ANDERSEN STERILIZERS

Operator Exposure Study

The AN74i operator exposure study[1], executed by Andersen Scientific, Inc., was performed to establish the average Ethylene Oxide (EO) concentration within the immediate vicinity of the AN74i sterilizer upon opening and unloading the sterilization bag.

Operator monitoring was performed using an AirScan® exposure badge and by direct air analysis of collected air samples using a gas-sampling pump and collection bag with a self-sealing septum (Andersen Sniffer™). The contents of the gas-sampling bags were quantitatively analyzed using gas chromatography, the most sensitive Ethylene Oxide detection device available.

MATERIALS:

AN74i Sterilizer
Andersen Sniffer™ with nylon gas sampling bags
Shimadzu gas chromatograph and detector
AN92 15-minute STEL AirScan® badges
PAN-TY cable ties and Thomas & Betts cable tie tool
Standard load:

- 10 AN10 Andersen tubes sealed in 4.5" Polyethylene/Polysurlyn pouch
- 2 Patient Gowns wrapped in CSR wrap
- 1 AN42 Sump Pump® wrapped in CSR wrap
- 6 Pairs of Latex Gloves sealed in Seal and Peel®
- 10 Cotton-Tipped Applicators sealed in Seal and Peel®
- 30 PPE Sutures inserted into aluminum pouches, sealed in a self-seal 7"x13" paper plastic pouch
- 4 Hemostats sealed in Seal and Peel®
- 12 Syringes (3 large, 3 medium and 6 small) sealed in a self-seal 7"x13" paper plastic pouch
- 10 Glass Vials (amber with rubber stopper) sealed in a self-seal 7"x13" paper plastic pouch
- 5 AN71 (4.5ml) Anprolene® Ampoules
- 1 Humidichip® placed in a Humiditube®
- 1 Dosimeter®

METHOD:

Environmental Conditions
All nine cycles performed under protocol AN74IOE were conducted in two independent laboratories measuring 1898 ft^3 and 5054 ft^3. The studies were staggered and performed on three different days. The 100-foot exhaust hose (0.5-inch diameter) was coiled and vented directly to the outside. The ambient room temperatures of both laboratories ranged between 18 and 22^{o} C with 45-65% relative humidity. All vents and re-circulatory fans were blocked and/or shut off, thereby creating a static environment without air circulation or exchange (a worst-case operator exposure scenario).

The operator wore a 15-minute STEL AirScan® badge and the collection tube connected to the gas sampling pump on their laboratory coat lapel (<6 inches from the breathing zone). The operator followed his/her routine daily procedures while performing these tests.

Sterilization and Unloading
Each AN74i sterilization cycle was performed using in excess of 21.0g of Ethylene Oxide, in order to create a worst-case operator exposure scenario. The cycles were loaded with the "standard load," and initiated at the end of the working day. Fourteen hours later, at the cycle's conclusion, the sterilizers were opened, and the sterilization bags were disconnected from the spool and transferred to the post-sterilization quarantine holding area. Items were carefully removed one at a time and placed on a metal aeration cart. Dosimeter readings were performed at this time.

The gas-sampling bags were appropriately labeled and immediately sent to Andersen Products Laboratory for quantitative analysis. The AirScan® badges were immediately developed following package instructions.

RESULTS:

Average 15-Minute STEL EO Levels in ppm

Detection device	Allowable limit	Detected level
AirScan®	<5.0	0
Sniffer™	<5.0	0.11

CONCLUSION:

The results derived from this testing procedure (AN74IOE) indicate that the AN74i operator was not exposed to Ethylene Oxide levels above the OSHA STEL limits when the unit was operated as recommended by the manufacturer.

[1] Andersen Scientific Protocol No.: AN74IOE, Title: AN74i STEL 15-Minute Operator Exposure Study.

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