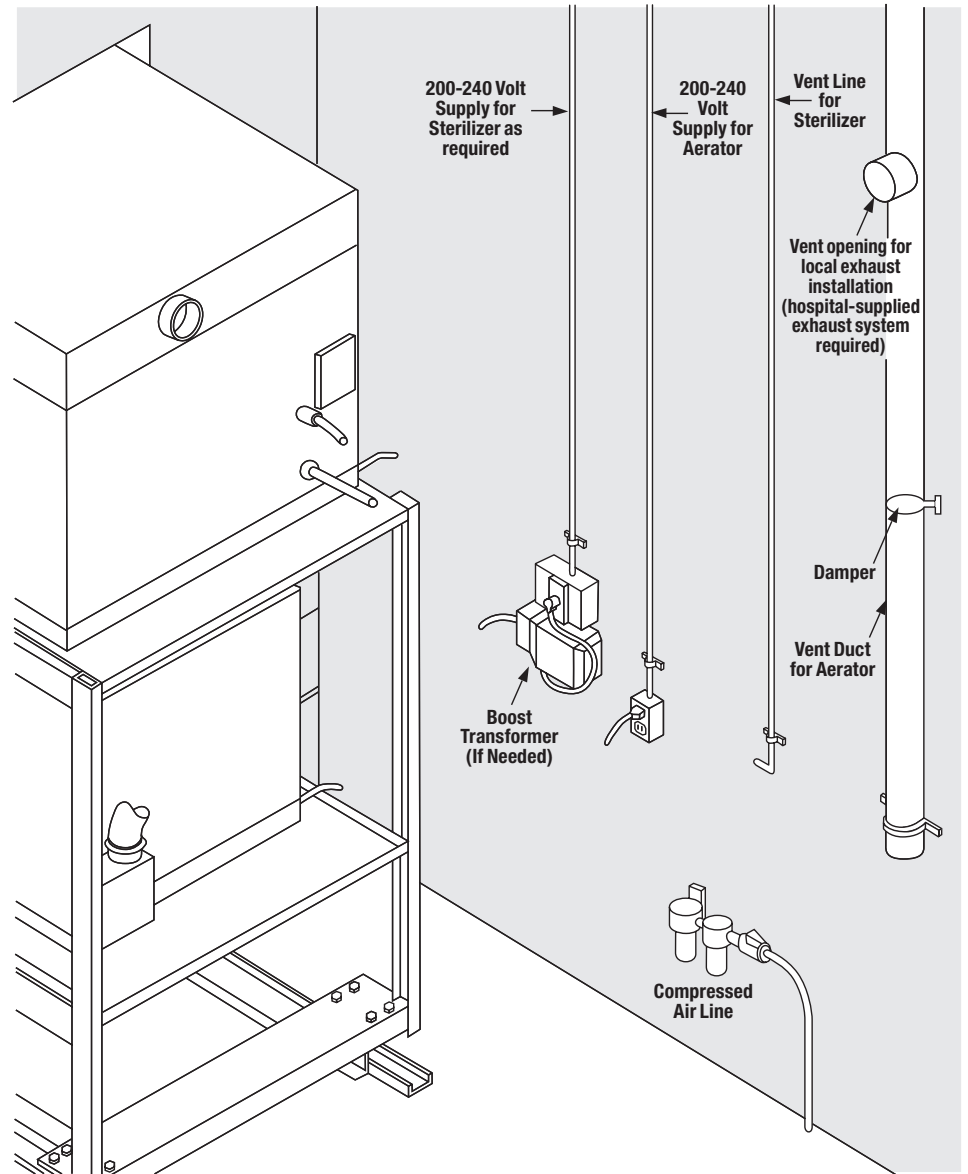
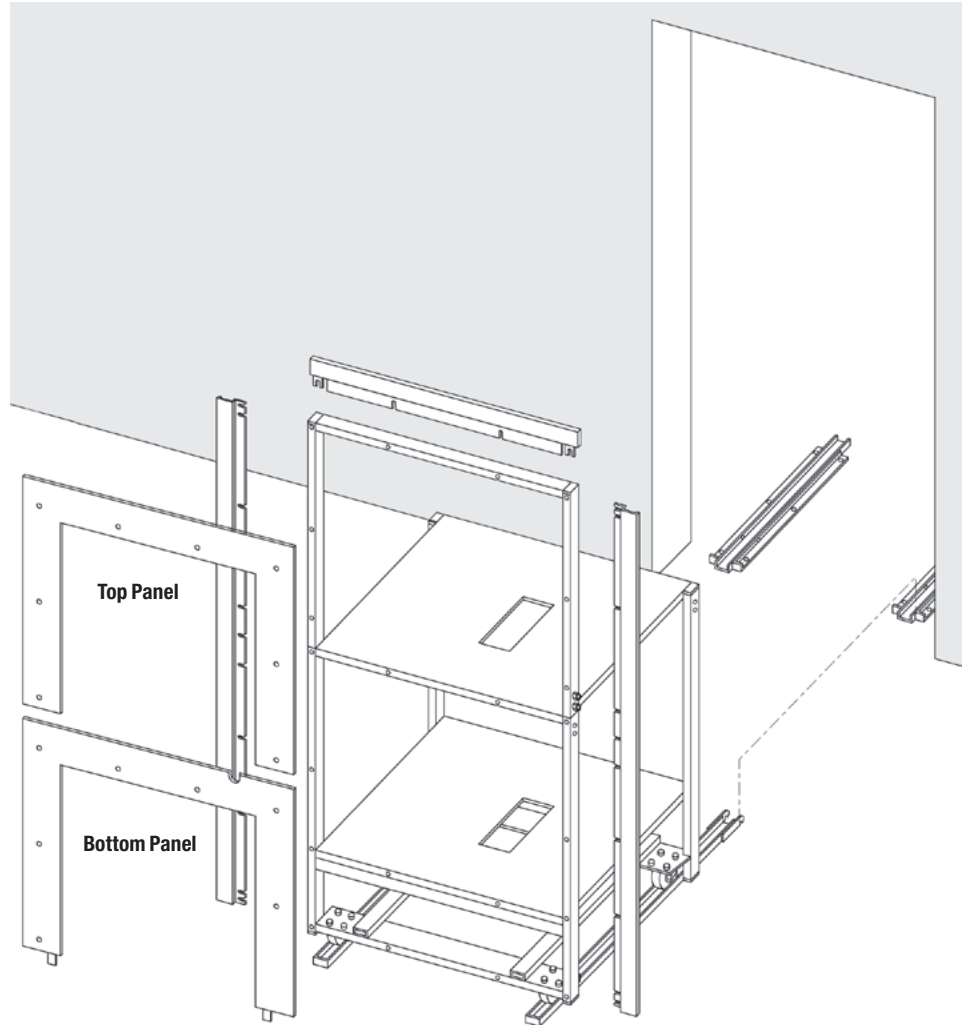
