# 3M™ Steri-Vac™ Sterilizer/Aerator GS Series Safety Summary

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## Introduction

**3M™ Steri-Vac™ Sterilizer/Aerator GS Series** ethylene oxide (EO) sterilizers have been designed for safe operation, and meet or exceed multiple United States and international safety standards when properly installed and operated. The **3M™ Steri-Vac™ Sterilizer/Aerator GS Series** EO sterilizers have a number of key safety design features to minimize occupational EO exposure risk.

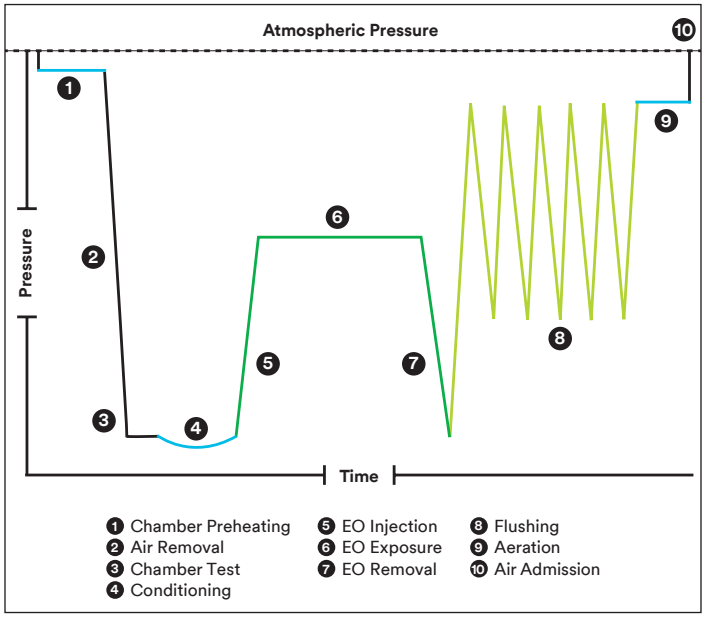
## 3M™ Steri-Vac™ Sterilizer/Aerator GS Series Safety in Design

**3M™ Steri-Vac™ Sterilizer/Aerator GS Series** EO Sterilizers were developed under 3M Infection Prevention Division's risk management process compliant with EN ISO 14971:2012, and all risk mitigation tools (design, usability, engineering controls, and labeling) have been used to reduce potential hazards.

The foundation of the safe design of the **3M™ Steri-Vac™ Sterilizer/Aerator GS Series** is based on the following three design features:

1. **Single dose EO cartridge based gas delivery** limits potential accidental EO release to less than 200 grams (<7 ounces). There is no risk of exposure from large multiple load sterilant containers, external tank changeover or external supply fittings and piping.

**Figure 1:** The 100% EO Sterilization Cycle is under vacuum and below ambient air pressure.




2. **Negative (below atmospheric) pressure throughout the cycle.** The Steri-Vac cycle operates under a vacuum, so any breach of the chamber would result in a leak of room air into the chamber rather than ethylene oxide gas leaking out of the chamber. At the beginning of each cycle, the sterilizer performs a chamber leak test. A chamber vacuum is required to puncture the EO cartridge and release the EO into the sterilization chamber. If the chamber leaks or there is not a deep enough vacuum, the cartridge puncture system will not operate, the cartridge remains un-punctured, and EO will remain safely in the single dose cartridge. The vacuum also holds the door closed and sealed independent of the controls or operator. The chamber door has a minimum of 80 mbar (1.3 psi) of pressure holding the door closed when EO is in the chamber, which equates to over 300 pounds (136kg) of force. The door cannot be opened when EO is in the chamber.

3. **The chamber door lock is isolated from electronic failure.** A magnetically-latched relay is used as both an indicator that EO is in the chamber and as part of a control system that prevents the door from being unlocked or opened when gas is in the chamber. The control system allows the sterilizer to either activate the EO cartridge puncture system or unlock the door, but not both. Since the control system can only perform one of the functions at a time, the system will not allow the door to open when the cartridge is punctured. This is a redundant safety feature in addition to a vacuum being required to puncture the EO cartridge. In the event of a power outage or an electronic failure, the door would remain latched, protecting the user from accidentally opening the door.

