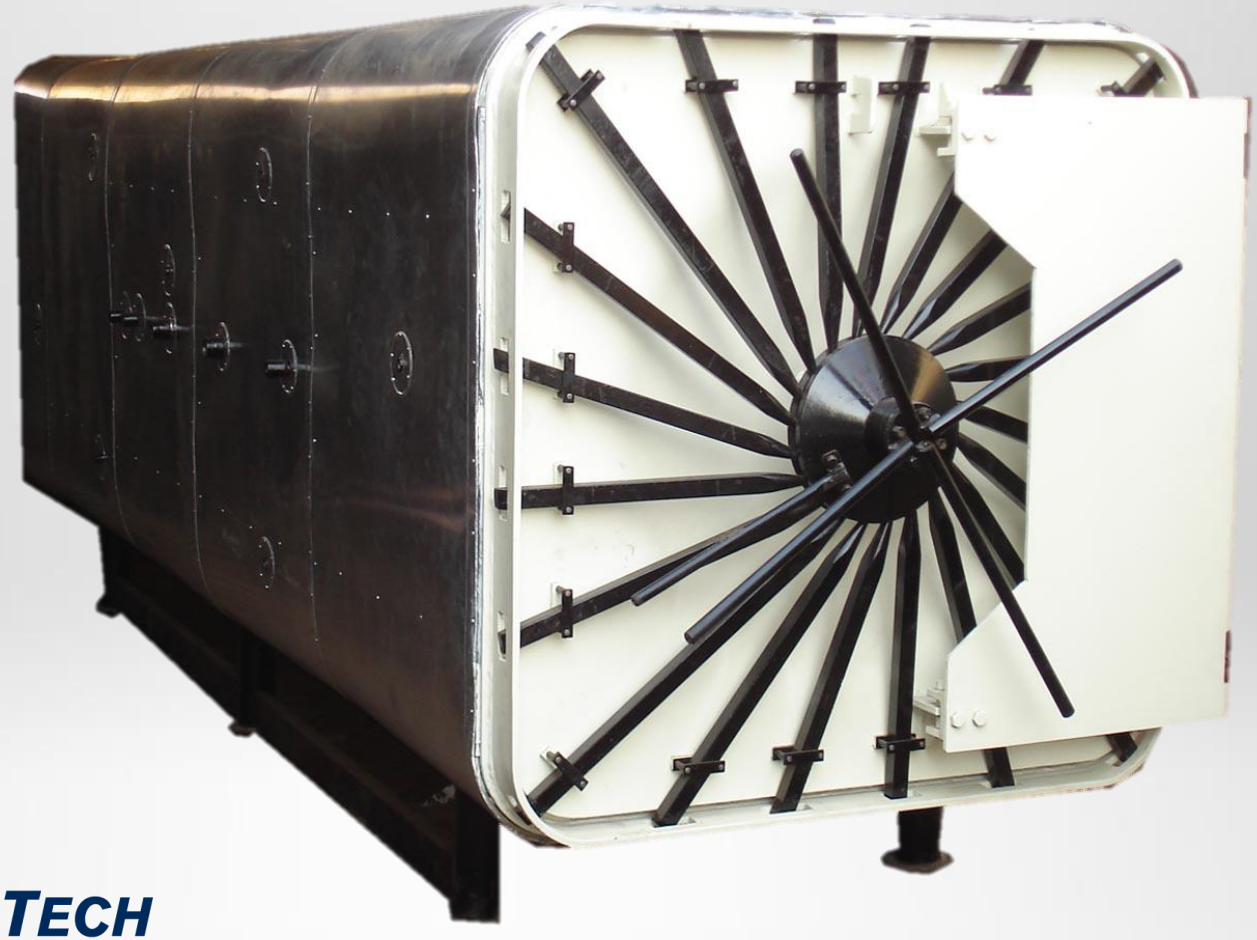
Introduction to

Ethylene Oxide *(EO/EtO)* Sterilization



MADGETECH
WE BUILD DATA LOGGERS

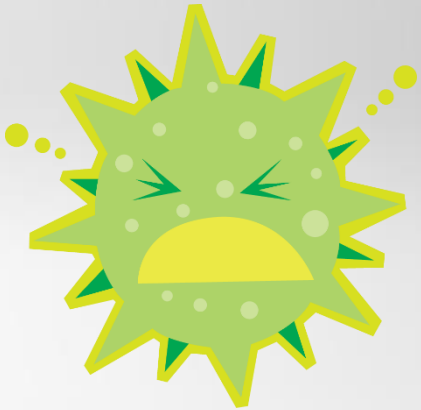
About Ethylene-Oxide

- EO is a gas that is 1.5 times heavier than air and tends to settle along the floor.
- At concentrations below 500 ppm, EO is colorless and odorless.
- At concentrations above 500 ppm, EO has a sweet, ether-like smell.
- EO vaporizes at 51 °F (10.7 °C).

