3M™ Steri-Vac™ Ethylene Oxide Sterilization Systems

Performance You Can Trust

For Health Care Facilities
Proven effective for broad use, low temperature sterilization of heat and moisture sensitive medical instruments and devices

3M™ Steri-Vac™ 5XL and 8XL dual-cycle 100% ethylene oxide (EO) gas sterilizer/aerator systems are designed to provide today’s highest level of sterilization assurance – using time-tested EO technology that has proven to offer a safe, effective and economical solution for low temperature sterilization applications.

Ethylene oxide is a highly-penetrating sterilant that offers superior efficacy for complex instrumentation, such as flexible endoscopes, and is compatible with most device materials. In fact, there are minimal design or lumen restrictions with EO technology, helping to simplify your sterilization procedures.

Standing the test of time

3M Steri-Vac systems have provided safe, effective and economical sterilization for decades. In fact, over half of all heat or moisture sensitive devices (including sterile single use devices made by manufacturers) are sterilized with ethylene oxide.

There are a number of other low- and high-temperature sterilizing technologies that do have their place in a healthcare facility’s overall equipment strategy; however, for best practice on today’s most critical low temperature sterilization challenges, you can rely on 3M Steri-Vac EO Systems.

Always consult the medical device manufacturer for their written reprocessing guidelines, including recommended ethylene oxide sterilization parameters and aeration time.
Compliance

3M™ Steri-Vac™ Ethylene Oxide Sterilization Systems are listed by Underwriters Laboratories Inc. (UL), and have met the requirements for the European Union Medical Device Directive CE marking. 3M™ Steri-Gas™ EO Cartridges are EPA registered (7182-1).

In addition, Steri-Vac systems have been cleared by the U.S. FDA as medical devices for healthcare settings. They allow the user to meet the requirements of ANSI/AAMI ST41: 2008: Ethylene Oxide sterilization in healthcare facilities: Safety and effectiveness.

Aeration begins automatically after the sterilization cycle is completed. The sterilization/aeration process can be accomplished in one chamber, allowing the user to comply with EPA single chamber process requirement.

3M Service

Steri-Vac Sterilization Systems are supported by a global network of field service technicians and affiliated service providers. These highly-trained professionals offer complete installation, operator training, preventative maintenance, emergency service and diagnostic assistance. In addition, 3M offers factory training to qualify your engineers to maintain and repair 3M equipment.

For more information, please contact your local 3M sales representative or call the 3M Health Care Helpline: 1-800-228-3957.

The 3M Advantage

3M's 45 technology platforms drive a product portfolio of more than 50,000 products sold to customers in nearly 200 countries. 3M has operations in more than 65 countries and 75,000 employees globally.

With 7,000 researchers in 34 laboratories worldwide, 3M invests heavily in continuing product improvement and development. That’s one reason why 3M is the leading supplier of small chamber ethylene oxide sterilization systems. And, 3M’s commitment to innovation, quality and customer focus has earned the trust of healthcare professionals, medical device manufacturers and researchers around the world. When you choose 3M, you choose the Gold Standard in trusted performance.
Balancing the concerns for safety, performance and environmental responsibility

Although it is a highly-effective sterilant, EO is regulated by the U.S. EPA. The EPA issued a Final Rule entitled, “National Emission Standards for Hospital Ethylene Oxide Sterilizers” designed to minimize EO emissions in the environment.

Specifically, the Final Rule requires that hospital EO sterilization facilities that do not have a pollution control device (such as a 3M™ EO Abator) must “… process full loads of items having a common aeration time, except where medical necessity dictates the use of less than a full load to protect human health.” In addition, such facilities must keep records detailing their compliance with these requirements.

Alternatively, a facility may demonstrate compliance with EPA standards by operating their sterilizers with a pollution control device – such as a 3M EO Abator. At normal operating temperatures and concentrations, the 3M Abator removes 99.9% of EO emissions, allowing hospitals to easily meet the most stringent emission requirements, and eliminating the need to only run full loads.

* When EO concentrations are greater than 100 ppm. When EO concentrations are less than 100 ppm, conversion efficiency is 99.0%.

3M™ EO Abator Model 50 System

The 3M™ EO Abator is a highly effective device used to convert EO exhausted from a sterilizer airstream. It is designed exclusively for use with 3M™ Steri-Vac™ Sterilizer Models 5XL and 8XL.

The 3M EO abator uses an exothermic (heat producing) reaction to convert EO exhaust into CO₂ and water vapor. At normal operating temperatures and concentrations, conversion efficiency is 99.9+%* – virtually eliminating emissions of EO to the environment!

