

Andersen EOGas 4® Sterilization Efficacy Using the Three-Hour Sterilization Cycle

The Andersen EOGas Series 4 sterilizer efficacy study was executed by Andersen Scientific, Inc., using a series of sub-lethal exposure protocols¹, to demonstrate that the three-hour exposure cycle is capable of delivering a Sterility Assurance Level (SAL) of 10⁻⁶.

MATERIALS & EQUIPMENT:

- Andersen EOGas Series 4 sterilizer
 Calibrated incubator,
 Shimadzu gas chromatograph and detector,
 Self-contained biological indicators (min. pop. 1x10⁶)
 Standard load (items sterilized in the Series 4 sterilizer):
- 10 AN10 tubes sealed in polyethylene/polysurlyn pouches
 - 2 patient gowns wrapped in CSR wrap
 - 1 AN42 Sump Pump wrapped in CSR wrap
 - 6 pairs of latex gloves sealed in Seal & Peel packaging
 - 10 cotton-tipped applicators sealed in Seal & Peel packaging
 - 30 PPE Sutures inserted into aluminum pouches, then sealed in self-sealing paper/plastic pouches
 - 4 hemostats sealed in Seal & Peel packaging
 - 12 syringes sealed in self-sealing paper/plastic pouches
 - 10 glass vials sealed in self-sealing paper/plastic pouches
 - 1 AN2018 Andersen EOGas™ cartridge
 - 2 Humidichips placed in a Humiditube

Items were placed in a 22 inch x 36 inch 5 mil Series 4 PE/Nylon/PE sterilization bag.

METHOD:

Sub-lethal Exposure Studies:

The Andersen EOGas Series 4 sterilizer used in this study was calibrated to 50°C. Each sterilization load was seeded with twenty self-contained biological indicators and processed with all sterilization parameters remaining constant except time. Exposure cycles times of 45, 60, 75 and 90-minutes were run on different days. All exposed biological indicators were incubated within 5-minutes of removal from the sterilization bag. The average Ethylene Oxide delivered during the four cycles was 18.02g with a standard deviation of 0.34.

RESULTS:

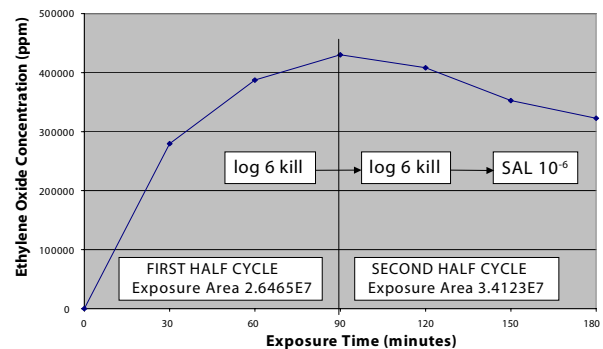
20 Bi's pulled at:	Passing BI	Failing BI
t=45 minutes	5	15
t=60 minutes	8	12
t=75 minutes	10	10
t=90 minutes	0	20

The self-contained biological indicators—containing a minimum of 1x10⁶ *Bacillus atrophaeus (subtilis)* spores, were rendered sterile after 90-minutes of exposure to Ethylene Oxide.

CONCLUSION:

The sub-lethal cycles suggest that a 6-log reduction can be achieved during a ninety-minute half cycle exposure cycle. We can extrapolate this data beyond the first ninety-minutes in order to determine the minimum achievable SAL during the full three-hour exposure cycle. Since the Ethylene Oxide within the sterilization bag is not sealed in a leak-proof system, we have to assume that the Ethylene Oxide concentration is not constant but is variable. To better understand this sterilization variable, an Ethylene Oxide concentration profile was performed under Andersen Scientific protocol 09070454—see graph below.

Ethylene Oxide Concentration Showing a Sterility Assurance Level of 10⁻⁶



The resulting profile clearly shows that the latter half of the sterilization cycle (90 to 180-minutes—with a mean temperature of 46.8°C) has an overall higher Ethylene Oxide concentration than the initial half (0 to 90-minutes with a mean temperature 39.6°C²). We can thus conclude that the latter or second half cycle will deliver a greater level of lethality than the first half cycle. Since the first half cycle has already proven a 6-log reduction of the test organism, we can assume that the second half cycle, will at a minimum, achieve the same level of lethality for a combined SAL of 10⁻⁶ over the full three-hour exposure cycle—the requirement for terminally sterilized devices.

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Andersen Scientific, Inc., November 16, 2004

¹ Andersen Scientific Protocol No.: 08300454, Title: Evaluation of the Andersen EOGas Series 4 Sterilizer: Partial BI exposure & Protocol No.: 09070454 Title: Evaluation of the Andersen Series 4 EOGas/Anprolene Sterilizer: GC Profile Comparison – 3 mil EOGas™ bag vs. 5 mil PE/Nylon/PE sterilization bag.

² Lower sterilization load temperature is result of sterilizer warm-up.