Common Uses

Chemical Intermediate (99%)

Fumigant/Insecticide



Steriliant (0.1%)

EO/EtO Sterilization

Advantages

- Materials sterilized with EO are not exposed to damage from excessive heat, moisture, or radiation. Therefore, a wide variation of materials, particularly plastic components commonly used in medical devices, are able to be sterilized with EO.
- Products that are **already packaged** for shipment can be sterilized, since EO will permeate sealed films and cartons.
- EO is highly diffusible and will penetrate areas not reached by liquid or steam.

Disadvantages

- EO/EtO is considered a carcinogen and can be harmful to people.
- There are more process variables to control than with steam or radiation.
- Cycle monitoring often requires more attention than heat or radiation processing.
- Residual levels of ethylene oxide and ethylene chlorohydrin may be present after EO sterilization and must be evaluated by the device manufacturer to assure they meet predefined maximum limits.
- Ethylene oxide is extremely flammable and can provide its own oxygen in the absence of air.

Material Compatibility

Material	Steam Sterilizing Response	Radiation Sterilizing Response	Ethylene Oxide Sterilizing Response	Dry Heat Sterilizing Response
Acetal	Good	No	Good	Good
Acrylic	Poor	Good	Good	-
Acrylonitrile butadiene styrene	Varies	Good	Varies	-
High-density polyethylene	Good	Good	Good	-
Nylon	Varies	Good	Good	No
Polycarbonate	Varies	Good	Good	Good
Polyester	Poor	Good	Good	-
Polyethylene	Poor	Good	Good	-
Polyglycolic acid	No	No	Good	-
Polymethyl pentene	Good	Poor	Good	OK, no load
Polypropylene	Good	Varies	Good	OK, no load
Polypropylene and polyethylene copolymer	Good	Good	Good	OK, no load
Polystyrene	Poor	Good	Good	-
Polysulfone	Good	Good	Good	Yes
Polyurethane	Poor	Good	Good	-
Polyvinyl chloride	Varies	Varies	Good	-
Polyvinylidene fluoride	Good	Good	Good	-
Silicone	Good	Good	Good	Low temp.
Teflon	Varies	No	Good	OK

Conventional EO Sterilization Phases

Environmental Preconditioning

Phase 1

EO/EtO Processing

Phase 2

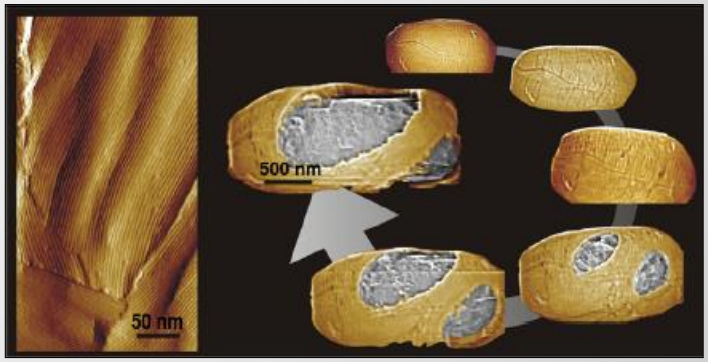
Aeration

Phase 3

Environmental Preconditioning

Purpose

To provide the bacteria with an ideal growing environment so that endospores will become exposed to the ethylene oxide. The endospore consists of the bacteriums DNA.



