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

For Life Science Applications

Product Profile

3M

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3M™ Steri-Vac™ Sterilizer/Aerator GSX Series ethylene oxide (EO) sterilizer/aerators are designed to be used with 3M™ Steri-Gas™ EO Gas Cartridges to provide a safe and effective low temperature sterilization process for medical device, pharmaceutical, veterinary, laboratory and other non-healthcare applications.

The GSX Series sterilizer, Models GS5X and GS8X can automatically aerate the processed load in the sterilization chamber after EO gas sterilization. The GSX Series sterilizer is a self-contained system which requires only power, compressed air and exhaust vent lines for operation. No floor drains or bulk tanks of ethylene oxide are used. In addition, no external steam or water connections are required, as each GSX Series sterilizer has a self-contained internal distilled water tank filled by the Operator. The GSX Series sterilizer requires minimal floor space and can be installed free-standing, on a rack, or in-wall. Both the GS5X and GS8X sterilizers are available in a single door or double-door configuration, facilitating pass-through processing for controlled environments. Mounting frames and finishing fascia panels are also available. The GS5X and GS8X provide 136 L (4.8 cubic feet) and 224 L (7.9 cubic feet) of usable chamber space, respectively.

Preprogrammed Cycles

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series has two preprogrammed sterilization cycles when shipped from the factory, identified as GSX 38ºC and GSX 55ºC. The user may select and use the preprogrammed cycles with appropriate consideration of verification, validation, and documentation for their application. These cycles cannot be deleted from the sterilizer.

The critical sterilization process set points (temperature, humidity level, sterilant concentration, exposure time) for the preprogrammed cycles GSX 38ºC and GSX 55ºC are identical to the critical process set points in 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Models GS5 and GS8 validated per "U.S. FDA Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities." The end user is responsible to determine if these preprogrammed cycles are suitable for the specific application in regards to Operator safety, product safety and efficacy, and for any verification or validation documentation required for the specific application.

The key set points for each preprogrammed cycle are provided in Table 1. The cycle profile of a typical 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series cycle is provided in Figure 1. A description of the GSX Series sterilization process stages is provided in Figure 2.

Table 1. Preprogrammed Cycle Set Points

	GSX 38°C Cycle	GSX 55°C Cycle
Cycle Temperature	38°C ± 3ºC	55°C± 3ºC
Relative Humidity	40–80%	40–80%
EO Exposure Time	4.5 hours ± 5.4 minutes	1 hour ± 1.2 minutes
Aeration Temperature	38ºC ± 3ºC	55ºC± 3ºC

3M™ Steri-Gas™ EO Gas Cartridges

3M™ Steri-Vac™ Sterilizer/Aerator GSX Series ethylene oxide (EO) sterilizers are designed to be used with 3M™ Steri-Gas™ EO Gas Cartridges. Steri-Gas EO Gas Cartridges are single dose containers of 100% ethylene oxide. Each cartridge has a unique 2D barcode that is read by the barcode scanner on the GSX Series sterilizer. Scanning the cartridge enables the sterilizer to verify the lot code to ensure that the cartridge is the correct cartridge for the GSX Series sterilizer, is unused, and within its shelf life. Steri-Gas EO Gas Cartridges are available with different net fill weights of ethylene oxide, providing some flexibility in selection of EO concentration in the sterilization process.

The available 3M Steri-Gas EO Gas Cartridges and their respective nominal weight of EO are listed in Table 3.

The calculated empty chamber EO gas concentrations for each GSX Series sterilizer are provided in Tables 4 and 5.

Table 3. 3M Steri-Gas EO Gas Cartridge Specifications

Steri-Gas EO Cartridge	Sterilizer/Aerator Model	Nominal Fill Weight
4-100	GS5X and GS8X*	100 grams
4-134	GS5X and GS8X*	127 grams
8-170	GS8X	170 grams

* requires adapter

Table 4. EO Gas Concentrations for GSX Series sterilizer, Model GS5X

Steri-Gas EO Cartridge	Calculated Empty Chamber EO Concentration (mg/liter)
4-100	735
4-134	933

