

This study was undertaken to gauge a worst-case scenario when an Andersen AN74i sterilizer door is accidentally left open by mistake. This study<sup>1</sup> was conducted to determine how long it would take the EO gas in the Anprolene sterilization liner bag to escape into the area outside the sterilizer cabinet when the door of the sterilizer was left open. Results showed that it took more than 75 minutes for ethylene oxide (EO) levels in the vicinity of the sterilizer to exceed OSHA regulation limits.

NOTE: The AN74i sterilizer will alarm if an operator tries to open the door during the sterilization cycle.

### CONDITIONS:

The ambient room environment was 68° to 70° F with approximately 45% relative humidity.

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
- 5 AN71 (4.5 ml) Anprolene® ampoules
- PAN-TY cable ties and Thomas & Betts cable tie tool
- Shimadzu gas chromatograph and analyzer
- 1.0ml gas-tight syringes for gas collection
- 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
  - 5 AN71 (4.5 ml) Anprolene® Ampoules
  - 1 Humidichip® placed in a Humiditube®

### METHODOLOGY AND EQUIPMENT:

This study was performed to test possible operator exposure under extreme conditions, specifically in the event that an operator failed to close the sterilizer door after activating the gas ampoule. In order to test the very worst scenario, this test measured air samples collected less than 10" (25.4cm) from the sterilization liner bag. Even in a worst-case scenario, the operator would not be this close to the door of the cabinet, and thus the ethylene oxide source.

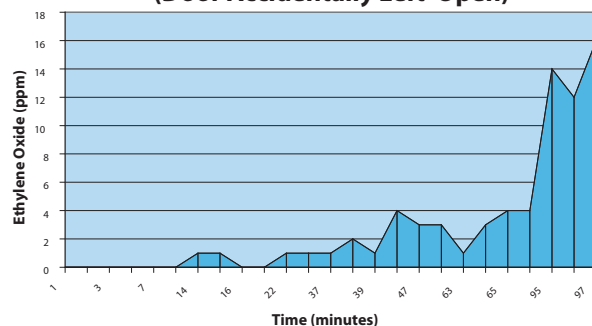
To measure how long it would take for the ethylene oxide gas in the Anprolene sterilization liner bag to diffuse into the area outside the sterilization cabinet, the cycle was started using five 4.5 ml ampoules with the door to the sterilization cabinet left open. Air samples were collected, using a 1.0 ml gas-tight syringe located at the doorway of the sterilization cabinet. A gas chromatograph (GC) was used to test the concentration of the ethylene oxide in the air samples.

### RESULTS:

#### Time it took to reach OSHA STEL limit for EO levels

	OSHA allowable limit	Amount of time to reach limit
Test 1101 (gas escaping outside sterilizer door)	5 ppm	75 < 95 minutes

#### Ethylene Oxide Concentration in the AN74i Doorway (Door Accidentally Left Open)



### CONCLUSION:

From this test, we can conclude that there is no immediate danger of operator exposure if the AN74i sterilization door is not closed upon beginning a cycle, because the OSHA limit was not reached in the doorway of the sterilizer until at least 75 minutes had passed.