Preconditioning Monitoring Requirements

- Attainment of minimum temperature in preconditioning room prior to product entry
- Temperature and Humidity levels in preconditioning room throughout this phase
- Length of time product is in preconditioning room
- Preconditioning room to sterilization chamber transfer time

Intrinsically Safe data loggers are required for monitoring

Conventional EO Sterilization Phases

Environmental Preconditioning

Phase 1

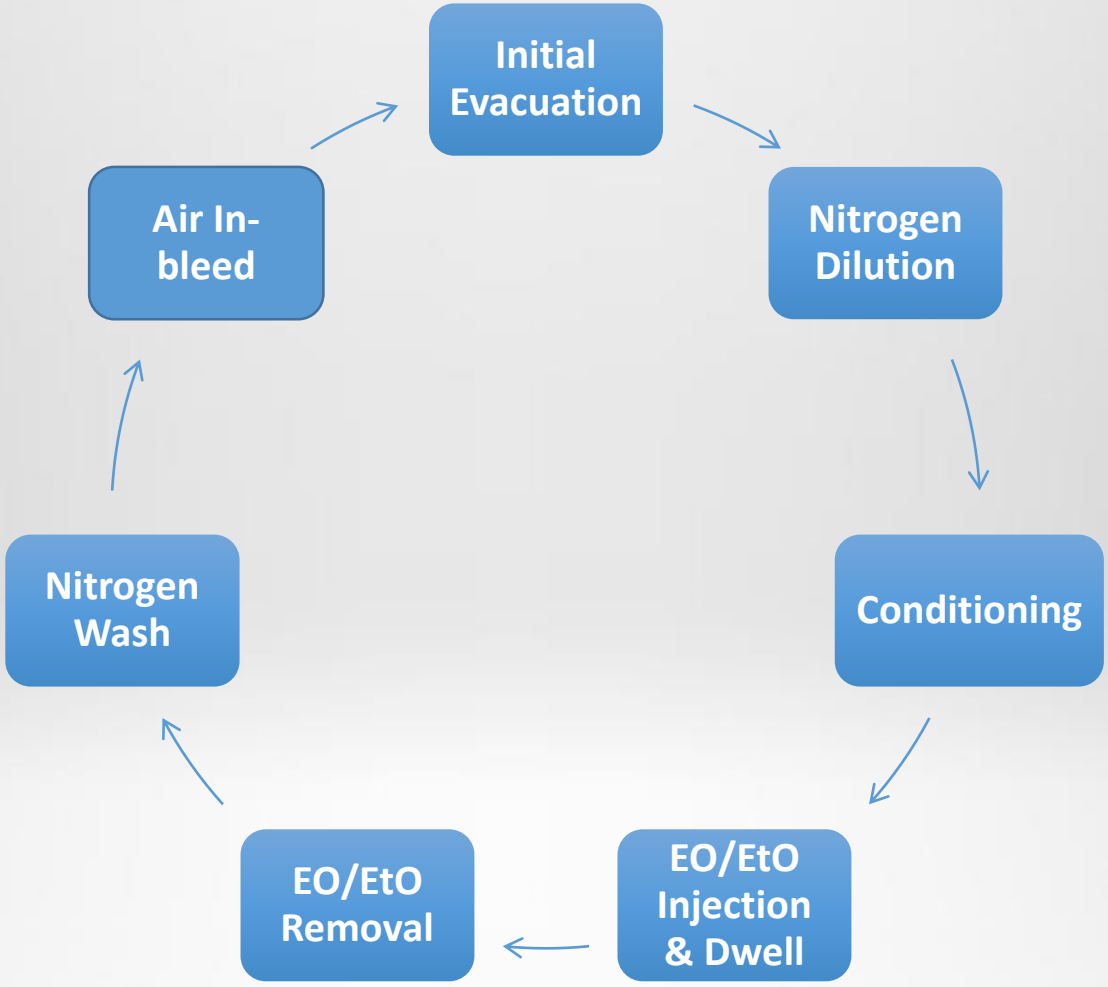
EO/EtO Processing

Phase 2

Aeration

Phase 3

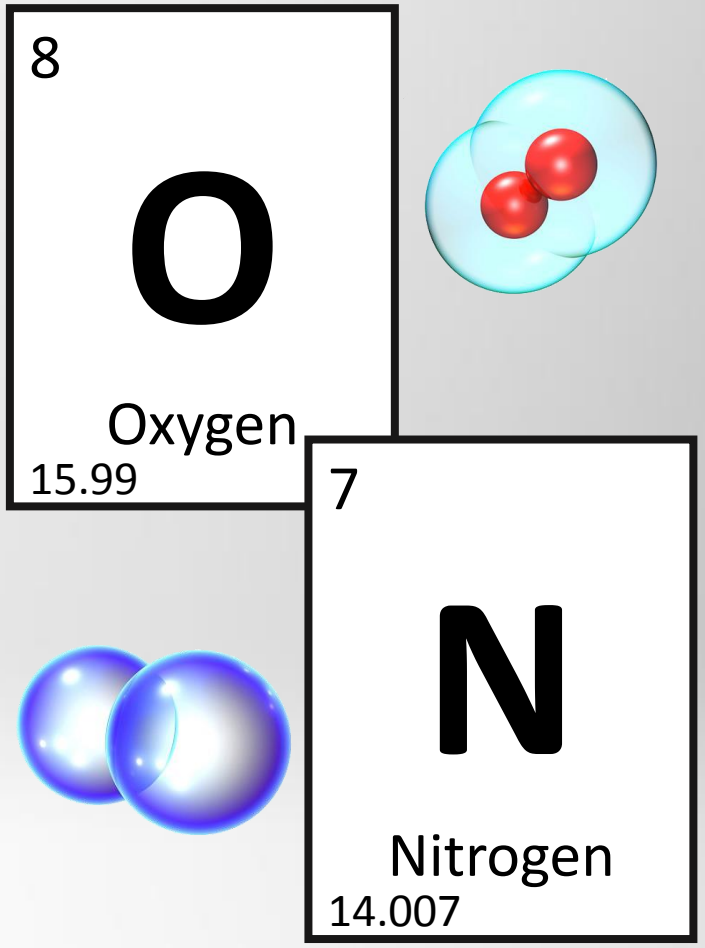
EtO / EO Processing Steps



EtO / EO Processing – Steps 1 & 2

Initial Evacuation & Nitrogen Dilution

- Removes at least 97% of the oxygen from the sterilization chamber.
  - > Allows the process to be performed below the flammability limits of EO.
- There are two methods of accomplishing this:
  - > Pull a deep vacuum *(1-2 inHgA).*
  - > Perform a series of "shallow" vacuums followed by nitrogen injections *(known as nitrogen dilutions or nitrogen washes).*
- The nitrogen dilution consists of injecting nitrogen and immediately removing it from the chamber. This helps in the removal of oxygen.



EtO / EO Processing – Step 3 & 4

Conditioning

- Heat and humidify the sterilization load
  - > Replacing moisture lost during initial evacuation and nitrogen dilution steps.
- Static Conditioning *(most common)*
  - > Steam is injected and maintained at a predefined pressure.

Sterilant (EO/EtO) Injection & Dwell

- Introduces the validated sterility assurance level of EO to the sterilization load.
- Sterilant is injected into the sterilization chamber to a pre-determined pressure.
- The sterilization load dwells
  (exposure to the sterilant) for a specified amount of time.

EtO / EO Processing – Step 5, 6 & 7

Sterilant Removal & Nitrogen Washes

