

3M Science.
Applied to Life.™



3M Sterilization

Cool and in Control.

3M™ Steri-Vac™ Sterilizer/ Aerator GSX Series Sterilization System for 100% Ethylene Oxide. Helping to Improve Throughput, Increase Control, Reduce Cost.

The Low Temperature Sterilization Process You Can Rely On.



3M™ Steri-Vac™ Sterilizer/Aerator GSX Series ethylene oxide (EO) sterilization system is the next generation in low temperature sterilization technology from 3M. Utilising 100% ethylene oxide – a traditional, efficacious and proven sterilant – the GS5X and GS8X sterilizer/aerators are designed for use in areas such as:

- Medical Device
- R&D
- Laboratory
- Contract Sterilization

3M Steri-Vac GSX Series sterilizer/aerators offer a state-of-the-art, fully compliant EO sterilization system with advanced features.

The unique design and capability of the GSX Series sterilizers allow manufacturers and suppliers the ability to improve throughput and efficiency. The 3M™ Cycle Programmer allows fast and easy custom design of cycles specific to the device to be sterilized – especially important for complex or combination drug/device type products.

The GSX Series sterilizers can help companies decrease cycle development and validation time, increase throughput time, simplify final lot release, and adapt to varying demands on production. Decreased production cycle time can provide a measurable, sustainable economic benefit and a solid return on investment.

The GSX Series sterilizer/aerator and related accessories provide an “order, install, qualify and run” system – reducing design, start-up and maintenance costs compared to custom-built systems. 3M also offers full service and consumable product support for EO sterilization.

3M™ Cycle Programmer

The unique 3M™ Cycle Programmer allows for custom cycle programming for up to 28 different cycle variables in 8 active stages of the sterilization process. It provides the ability to create and modify custom cycles quickly and with greater flexibility. The designated cycle designer creates custom cycles on a PC to import to the GSX Series sterilizer. The operator simply selects the customised cycle to run based on the load or test. Optimised cycles are programmed for the specific product to be sterilized.¹

GSX Series Design Features

- Single chamber capability for preconditioning, exposure and aeration
- Large, high-resolution colour touch screen with graphical user interface displays sterilization cycle stage, cycle temperature, real-time cycle status of the system, time elapsed, error codes and more
- Provides independent, dual monitor and control sensors for the critical parameters of temperature, pressure, relative humidity, per EN 1422
- State-of-the-art, proprietary, dynamic humidification process adapts and controls chamber relative humidity (RH) to accommodate various load configurations and packaging materials
- Three zone temperature control
- Continuous parameter monitoring
- Built-in, pre-programmed 38°C and 55°C cycles, if custom cycles are not needed
- GS5X and GS8X provide 136L (4.8 cubic feet) and 224 L (7.9 cubic feet) of usable chamber space, respectively
- Automatic door latch system and integrated vent hood
- Available in 14 languages

Operator Safety Design Features

- 3M™ Steri-Gas™ EO Gas Cartridges are sealed, single-dose cartridges designed to improve worker safety over large bulk ethylene oxide (EO) tanks or containers
- Barcode scanning system to verify and record the correct Steri-Gas EO Gas Cartridge is selected for the specified sterilizer and verifies the sterilant is within shelf life
- GSX Series sterilizers are designed for use only with the Steri-Gas EO Gas Cartridges and require the sterilizer door to be locked and chamber vacuum achieved before puncture
- Cycle will only run under negative chamber pressure to ensure the EO gas cannot escape into the operator work area
- Electronic controller will automatically cancel the cycle if errors are detected
- Aeration begins automatically after the sterilization exposure and gas purge phases are complete
- Integral safety vent hood is built in

Ethylene Oxide Sterilant

3M™ Steri-Vac™ Sterilizer/Aerator GSX Series ethylene oxide (EO) sterilizer/aerators are designed to be used only with 3M™ Steri-Gas™ EO Gas Cartridges that contain a single-dose of 100% ethylene oxide. Steri-Gas EO Gas Cartridges are available in three different EO net fill weights that provide options for various EO gas concentrations in the chamber.

