

# OVERVIEW OF ETHYLENE OXIDE RESIDUALS



Applied Sterilization Technologies

## TECHNICAL TIP #36

### Overview

Sterilizing medical devices with ethylene oxide (EO) is a common practice primarily due to its extensive material compatibility. The main side effect of using EO as a sterilization agent is that it can leave a residue on the devices being processed. The residues that may be found after processing are as follows:

- **Ethylene Oxide (EO)** – the residue that may remain after processing has been completed
- **Ethylene Chlorohydrin (ECH)** – the residue that may form when EO comes into contact with free chloride ions
- **Ethylene Glycol (EG)** – the residue that may form when EO comes into contact with water

The residues can be harmful to the end user or patient so it is important that all devices meet the limits set forth in the AAMI 10993-7 standard. The limits will vary depending upon the intended use of the device so there are three main categories a device may fall under: Limited Use, Prolonged Use and Permanent Use. In addition, there are several special device categories that have their own unique set of limits. Devices that do not have patient contact are not required to meet this standard. The table below, extracted from the AAMI 10993-7 standard, provides a summary of the various categories and their limits.

Device Category	Ethylene Oxide Limits	Ethylene Chlorohydrin Limits
Limited (<24 h)	4mg	9mg
Prolonged (>24 h <30 d)	60mg / 30 d	60mg / 30 d
Permanent (>30 d)	2.5g / lifetime	10g / lifetime
Tolerable contact limit (TCL)	10µg/cm <sup>2</sup> or negligible irritation	5µg/cm <sup>2</sup> or negligible irritation
Intraocular lens	0.5 µg/lens/d 1.25 µg/lens	4 x EO limits suggested
Blood cell separator (apheresis)	10mg	22mg
Blood oxygenators	60mg	45mg
Cardiopulmonary bypass devices	20mg	9mg
Blood purification devices	4.6mg	4.6mg
Drapes contacting intact skin	10µg/cm <sup>2</sup> or negligible irritation	5µg/cm <sup>2</sup> or negligible irritation

Per the AAMI 10993-7 standard, “No exposure limits are set for ethylene glycol because risk assessment indicated that when EO residues are controlled, it is unlikely that biologically significant residues of EG would be present.” Ethylene glycol is not a genotoxin nor is it considered to be a carcinogen, thus the need to monitor for EG is not critical. The primary concern is to ensure the EO and ECH residues are within the allowable limits.

Devices considered as surface contacting or implantable must meet an additional set of criteria called the Tolerable Contact Limit (TCL). The purpose of this limit is to prevent localized irritation due to the release of EO or ECH from the device. The TCL is a calculated value that takes into consideration the surface area of a device and the EO and ECH residue levels in order to determine if irritation will be an issue.

### Common Root Causes

There are several reasons why a device may contain high levels of residues after being exposed to the ethylene oxide sterilization process.

- **Material** – certain materials will absorb and retain gas molecules more than others. Natural materials such as cellulose and cotton are known to be very absorbent. Some types of plastics have also shown a high absorption rate when exposed to EO processing.
- **Packaging** – EO processing requires breathable packaging such as Tyvek or medical grade paper to allow the gas molecules to pass through. Packaging with a minimal or obstructed breathable surface area (i.e. large adhesive label) will not allow the gas to move as freely across the breathable barrier.
- **Load configuration** – the volume, density and overall configuration of the load on a pallet can impact the ability of gas removal after processing.

### Residue Reduction Methods

The good news is that most residue issues can be overcome with a few simple changes to the existing sterilization parameters if an ethylene oxide process is currently in place. For new device manufacturers, residue issues can likely be eliminated up front by considering the following methods while developing the sterilization parameters.

- **Nitrogen washes** – all cycles will have a Nitrogen wash phase after the EO gas has been evacuated from the sterilization chamber. Adding Nitrogen aids in diluting the EO in the headspace of the chamber, thus reducing the residues left behind. Increasing the number of Nitrogen washes as well as performing them at a deeper vacuum can be beneficial.
- **Added heat** – heat aids in the off-gassing process so it is helpful to keep as much heat in the chamber as possible after the sterilization process. This can be done a few ways such as increasing the overall processing temperature set point or adding a moisture conditioning phase after the EO has been removed.
- **Extended aeration** – after the in-chamber process has been completed the load may be transferred into a heated aeration cell to aid in further off-gassing. The industry average for a typical aeration time is 6 to 24 hours. Some devices may require no heated aeration and others may require a period beyond the industry average. Extending the duration that a load is in heated aeration can be beneficial if necessary.
- **Load configuration** – the configuration of the load on the pallet can assist with off-gassing. If the load is very dense it may be a good idea to leave pathways or “chimneys” throughout each pallet. Removing or minimizing the use of pallet wrap (if possible) could also be considered.

If residue issues are currently a problem or may present a challenge to a new device, consult with a sterilization provider to discuss minimizing the effects of the ethylene oxide sterilization process. In addition, the test methods for analyzing EO residues will vary depending on the device. It is also beneficial to contact a laboratory service provider to ensure that the correct test methods for the device are employed.

### References

*ANSI/AAMI/ISO 10993-7:2008/(R) 2012, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*

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