

# Stored Energy Safety Assessment for Ethylene Oxide Sterilization



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Rapid innovation in medical device technology and booming demand in healthcare has fueled the growth of battery-powered devices to improve product quality and patient outcomes.

**Ethylene oxide (EO)** is the most common industrial sterilization technique for medical devices due to its high compatibility with most materials used in the manufacture of medical devices and effectiveness driven by a lethal chemical reaction (alkylation) with the DNA of bacteria, viruses, molds, and yeasts. The process involves exposing the medical device to EO gas under a vacuum in a sealed chamber. When using EO gas to sterilize medical devices with batteries or other energy containing components, a thorough assessment must be conducted to ensure the safety of the facility, staff, customers, product, and the community.

Due to concerns with EO ignition, medical devices that store energy should first undergo a full safety assessment by experts prior to EO sterilization. The Nelson Laboratories Expert Advisory Services team is available to conduct these assessments as well as consult in the design process to guide the device design to minimize ignition potential within the finished product.



**Primary device information** is required for analysis including product specifications, design details and use information.



**The safety assessment** analyzes the device for worst-case conditions and points of failure to ensure the energy contained within or generated by a device is incapable of igniting EO in the chamber via mechanical, chemical, or electrical means.













**Results** from a standard analysis are available in 4–8 weeks.



**Contact your Nelson Labs account manager to discuss the need for a stored energy safety assessment for EO sterilization.**

Call **801-290-7502** or email [advisoryservices@nelsonlabs.com](mailto:advisoryservices@nelsonlabs.com)

## Stored Energy Device Safety Assessment Checklist

	Manufacturer's name
	Unique manufacturer part number or identifier
	Description/claims to be used in promotion to denote this specific device
	Device operating instructions
	Battery type and specifications
	Details of any battery isolation means (e.g., switches, pull tabs, separated battery pack)
	Electrical schematics including highest voltages in the device
	Component listing (e.g., capacitor 100 pF, inductor 20mH, resistor 120 ohms)
	Name and contact information for technical clarification on energy levels within the device
	Other technical information/specifications as requested to support analysis including device, if necessary



Safety is a core value of Nelson Labs. We are uncompromising in our commitment to health and well-being.

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Nelson Labs is a global leader in microbiological and analytical chemistry testing and advisory services for the medical device and pharmaceutical industries. We serve over 3,000 customers across 13 facilities in the United States, Mexico, Asia and Europe. With a comprehensive array of over 900 laboratory tests and the expertise of Regulatory Compliance Associates, a recognized leader in life science consulting, we support our customers from initial product development and sterilization validation, through regulatory approval and ongoing product testing for sterility, safety and quality assurance. We are regarded as a best-in-class partner with a strong track record of collaborating with customers to solve complex issues.

**Safeguarding Global Health® – with every test we complete.**