Compliance

GSX Series sterilizer/aerators meet applicable device, safety, electrical and EMC standards. The units are compliant with EN 1422 (Sterilizers for medical purposes – Ethylene oxide sterilizers – Requirements and test methods). EN 1422 compliance enables cycle development for compliance to ISO 11135 (Sterilization of health-care products – Ethylene oxide – Requirements of the development, validation and routine control of sterilization process for medical devices). The GSX Series sterilizer/aerator is also compliant with:

- RoHS (2011/65/EU), CE Mark EMC (2004/108/EC), and Low Voltage (2006/95/EC) Directives
- IEC/EN 61010 (Safety requirements for electrical equipment for measurement, control and laboratory use – applicable sections); IEC 62304 (Medical device software – software life cycle processes)
- AOAC (Official method of Association for Analytical Communities, Method 966.05 Sporidical Activity of Disinfectants.)

If regional or local regulations call for EO abatement, the GSX Series sterilizer is compatible for use with the 3M™ Abator.



3M™ Steri-Vac™ Sterilizer/Aerator, Model GS5X

GSX Series sterilizer, Model GS5X provides a compact unit available in both single- and double-door designs (e.g., double-door is commonly used for clean-room or biological level containment environments). The GS5X is typically freestanding on a mounting rack or placed on a counter/table but can also be enclosed in a wall. This model is often used for R&D and other laboratory applications for cycle development and specialised testing.

Product Code	Description	Chamber Capacity	Chamber Dimensions (H x W x D)
GS5X - 1D	3M™ Steri-Vac™ Sterilizer/Aerator – Single Door	136 L (4.8 ft³)	38 × 43 × 83 cm (15 × 17 × 32.5 in.)
GS5X - 2D	3M™ Steri-Vac™ Sterilizer/Aerator – Double Door	136 L (4.8 ft³)	38 × 43 × 83 cm (15 × 17 × 32.5 in.)

3M™ Steri-Vac™ Sterilizer/ Aerator, Model GS8X

The GSX Series sterilizer, Model GS8X is a large capacity sterilizer/aerator that offers nearly twice the volume of the GS5X. Available in single-door or double-door (pass-through) designs, the GS8X is often installed in multiple unit configurations in production or sterile use settings, offering flexibility in responding to product demands by eliminating the need to build full pallets to process. Devices are often terminally sterilized in primary packaging and then proceed to final pack-out for release and shipment.

Product Code	Description	Chamber Capacity	Chamber Dimensions (H x W x D)
GS8X - 1D	3M™ Steri-Vac™ Sterilizer/Aerator – Single Door	224 L (7.9 ft³)	46.0×51.0×97.0 cm (18.0×20.0×38 in.)
GS8X - 2D	3M™ Steri-Vac™ Sterilizer/Aerator – Double Door	224 L (7.9 ft³)	46.0×51.0×97.0 cm (18.0×20.0×38 in.)

3M™ Abator, Models 50AN, 50AE and 50AJ

The 3M™ Abator is a highly effective device used to catalytically convert EO gas exhausted from the GSX Series sterilizer/aerators to CO₂ and water vapour. At normal operating conditions, removal efficiency is 99.9+% (when EO is > 100ppm), virtually eliminating emissions to meet environmental requirements. The 3M Abator is designed exclusively for use with 3M™ Steri-Vac™ GS and GSX Series sterilizer/aerators.

3M™ Steri-Vac™ XL Aerator

The 3M Steri-Vac XL Aerator is a cabinet that circulates warm, filtered air in the 136 L (4.8 ft³) chamber to effectively remove EO residuals from the goods or devices. Available in a compatible size for the GS5X, the XL Aerator has a selectable aeration temperature in the range of 36–55°C (99–131°F), will operate continuously, and offers a digital display of temperature and elapsed time. The XL Aerator can improve operational efficiency by allowing transfer of the load to free the GS5X to sterilize the next load. It is controlled via an adjustable timer.