## Software and Mechanical Design Safety Features

In addition to the three mechanical design features, there are control and monitoring sensors (two separate sets of sensors) for the critical process parameters of temperature, pressure and relative humidity. These sensors are used by the system that controls and monitors all sterilizer operations. If the control system detects an unpredicted event, it will inform the operator by displaying an ERROR or CAUTION code on the display screen, cycle report, and with an audible tone (if enabled). If a fault occurs, after EO has been released into the chamber, the control software will automatically evacuate the EO from the chamber or lock down the sterilizer, until it is repaired by a trained service technician. The system will indicate the "Error Level", which will dictate the appropriate corrective action taken by the sterilizer. These indications are summarized in the Table 1 below.

### Safety Features if Malfunctions Occur

The engineered, mechanical fail-safe feature requires a vacuum (a pressure below atmospheric pressure) in the chamber before EO can be released from the single dose cartridge. This ensures that EO will not be released from the cartridge and into the chamber if the chamber door is not properly locked and sealed. The cartridge puncture mechanism is a pressure piston that can only be activated if there is a vacuum in the chamber. If the chamber cannot reach a safe vacuum level, the puncture mechanism cannot function, the cartridge will not be punctured, and no EO will be released into the chamber.

In addition, the door latching relays prevent any unauthorized access to chamber. The latching relays will not permit the door to be opened unless the system is set to "Gas Not Present", and after "EO Removal" and "Flushing" stages are complete. The chamber status is stored in permanent, non-volatile memory and will retain their last known state throughout system power loss and power recovery.

### Power Interruptions

In the event of a power failure, all solenoid valves and door lock actuators will be de-energized to prevent EO from being released from the chamber. The chamber doors will remain locked as the actuators require power to unlock the door. **Without power, the chamber cannot be accessed.** The solenoid valves in the EO gas path are also closed and prevent gas from escaping from the chamber.

Upon power up, and anytime a cycle is started, the system performs an integrity check to insure proper operation. If a cycle was running when the power was interrupted, an error will be generated and saved in the permanent memory. Upon power recovery, if the error was critical to sterilization, the sterilizer will abort the cycle, alert the user and purge the chamber of EO gas preventing operator exposure or will simply lock the chamber from further access. Depending on the error level, the user or supervisor may be able to correct the system, otherwise a 3M trained service technician will be needed.

The system continuously stores information on the current state of the sterilizer. Upon power recovery, the system will resume the current cycle if all critical process parameters are still within acceptable range. If any critical process parameters are out of acceptable range, the system will generate an error, stop the cycle and take appropriate error recovery actions and alert the user. If the current system state is unknown or corrupt upon power recovery, the system will assert "Unsupervised Shutdown Error", stop any cycle that may be in progress, lock the chamber and alert the user.

### Stop Cycle

If the operator wishes to intervene and stop a cycle, the system will respond appropriately during each cycle stage. The "Stop"

**Table 1:**

| Error Level(s) | Description |
|---|---|
| L1 | Errors that occur **before** the EO cartridge has been punctured and before EO gas has been released into in the chamber. The level of error can be cleared by the user. |
| L2 | Errors that occur **before** the EO cartridge has been punctured and before EO gas has been released into in the chamber. This level of error allows the door to be opened so the load can be retrieved, but service attention will be required before another cycle is attempted. |
| L3 | Errors that occur **before** EO gas has been released into the chamber, but requires Service attention before the Operator can open the load door. |
| L4 | Errors that occur **after** EO gas is in the chamber. The system will attempt to return the sterilizer to a safe state. The CS Supervisor with higher security access must clear the error. If the sterilizer is safe, it will return to the main screen where the door can be opened. |
| L5 | Errors that occur **after** EO is in the chamber. The system will attempt to return the sterilizer to a safe state. Service is required to clear the error before the door can be opened. |
| L6 | Errors that occur **after** EO is in the chamber. The system will attempt to return the sterilizer to a safe state. Service is required to clear the error before the door can be opened. |
| L7 | EO may or may not be present in the chamber. Errors that occur during an Error Recovery stage, due to lower level errors, will be elevated to L7. Service attention is required. |
| A1 – A3 | Errors that occur during aeration. Service attention is required. |

button is unavailable to the operator during the short duration of the Gas Injection stage so that the system can make sure the EO canister is completely empty. During Gas Exposure stage, the “Stop” button is available to operator. If the operator stops a cycle during the Gas Exposure stage or any time the “EO” symbol is present on the display screen, a user abort error will be displayed and the cycle is advanced through Gas Removal and Flushing stages to bring the sterilizer to a safe state.

