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Applied to Life.™



Product Profile.

3M™ Steri-Vac™ Sterilizer/Aerator GSX Series
For Life Science Applications

Product Profile.

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. Both the GS5X and GS8X can be used in one of two operational modes. Either preprogrammed sterilization processes may be used or the user may develop customised processes.

Preprogrammed Cycles

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series has two preprogrammed sterilization cycles when shipped from the factory, identified as GSX 38°C and GSX 55°C. 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 38°C and GSX 55°C 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		
	GSX 38°C Cycle	GSX 55°C Cycle
Cycle Temperature	38°C ± 3°C	55°C ± 3°C
Relative Humidity	40–80%	40–80%
EO Exposure Time	4.5 hours ± 5.4 minutes	1 hour ± 1.2 minutes
Aeration Temperature	38°C ± 3°C	55°C ± 3°C



Figure 1. GSX Series Cycle Profile

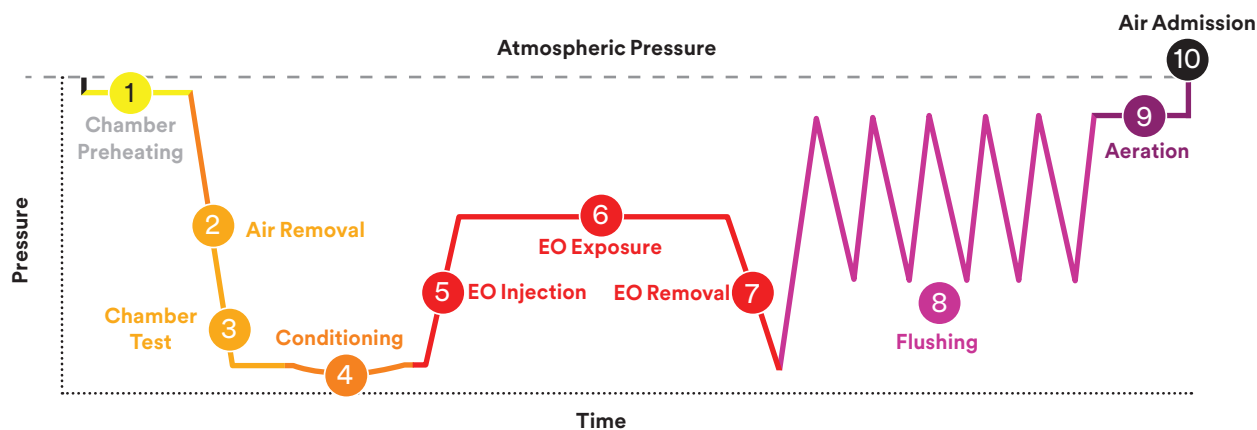
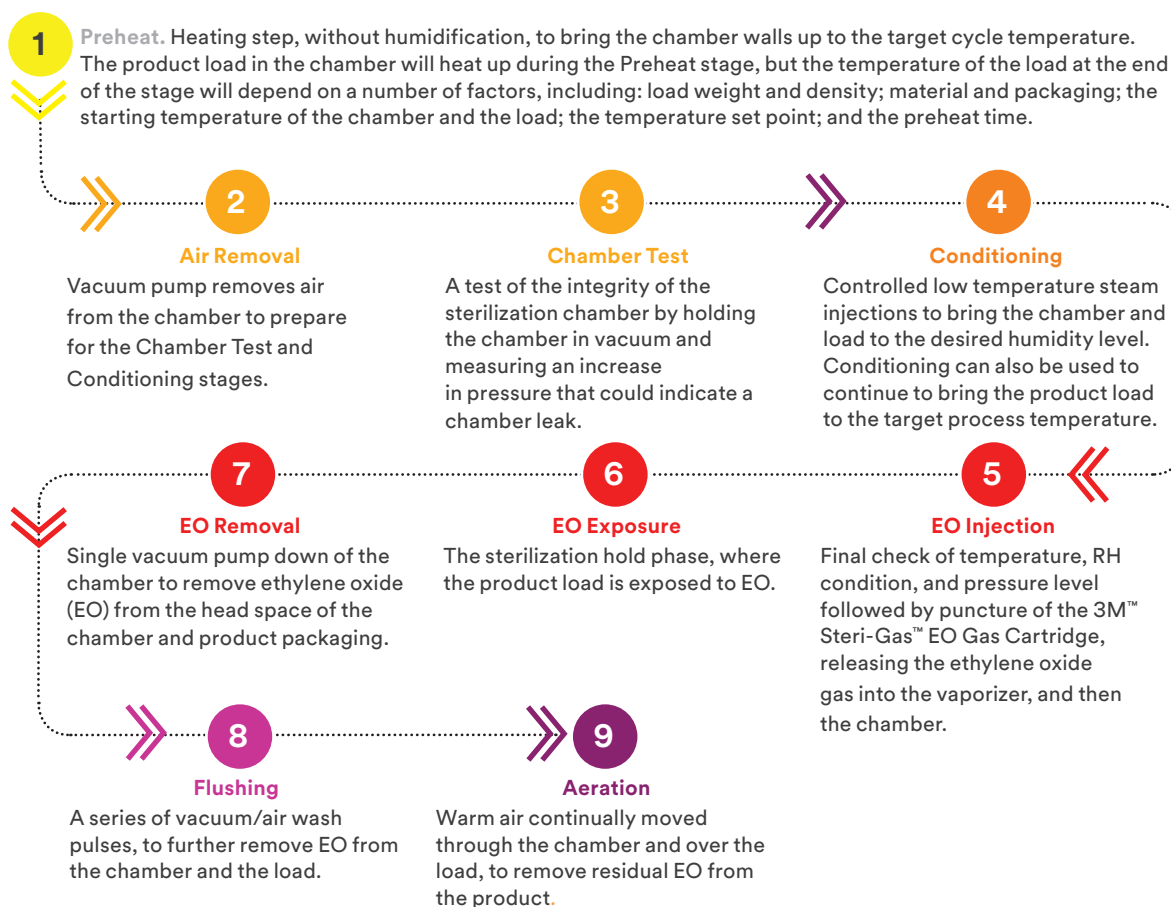