3M™ EO Abator



Equipment, Qualification and Support Services.

Equipment, Qualification and Support Services

3M Health Care service personnel and authorised 3M service personnel offer complete services and support for 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series and accessory equipment. Provided by 3M authorised service professionals, a wide range of services are available worldwide to support and meet requirements for installing, maintaining and optimising performance of 3M manufactured equipment. In addition to basic installation, preventive maintenance contracts and emergency support, and qualification and calibration services, training programmes are available to qualify engineers to maintain and repair 3M equipment. 3M Technical Service specialists offer diagnostic consultations. Site planning information and assistance is available from 3M to help plan, execute and comply with site and equipment installation requirements.

Service	Recommended Frequency / Description
Installation Support	At installation of GSX Series sterilizer and sterilizer accessory equipment. Includes final connection and testing to specification.
Site Planning	On-site facility and site planning review. Includes site readiness verification.
Preventive Maintenance Agreement (PMA) for GSX Series sterilizer and accessory equipment	Available in both single year and extended agreements, PMA includes 6 month interval preventive maintenance visits, emergency service calls and technical telephone support.
Emergency On-site Service Call	Available as part of PMA or as per-call charge that provides diagnostic and repair service.
Installation and Operational Qualification	At installation and upon relocation of equipment. Available for GSX Series sterilizer, XL Aerator, 3M™ Abator and 3M™ Attest™ Auto-Reader 390G.
Calibration – GSX Series sterilizer	At installation as part of initial Operational Qualification Service and performed annually thereafter on-site.
Calibration – 3M™ Attest™ Auto-reader 390G	Mail-in service with loaner 3M™ Attest™ Auto-Reader 390G available. Includes general maintenance/repair and calibration.
3M Certified Service Training Programme	Provides training on basic maintenance and troubleshooting procedures. Includes 3M training and support materials.
3M Certified IOQ Training Programme	Provides training on installation qualification, operational qualification and sensor calibration procedures. Includes 3M training and support materials.
On-site Consultation	Post-installation service available on hourly basis.
Equipment Telephone Technical Support	Included with PMA and available for single session or annual programmes.
3M™ Cycle Programmer Technical Support (IT related)	No charge for 90 days from installation and available for single session or annual programme thereafter.

Self-contained Biological Indicator Systems for Ethylene Oxide Sterilization.

3M sterilization monitoring products provide reliable, compliant solutions to meet manufacturing and validation requirements for ethylene oxide (EO) sterilization processes. 3M developed the first self-contained biological indicator and the 3M™ Attest™ Rapid Readout Biological Indicator for Ethylene Oxide, providing the shortest incubation time for a biological indicator available with release time in 4 hours when used with 3M™ Attest™ Auto-reader 390G. Faster biological indicator final readout can allow for quicker release of production lots and can shorten validation timelines. 3M also offers 3M™ Comply™ Indicator Tape for Ethylene Oxide that can assist with material control.

3M™ Attest™ Rapid Readout Biological Indicator for Ethylene Oxide1294-S

- 3M proprietary technology
- Highly resistant, standardised population of Bacillus atrophaeus spores for EtO
- Provides all of the benefits of self-contained technology plus results in four hours
- Reduced incubation can improve inventory levels and increase turns
- Meets FDA classification as a biological indicator
- Complies with ISO 11138:2006, (R 2010), Parts 1 and 2

Code	Description	Packaging	Shipping
1294-S	3M™ Attest™ Rapid Readout Biological Indicator for Ethylene Oxide	300 each/box	2 boxes/case