### Pressure Failure

Near the beginning of every cycle, the system checks to make sure the chamber is sealed. The system pumps out the air in the chamber to create a vacuum and performs a chamber integrity check. If the system detects a chamber leak where air is leaking into the chamber, the system will abort the cycle and alert the user. If the chamber integrity test fails, a 3M trained repair technician will need to repair the system.

### Partial Release of EO Cartridge in Chamber

The system can detect an insufficient release of EO during the EO Injection stage. This error can be caused by attempting to use an empty cartridge, an under filled cartridge or a failure of the EO injection system. If this happens, the system will assert a “Gas Cartridge Empty Error”, “Gas Low Pressure Error”, and/or “Monitor Gas Low Pressure Error”, abort the cycle purge the chamber and alert the user.

## Safe Environment for the Operator

### Ventilation

Proper installation of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series requires providing air flow away from operator’s breathing zone with a minimum of 10 room air exchanges per hour (ACH) as described in the installation guide as well as the AAMI/ANSI ST41 Ethylene oxide sterilization in health care facilities: Safety and Effectiveness standard. This can be seen in the figures below:

**Figure 2:** The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series also include a door vent hood. The vent hood is an additional layer of safety for the operator that pulls room air past the operator into the hood vent insuring fresh air in the operator’s breathing zone. The door vent hood (exhaust hood) supplements the room’s directional air flow.

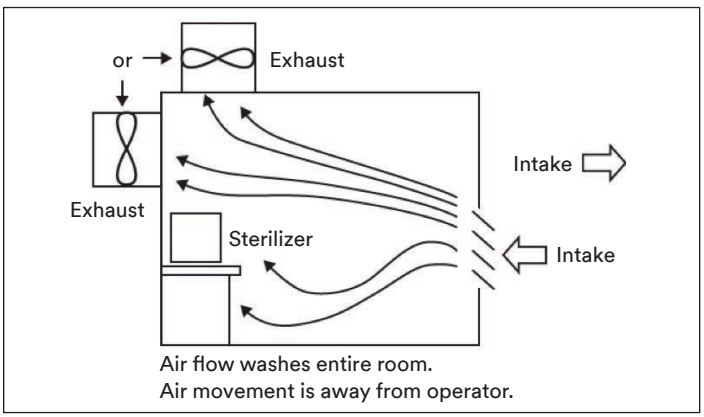



**Figure 3:** The door vent hood draws air from above the chamber opening reducing the amount of chamber air reaching the operator.


EO should always vented to the outside of the facility and away from any of the building intake vents. Ethylene oxide is not persistent in the environment because it is reactive and is biodegradable by biotic and abiotic processes such as rapid evaporation, biochemical oxidation, reactivity, volatilization and dilution. Ethylene oxide has also been shown to have low-to-moderate aquatic toxicity, and as a result, does not present a significant risk to the environment.[1]

### EO Abatement

Abatement of EO is required in several states in the United States of America and some countries. The 3M EO Abator is air pollution control equipment that converts exhausted EO to $CO^2$ and water vapor with 99.9% efficiency providing additional safety to the environment.

**Figure 4:** A pair of 3M™ EO Abators properly installed.

### Service

Regular preventive maintenance provided by 3M trained service providers is effective in assuring the system is operating properly and kept current with software or general maintenance updates. 3M trains and qualifies Service Technicians for proper installation and service of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. The Service Technicians also provide in-service training for the facility’s staff.

## Reduced Flammability Risk

Ethylene oxide gas is flammable in concentrations between 3% and 100% in air. The 3M™ Steri-Vac™ GS Series Sterilizer/Aerators are designed to reduce risks associated with the use of the ethylene oxide gas:

### EO Gas Cartridges

The small, single use 3M™ Steri-Gas™ EO Gas Cartridges eliminate the need for large tanks of ethylene oxide, and the risks associated with potential release from gas leaks or during tank changes.