Table 5. EO Gas Concentrations for GSX Series sterilizer, Model GS8X

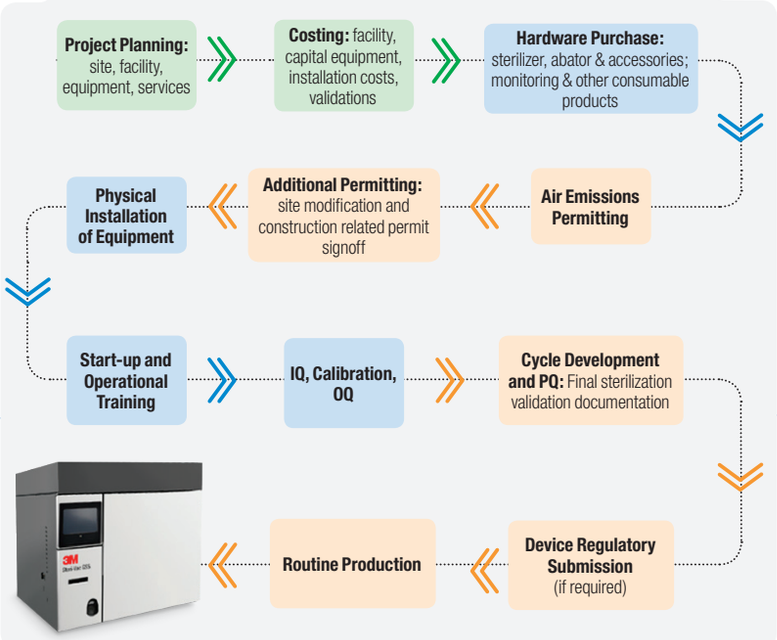
Steri-Gas EO Cartridge	Calculated Empty Chamber EO Concentration (mg/liter)
4-100	446
4-134	567
8-170	759

Setting up In-house Ethylene Oxide (EO) Sterilization

To establish in-house ethylene oxide (EO) sterilization capability with the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series, a number of actions are required. Figure 4 presents a high-level overview of this process.

3M will provide guidance and management of the steps noted in the blue shaded boxes. The green boxes represent tasks where 3M will provide information and advice but the user's facility will manage. The orange boxes are the responsibility of the user's facility, sometimes completed with assistance from external consulting organizations.

Figure 4. In-house Ethylene Oxide Sterilization Set-up Process



Reports and Data

The end user can select from three different cycle report formats (graph, table, or detailed) depending on preference and recordkeeping requirements. The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series allows end users to export one or more condensed cycle physical parameter files to a USB drive and can export up to 100 of the most recent cycle physical parameter files in under 60 minutes. The sterilizer also automatically retains the last 100 condensed cycle physical parameter files in a read-only folder on the sterilizer's local area network (LAN) accessible by Supervisor or higher access level users.

The GSX Series sterilizer allows users to view and print parameter values for any custom cycle installed on the sterilizer. This cycle report will display all parameters used by the custom cycle and the corresponding set point for each parameter.

Regulatory Status

Ethylene oxide (EO) sterilizers sold for use in industrial applications (i.e. outside a health care facility) are not regulated as medical devices by the United States Food and Drug Administration (FDA); therefore, they are not eligible for FDA 510(k) review and clearance. In the European Union, EO sterilizers sold for use in industrial applications are not considered medical devices and are not required to comply with the Medical Device Directive. In other countries, refer to local regulatory requirements. 3M Steri-Vac Sterilizer/Aerator GSX Series products are manufactured in the United States.

Figure 1. GSX Series Cycle Profile

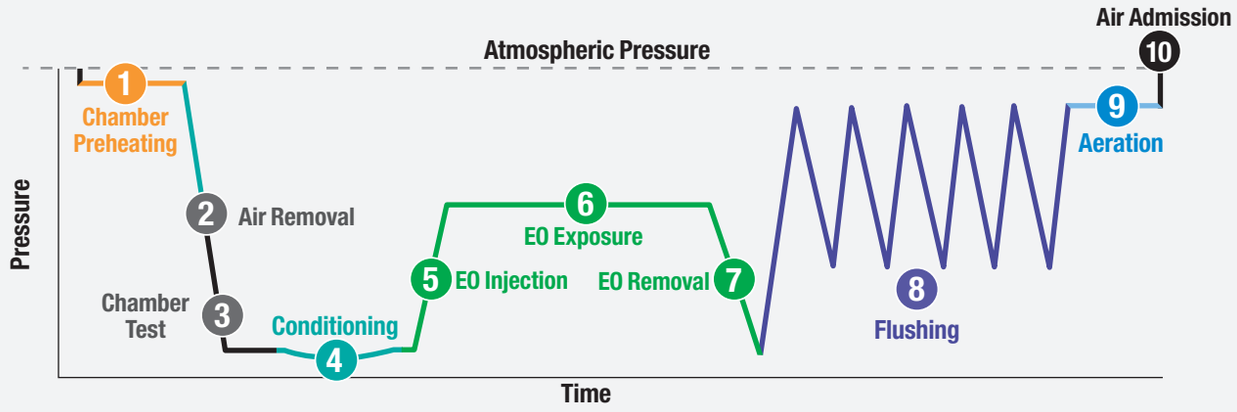


Figure 2. GSX Series Sterilization Process Stages

1 Preheat. Heating step, without humidification, to bring the chamber walls up to the target cycle temperature. The product load in the chamber will heat up during the Preheat stage, but the temperature of the load at the end of the stage will depend on a number of factors, including: load weight and density; material and packaging; the starting temperature of the chamber and the load; the temperature set point; and the preheat time.