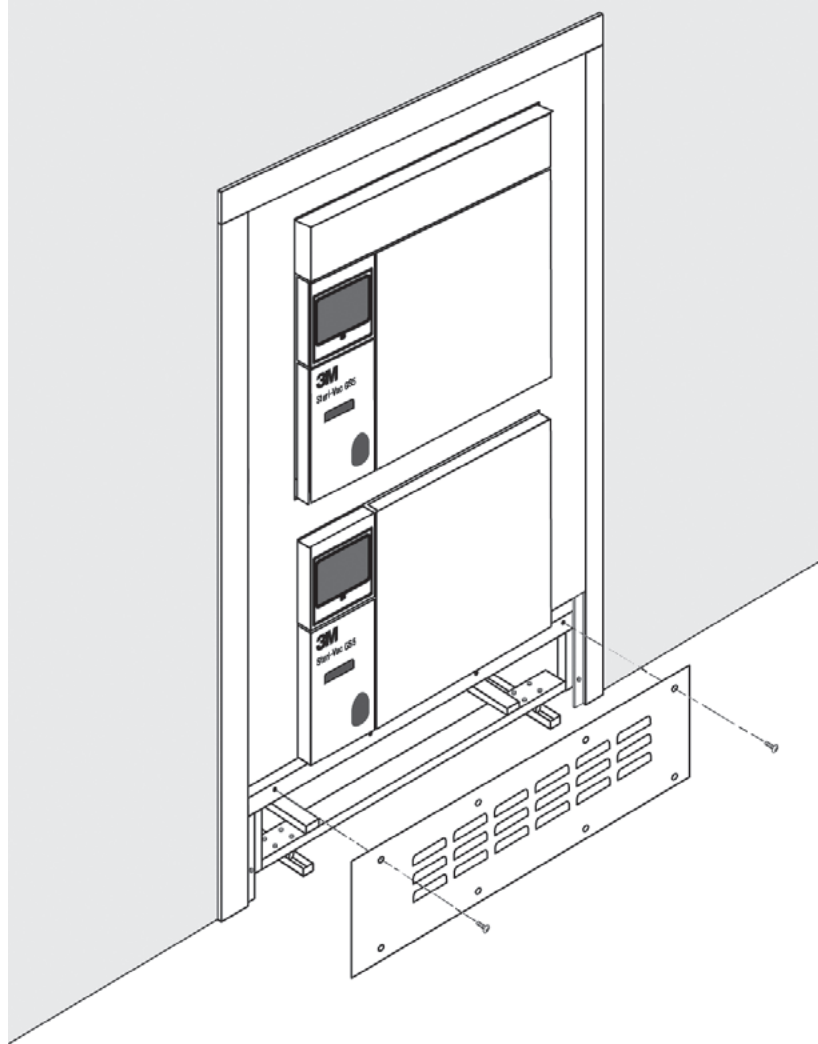


