

CONSIDERATIONS FOR ETHYLENE OXIDE PROCESSING OF DEVICES WITH ELECTRONIC COMPONENTS



Applied Sterilization Technologies

TECHNICAL TIP #34

With today's rapid advancement in medical device technology, manufacturers are moving towards devices with electronic components to ensure that patient health is quickly and accurately achieved. For more complex procedures, many physicians employ the use of high-tech equipment. And most often, that equipment has been sterilized using ethylene oxide (EO).

EO gas is a very effective means of sterilizing medical devices because of its ability to penetrate the tiniest of pathways and destroy spores. When using ethylene oxide to sterilize electrical equipment containing batteries or other energy containing components, thorough evaluation must take place to ensure the safety of those in the sterilization facility.

Due to concerns with EO ignition, there are several components of a risk and safety assessment that must take place before a device can be considered for ethylene oxide sterilization. This assessment should be performed by the device manufacturer, perhaps in conjunction with a third party electrical engineering or failure analysis consultancy. At a minimum, the following information should be provided:

- Documentation stating the product's instructions for use must be supplied so it can be understood how the device operates and how the energy circuit is engaged.
- Product and design details including battery current, voltage and circuit diagrams (showing voltage, currents, switches, controllers, capacitors, resistors, voltage transformers, etc.).

Questions that should be considered include, but are not limited to:

- Is there potential for the device to become charged during EO processing?
- If so, are there multiple layers of protection present that could prevent an ignition, such as an on/off switch or a power isolation tab.
- Are the components of the battery compatible with EO?

In order to execute a thorough assessment, a copy of the proposed sterilization cycle is required. This will aid in determining the potential impact between the device and environment it will be exposed to during sterilization. As a reference, The Ethylene Oxide Sterilization Association, Inc. (EOSA) has prepared a sample powered component safety review checklist (see page 2 of this document).

SAMPLE: POWERED COMPONENT SAFETY REVIEW CHECKLIST

Item #:	Description:
Vendor Name:	Power Source: (Include size if battery)
Sterilizer: (circle one)	Other: _____ Cycle ID: _____

Product Specifications and/or other design details attached?	YES	NO
Does the device exceed 5 amps at 12 volts?	YES*	NO
Does the device store any energy (e.g., capacitors)?	YES	NO
Is there On/Off switch on the device?	YES	NO
Is there an isolation tab to prevent the device from turning ON automatically?	YES	NO
Can the device activate during sterilization?	YES*	NO
Can the device exceed a known safe level of electrical potential or temperature that could ignite EO	YES*	NO
Is the cycle non-flammable after EO inject?	YES	NO*
Is the cycle temperature acceptable for the battery?	YES	NO*
Are the cycle vacuum washes acceptable for the battery?	YES	NO*
Are the chemical components of the battery compatible with EO?	YES	NO*
is an exothermic test required to confirm battery compatibility?	YES	NO
Does the device contain a motor?	YES	NO
If yes, evaluate the energy that could be generated during sterilization before proceeding. Is energy >5 amps @ 12 volts?	YES*	NO
* Do not proceed. Device cannot be EO sterilized.		

At a minimum, these questions should be addressed and documented. STERIS will not process any battery-operated devices without proper assessment. STERIS has the right and responsibility to refuse devices for sterilization if there is a potential for harm to be inflicted.

For more information, please contact:

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