- Removes ethylene oxide from the sterilization chamber and product packaging
- Accomplished by performing a series of post-exposure vacuums, each followed by a nitrogen injection

Air In-bleed

- Brings the sterilization vessel to atmospheric pressure *(so the sterilizer doors can be opened)*
- In-bleed filtered air into the sterilization chamber

EtO / EO Processing

Chamber Monitoring Requirements

- Temperature and Pressure levels throughout cycle
- Conditioning Humidity levels
  - > RH by pressure or direct
- Conditioning Time

- Evidence of gaseous EO
- Gas circulation during exposure
- Exposure time
- EO pressure and volume

Conventional EO/EtO Sterilization Phases

Environmental Preconditioning

Phase 1

EO/EtO Processing

Phase 2

Aeration

Phase 3

Aeration

Heated Aeration

Heated air is continuously circulated through the aeration area and residual gases are removed via an abatement system to eliminate remaining EO from the sterilization load.

Aeration Monitoring Requirements

- Temperature levels in Aeration Cell
- Pressure level changes
- Operation of the air supply and circulation

Variables that Impact Lethality

The four primary variables in the EO/EtO sterilization process are:

Temperature

Humidity

Gas Concentration

Gas Exposure Time

The set points for these variables are established during process, development and validation.

Variables that Impact Lethality

Temperature

- The higher the temperature, the higher the lethality of the cycle.
- Q10 Effect: For every +18 °F (+10 °C) increase, lethality doubles.
- Heat is transferred to the sterilization load during preconditioning and conditioning via a controlled steam process.
- The sterilization vessel temperature setting will also affect the heat transfer to the sterilization load.

Common range:
+120 °F to +135 °F
(+48 °C – +57 °C).