Figure 29. Installation Print No. 9: Mounting Top Two (2) Panels



**Figure 30. Installation Print No. 12: 3M™ In-Wall Mounting Unit Model 1238
Remove Extensions Mount Bottom Panel**



ANNEX A Symbols, Safety Warnings and Cautions

Document Conventions

Explanation of Single Word Consequences



Danger: Indicates a hazardous situation which, if not avoided, will result in death or serious injury.



Warning: Indicates a hazardous situation, which, if not avoided, could result in death or serious injury.



Caution: Indicates a hazardous situation, which, if not avoided, could result in minor or moderate injury.

NOTICE: Indicates a hazardous situation which, if not avoided, may result in property damage.

3M™ Steri-Vac™ Sterilizer/Aerator GS Series – Explanation of Product and Packaging Label and Symbols



Attention: Refer to the Operator Manual for additional information.



Warning: Indicates a hazardous situation, which, if not avoided, could result in death or serious injury.



Waste Electrical and Electronic Equipment (WEEE) and EU Battery Directive. This symbol indicates that both the device and lithium ion battery contained therein need to be disposed of properly.



UL Listed to U.S. and Canadian Safety Standards.



Mark of Conformity to European Directives.



Compliant to all applicable ACMA regulatory arrangements (RCM).



Serial number: This symbol is accompanied by the serial number relevant to the device bearing the symbol.



Catalog: This symbol is accompanied by the catalog number relevant to the device bearing the symbol.



Authorized representative for the European Community: This symbol is accompanied by the name and the address of the authorized representative in the European Community.



Manufacturer: This symbol is accompanied by the name and address of the manufacturer.



Date of Manufacture: This symbol is accompanied by the date of manufacture.

