

Science.
Applied to Life.

3M GS Steri-Vac Sterilizer

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Vietnam

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3M Steri-Vac 100% EO Sterilizer History



Introduction – Low Temp. Sterilizer vs EO Sterilizers

<p>Mixed EO Sterilizer</p>	<p>H2O2 Plasma</p>	<p>3M 100% Steri-Vac</p>
	<p>Steam Formaldehyde</p>	

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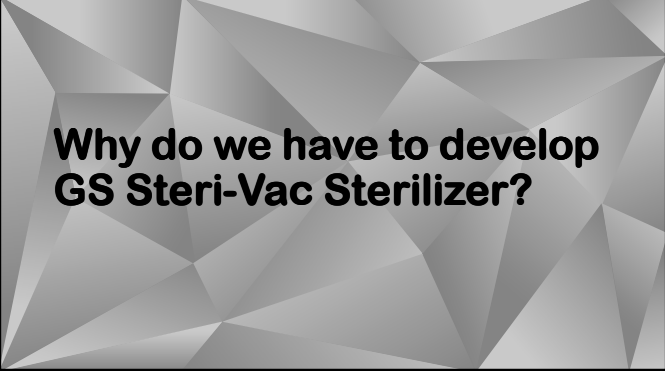
3M™ Steri-Vac™ EO Sterilizers - History of Innovation

- 1960's** – 3M Steri-Vac Models introduced
 - 100% EO single dose cartridges
- 1970's** - Updated sterilizer introduced
- 1980's** – 4XL model introduced
- 1990's** – 5XL models introduced
- 2000's** – Abator introduced and 5XL RH monitoring
- 2014** – GSX Series introduction
 - 3M Cycle Programmer
 - Chamber uniformity
 - Improved RH control

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Why do we have to develop GS Steri-Vac Sterilizer?



Compliance with Standards

The GS/GSX Series complies with all applicable requirements of the following U.S., European, and International standards . . .

- ISO 11135-1:2014** – Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- EN 1422:2014** – Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.
- ANSI/AAMI ST24:1999/(R)2013** – Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities
- AAMI ST41:2008/(R)2012** – Ethylene oxide sterilization in health care facilities: Safety and effectiveness
- EN ISO 15223-1:2012** – Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied Part 1: General requirements
- EN 1041-1:2008** – Information supplied by the manufacturer with medical devices

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Key International Standards

ISO 11135 (2014)

ISO 11135 compliant ethylene oxide sterilization processes can be developed, validated, and routinely operated using GS/GSX series Steri-Vac sterilizers.

- Capable of fractional and half cycles, varying RH, temperature, and EO concentration*
- Controlling and monitoring pressure, temperature and RH sensors
- Chamber uniformity to meet $\pm 3^\circ\text{C}$ exposure phase temperature uniformity recommendation (Informative Annex D, D.9.3.2 (b))

* Limited by EO cartridge fill weight



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Key International Standards

EN 1422 (2014)

3M Steri-Vac GS/GSX Series Sterilizers comply with all requirements of EN 1422 (2014) *Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.*

- Design, performance, and safety requirements

• Examples . . .

- Temperature sensors – maximum permissible error of 1°C
- Controlling and monitoring sensors, incl. minimum of two probes to measure chamber temperature, pressure
- RH instrumentation accuracy of ±10%

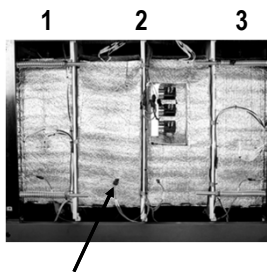


Sterilizer Design

Temperature control

Hardware

- Heating blankets and insulation
 - 95+ % of chamber wall, doors, sensors
- Three (3) zone temperature control
 - 3 independent (RTDs) / optimized positioning
- Allows for precise calibration
- Controlling & monitoring temperature sensors inside chamber

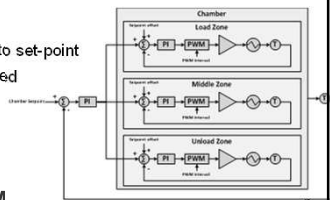


Sterilizer design

Temperature control (cont.)