The 3M EO Abator includes an enclosed catalyst bed, air heater, fan and all controls necessary for complete operation. The estimated life of the catalyst is three years, based on average use of 250 cycles per year. The unit comes complete, ready for installation and connection to the building utility service lines and sterilizer exhaust. Each EO Abator can be used with a maximum of two model 5XL or 8XL Sterilizers.

Exterior Dimensions

<table>
<thead>
<tr>
<th>Net Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 H x 32 W x 41 D (80 H x 82 W x 105 D)</td>
</tr>
</tbody>
</table>

At normal operating temperatures and concentrations, conversion efficiency is 99.9+%* – virtually eliminating emissions of EO to the environment!

1 Federal Register; Dec. 28, 2007, Vol. 72, No. 248
Trusted, proven technology – designed for safety and ease of use

Safer conditions for patients
The 100% EO sterilant used in Steri-Vac Systems is the most efficacious low temp sterilization option for all types of devices. It allows you to provide every patient with a wrapped, terminally sterilized device.

Safer for workers
Unlike older mixed gas systems which operate at or above atmospheric pressure, Steri-Vac systems operate at a vacuum (ie, under negative pressure) in a locked chamber. Designed for operator safety, Steri-Vac Systems use easy-to-handle, single dose 3M™ Steri-Gas™ EO cartridges.

Easier on instruments
EO is gentler on device materials compared to oxidative sterilants (such as hydrogen peroxide), helping to extend device life and reduce the need for repairs. In fact, EO sterilizers are the only low temperature sterilizers available without lumen or materials restrictions.

Easier on the environment
Ethylene oxide is a regulated material – meaning that procedures have been established for its safe, responsible use. A 3M™ Steri-Vac System provides a sustainable, responsible solution for the environment. The 3M EO Abator converts EO exhaust to CO₂ and water vapor with a conversion efficiency of 99.9%.*

Easy on your budget
The 100% EO technology of Steri-Vac 5XL and 8XL systems provides you a lower cost per sterilization cycle than either vaporized hydrogen peroxide or conventional mixed EO gas systems. And, with large chambers and broad configuration options, Steri-Vac systems offer simple and cost-effective operation.

*When EO concentrations are greater than 100 ppm. When EO concentrations are less than 100 ppm, conversion efficiency is 99.0%.

Achieving the highest level of assurance for complex, heat-sensitive devices

Why high-level disinfection may not be “good enough”
Because they offer so many places for microorganisms to hide, medical devices with complex configurations, such as flexible endoscopes, are inherently difficult to clean and sterilize. In fact, cross-contamination of flexible endoscopes is a growing safety risk to patients.

Although current standards allow the use of high-level disinfection for flexible endoscopes, it’s important to know that this method does not provide the highest level of patient safety. By definition, “disinfection” will reduce or eliminate most pathogens, but not the more resistant bacterial spores. Only some form of sterilization will kill all viable microorganisms, including spores.

Instruments and devices that could be damaged by the heat and moisture in steam sterilization should be sterilized in a low temperature system such as ethylene oxide, as employed in 3M™ Steri-Vac™ Systems, or by using a chemical sterilant, such as hydrogen peroxide.

The use of chemical sterilants on flexible endoscopes, however, may be limited by the lumen length and scope diameter. In fact, according to the U.S. FDA, “Sterilization with a liquid chemical sterilant may not convey the same sterility assurance as sterilization achieved using thermal or low temperature chemical gas/plasma/vapor sterilization methods. Liquid chemical sterilants should be limited to reprocessing only critical devices that are heat-sensitive and incompatible with other sterilization methods.”*

Ever since 3M introduced the first small chamber ethylene oxide sterilizer over 40 years ago, health care professionals around the world have come to trust the 3M Steri-Vac brand as the “Gold Standard” of protection for the patients in their care.

* “Preventing Cross-Contamination in Endoscope Processing” www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm
Product Overview

3M™ Steri-Vac™ Sterilizer/Aerator Model 8XL

Our largest capacity EO sterilizer. The extra-large chamber with a full-sized lower basket and two half-size upper baskets provides economical processing of large loads or larger surgical instruments.

The model 8XL features a sensing system that continuously monitors and controls relative humidity during the pre-conditioning phase to optimize moisture required for the exposure cycle (two temperature cycles: 55°C and 37°C). Dependable computer controlled electronic design provides accuracy, and automatically stops the cycle and displays codes if an error is detected.