3M™ Steri-Gas™ EO Gas Cartridges – Explanation of Label and Symbols



Flammable Gas: Category 1



Gas Under Pressure: Liquefied Gas



Acute Toxicity (inhalation): Category 3

Specific Target Organ Toxicity (single exposure): Category 1

Specific Target Organ Toxicity (repeated exposure): Category 1

Specific Target Organ Toxicity (central nervous system): Category 3



Carcinogenicity: Category 1A

Reproductive Toxicity: Category 2

Germ Cell Mutagenicity: Category 1B

Eye Irritation: Category 2A

Skin Irritation: Category 2

Danger



DANGER: Potential health effects of ethylene oxide

Users must follow the requirements of the United States Occupational Exposure Standard for Ethylene Oxide OSHA (29 CFR 1910.1047). 100% ethylene oxide (EO) CAS number 75-21-8 is a colorless gas at ambient conditions. **Do not rely on sense of smell for the detection of ethylene oxide.** Ethylene oxide has a high odor threshold and can only be detected by sense of smell when it exceeds 500 – 700 parts per million (PPM). Ethylene oxide has a characteristic ether-like odor, a sweet and irritating solvent smell.

First Aid

Inhalation:

Move the person to fresh air and seek medical attention.

Skin or Clothing Contact:

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, seek medical attention.

Eye Contact:

Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do so. Continue rinsing. Immediately seek medical attention.

If Swallowed:


Rinse mouth. DO NOT INDUCE VOMITING. Immediately seek medical attention.

Hazard Statements of Ethylene Oxide (EO):



- Extremely flammable gas
- Contains gas under pressure, may explode if heated
- Toxic if inhaled
- Causes serious eye irritation
- May cause drowsiness or dizziness
- Suspected of damaging fertility or an unborn child
- May cause cancer
- May cause genetic defects

Reference – consult the 3M™ Steri-Gas™ EO Gas Cartridges Safety Data Sheet (SDS) for additional information (www.3M.com).



Dangers

	DANGER: To reduce the risks associated with exposure to ethylene oxide:
	Ensure a minimum of ten (10) air exchanges per hour (ACHs) for the room in which the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is installed.
	Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series outside the environmental conditions as stated in this manual.
	Only use 3M™ Steri-Gas™ 100% Ethylene Oxide (EO) Gas Cartridges as listed in this manual. Do not use other brands or types of sterilant cartridges.
	Do not use damaged 3M™ Steri-Gas™ EO Gas Cartridges.
	Ensure compressed air supply is clean, with a maximum allowable dirt particle size of 0.5 microns, and free of oil. Ensure air filters on compressed air supply contain a water trap and are cleaned and maintained properly.
	It is the user's facility management's responsibility to ensure that all personnel working with toxic chemicals, gases, and vapors are given comprehensive instruction in the process. This instruction includes information on relevant health hazards; national, state and local regulations; methods for safe use; and methods to detect escape of the agent.
	It is the user's facility management's responsibility to ensure regular training of all personnel concerned with the operation and maintenance of the equipment, including emergency procedures for any toxic, flammable, or explosive material released into the environment. Records of attendance at training are maintained, and evidence of understanding demonstrated.

Warnings

	WARNING: To reduce the risks associated with fire and explosion:
	3M™ Steri-Gas™ EO Gas Cartridges contain 100% Ethylene Oxide (EO), which is an extremely flammable gas and liquid under pressure. Do not use near flame, electrical sparks, or hot surfaces, or allow sources of ignition near the cartridge. Do not puncture the cartridge outside of the sterilization chamber. Do not incinerate cartridges. Exposure to temperatures above 65.5°C (150°F) may cause cartridge to burst.
	Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. Operators should not service the sterilizer as there are no user serviceable parts.
	WARNING: To reduce the risk of shock due to hazardous voltage:
	Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. Operators should not service the sterilizer as there are no user serviceable parts.
	The purchaser must provide a properly grounded outlet (an earth ground), for installation, per applicable codes and regulations.
	Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series outside the environmental conditions as stated in this manual.
	Use only trained 3M Health Care service personnel or authorized 3M service personnel for installation support and maintenance.
	Do not modify any part of 3M™ Steri-Vac™ Sterilizer/Aerator GS Series.
	Use only 3M designated replacement parts.

