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The Andersen EOGas 100% EtO Sterilization System and ISO 11135

Following is a description of the Andersen EOGas™ process and how it relates to ISO 11135.

The Andersen EOGas™ Sterilization system is a unique alternative to traditional pressure vessel ethylene oxide sterilization systems. The EOGas system utilizes gas diffusion technology, which allows for a sterilization process without the use of a deep vacuum, steam injection, or a pressurized chamber. As a result, many of the requirements of EN 11135 do not apply to the EOGas system.

Description of the Andersen EOGas™ Process

The EOGas system in operation at Andersen Scientific uses a gas impermeable, hermetically sealable plastic bag as the sterilization chamber. At a minimum, a Humidichip® humidity stabilizing chip, a Dosimeter® ethylene oxide dose indicator and an EOGas cartridge containing liquid ethylene oxide are placed in the sterilization bag along with the items to be sterilized. The loaded bag is sealed and excess air is withdrawn from the bag. The gas cartridge is then activated through the flexible wall of the sterilization bag releasing pure ethylene oxide into the interior of the sterilization bag.

The sterilization bag and its contents are then placed at atmospheric pressure in a thermostatically controlled, vented sterilization cabinet and maintained at, typically, 50^{o} C. for 16 hours. The concentration of ethylene oxide in the sterilization bag rapidly peaks as the ethylene oxide in the cartridge is converted from liquid to gas. The gas diffuses rapidly through the product packaging and around the product. After the concentration of ethylene oxide peaks after the first hour (and after some degree of absorption by the load) it remains static for the duration of the cycle.

Unlike conventional ethylene oxide chamber systems, the EOGas system does not pull a vacuum and does not inject steam into the chamber at the beginning of the cycle. It does not inject ethylene oxide into the chamber under pressure, nor does it use a deep vacuum to help remove the ethylene oxide at the end of the cycle.

The Andersen EOGas™ System and ISO 11135 Certification

EOGas complies with ISO11135, (with the exception of those specifications listed in 1 through 4 below), which covers chamber pressurization, steam injection, a static gas concentration and the ability to measure such concentrations from the chamber environment; all of which are not employed by the EOGas gas diffusion sterilization process.

1. Section 6.1.3 (a) - Chamber air removal is not used in the EOGas™ sterilization process. Excess air is removed from the sterilization bag at the start of the cycle, but this is not a critical cycle parameter.

2. Section 6.1.3 (g) - Since the EOGas sterilization process does not employ chamber pressurization, it is not necessary to bring the chamber back to atmospheric pressure using air admission.

3. Section 6.1.3 (c) and 9.3.3.2 (d) – Andersen Scientific reports will not include sterilant injection pressure rise or final pressure, since the EOGas sterilization process does not pressurize the chamber or product load. The EOGas system does not determine sterilant concentration by direct analysis of chamber atmosphere and so we rely on a combination of the Dosimeter (a quantitative measuring device, Class V integrator) and the measurement of the net-weight of sterilant released in the cycle (see 9.5.4.c.1.i).

4. Section 6.2.2 d) – Purity and quality of steam - Traditional EtO chambers employ a vacuum at the start of the cycle, which effectively removes all humidity from the chamber. The use of inert gases to mitigate the explosive hazard of EtO further reduces the humidity in the in the chamber and hence in the load. Traditional EtO chambers require steam injection to overcome these characteristics of their cycle else the load may become desiccated and much harder to sterilize. Since EtO gas diffusion systems do not employ a deep vacuum or inert gases, supplemental humidity during the cycle is far less critical. Loads that have been properly preconditioned prior to sterilization only require that a minimum level of relative humidity be maintained during sterilization.

   In the EOGas system cycle humidity is not generated by direct injection of steam but by the Humidichip. The Humidichip is a Tyvek packaged chip manufactured under controlled conditions that has a known water content. Water vapor is released from the Humidichip into the sterilization bag as cabinet temperature increases, thereby maintaining RH inside of the sterilization bag within cycle parameters.

If you have additional questions, please do not hesitate to call Ted May at 336 376-3000, or e-mail me at tmay@anpro.com.