Figure 2. GSX Series Sterilization Process Stages



Customised 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

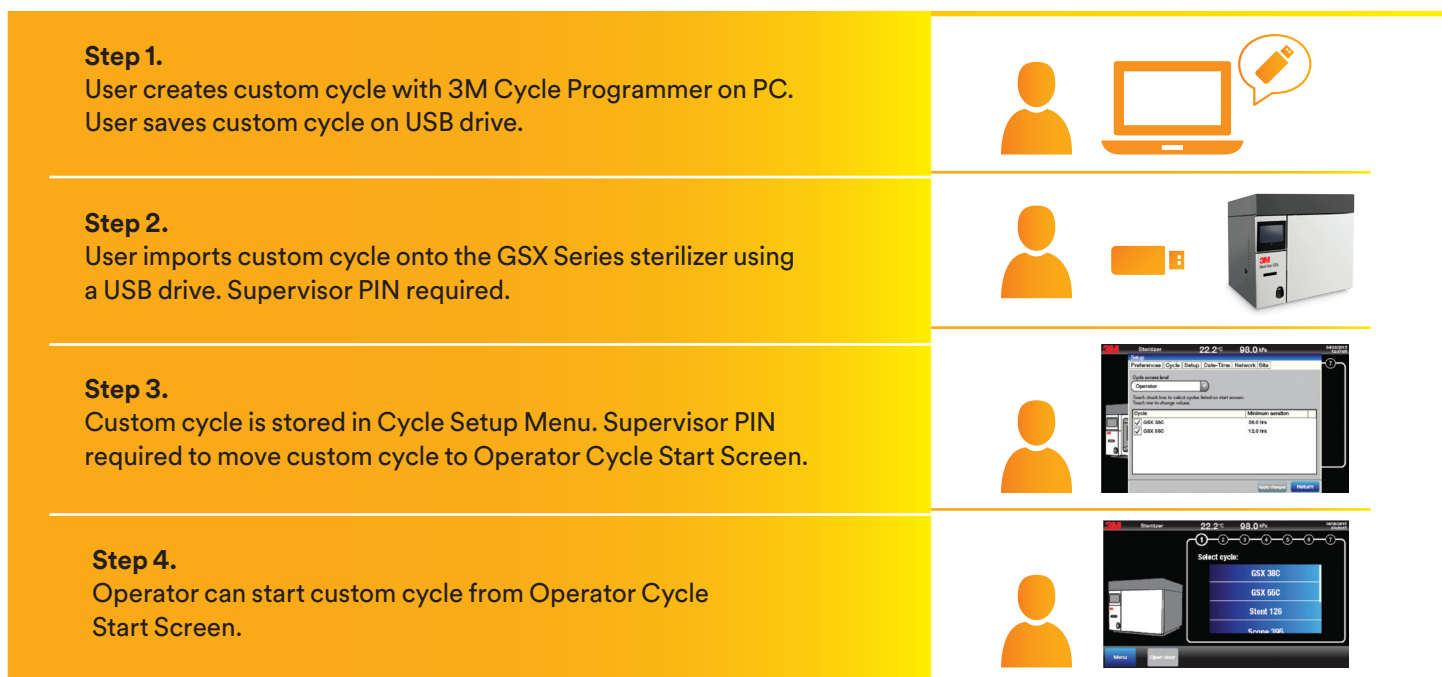


Table 2. 3M™ Cycle Programmer -Process Parameters

	Parameters	Selectable Range	Description
1	Preheat	Cycle temperature	34–60°C
		Timeout	30–200 minutes
		Hold time	0–999 minutes
2	Air Removal	Vaporizer temperature	95–99°C
		Vacuum level	10–16 kPa
		Vacuum rate	25, 50, 75, 100%
3	Chamber Test	Duration	5–99 minutes
4	Conditioning	Relative Humidity (RH)	20–80%
		Timeout	30–360 minutes
		Hold time	1–999 minutes
		RH injection rate	Slow, Medium, Fast
		RH lower limit	Varies with RH set point
		RH upper limit	Varies with RH set point
5	EO Injection	Simulate EO	No, Yes
		Vacuum level	10–16 kPa
		Minimum pressure increase	10–55 kPa
		RH lower limit	10–55%
		RH upper limit	65–90%
6	EO Exposure	Duration	0–999 minutes
7	EO Removal	N/A	N/A
8	Flushing	Number of flushing cycles	2–99
		Vent rate	25, 50, 75, 100%
		Hold time: top	1–99 minutes
		Vacuum level	10–30 kPa
		Hold time: bottom	1–99 minutes