Cautions

	CAUTION: To reduce the risk of injury,
	always follow the procedures described in this 3M Site Planning and Installation Guide.
	CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,
	do not install 3M™ Steri-Vac™ Sterilizer/Aerators GS Series near any device emitting strong electronic magnetic fields (EMFs).

ANNEX C Site Readiness and Installation Verification Forms

Site Readiness Verification Form: 3M™ Steri-Vac™ Sterilizer/Aerator GS Series

Note: The following form must be completed by the purchaser facility prior to scheduling the installation support service visit by 3M Health Care service personnel or authorized 3M service personnel.

Facility Name: _____
 Address: _____
 City: _____ State/Province: _____
 Country: _____ ZIP/Post Code: _____
 Contact Person: _____
 3M Representative: _____

General							
1.	All national, state and local regulations related to the use of Ethylene Oxide have been obtained and reviewed, and the requirements met. <input type="checkbox"/> Yes <input type="checkbox"/> No						
Electrical Supply							
2.	Enter the supply circuit current rating (15–20 amps). Amps _____						
3.	Minimum supply voltage is greater than 200 volts (200–240 VAC, 50/60 Hz single phase). <input type="checkbox"/> Yes <input type="checkbox"/> No						
	Enter supply voltage. Supply Voltage _____ VAC						
Compressed Air							
4.	The compressor is labeled to verify the air supply is clean, with a maximum allowable dirt particle size of 0.5 microns, and free of oil and is dry to 10°C (50°F) dew point at 38°C (100°F) ambient. <input type="checkbox"/> Yes <input type="checkbox"/> No						
5.	The supply pressure is 7.0 kg/cm ² (100 psig) minimum to 10.5 kg/cm ² (150 psig) maximum. <input type="checkbox"/> Yes <input type="checkbox"/> No						
6.	The air flow rate is 2.2 liters per second at 5.6 kg/cm ² (4.7 cubic feet per minute at 80 psig) per sterilizer/aerator based on 100% duty cycle compressor. <input type="checkbox"/> Yes <input type="checkbox"/> No						
7.	The volume of the air tank is adequate to meet the demand of all equipment used by the same air compressor. <input type="checkbox"/> Yes <input type="checkbox"/> No						
Venting							
8.	The vent line goes from the GS Series sterilizer to the outside atmosphere directly without being terminated into any existing recirculating air flow system or ventilation system. <input type="checkbox"/> Yes <input type="checkbox"/> No						
9.	The vent line is a hard drawn copper tube. <input type="checkbox"/> Yes <input type="checkbox"/> No						
10.	Enter the total linear length of the vent line from the GS Series sterilizer to the termination point on the outside of the building. _____ m / ft. <i>CIRCLE UNIT</i>						
10a.	If the answer to Question 10 is greater than 91 m (300 ft), has the system been approved by 3M? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A						
11.	Enter the outside diameter of the vent line. _____ cm / in. <i>CIRCLE UNIT</i>						
12.	The vent line termination is located more than 7.6 m (25 ft.) from any possible sources of ignition or any openings to the building (e.g., doors, fresh air intakes, unsealed windows, pedestrian walkways). <input type="checkbox"/> Yes <input type="checkbox"/> No						
13.	The vent line is gas tight. <input type="checkbox"/> Yes <input type="checkbox"/> No						
14.	If the vent line extends outside of the building: <table border="0" style="width: 100%;"> <tr> <td style="width: 20px;">a.</td> <td>The vent line is insulated to protect from freezing (where required). <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</td> </tr> <tr> <td>b.</td> <td>There is a 180° downward bend at the end for the vent line if a vertical installation. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</td> </tr> <tr> <td>c.</td> <td>There is a 90° downward bend at the end for the vent line if a horizontal installation. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</td> </tr> </table>	a.	The vent line is insulated to protect from freezing (where required). <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	b.	There is a 180° downward bend at the end for the vent line if a vertical installation. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	c.	There is a 90° downward bend at the end for the vent line if a horizontal installation. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
a.	The vent line is insulated to protect from freezing (where required). <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A						
b.	There is a 180° downward bend at the end for the vent line if a vertical installation. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A						
c.	There is a 90° downward bend at the end for the vent line if a horizontal installation. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A						
Local Exhaust System (only applicable when the local exhaust hood is connected and operating)							
15.	The local exhaust system meets the air flow requirements stated in the exhaust ventilation specifications in the 3M Site Planning and Installation Guide. <input type="checkbox"/> Yes <input type="checkbox"/> No						
16.	The flow rate at the end of the facility exhaust duct at the sterilizer hood is from 59 to 66 L/sec (125 to 140 cfm) for a single door unit or 118 to 132 L/sec (250) to 280 cfm for a double door unit. <input type="checkbox"/> Yes <input type="checkbox"/> No						
17.	The ductwork material is impervious to EO (galvanized metal or SST). <input type="checkbox"/> Yes <input type="checkbox"/> No						
18.	The local exhaust system termination is located more than 7.6 m (25 ft.) from any openings to the building. <input type="checkbox"/> Yes <input type="checkbox"/> No						
19.	The exhaust hood blower is suitable for continuous operation and protected from adverse weather. <input type="checkbox"/> Yes <input type="checkbox"/> No						