Because of the small quantity of ethylene oxide, Steri-Gas cartridges are excluded from the requirements of NFPA 55 (Compressed Gases and Cryogenics Code; 2013) and NFPA 560 (Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation; 2007). These standards exclude containers that contain 200g of ethylene oxide or less.

### Sterilizer Chamber

The sterilizer controls the temperature in the chamber to keep the maximum chamber temperature (60°C) well below the EO auto ignition temperature (>426°C). In addition, the 3M™ Steri-Vac™ GS series sterilizers are designed **without any source of ignition** inside the sterilizer chamber during the process. The sensors and mechanical components contacting the EO gas inside the chamber are not an ignition source.

(NOTE: Operator Manual Warning: “To reduce flammability risk, do not sterilize devices with energy sources that could create a spark in the sterilization chamber during the sterilization cycle”).

Because of the relatively small chamber size of the 3M™ Steri-Vac™ GS series sterilizer/aerators, these sterilizers are excluded from the requirements of NFPA 560 (Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation; 2007). This standard excludes chambers 10 $ft^3$ (0.28$m^3$) or less in volume.

## Standards Compliance

The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is cleared by the U.S. Food and Drug Administration (FDA) and carries a CE mark per the European Union Medical Device Directive (MDD) and related to the Medical Device Directive 93/42/EEC. The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series 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 GSX Series is designed, manufactured, and tested to meet the applicable device safety, electrical and EMC standards:

- **IEC/EN 61010-1:2010** — Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements.
- **IEC/EN 61010-2-010:2014** — 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 61010-2-040:2015** — 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.
- **IEC 61326-1:2012** — 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.
- **EMC per IEC/EN 61326-1** — and Australian C-tick and Japan JSS.
- **ISO 11135:2007** — Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.
- **ANSI/AAMI ST41:2008/(R)2012** — Ethylene oxide sterilization in health care facilities: Safety and effectiveness.
- **EN 1422:2014** — Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.
- GS-series sterilizers meet the requirement for the Official Method of Association for **Analytical Communities (AOAC), 14th ed., Chapter 4, Disinfectants, Par. 4.033-4.035 [Method 966.04]** Sporicidal Activity of Disinfectants.
- Development process compliant with **ANSI/AAMI/IEC 62304:2006** Medical devices software — Software life cycle processes.

## Occupational EO Gas Exposure Studies[2]

3M has conducted comprehensive testing that measured worker exposure levels to EO upon opening the sterilizer door with various types of loads, after the sterilization cycles were complete. The testing characterized the potential operator exposure to airborne ethylene oxide when using the pre-programmed cycles cleared by the FDA (38°C or 55°C) and operated in a properly ventilated room with the minimum required 10 air changes per hour (ACH). Aeration times ranged from the 90-minute minimum for GS series sterilizers with a functional vent hood, to the 180-minute minimum when the GS series vent hood is not functional, and after a full aeration cycle of 12 hours when the load has been adequately aerated for patient use.

The testing involved more than 100 sterilization cycles. Air quality was measured (i.e., EO concentrations) both in the operator's breathing zone and at a point "170 cm from the floor and 1m directly in front of the middle of the door" as required by IEC 61010-2-040:2005 standard.*

Three different load types were used to simulate the range of load types that may be encountered in a health care setting:

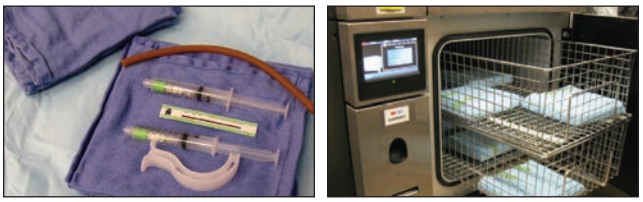
1. **Light Load** — consisting of ANSI/AAMI ST41 challenge test packs used to qualify the sterilizer after installation or repair.
2. **Typical Product Load** — consisting of a representative mix of large and small instruments.
3. **Reasonable Worst Case Load** — consisting of a large quantity of PVC and latex tubing, materials known to absorb copious amounts of ethylene oxide and pose a significant challenge to adequate aeration.