Software - Cascade controller

- Cycle set-point accepted by outer proportion-integral (outer PI) loop
- Outer PI loop samples inside chamber
- Outer PI sends set-points to inner PI loop
- Inner PI loop (3 individual zones) controls to set-point
- Tighter control as cycle set-point approached
- Precision calibration inputs
- Monitoring sensor function



Sterilizer design

Relative humidity (RH) control

Hardware

- Improved sterilization cycle temperature
- Contiguous design
 - %RH sensors / valves / manifolds
- Temperature controlled custom manifolds
- Three (3) valve system for chamber sampling
 - Sequestered from EO exposure
 - Circulation of chamber environment
 - Every cycle dynamic sensor drying
- Controlling and Monitoring sensors

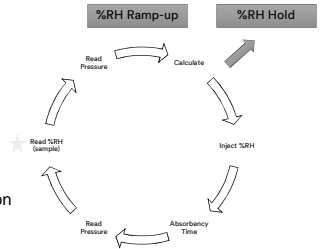


Sterilizer design

RH Control (cont.)

Software

- Partitioned to %RH Ramp-up and Hold
- Responds to (non)absorbency of load
- %RH sensor temperature compensations
- Dynamic in response
- Facilitates chamber environment circulation



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

Model GS5/GS5X

- Chamber Size: 4.8 ft³ (136 l)

Model GS8/GS8X

- Chamber Size: 7.9 ft³ (223 l)

- Single or double door
- In-wall, free standing on rack or table-top
- Product load baskets provided with each sterilizer



3M Steri-Vac Sterilizer/Aerator GS/GSX Series Ethylene Oxide Concentration Options

3M™ Steri-Gas™ EO Gas Cartridges



Nominal Empty Chamber EO Gas Concentrations (mg/l)

Steri-Gas Cartridge	GS5/GS5X	GS8/GS8X
4-100	735	N/A
8-170	N/A	762

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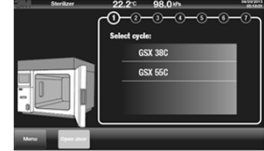


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3M Steri-Vac Sterilizer/Aerator GS/GSX Series

GS Cycle Selection for Hospital

GSX Cycle Selection for Industrial

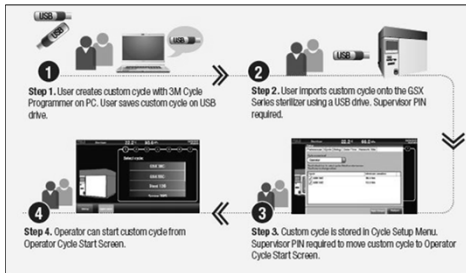


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Custom cycle design capability for Industrial (GSX)



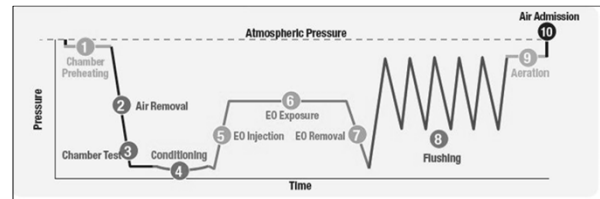
28 Process Set Points

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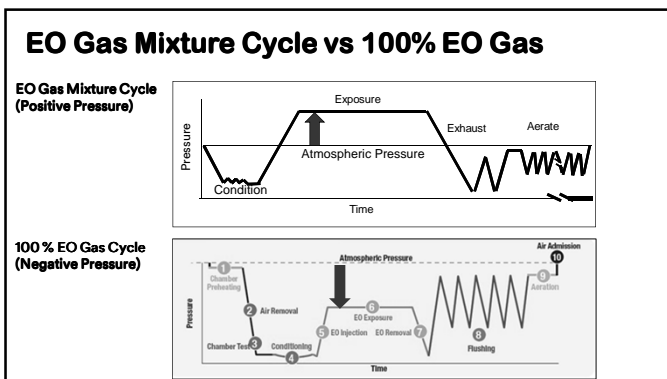
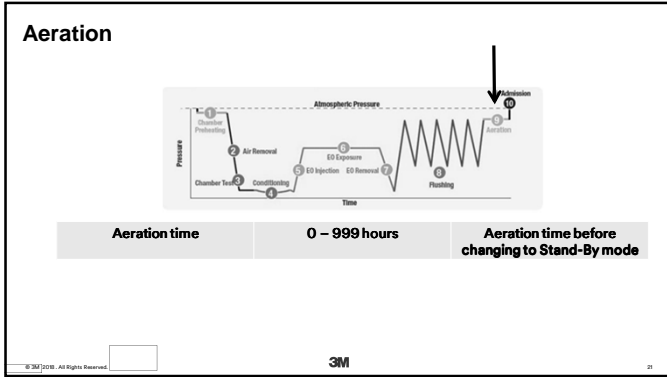
3M Steri-Vac EO Sterilization Cycle Stages