I certify that I have assessed the above conditions and all have been met.

Facility Representative (print): _____ Date: _____

Facility Representative (signature): _____

Installation Verification Form: 3M™ Steri-Vac™ Sterilizer/Aerator GS Series

Facility Name: _____	
Address: _____	
City: _____	State/Province: _____
Country: _____	ZIP/Post Code: _____
Contact Person: _____	
3M Representative: _____	

Compressed Air Line		
1.	The supply pressure is 7.0 kg/cm ² (100 psig) minimum to 10.5 kg/cm ² (150 psig) maximum. The compressor maintains a flow rate of 2.2 liters per second at 5.6 kg/cm ² (4.7 cubic feet per minute at 80 psig) per sterilizer/aerator based on 100% duty cycle.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	The air supply is clean, dry to a dew point of 10°C (50°F), and free of oil.	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Supplied air filters are installed in the supply line.	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	The air enters the filter through the port marked IN.	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	The supply line filters are accessible for maintenance.	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	A shutoff is installed upstream from the air filter so that air can be turned OFF for machine service.	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	An air pressure gauge is installed between the filters and the air inlet to the GS Series sterilizer.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sterilizer/Aerator Location		
8.	A minimum clearance of 51 cm (20 in.) is maintained on all sides and the top of the GS Series sterilizer. If the answer to this question is 'No', the answer to Q8a must be 'Yes'.	<input type="checkbox"/> Yes <input type="checkbox"/> No
	8a. If answer to Q8, is 'No', can the GS Series sterilizer be moved?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	8b. If the GS Series sterilizer is movable, is a stainless steel braided, flexible tubing used for the vent line?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	8c. Is there a flexible line used on the air service so the GS Series sterilizer can be moved without disconnecting that service?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	The unit has been installed in an area free of flammable gases and liquids, other than ethylene oxide (EO).	<input type="checkbox"/> Yes <input type="checkbox"/> No
10.	The unit has been installed in an area with at least 10 air exchanges per hour.	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Do you have documentation that confirms a minimum of 10 air exchanges per hour is available for the installed unit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	The room air flow pattern is directed away from the equipment operator.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Local Exhaust System (only applicable when the local exhaust hood is connected and operating)		
13.	The local exhaust system meets the air flow requirements stated in the exhaust ventilation specifications in the 3M Site Planning and Installation Guide.	<input type="checkbox"/> Yes <input type="checkbox"/> No
14.	The flow rate at the end of the facility exhaust duct at the sterilizer hood is from 59 to 66 L/sec (125 to 140 cfm) for a single door unit or 118 to 132 L/sec (250) to 280 cfm for a double door unit.	<input type="checkbox"/> Yes <input type="checkbox"/> No
15.	The ductwork material is impervious to EO (galvanized metal or SST).	<input type="checkbox"/> Yes <input type="checkbox"/> No
16.	The local exhaust system termination is located more than 7.6 m (25 ft.) from any openings to the building (e.g., doors, fresh air intakes, unsealed windows, pedestrian walkways).	<input type="checkbox"/> Yes <input type="checkbox"/> No
17.	The exhaust hood blower is suitable for continuous operation and protected from adverse weather.	<input type="checkbox"/> Yes <input type="checkbox"/> No