### 1. Light (ANSI/AAMI ST41) Load

This load consisted of a fixed number of standard challenge test packs as specified by ANSI/AAMI ST41:2008/(R)2012 Ethylene oxide sterilization in health care facilities:

Safety and effectiveness. Each pack contained biological indicators (BIs) in a syringe, a chemical indicator (CI), airways and latex tubing that were wrapped in standard challenge test packs as specified by ST41. Virgin (i.e., unexposed) materials were used for all loads; no materials were reused.

**Figure 5:** Light (ST41) Case Load for 3M™ Steri-Vac™ GS8/GSX8 Sterilizer.



* IEC 61010-2-040:2005 Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials, Section 13.1.103.2 Protection against gases liberated from the LOAD.

### 2. Typical Healthcare Product Load

This load consisted of full baskets of:

- Large bore, multi-channel flexible endoscopes in both metal containers and/or wrapped plastic sterilization trays.
- Long, narrow stainless steel, lumened instruments in wrapped trays.
- Assorted small instrument sealed in film pouches.

After each sterilization cycle, all disposable wraps were discarded and all instruments were aerated at 55°C for minimum of 48 hours in a 3M™ Steri-Vac™ XL Aerator before repackaging for reuse.

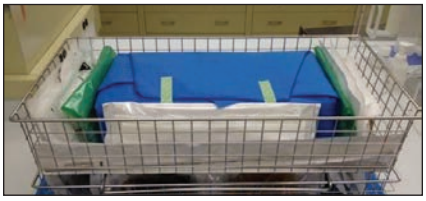


**Figure 6:** Typical Product Load for 3M™ Steri-Vac™ GS5/GSX5 Sterilizer.

### 3. Reasonable Worst Case Load

These loads consisted of PVC and Latex tubing sealed in film pouches or placed loose in the designated metal containers. These materials were chosen for their known characteristic of absorbing high amounts of EO and their differing rates of degassing during aeration — latex is known to degas quickly, while PVC is known to degas more slowly. All materials were virgin (i.e., unexposed) for all loads in the initial testing phase (60 + loads). Later testing reused the latex and PVC tubing after degassing of 72 hours at 55°C and 7 days at ambient conditions.

**Figure 7:** Reasonable Worst Case Load for 3M™ Steri-Vac™ GS5/GSX5 Sterilizer.

## Methods

The air quality was measured in the operator breathing zone and at various locations in the worker area; from immediately opening of the sterilizer door to 45 minutes after the sterilizer door was opened. These measurements were taken using:

- **Portable Analyzer for Ethylene Oxide**: This analyzer was equipped with an ethylene oxide sensor capable of sensing concentrations from 0–2 ppm, with a resolution of ± 0.02 ppm The instrument was carried in a pouch attached to the back of the vest worn by the operator. Air sampling was performed with the instrument intake tube in the operator's breathing zone (BZ), i.e., same height as the operator's nose and mouth. EO concentration data was collected at 1-second intervals.
- **Mini-canister**: Air sampling was performed using evacuated, fused silica mini-canisters (0.380 L) with flow regulators placed either in a front-facing pouch attached to the operator's vest and/or attached to the modular stand. The capillary intake tubes were placed either in the breathing zone of the operator or at a point specified by IEC 61010-2-040, Appendix II (IEC Point). These samples were subsequently analyzed for EO concentration in a GMP-certified lab. Air sampling with mini-canisters is considered the gold standard for measuring exposure levels.

The data collection area and monitors are shown in the photographs below:

**Figure 8:** The supplied air respirator as shown in the figure was used for experimental purposes during the development of the new sterilizer. The use of air respirator is not required for normal sterilizer use in a health care setting.


For sterilizers used in the health care setting utilizing FDA-cleared cycles, operator exposure was divided into three main phases.

- **Initial Unloading Phase:** The initial unloading phase consisted of retrieval of biological indicators (BIs) and chemical indicators (CIs), followed by vigorous handling of all sealed pouches, wrapped trays and containers while the load was transferred to a separate aerator. The task of unloading the sterilizer, expected to take no longer than 5 minutes, was intended to simulate the maximum exposure to a load at the earliest possible entry point of only 90 minutes aeration (and longer time points as well). After the initial 5 minutes, the sterilizer door was closed and EO measurement continued for an additional 10 minutes while the operator remained within close proximity to the empty sterilizer. This was intended to simulate the operator reviewing of the sterilizer cycle reports and other related tasks. The 15-minute air samples were collected simultaneously using two methods; evacuated canisters for later analysis in a GMP-complaint laboratory and real-time measurements using the EO Portable Analyzer.
- **Second Phase:** The second measurement phase consisted of two extra 15-minute periods simulating potential situations where the operator may remain in the vicinity of the sterilizer to complete paperwork and other job duties. The sterilizer door remained closed during this time.
- **Final Phase:** The last phase consisted of a 35-minute period spent outside the sterilizer room where exposures to EO were assumed to be zero.

