

Operator Exposure Study During Normal Use of the Andersen EOGas 3 Sterilizer (STEL and TWA)

The Andersen EOGas Series 3 operator exposure study¹, executed by Andersen Scientific, Inc., was performed to establish the average daily operator Ethylene Oxide (EO) exposure (STEL² & TWA³) with the sterilizer in Industrial mode (all bags loaded at once), as well as in Batch mode (additional bags loaded to a sterilizer while other loads are processing). This study was performed with an Andersen abator attached.

Operator monitoring was performed by direct air analysis twelve inches from the sterilizer—level with the door handle. 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 3 Plus sterilizer (AN310 & AN333)⁴, Shimadzu gas chromatograph and detector, Andersen gas sampling pump, air collection bags and two timers, Hamilton gas-tight syringes: Ranging from 10 µl to 1500 ml Miscellaneous Loads (examples):

- AN10 and AN3200 Andersen nasogastric tubes
- Surgery Kits
- Bone biopsy kits
- Percutaneous introducer kits
- Syringes
- Gowns, drapes, towels and gauze
- AN42 Andersen pump
- Implantable devices
- Compression sleeves
- Glass vials and cotton-tipped applicators
- 1 AN2011 Andersen EOGas™ cartridge⁵
- 1 Humidichip placed in a Humiditube

Items were placed in a standard 22 inch x 36 inch 3 mil Series 3 EOGas sterilization bag.

METHOD:

Environmental Conditions

The exposure studies were performed in a laboratory measuring 13,392 ft³. The airflow system within this room was set to deliver eight air exchanges per hour. The average ambient room temperature within the laboratory was 72°F.

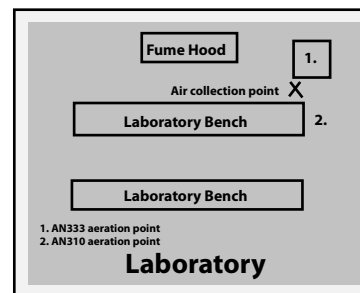
Sterilization and Unloading

The first phase of the study was designed to quantify a part per million exposure level while unloading the AN310 or the AN333 sterilizers.

Both 15-minute (STEL) and 8-hour (TWA) samples were collected and analyzed—OSHA required limits. The sterilized devices from the AN310 were removed and placed on an aeration cart within the laboratory—no more than four feet from the air sample collection point, while the devices from the AN333 were allowed to aerate within the sterilizer (all power to the sterilizer was removed and the door was left open). All devices were left in the laboratory for the remainder of the study.

The second phase of the study was performed to illustrate that the addition of a tenth sterilization bag to an almost fully loaded AN333 sterilizer would not trigger an event that would breach OSHA's 15-minute STEL limit. The tenth bag was added two hours into the exposure phase—a time when the potential for increased Ethylene Oxide exposure was at its peak.

The average gas delivered per AN2011 EOGas cartridge was 10.369 g.



All air samples were quantified using Gas Chromatography.

RESULTS:

Concentration of Ethylene Oxide Detected (ppm)			
Model.	Door opened at	STEL	TWA
AN310	16 hours	0.76 ppm	<0.25 ppm
AN333	16 hours	1.07 ppm	0.27 ppm
AN333	2 hours	1.30 ppm	N/A
OSHA LIMITS		5.00 ppm	1.00 ppm

All air samples were below OSHA's STEL and TWA limits.

Daryl L. Woodman, B.Sc.
 Andersen Scientific, Inc., June 22, 2005

¹ Andersen Scientific Protocol No.: ANSCI042805 Title: Series 3 Plus operator exposure⁴ studies during routine use.
² Short-term excursion limit—a 15-minute air sample.
³ Time Weighted Average—an 8-hour air sample.
⁴ Both the AN310 and AN333 used in this study were not fitted with the Dutch- Doors. The Dutch-doors are designed to further reduce operator exposure.
⁵ The AN2011 and AN1006 are functionally identical.