I certify that I have assessed the above conditions and all have been met.

Facility Representative (print): _____ Date: _____

Facility Representative (signature): _____

ANNEX D 3M™ Steri-Gas™ EO Gas Cartridge Dilution Charts

The following Tables provide estimates of air concentrations of ethylene oxide (EO) if the identified 3M™ Steri-Gas™ EO Gas Cartridge should empty into a room, and provide the time needed for a room ventilation system to reduce the EO concentrations to acceptable levels. These charts are based on rooms with 10 air exchanges per hour.

3M™ Steri-Gas™ EO Gas Cartridge 4-100

Room volume (ft ³)	Room volume (m ³)	Room airflow (cfm)	EO gas weight (g)	Room EO concentration after spill (ppm)	Time to reach 0.5 ppm (minutes)
600	17	100	100	3270	53
700	20	117	100	2803	52
800	23	133	100	2452	51
900	25	150	100	2180	50
1000	28	167	100	1962	50
1500	42	250	100	1308	47
2000	57	333	100	981	45
2500	71	417	100	785	44
3000	85	500	100	654	43
3500	99	583	100	561	42
4000	113	667	100	490	41
4500	127	750	100	436	41
5000	142	833	100	392	40
5500	156	917	100	357	39
6000	170	1000	100	327	39
6500	184	1083	100	302	38
7000	198	1167	100	280	38
7500	212	1250	100	262	38
8000	227	1333	100	245	37
8500	241	1417	100	231	37

3M™ Steri-Gas™ EO Gas Cartridge 8-170

Room volume (ft ³)	Room volume (m ³)	Room airflow (cfm)	EO gas weight (g)	Room EO concentration after spill (ppm)	Time to reach 0.5 ppm (minutes)
600	17	100	170	5559	56
700	20	117	170	4765	55
800	23	133	170	4169	54
900	25	150	170	3706	53
1000	28	167	170	3335	53
1500	42	250	170	2224	50
2000	57	333	170	1668	49
2500	71	417	170	1334	47
3000	85	500	170	1112	46
3500	99	583	170	953	45
4000	113	667	170	834	45
4500	127	750	170	741	44
5000	142	833	170	667	43
5500	156	917	170	606	43
6000	170	1000	170	556	42
6500	184	1083	170	513	42
7000	198	1167	170	476	41
7500	212	1250	170	445	41
8000	227	1333	170	417	40
8500	241	1417	170	392	40

$$\text{Spill ppm} = [(\text{gas weight in mg}) / (\text{room volume in cu m})] * [(1 \text{ ppm} / (1.80 \text{ mg/cu m}))]$$

$$\text{cfm} = (\text{room volume in cu ft}) * (10 \text{ air exchanges per hour}) / (60 \text{ min/hr})$$

$$\text{time} = [\log_{10}(0.5 \text{ ppm} / \text{spill-ppm})] * [(-2.303) * (\text{room volume in cu m}) / (\text{cfm})]$$

Employee monitoring may be required by national, state and local regulations. In the U.S., the Occupational Safety and Health Administration (OSHA) requires breathing zone monitoring of employees for exposure to ethylene oxide after the 3M™ Steri-Vac™ GS Series Sterilizer/Aerator GS Series installation to establish a baseline (OSHA 29 CFR 1910.1047). The 3M™ Ethylene Oxide (EO) Monitoring Badge 3550 can be used to facilitate personal monitoring compliance to the OSHA standard.

