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LEARNING OBJECTIVES

- 1. Understand the fundamentals of the ethylene oxide (EO) sterilization process.
- 2. Understand the safety features of an EO sterilizer.
- 3. Identify the safety standards that govern EO sterilizers.



SELF-STUDY SERIES Ethylene oxide

Safe and effective low temperature sterilization

Jeff Wiser, BSEET, MSSE, CCSVP

thylene oxide (EO) is the traditional gold standard for low-temperature sterilization with its robust process that can sterilize heat and moisture sensitive devices. The ability to penetrate complex medical devices and long lumens without condensing or breaking down, and its excellent materials compatibility are the basis for its long-term use in both hospital and industrial sterilization practices.

Flexible endoscopes have been linked to several significant clinical outbreaks.¹ Often, infections continued despite endoscopes being properly cleaned and reprocessed according to the manufacturer's instructions and in compliance with the guidelines.² Several outbreaks were halted by adding EO sterilization to the process.²

Based on their initial use as an observation and diagnostic tool, flexible endoscopes are typically considered a semi-critical device and are therefore high level disinfected. High level disinfection (HLD) is designed to kill all vegetative bacteria, but not necessarily all bacterial spores. In the past, infections related to improperly reprocessed endoscopes may have been easily treated with antibiotics, but with the rise of multidrug resistant organisms (MDROs) there is concern regarding this approach. The true risk of infection related to endoscopy procedures is currently unknown, but a recent study suggested that for certain types of procedures, infections may be in the 'common' range with current practices.3 In addition, endoscope technology has advanced from an observational instrument to a surgical accessory that is used in complex minimally invasive surgical procedures. Flexible endoscope accessories now commonly enter sterile tissue and/or have contact with blood which can increase the infection risk for the patient. Endoscope sterilization is becoming more common and experts are recommending to consider these devices as critical devices to align with their clinical use.4

As health care facilities explore terminal sterilization of flexible endoscopes, there has been renewed interest in EO sterilization, as this sterilization modality is often validated by flexible endoscope manufacturers and included in the IFUs. This article will discuss the operation of modern EO sterilizers and address some common misconceptions.

Is ethylene oxide sterilization safe for patients and staff?

Yes, EO sterilization is a safe and effective process for both staff and patients. As a microbiocidal chemical, EO is an effective sterilant, just like vaporized hydrogen peroxide and other low-temperature chemical sterilants. And like other sterilization processes, EO sterilization is safe when performed properly. While state and local regulations relating to EO sterilization exist, at the federal level, the US Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and Occupational Safety and Health Organization (OSHA) regulate the sterilization equipment, sterilant, and sterilization process to ensure patient and operator safety. To protect workers, OSHA has established EO exposure limits just like all other chemical sterilants.5 EO sterilizers, when properly installed and operated according to manufacturer's instructions, are designed to ensure operator exposure is below these levels.

For the safety of patients and staff, the sterilized items must be properly aerated to remove the EO that has penetrated into the medical devices. The device manufacturer's IFU will determine how long of an aeration is required. The EO sterilizer may have a default aeration time, but it is recommended to follow the medical device manufacturers IFU instead. The sterilizer operator should review the aeration parameters along with the cycle parameters after each cycle to make sure that all parameters were met.

Sterilizer safety features:

Currently marketed, compliant EO sterilizers with a rigid chamber have a number of safety features that are designed to keep both staff and patients safe. The design

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features can be grouped into 4 main categories, single dose EO cartridge-based gas delivery, negative (below atmospheric) pressure throughout the cycle, smart software control systems, and in-chamber aeration.

The foundation of the safe design of the typical rigid chamber EO sterilizer is based on the following design features:

- 1. Single Dose EO Cartridge Based Gas Delivery has eliminated the need for handling/switching out of large EO tanks and reduced potential accidental EO release to less than 200 grams (< 7 ounces). There is no risk of exposure from large multiple load sterilant containers, external tank changeover or external supply fittings and piping as there was in the past.
- 2. Negative (below atmospheric) Pressure throughout the Cycle The sterilization cycle operates under a vacuum, so any breach of the chamber would result in a leak of room air into the chamber rather than ethylene oxide gas leaking out of the chamber. At the beginning of each cycle, the sterilizer performs a chamber leak test. If the chamber leaks or there is not a deep enough vacuum, the sterilizer will error and halt operation prior to EO injection. In addition, a chamber vacuum is required to puncture the EO cartridge and release the EO into the sterilization chamber. If the chamber leaks or there is not a deep enough vacuum, the cartridge puncture system will not operate, the cartridge remains un-punctured, and EO will remain safely in the single dose cartridge. The vacuum also holds the door closed and sealed independent of the controls or operator. The door cannot be opened when EO is in the chamber.⁶



Figure 1:Typical EO sterilization cycle.

