Exponent®

THOUGHT LEADERSHIP

Is It Safe to Sterilize Your Medical Device?

Ethylene Oxide Sterilization of Medical Devices Containing Stored Energy

Ethylene oxide (EO) processing is a common sterilization technique for electronic and other heat- and moisture-sensitive medical devices because it is effective in relatively low temperature and relatively low humidity environments, has good penetrability, and is chemically compatible with a wide range of materials, including most plastics. While there are many benefits to EO as a sterilization agent, one significant drawback is its flammability. Ethylene oxide can form explosive mixtures that ignite across a broad range of concentrations. For example, sufficient energy from an electrical spark or hot surface in the presence of EO can initiate an explosive chain reaction with serious potential risks to life and property.

Due to the risk of explosion from EO gas, special considerations must be made when electronics containing stored energy in batteries, capacitors, or inductors are intended for EO sterilization. As pacemakers, neurostimulators, ventilators, smart catheters, ingestible biosensors, and other implantable and wearable medical devices are increasingly powered by batteries, more sterilization facilities and device manufacturers are integrating explosion risk hazard assessments into the risk management process. Medical device manufacturers can help protect the health and safety of all users and prevent costly delays to product launch by evaluating a device's EO explosion risk early in the product design process.

Medical device manufacturers are accustomed to performing hazard analyses under ISO 14971 to ensure that devices are safe and functional when used in situ, and current MDR - Annex I General Requirements instruct medical device manufacturers to ensure their devices are "designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition" and "sterilized by an appropriate, validated method … in appropriately controlled (e.g. environmental) conditions." However, many manufacturers are not used to navigating the risk of device explosion in a sterilization environment. For example, electrical engineers may design a circuit to function electrically but fail to consider the ideal location and spacing of components to minimize the risk of ignition events. Likewise, biomedical engineers may consider how a device will perform in a high-oxygen operating room environment, or in the body, but traditionally have not considered performance issues in a sterilization environment. Designers of medical devices that use stored energy must work at the intersection of the electrical, thermal, and biomedical disciplines to optimize the safety of a device across environments. Doing so early and often can help designers make necessary adjustments to circuitry or other device components while minimizing potentially costly delays to product launch.

Although published standards are available for the approval of devices for use in potentially explosive environments, a one-time EO sterilization is an application generally not covered by such standards. These standards can, however, be used to guide EO sterilization risk assessments of battery-powered devices. If certain parameters of a given device do not align with a standard's stated limit, additional calculations and experiments can

determine whether the deviance poses an ignition hazard or aligns with the standard's original intent.

How Exponent Can Help

Exponent's multidisciplinary team of electrical, biomedical, and thermal science engineers and battery experts can evaluate the risk profile of a battery-powered medical device based on the device design, the relevant standards, and the sterilization cycle. Our feedback to both EO sterilization facilities and medical device manufacturers can help optimize the EO sterilization cycle and support timely adjustments to medical device design and safety.

Jorge A. Ochoa, Ph.D., P.E.
Biomedical Engineering & Sciences
Principal Engineer
Austin
(512) 634-2951 | jochoa@exponent.com

Joel E. Sipe, Ph.D., P.E., CFEI
Thermal Sciences
Principal Engineer
Menlo Park
(650) 688-7103 | jsipe@exponent.com