ANDERSEN STERILIZERS

An74i Pump Failure Study

This study[1] was conducted to determine the consequences of a ventilation pump failure in an Andersen AN74i sterilizer. Of particular concern was possible operator exposure to ethylene oxide (EO) in the vicinity of the sterilizer. Measurements taken at the cycle's peak concentration of EO resulted in an undetectable level (< 1 part per million).

CONDITIONS:

The temperature inside the sterilization liner bag measured at 24.3 to 25° C. The relative humidity ranged from 42.4 to 60.5 percent.

The test room itself had no air changes. Performing the test in an unventilated room increases the risks associated with a malfunction of this kind. Andersen Products, Inc. recommends that the sterilizer be installed in a room with at least 10 air changes per hour. Operation of the sterilizer in a room with no air changes constitutes a gross misuse of the system.

MATERIALS:

AN74i Sterilizer
PAN-TY cable ties and Thomas & Betts cable tie tool
Andersen Sniffer™ with nylon gas sampling bags
Gas sampling pump and collection bag
Shimadzu gas chromatograph and analyzer
1.0 ml gas-tight syringes for gas injection into GC
Standard Load:

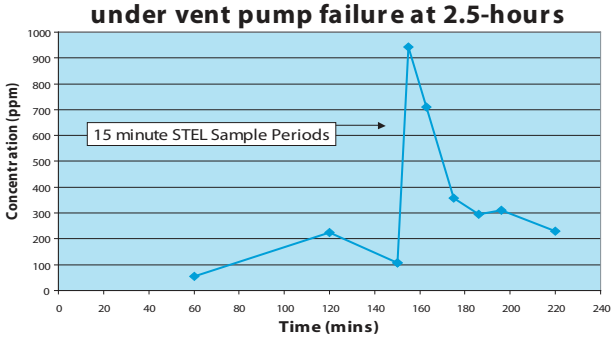
- 10 AN10 Andersen Tubes sealed in 4.5" PolyEthylene/PolySurlyn pouch
- 2 Patient Gowns wrapped in CSR wrap
- 1 AN42 Sump Pump® wrapped in CSR wrap
- 6 Pairs of Latex Gloves sealed in Seal and Peel®
- 10 Cotton-Tipped Applicators sealed in Seal and Peel®
- 30 PPE Sutures inserted in aluminum pouches 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 stoppers) sealed in a self-seal 7"x13" paper/plastic pouch
- Cox Recorder
- AN79 (17.6ml) Anprolene® Ampoule

METHODOLOGY AND EQUIPMENT:

The study was conducted to measure possible operator exposure levels to EO should there be a vent pump failure. It has been previously established that the highest concentration of EO occurred inside the liner bag at 2.5 hours after activating the ampoule. This test simulated a vent pump failure 2.5 hours into the AN74i sterilization cycle.

For the study, one 17.6 ml ampoule was activated (broken) inside the sterilization liner bag after the initial purge of the sterilization liner bag was completed. Samples of air were collected using a 1.0 ml gas-tight syringe at approximately 18 inches (45.4 cm) from the cabinet. Samples were taken at 2.5 hours after the activation of the ampoule and again 40 minutes later after the vent pump has been disabled.

GC Profile of AN74i cabinet under vent pump failure at 2.5-hours



A gas chromatograph (GC) was used to test the concentration of ethylene oxide in the air samples.

RESULTS:

15 minute OSHA STEL levels

Operator Breathing Zone Air Sample	OSHA allowable limit	Detected level
149 - 164 min. into cycle	5 ppm	<1.0 ppm[2]
174 - 184 min. into cycle	5 ppm	<1.0 ppm[2]

While the gas concentration increased inside the sterilizer cabinet, no EO was detected outside the cabinet 40 minutes after the ventilation pump was disabled. At the peak concentration of EO inside the cabinet and sterilization liner bag, the gas chromatograph reading was less than 1.0 ppm (undetectable). These measurements are below OSHA short term exposure limit allowed of 5.0 ppm.

CONCLUSION:

The operator is not at risk for ethylene oxide exposure should a vent pump fail during an AN74i cycle, even at times of peak EO concentration. Actual measured EO levels were less than 1 part per million, well below the OSHA short-term exposure level (STEL) allowable limit of 5.0 ppm over a 15-minute time period.

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[1] The test, AN74i AmpExp 1102, was conducted by Andersen Scientific, Inc.