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Comparative Toxicity of EO, H2O2 and Formaldehyde

Sterilant	OSHA PEL	NIOSH IDLH
EO	1 ppm	800 ppm
H2O2	1 ppm	75 ppm
Formaldehyde	0.75 ppm	30 ppm

Source: Hilliker, D.J., *Employee Safety and Sterilant Gasses*, Infection Control Today, March 1998

Error Codes and Alarms

Error Codes

- 82 Error Codes

Recovery processes

- 9 Levels
- Described in Op Manual

ControllerChamberTempSensorError	1	Controller temperature sensor returns invalid reading beyond reasonable sensor range	Sensor output not in range 5°C < T < 65 °C
MonitorChamberTempSensorError	2	Monitor chamber temperature sensor returns invalid reading beyond reasonable sensor range	Sensor output not in range 5°C < T < 65 °C
LoadTempSensorError	3	Load zone temperature sensor returns invalid reading beyond reasonable sensor range	Sensor output not in range 5°C < T < 65 °C
MiddleTempSensorError	4	Middle zone temperature sensor returns invalid reading beyond reasonable sensor range	Sensor output not in range 5°C < T < 65 °C
UnloadTempSensorError	5	Unload zone temperature sensor returns invalid reading beyond reasonable sensor range	Sensor output not in range 5°C < T < 65 °C
HeatsinkTempSensorError	6	Heatsink temperature sensor returns invalid reading beyond reasonable sensor range	Sensor output not in range 5°C < T < 90 °C
ControllerRHTempSensorError	7	Controller RH temperature sensor returns invalid reading beyond reasonable sensor range	Sensor output not in range 0°C < T < 150 °C

Error Level	Description	Example Error	Corrective Action
11	Errors that occur before ethylene cycle (EO) are in the chamber and do not require immediate service attention.	Chamber has not shut as expected. Tripped interlocks. No "Open Door" or "Open Load Door" button is lit.	Operator can clear error and restart load. If tripped interlocks, check door. Push "Open Door" or "Open Load Door" button to clear. Clear the error. Reattempt per facility requirements.

Safety - Flammability

Small chamber – below requirements set in NFPA 560 (EO Sterilization/Fumigation)

- Steri-Gas below NFPA 55 (Compressed gasses) limits



1.1.1 This standard shall not apply to the following:

- (1) Nonflammable mixtures of ethylene oxide with other chemicals
- (2) Ethylene oxide manufacturing facilities, and container filling, refilling, or transfilling facilities
- (3) The off-site transportation of portable containers of ethylene oxide
- (4) Facilities using ethylene oxide as a chemical feedstock
- (5) Ethylene oxide in chambers 0.283 m³ (10 ft³) or less in volume, or for containers holding 200 g (7.05 oz) of ethylene oxide or less

NFPA 560 (2007)

1.1.2 Specific Applications. This code shall not apply to the following:

- (15) Ethylene oxide in chambers 10 scf (0.283 Nm³) or less in volume or for containers holding 7.05 oz (200 g) of ethylene oxide or less

NFPA 55 (2013)

Safety (flammability) (cont.)

➢ 3M Risk Management process (per EN ISO 14971:2012)

- Electromechanical design assessment (ignition source)
- UL Certification – Compliance to IEC 61010-1, 61010-2-10, and 61010-2-40

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

Environment – EO Abatement

Catalytic conversion of EO to CO₂ and H₂O (99.9%)

2 unit of GS/GSX Series/1 Abator

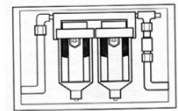
Internal or external installation



Preventative Maintenance And Professional Service

Daily Cleaning and Maintenance

- Chamber walls and floor
- Outer lip of chamber
- Inside surface of chamber
- Outer surface of chamber
- Door gasket
- Compressed Air Line Filters



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Preventative Maintenance Service Agreement / Optional Service

- **3M** Preventative Maintenance Agreement Program
 - Every 6 months
 - Conducted by 3M Authorized and Qualified Engineer
 - Charge Service Options
- 1 Customer

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