Additional Features

• Digital display continuously shows cycle status
• Single unit-dose EO cartridge is punctured inside the locked, negative pressure chamber only when proper chamber conditions are achieved
• Continuous temperature monitoring automatically maintains the selected cycle temperature

<table>
<thead>
<tr>
<th>Exterior Dimensions</th>
<th>Chamber Dimensions</th>
<th>Chamber Capacity</th>
<th>EO Exposure &amp; Evacuation Cycles (Aeration is additional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inches (cm)</td>
<td>Inches (cm)</td>
<td></td>
<td>With Hood</td>
</tr>
<tr>
<td>70.5 H x 37 W x 43 D (179 H x 94 W x 109 D)</td>
<td>18 H x 20 W x 38 D (46 H x 51 W x 97 D)</td>
<td>7.9 cubic feet (223.7 liter)</td>
<td>Warm cycle: 131°F (55°C) Approx. 3.75 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cool cycle: 99°F (37°C) Approx. 5.5 hours</td>
</tr>
</tbody>
</table>

Options:

• Remote display panel can control/monitor up to four Steri-Vac Sterilizers/Aerators from a distance of up to 200 feet
• Free standing or in-wall recessed mounting system
• Single door or double door pass-through systems

Proven safety, performance and convenience

Both the Steri-Vac 8XL and 5XL systems allow in-wall installation or can be used freestanding, and offer a two-door pass-through feature for clean room applications. Their large capacity chambers allow you to sterilize more instruments per load, helping to keep your cost per item sterilized low. An automatic aeration cycle begins after the sterilization cycle is complete, reducing the potential for ethylene oxide exposure, and permitting compliance with the EPA single chamber process requirement. In addition, the system operates under vacuum for operator safety. A built-in printer records chamber temperature and vacuum, cycle number, temperature selected and aeration time for each load. Steri-Vac systems utilize small, sealed single-dose EO cartridges — eliminating the need for large bulk tanks.
3M™ Steri-Vac™ Sterilizer/Aerator Model 5XL

The model 5XL is a dual-cycle EO gas sterilizer that allows you to monitor and trace cycle operation. A single unit-dose EO cartridge is punctured inside the negative-pressure chamber only when proper chamber conditions are achieved. Continuous temperature monitoring maintains temperature of the selected cycle and automatically shuts off if the temperature exceeds setpoint.

Additional Features

• Digital display continuously shows cycle status
• Automatic, built-in aeration cycle
• Relative humidity is monitored during the precondition phase and prints RH level on output chart

<table>
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<tr>
<th>Exterior Dimensions</th>
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<tr>
<td>Inches (cm)</td>
<td>Inches (cm)</td>
<td></td>
<td>With Hood</td>
</tr>
<tr>
<td>27.5 H x 30 W x 35 D (70 H x 76 W x 89 D)</td>
<td>15 H x 17 W x 32.5 D (38 H x 43 W x 83 D)</td>
<td>4.8 cubic feet (136 liters)</td>
<td>Warm cycle: 131°F (55°C) Approx. 2.75 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cool cycle: 99°F (37°C) Approx. 4.75 hours</td>
</tr>
</tbody>
</table>

Options:

• Remote display panel can control/monitor up to four Steri-Vac Sterilizers /Aerators from a distance of up to 200 feet
• Local exhaust hood
• Free standing or in-wall recessed mounting system
• Single door or double door pass-through systems

3M™ Steri-Gas™ Ethylene Oxide Cartridges for 8XL and 5XL systems

Steri-Vac ethylene oxide systems are engineered to provide a safer system than gas tank systems. Our easy-to-handle, single-dose 3M™ Steri-Gas™ EO Cartridges reduce the potential for gas leakage and EO exposure.

Engineered to provide operator safety, the canister is punctured only when the chamber door is sealed and the proper vacuum has been drawn inside the negative pressure sterilizer chamber.
<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog Number</th>
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<tbody>
<tr>
<td>3M™ Steri-Vac Sterilizer/Aerator Model 8XL</td>
<td>Model 8XL</td>
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<tr>
<td>3M™ Steri-Vac Sterilizer/Aerator Model 5XL</td>
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</tr>
<tr>
<td>3M™ EO Abator Model 50 System</td>
<td>Model 50</td>
</tr>
<tr>
<td>3M™ Steri-Gas™ 100% EO Cartridge</td>
<td>8-170, 4-100</td>
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<tr>
<td>EO Monitoring Badges</td>
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<td>Remote Display Panel</td>
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<td>In-Wall Mounting Units</td>
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<td>Stainless Steel Baskets</td>
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