3M™ Attest™ Biological Indicators for Ethylene Oxide Sterilization1264-S

- Highly resistant, standardised population of Bacillus atrophaeus spores for EtO
- Reduces the risk of post-processing contamination and false positives associated with spore strips
- Conventional self-contained technology benefits:
 - Simple culturing
 - Minimises false positives due to contamination
 - Cost-effective
- Routinely documented for incubation times of less than seven days (typically 48 hours)
- Complies with ISO and ANSI/AAMI/ISO 11138:2006, Parts 1 and 2

Code	Description	Packaging	Shipping
1264-S	3M™ Attest™ Biological Indicators for Ethylene Oxide Sterilization	300 each/box	2 boxes/case

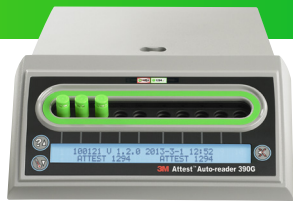


Featuring advanced electronics and internet connectivity, the 3M Attest Auto-reader 390G offers simplicity in use, remote interrogation of results via smartphone/tablet and easy integration into electronic quality management systems (LIMS). 3M™ Attest™ Auto-reader 390G is designed to incubate and automatically read the fluorescence of the Attest 1294-S Rapid Readout Biological Indicator in 4 hours.

Attest Incubators provide optimal conditions for accurate readout of Attest 1264-S Biological Indicators.

3M™ Attest™ Auto-readers390G

- Easy custom configuration buttons on top of the unit
- Remote viewing of BI results from your smart phone, tablet or PC
- Saving or printing incubation records from web app
- Ability to connect to select instrument-tracking software systems



Code	Description	Packaging	Shipping
390G	Auto-reader for Ethylene Oxide Sterilization. For use with 3M Attest Rapid Readout BI 1294, (37°C (98.6°F))	1 unit/box	1 box/case

3M™ Attest™ Biological Indicators Incubator127 & 129

- Convenient, 28-vial capacity visible from above
- Dry-block design pre-set to recommended 37°C incubation temperature



Code	Description	Packaging	Shipping
127	Biological Indicator Incubator 28 vial (2 tier), 37°C EtO 120 volt	1 unit/box	1 box/case
129	Biological Indicator Incubator 28-vial (2-tier), 37°C EtO 220/240 volt	1 unit/box	1 box/case

3M™ Comply™ Indicator Tapes for EO*1224

- Offers a reliable ethylene oxide process indicator in various widths to provide immediate identification of processed and unprocessed goods
- Assists with material flow and inventory operating procedures
- Compliant with ISO 11140:2005, Part 1 as a Class 1 Process Indicator
- Chemical indicator lines turn red when exposed to EO sterilization process



Code	Description	Shipping
1224-0	12.5 mm x 55 m (1/2 in x 60 yds) green	36 rolls/case
1224-25	25 mm x 55 m (1 in x 60 yds) green	18 rolls/case
1224-19	19 mm x 55 m (3/4 in x 60 yds) green	24 rolls/case

*Contains Dry Natural Rubber

Ordering Information

3M™ Steri-Vac™ Sterilizer/Aerator Products

Product	Description	Catalogue Number(s)	Size (H x W x D)	Packaging	Shipping
3M™ Steri-Vac™ Sterilizer/Aerator GSX Series, Model GS5X	Single Door	GS5X – 1D	70.9 × 76.2 × 95.0 cm (27.9 × 30.0 × 37.4 in.)	1/unit	1 unit/carton
	Double Door	GS5X – 2D	70.9 × 76.2 × 95.0 cm (27.9 × 30.0 × 37.4 in.)	1/unit	1 unit/carton
3M™ Steri-Vac™ Sterilizer/Aerator GSX Series, Model GS8X	Single Door	GS8X – 1D	179.8 × 94.0 × 109.0 cm (70.8 × 37.0 × 42.9 in.)	1/unit	1 unit/carton
	Double Door	GS8X – 2D	179.8 × 94.0 × 109.0 cm (70.8 × 37.0 × 42.9 in.)	1/unit	1 unit/carton
3M™ EO Abator	–	50, 50 AE, 50 AN, 50 AJ	80 × 82 × 105 cm (31 × 32 × 41 in.)	1/unit	1 unit/carton
3M™ Steri-Vac™ Aerator	Single Door	XL	41 × 46 × 84 cm (16 × 18 × 33 in.)	1/unit	1 unit/carton
	Double Door	XLS	41 × 46 × 84 cm (16 × 18 × 33 in.)	1/unit	1 unit/carton

