

Purpose:

The Andersen EOGas Series 4 operator exposure study¹, executed by Andersen Scientific, Inc., was performed to establish the average Ethylene Oxide (EO) concentration (STEL²) within the immediate vicinity of the Andersen EOGas Series 4 sterilizer during the unloading procedure in a sterilization room with zero air changes. This study performed with the sterilization load aerating within the room and with the load removed from the room—a comparative table is shown below.

Operator monitoring was performed by direct air analysis at six points within the sterilization room. Air samples were collected using a gas-sampling pump and collection bag. Collected samples were quantitatively analyzed using gas chromatography—the most sensitive Ethylene Oxide detection device available.

MATERIALS & EQUIPMENT:

Andersen EOGas Series 4 sterilizer
 Shimadzu gas chromatograph and detector
 Andersen gas sampling pump, air collection bags and a timer
 Hamilton gas-tight syringes: Ranging from 10 µl to 1500 ml
 Self-contained biological indicators (min. pop. 1x10⁶)
 Calibrated incubator
 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:

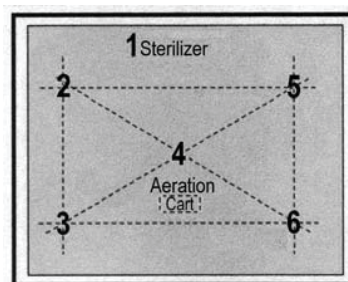
Environmental Conditions:

All six cycles performed under Andersen Scientific protocol 101104S4 were performed in a laboratory measuring 1800 ft³. The airflow system within this room was disabled, and all re-circulation vents were blocked and / or shut off, thereby creating a static environment without air circulation or exchange (a worst-case operator exposure scenario). The average ambient room temperatures over the twelve-day test period ranged between 72°F and 75°F with 46.0 – 60.0% relative humidity.

EOGas 4 Operator Exposure Study

Sterilization and Unloading:

Each sterilization cycle was performed using an AN2018 EOGas cartridge (mean net-release of 18.10 g). The cycles were loaded with the “standard load” and processed using the three-hour exposure cycle. At the conclusion of the exposure phase, the Andersen EOGas Series 4 sterilizer was left to ventilate each sterilization bag for 30-minutes. After each ventilation period, the sterilizer door was opened, the sterilization bags were disconnected from the purge probe and the devices were carefully removed one at a time and either placed on a metal aeration cart—where they were left to aerate, or they were placed into a blue tote where they were removed from the laboratory. The gas sampling pump and collection bags were placed on a stool at breathing zone height (approx. 62 inches) and approximately 12 inches from the sterilizer during the unloading procedure. Each unloading procedure took an average of 58 seconds. Six air samples were collected at six different locations—each location was sampled for 2.5-minutes, starting at location (1)—the sterilizer, and then sequentially at different locations within the room – see diagram below:



All air samples were quantified using Gas Chromatography.

Results:

Concentration of Ethylene Oxide Detected (ppm)

Load aerating in Lab	Load removed from Lab
3.03	1.40
3.44	1.58
1.76	1.76
AVG: 2.74	1.58

All air samples were below the OSHA STEL limit of 5.0ppm. Even though this study indicates that the levels of EO are safe within a room with zero air changes, we recommend a minimum of ten air exchanges per hour.

Daryl L. Woodman, B.Sc.

Andersen Scientific, Inc., November 17, 2004

¹ Andersen Scientific Protocol No.: 101104S4, Title: Evaluation of the Andersen EOGas Series 4 Sterilizer: Operator Exposure in a Room with Zero Air Changes / Movement.

² Short Term Exposure Limit—a 15 minutes air sample.

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