2 Air Removal
Vacuum pump removes air from the chamber to prepare for the Chamber Test and Conditioning stages.

3 Chamber Test
A test of the integrity of the sterilization chamber by holding the chamber in vacuum and measuring an increase in pressure that could indicate a chamber leak.

4 Conditioning
Controlled low temperature steam injections to bring the chamber and load to the desired humidity level. Conditioning can also be used to continue to bring the product load to the target process temperature.

5 EO Injection
Final check of temperature, RH condition, and pressure level followed by puncture of the 3M™ Steri-Gas™ EO Gas Cartridge, releasing the ethylene oxide gas into the vaporizer, and then the chamber.

6 EO Exposure
The sterilization hold phase, where the product load is exposed to EO.

7 EO Removal
Single vacuum pump down of the chamber to remove ethylene oxide (EO) from the head space of the chamber and product packaging.

8 Flushing
A series of vacuum/air wash pulses, to further remove EO from the chamber and the load.

9 Aeration
Warm air continually moved through the chamber and over the load, to remove residual EO from the product.

Customized Cycles: 3M™ Cycle Programmer

The 3M™ Cycle Programmer is a software program that allows the user to develop unique and optimized ethylene oxide (EO) sterilization processes specifically tailored to their product requirements. The 3M Cycle Programmer allows programming of 29 different parameters in eight of the nine active stages of the EO sterilization process and operates on a personal computer (PC) supplied by the user. Custom cycles are created with the 3M Cycle Programmer and imported to the GSX Series sterilizer using a USB drive. The 3M Cycle Programmer does not function directly on the GSX Series sterilizer. The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series can be set up with different security levels (e.g. Supervisor, Operator) to allow control of the cycles on the equipment.

The 3M Cycle Programmer process flow is shown in Figure 3. For a summary of the programmable parameters, see Table 2.

The GSX Series sterilizers can be programmed with three different cycle report format options, as well as easy access to condensed cycle physical parameter files of the last 100 cycles. The condensed files can be exported in a read-only format via a USB drive.