- 3. **Software Control System:** The software control system monitors the sterilizer performance and generates errors in case of malfunction. Most EO rigid chamber sterilization systems will lock the chamber to prevent operator access if an unsafe condition exists.⁶
- 4. **In-chamber aeration** immediately following the sterilization cycle removes the need to handle loads prior to full aeration and facilitates compliance with the EPA requirement for a single-chamber process.⁷

Safe environment for the operator

Ventilation

Proper installation of the EO sterilizer requires providing air flow away from operator's breathing zone and installation in a room with a minimum of 10 room air exchanges per hour as described

Test Answers: 1. A, 2. A, 3. A, 4. A, 5. B, 6. B, 7. A, 8. A, 9. A, 10. A



Air flow washes entire room. Air movement is away from operator.

Figure 2: This illustration indicates the proper airflow pattern for rooms with EO sterilizers.

in the AAMI/ANSI ST41: Ethylene oxide sterilization in health care facilities: Safety and Effectiveness standard.⁸ This can be seen in the figures above:

Some EO sterilizers also include a door vent hood. The vent hood is an additional layer of safety for the operator that pulls room air past the operator into the hood vent supplying fresh air into the operator's breathing zone. The door vent hood (exhaust hood) supplements the room's directional air flow.



Figure 3: The door vent hood draws air from above the chamber opening reducing the amount of chamber air reaching the operator.

EO should always be vented to the outside of the facility and away from any of the building intake vents. Ethylene oxide is not persistent in the environment because it is reactive and is biodegradable by biotic and abiotic processes such as rapid evaporation, biochemical oxidation, reactivity, volatilization, and dilution. Ethylene oxide has also been shown to have low-to-moderate aquatic toxicity, and as a result, does not present a significant risk to the environment.⁹

EO Emissions

To minimize EO emissions, the US EPA recommends that hospitals sterilize full loads of items having a common aeration time



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except during emergency circumstances.⁷ In addition, the use of pollution control equipment to minimize EO emissions is required in several states in the United States of America and some countries. An abator, or an air pollution control device that converts exhausted EO to CO_2 and water vapor with high efficiency, can be used to satisfy this requirement.

Reduced flammability risk

Ethylene oxide gas is flammable in concentrations between 3% and 100% in air. Modern EO sterilizers are designed to reduce these risks associated with the use of ethylene oxide gas:

EO gas cartridges

Because of the small quantity of ethylene oxide in a single dose cartridge, EO cartridges are excluded from the requirements of NFPA 55 (Compressed Gases and Cryogenics Code; 2013) and NFPA 560 (Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation; 2007). These standards exclude containers that contain 200g of ethylene oxide or less.¹⁰

Sterilizer chamber

The sterilizer controls the temperature in the chamber to keep the maximum chamber temperature well below the EO autoignition temperature (>429°C). In addition, the sterilizers are designed <u>without</u> <u>any source of ignition</u> inside the sterilizer chamber during the process. The sensors and mechanical components contacting the EO gas inside the chamber are not an ignition source.

The small chamber size is also excluded from the requirements of NFPA 560 (Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation; 2007). This standard excludes chambers 10 ft³ (0.28 m³) or less in volume.¹⁰

Standards compliance

EO sterilizers marketed in the US must be cleared by the U.S. Food and Drug Administration (FDA). In addition, there are several US and global standards and regulations that apply to EO sterilizers. When considering the purchase of an EO sterilizer check, for FDA clearance and compliance to:

• <u>IEC/EN 61010-1:2010</u> Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.