Humidity

- Moisture is not only helpful in the transfer of heat to the product, but it also aids in the absorption and desorption of EO/EtO into and out of the product/packaging.
- Moisture is transferred to the sterilization load during preconditioning (if utilized) and conditioning via a controlled steam process.

Common range:
30 %RH – 80 %RH

Variables that Impact Lethality

EO Gas Concentration

- The gas concentration should be enough to sterilize the product, but not enough to create EO and ECH residual problems.
- The concentration of gas may be calculated using the ideal gas law *(PV=nRT)*

Common range:
400 – 800 mg / L

Gas Exposure Time

- The exposure time should consider the time it takes for the gas to penetrate into all areas of the devices and the microbiological kill time.
- The duration is determined at the cycle design/development stage.
- It can be based on a D-value study or on the experience of the sterilization scientist

Common range:
3 – 5 hours

The MadgeTech Solution

Data Loggers and Secure Software for EO/EtO Sterilization

The MadgeTech 4 Secure Software contains criteria such as electronic signatures, access codes, secure data files, and an audit trail which meet the requirements of 21 CFR Part 11 and help provide data integrity. As a requirement for good manufacturing processes, MadgeTech's Secure Software is an essential tool.

MadgeTech provides data logging solutions for temperature & humidity monitoring. These solutions are intrinsically safe and designed specifically for use in EO/EtO environments.

Free support is provided to ensure users feel comfortable and confident using the MadgeTech system.

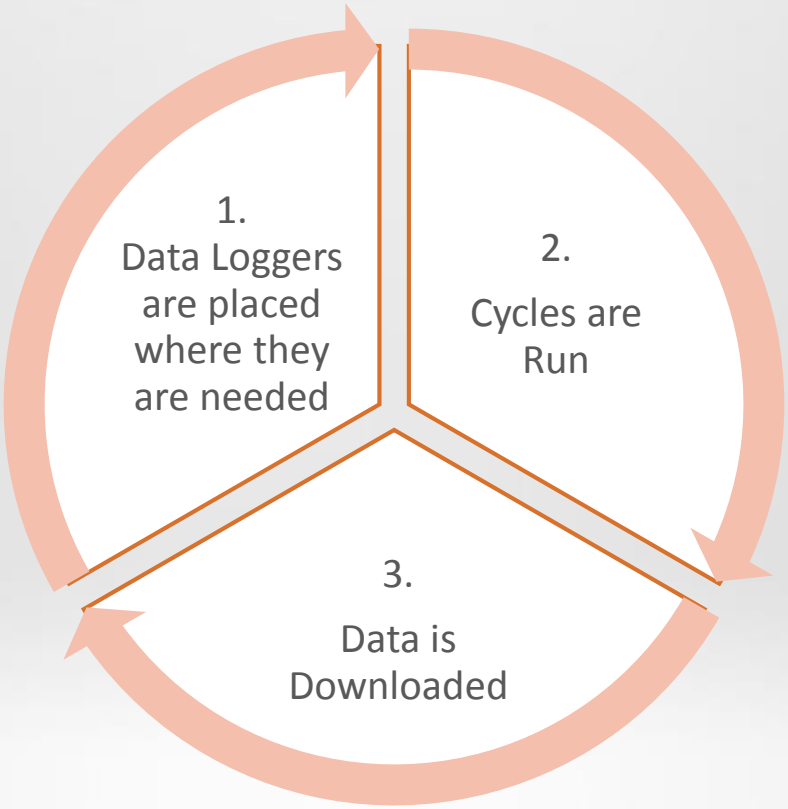
For a complete EtO data logging system, the following is required:

- Data loggers such as the RHTemp1000IS and Temp1000IS
- IFC400 and/or IFC406
- Computer
- MadgeTech 4 Secure Software

The MadgeTech Solution

EtO Sterilization Process Overview

Units are placed throughout and around the pallet or load to measure stratification



No wires – Completely self-sufficient. Loggers can record through the entire sterilization cycle

After each EO cycle, data is retrieved to validate temperature and humidity over time using MadgeTech 4 Secure Software

MadgeTech Customer Support

MadgeTech data loggers come with a one year manufacturers warranty.

Free support available for the lifetime of the product.

Contact Information:

Phone: 603-456-2011

Fax: 603-456-2012

Email: info@madgetech.com

MADGETECH
WE BUILD DATA LOGGERS