Figure 3.
3M™ Cycle Programmer Process Flow

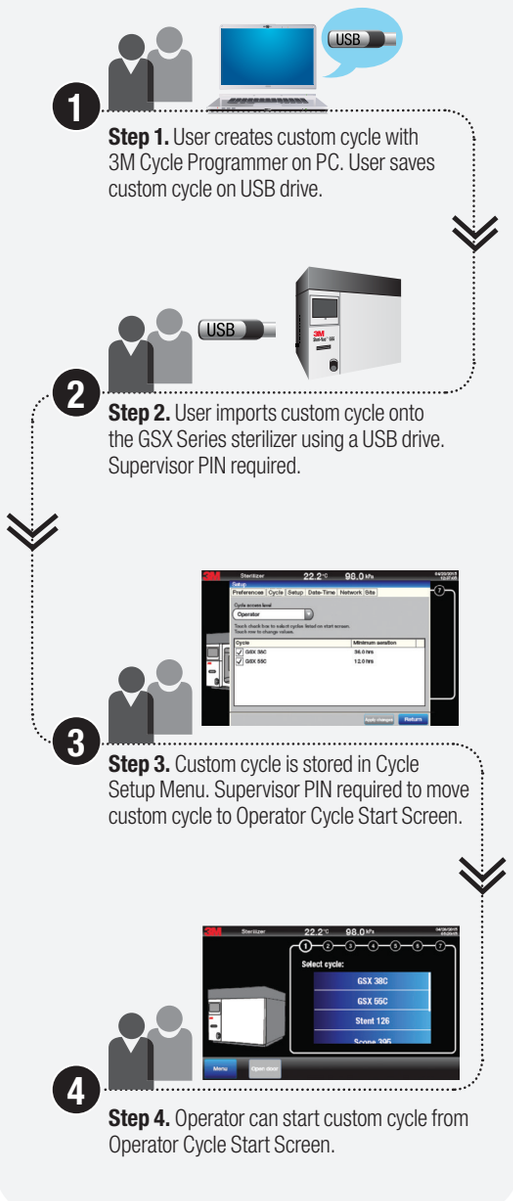


Table 2. 3M™ Cycle Programmer – Process Parameters

GSX Series Cycle Stages

	Parameter	Selectable Range	Description
1 Preheat	Cycle temperature	34–60°C	Chamber wall temperature set point.
	Timeout	30–200 minutes	Maximum time to reach the chamber wall temperature set point before the cycle is automatically cancelled.
	Hold time	0–999 minutes	Amount of time the sterilizer will stay in Preheat stage once the chamber wall temperature is reached.
2 Air Removal	Vaporizer temperature	95–99°C	Temperature of the heater block of the water and ethylene oxide (EO) vaporizer.
	Vacuum level	10–16 kPa	Target for the chamber pressure after air removal.
	Vacuum rate	25, 50, 75, 100%	Relative rates of air removal. This rate will be applied to all vacuum steps in the sterilization process.
3 Chamber Test	Duration	5–99 minutes	Amount of time the chamber must be within 1.8 kPa of the desired pressure, to measure for chamber integrity.
4 Conditioning	Relative Humidity (RH)	20–80%	Chamber relative humidity set point.
	Timeout	30–360 minutes	Maximum time to reach the RH set point before the cycle is automatically cancelled.
	Hold time	1–999 minutes	Time the chamber is held at the target temperature and RH, after the RH set point is reached.
	RH injection rate	Slow, Medium, Fast	Relative rates of steam injection.
	RH lower limit	Varies with RH set point	Low level of the RH tolerance range. Lowest acceptable chamber RH level tested during the Hold period. The cycle will automatically cancel if the chamber RH falls below this value. The lower limit set point options will vary based on the RH set point.
	RH upper limit	Varies with RH set point	Upper level of the RH tolerance range. Highest acceptable chamber RH level tested during the Hold period. The cycle will automatically cancel if the chamber RH rises above this value. The upper limit set point options will vary based on the RH set point.
5 EO Injection	Simulate EO	No, Yes	Cycle development or test option. No EO cartridge is needed if selecting the 'Yes' setting. The sterilizer will bring air into the chamber to increase the chamber pressure to simulate EO exposure.
	Vacuum level	10–16 kPa	Target chamber pressure before the EO cartridge is punctured.
	Minimum pressure increase	10–55 kPa	Minimum pressure increase expected 70 seconds after release of EO into the chamber. Failure to reach this pressure increase will automatically cancel the cycle.
	RH lower limit	10–55%	Lower level of the RH tolerance range. Lowest acceptable chamber RH level tested just before EO Injection. The cycle will automatically cancel if the chamber RH falls below this value.
	RH upper limit	65–90%	Highest level of the RH tolerance range. Highest acceptable chamber RH level tested just before EO Injection. The cycle will automatically cancel if the chamber RH goes above this value.
6 EO Exposure	Duration	0–999 minutes	EO sterilization phase hold time.
7 EO Removal	N/A	N/A	No programmable parameters.
8 Flushing	Number of flushing cycles	2–99	Number of fresh air purges followed by vacuum.
	Vent rate	25, 50, 75, 100%	Relative rate that fresh air is allowed into the chamber in flushing cycles.
	Hold time: top	1–99 minutes	Amount of time at the higher pressure end of a flushing cycle.
	Vacuum level	10–30 kPa	Target chamber pressure at the low vacuum end of each flushing cycle.
	Hold time: bottom	1–99 minutes	Amount of time at the lower pressure end of a flushing cycle.
	Locked aeration time	0–999 minutes	Amount of aeration before user can access the chamber.
	No exhaust hood aeration time	0–999 minutes	Amount of aeration before user can access the chamber if the exhaust hood option is not enabled or the air flow drops below 125 scfm in the hood.
9 Aeration	Aeration temperature	34–60°C	Target chamber temperature for the Aeration stage.
	Minimum aeration time	0–999 hours	Amount of time that aeration will continue before the sterilizer moves to Stand-by.

Product Support

3M offers equipment services to support installation, qualification and on-going maintenance of 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series products and accessory equipment. The following documents provide additional information related to accessory equipment, planning, installation, qualification, calibration and compliance:

- 3M™ Steri-Vac™ Ethylene Oxide Sterilization Systems (brochure)
- 3M™ Steri-Vac™ Sterilizer/Aerator Site Planning and Installation Guide
- 3M™ EO Abator Model 50 System (brochure)
- 3M™ EO Abator Site Planning and Installation Guide
- 3M™ Steri-Gas™ EO Gas Cartridge Product Profile
- SDS 3M™ Steri-Gas™ Cartridge 4-100
- SDS 3M™ Steri-Gas™ Cartridge 4-134
- SDS 3M™ Steri-Gas™ Cartridge 8-170
- 3M™ Steri-Vac™ Equipment Services (brochure)

To obtain these documents, visit **www.3m.com/infectionprevention** or contact your local 3M representative.

For general product information or to find your local U.S. 3M representative:

3M Health Care Customer Helpline
1 800 228 3957

Outside of the U.S. contact your local 3M office. Global office locations are available on our website: visit **www.3M.com** and select the specific country for access to your local 3M contacts.

Contact Information

Product Technical Information

3M Sterilization Tech Line (U.S. only)
1-800-441-1922, option 2

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