3M™ Steri-Gas™ EO Gas Cartridge Safety Data Sheets (SDS) are available at: www.3M.com/msds

ANNEX E Bibliography and Compliance References

Equipment and Ethylene Oxide (EO) Compliance Documents

AAMI/ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residues	EMC Directive 2004/104/EC	Electromagnetic Compatibility
AAMI/ISO 11135-1	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.	EN 1422	Sterilizer/Aerators for Medical Purposes – Ethylene Oxide Sterilizer/Aerators – Requirements and Test Methods
ANSI/AAMI ST24	Automatic, general purpose ethylene oxide Sterilizer/Aerators and ethylene oxide sterilant sources intended for use in health care facilities	EN 62366	Medical Devices – Application of usability engineering to medical devices
ANSI/AAMI ST41	Ethylene oxide sterilization in health care facilities: Safety and effectiveness	EPA 40 CFR Part 63; Subpart WWWW	National Emission Standards for Hazardous Air Pollutants for Source Categories – National Emission Standards for Hospital Ethylene Oxide Sterilizer/Aerators
ANSI/AAMI/IEC 80001-1:2010	Application of risk management for IT Networks incorporating medical devices – Part 1: Roles, responsibilities and activities	FCC part 15	Electromagnetic Compatibility
ANSI/AAMI/ISO 62304	Medical device software – Software life cycle processes	IEC/EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General Requirements
AOAC	AOAC Official Method of Analysis of Official Analytical Chemist (AOAC), 14th Ed., Chapter 4, Disinfectants, Par. 4.033-4.035.	IEC/EN 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers. Ventilation of health care facilities. ANSI/ASHRAE Standard 170. Atlanta: ASHRAE, 2008.	IEC/EN 61010-2-040	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for Sterilizer/Aerators and washer-disinfectors used to treat medical materials.
ASHRAE; 201.4	American Society of Heating, Refrigerating, and Air-Conditioning Engineers. HVAC Design Manual for Hospitals and Clinics; 2nd ed. Atlanta, GA. ASHRAE; 201.4	ISO 10993-17	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
Australian Standard for EMC – AS/NZS 2064	Limits and methods of measurement of electronic disturbance characteristics of industrial scientific and medical (ISM) radiofrequency equipment.	OSHA 29 CFR 1910	“Sterilant Use of EO in Hospitals & Health Care Facilities,” ANNEX A, Table VII; OSHA EO Standard: 29 CFR 1910 Occupational Exposure to Ethylene Oxide.
		OSHA 29 CFR 1910.1047	General Industry Standard Subpart Z (Toxic and Hazardous Substances; Ethylene Oxide)

ANNEX F Disposal of Packaging

Recycle packaging materials according to facility policy. Dispose of non-recycled packaging materials into general waste or according to facility policy.

Contact Information

For additional information on installation, seismic bracing, accessories, preventive maintenance agreements, services or other questions, contact 3M at the sites listed below or your local 3M office.

3M Health Care

3M Health Care Service Center
Building 502-1W-01
St. Paul, MN 55128

1-800-292-6298
www.3m.com/infectionprevention

3M Canada, Inc.

P.O. Box 5757
London, Ontario,
Canada, N6A4T1

1-800-563-2921

3M Deutschland GmbH

Health Care Business
Carl-Schurz-Str.-1
41453 Neuss, Germany