- <u>IEC/EN 61010-2-010:2014</u> Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.
- <u>IEC/EN 61010-2-040:2015</u> Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for Sterilizer/Aerators and washerdisinfectors used to treat medical devices.
- <u>RoHS Directive, Directive 2011/65/EU</u> of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
- <u>IEC 61326-1:2012</u> Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.
- EMC requirements of the <u>CE mark EMC</u> <u>Directive 2004/108/EC</u>.
- Australian EMC requirements as confirmed in the Supplier's Declaration of Conformity that is linked to the RCM Mark.
- As a Class A digital apparatus meeting all requirements of the Canadian Interference-Causing Equipment Regulations.
- EMC per <u>IEC/EN 61326-1</u>, and Australian C-tick and Japan JSS
- <u>ISO 11135:2007</u> Sterilization of healthcare products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
- <u>ANSI/AAMI ST41:2008/(R)2012</u> Ethylene oxide sterilization in health care facilities: Safety and effectiveness
- <u>EN 1422:2014</u> Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.
- Official Method of Association for <u>Ana-lytical Communities (AOAC)</u>, 14th ed., <u>Chapter 4, Disinfectants, Par. 4.033-4.035</u> [Method 966.04 Sporicidal Activity of Disinfectants
- Development process compliant with <u>ANSI/AAMI/IEC 62304:2006</u> Medical devices software—Software life cycle processes.
- ANSI/AAMI ST24?

Is EO banned?

EO is not banned by any U.S. regulatory agencies. Ethylene oxide continues to be broadly used for the processing of medical devices, food products, cosmetics, museum artifacts and manufacturing. According to the Ethylene Oxide Sterilization Association (EOSA), over 4 billion pounds of EO is produced each year in the United States.¹¹ While most of the EO is used to make common household products such as detergents, polyester, cosmetics and antifreeze, only a small fraction is used as a medical sterilant.

In the U.S., FDA, EPA and OSHA, among others, have all established regulations for the use of EO. They have not banned its use but recognize the critical need for its use. Confusion regarding this point may be the result of the EPA regulation banning CFCs and HCFCs formerly used in large EO bulk tank gas mixtures. This type of EO gas mixture is no longer available in the US.

Isn't EO going away?

EO sterilization remains an effective and robust sterilization method for heat and moisture sensitive instruments and is a leading choice for terminal flexible endoscope sterilization. Thousands of 100% EO sterilizers are in use today, in over 70 countries and every state in the continental U.S. Just as important, companies continue to install more units to address the growing needs of sterilizing complex medical devices, as well as the need for low-cost, low-temperature sterilization. You can expect EO sterilizers and accessories to be available today and long into the future. **HPN**

Jeff Wiser is a Technical Service Engineer with 3M Medical Solutions Division. He provides technical assistance for 3M products includ-

ing Steri-Vac Ethylene Oxide Sterilizers, 3M Red Dot Electrodes, ECG Cables/Lead wires and Electrosurgical pads. Jeff has over 25 years of experience working in the medical device industry



including patient monitoring, implantable cardiac devices and sterilization equipment. He is an expert in electro-mechanical systems and participates in standards development activities both at AAMI and at the international level with the – IEC International electrotechnical commission – which develop standards for medical electrical devices and accessories.

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CONTINUING EDUCATION TEST · FEBRUARY 2019

Ethylene oxide

Safe and effective low temperature sterilization

Circle the one correct answer:

- 1. Ethylene oxide does not condense or break down during the sterilization process.
 - A. True B. False
- 2. Flexible endoscopes are used in surgical procedures. A. True B. False
- When added to endoscope reprocessing, ethylene oxide sterilization has contributed to the halting of endoscope related outbreaks.
 A. True
 B. False
- 4. The entire EO sterilization process is performed in a sealed chamber under a vacuum.
 - A. True B. False
- 5. The EO sterilizer should be installed in a room with no ventilation. A True B False

- 6. Ethylene Oxide is the only low chemical sterilant with OSHA permissible exposure limits.
- 7. Multiple US federal regulatory agencies have regulations that apply to the EO sterilization process and the sterilizers.
 - A. True B. False
- 8. EO sterilization has not been banned in any US state. A. True B. False
- 9. Modern sterilizers manufactured in the US should conform to multiple US and international safety standards. A. True B. False
- 10. Small single does EO cartridges are not regulated by the National Fire Protection Agency (NFPA)
 - A. True B. False

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exposure limits. A. True B. False