3M™ Steri-Gas™ EO Gas Cartridges

Catalogue Number(s)	EO Net Fill Weight	Packaging	Shipping
4-100	100 g	12 units/box	1 box/case
4-134	127 g	12 units/box	1 box/case
8-170	170 g	12 units/box	1 box/case

Accessory Options for 3M™ Steri-Vac™ Sterilizer/Aerator Products

Product	Catalogue Number(s)	Size (H x W x D)	Packaging	Shipping
3M™ EO Monitoring Badge	3550	–	1/each	5 each/case
3M™ Printer Paper	1271	79 mm (3 ¼ in.) wide	1 roll/each	2 rolls/case
Loading Basket – Stainless Steel Lower Basket for GS5X	78805560402	39.0 × 80.0 × 18.0 cm (15.5 × 31.5 × 7.0 in.)	1/unit	1 unit/box
Loading Basket – Stainless Steel Upper Basket for GS5X, XL or XLS Aerator	78805560394	39.0 × 80.0 × 18.0 cm (15.5 × 31.5 × 7.0 in.)	1/unit	1 unit/box
Loading Basket – Stainless Steel Upper Half Basket for GS8X	78807853995	47.0 × 47.0 × 20.0 cm (18.5 × 18.5 × 8.0 in.)	1/unit	1 unit/box
Basket Cover – Stainless Steel Basket Cover/Chamber Tray for GS5X	78807832023	–	1/unit	1 unit/box
Stackable Basket – Stainless Steel for GS8X	78807883133	34.0 × 95.0 × 20.0 cm (18.5 × 37.5 × 8.0 in.)	1/unit	1 unit/box
Basket Cover – Stainless Steel Basket Cover for GS8X	78807862517	–	1/unit	1 unit/box

Monitoring Products for Ethylene Oxide Sterilization

Product	Description	Catalogue No(s)	Packaging	Shipping
3M™ Attest™ Rapid Readout Biological Indicator	Readout in 4 hrs.	1294-S	300 each/box	2 boxes/case
3M™ Attest™ Biological Indicator	Readout in ≥ 48 hrs.	1264-S	300 each/box	2 boxes/case
3M™ Attest™ Auto-reader	120 volt, for use with Attest 1294-S Rapid Readout BI	390G	1 unit/box	1 box/case
3M™ Attest™ Biological Indicator Incubators	220 volt, for use with Attest 1264-S BI	127	1 unit/box	1 box/case
	240 volt, for use with Attest 1264-S BI	129	1 unit/box	1 box/case
3M™ Attest™ Rapid Readout Test Pack	Each pack contains an Attest 1294-S Rapid Readout BI	1298	25 each/box	25 boxes/case
3M™ Attest™ Test Pack	Each pack contains an Attest 1264-S BI	1278	25 each/case	–
3M™ Comply™ Indicator Tapes	12.5 mm × 55 m (½ in × 60 yds), Green	1224-0	–	36 rolls/case
	25 mm × 55 m (1 in × 60 yds), Green	1224-25	–	18 rolls/case
	19 mm × 55 m (¾ in × 60 yds), Green	1224-19	–	24 rolls/case
3M™ Heavy Duty Tape Dispenser	Holds 2 rolls of 19 mm tape	C22	–	2 each/case



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