		Locked aeration time	0–999 minutes
		No exhaust hood aeration time	0–999 minutes
9	Aeration	Aeration temperature	34–60°C
		Minimum aeration time	0–999 hours



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.

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.



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 yellow shaded boxes. The light orange 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

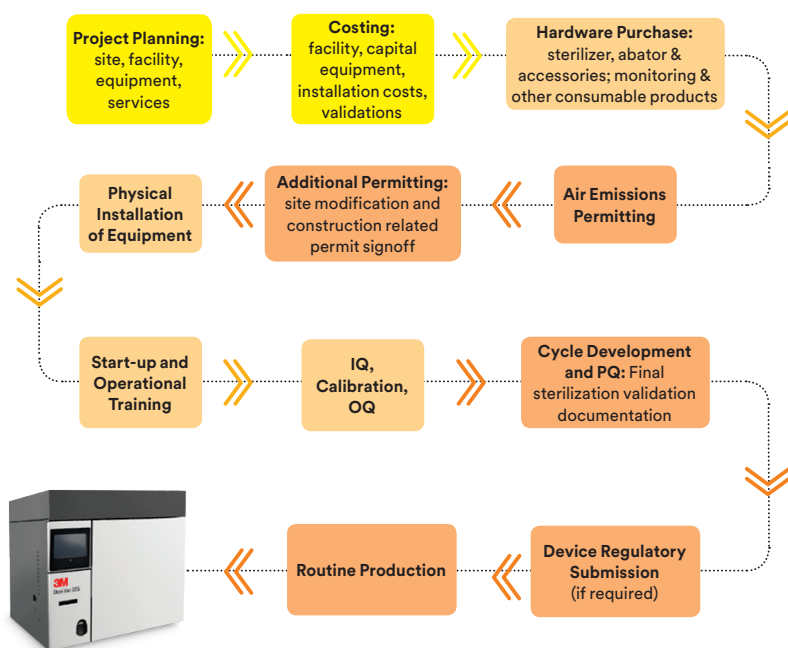


Table 3.

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



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 further information

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.

We're here to help!

Contact us for answers to any questions you may have, including guidance on choosing the correct Sterilizer and Monitoring products for your process. We also offer general application advice, product data, information on purchasing test samples and more.

Visit www.3M.ie or contact your local 3M representative to get started today.



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