Full shift (8 hour) time weighted average exposures were calculated from the data with the assumption that an operator would handle no more than 6 loads in a single shift.

The following summarizes the current OSHA[3] limits, called permissible exposure limits (PELs):

- **8-hour time-weighted average (TWA):** 1 part EO per million parts of air (1 ppm) measured as an 8-hour, time-weighted average.
- **15-minute Short-Term Excursion Limit (STEL):** 5 part EO per million parts of air (5 ppm) measured as a 15-minute, time-weighted average.

## Results

Operator breathing zone EO concentrations for each scenario were tabulated. The results for 38°C cycles from a 3M™ Steri-Vac™ GS8 are reported. The 38°C cycles resulted in higher concentrations (ppm) than 55°C and the GS8 has a slightly higher EO gas concentration in the chamber, therefore the GS8-38°C cycles are considered "worst case" from an operator exposure perspective. The table below indicates the 15-minute average EO concentrations measured for the initial handling phase after 38°C cycles.

**Table 2:** Average EO concentrations for GS8 loads after 90 minutes of aeration compared to the 15-minute STEL and 8-hour TWA. The 38°C cycles resulted in higher concentrations than 55°C and the GS8 has a slightly higher EO gas concentration, therefore the GS8-38°C cycles are considered "worst case" from an operator exposure perspective.

| Cycle Temp | Load Type | Initial 15-minute Load Handling Phase (ppm) | 15-minute STEL (ppm) | 8-hour TWA (ppm) |
|---|---|---|---|---|
| 38°C | Light | 0.06 ± 0.02 | 5.0 | 1.0 |
| | Product | 0.18 ± 0.11 | | |
| | Worst Case | 0.93 ± 0.52 | | |
| 55°C | Light | 0.02 ± 0.00 | | |
| | Product | 0.09 ± 0.03 | | |
| | Worst Case | 0.43 ± 0.20 | | |

## Exposure Study Conclusions

At no point did the measured exposure level exceed either the 15-minute average short-term exposure limit (STEL) of 5 ppm or the 8-hour time-weighted average (TWA) of 1 ppm in any of the 100+ test cycles.

Data analysis based on sterilizer installation according to 3M recommendations for sterilizer installation and operation as used in healthcare settings and analysis using the American Industrial Hygiene Association exposure assessment methodology[4] showed that:

- Loads aerated for 90 minutes showed that exposures were below 5 ppm for the 15-minute short term exposure and below 1 ppm for the 8-hour TWA when the load is handled for a maximum of 5 minutes **with** a functional hood.
- In the event of insufficient air flow to the door vent hood the sterilizer will automatically default to a minimum of a 3 hour aeration before the door can be opened. In this condition, loads aerated for 3 hours showed that exposures were below the 5 ppm STEL 15-minute short-term exposure limit and 0.55 ppm for the 8-hour TWA when the load is handled for a maximum of 5 minutes **without** a functional hood.
- Fully aerated loads (12 hours aeration) before removal, show that exposures were below 1 ppm for the 15-minute short-term exposure and 0.45 ppm for the 8-hour TWA when the load is handled for a maximum of 5 minutes **with** a functional hood.

## Conclusion

The GS series 3M™ Steri-Vac™ Sterilizer/Aerator sterilizers have demonstrated that they are safe when following installation and operating recommendations. The system incorporates a safe design with multiple controls to ensure operator safety including a below ambient pressure cycle, small single use cartridges, and software controls to minimize EO gas exposure. When installed properly, the sterilizer environment adds to the operator safety with a constant flow of fresh air that exchanges the room air volume 10 times per hour. In addition, operator safety was verified in an industrial hygiene study with state-of-the-art EO gas monitoring equipment.[2] Users can operate the sterilizer with confidence.

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