

**Project Name:** Experiment to Determine ETO Desorption Rate from a Medical Device

**Site:** Colorado

**Client:** Confidential

## **Project Description**

A medical device company in Colorado had designed and built a new product, for confidentiality we will refer to it as Q. The Q system incorporates two major parts one reusable and one a disposable component (disposable). The disposable is sterilized by the use of ethylene oxide (ETO). After sterilization there is a residue of ETO that is adsorbed by the product. The product is aeration to drive off the residual ETO, but it is known that some ETO is still adsorbed to the unit. The goal of the experiments conducted in 2010 was to accurately measure the airborne release of ETO (desorption)-(off-gassing) from the disposable set in a controlled fashion, so that a release rate could be experimentally determined. The release rate could then be employed to model occupational exposure scenarios to determine if there is a potential for workers who would be using the product to be exposed to ETO above an action level.

## **General Description of Test Device**

To facilitate the testing of the disposable set in a controlled fashion an experimental testing chamber was initially designed and built. The testing chamber was composed of a flexible Teflon chamber with two connection ports. Teflon tubing was used to connect the flexible chamber to the detector.

## **Detector**

The detector was a portable single beam infrared spectrophotometer, MIRAN 205B Series SaphIRE; portable ambient air analyzed manufactured Thermo Electron Corporation (Miran).

## **Results of Test:**

The following is the summary of the results from the test:

- 1) The test system as built was capable of accurately measuring the ETO desorption rate.
- 2) ETO was released from the disposable set whether the set was enclosed in a protective plastic bag or removed from the bag.
- 3) The ETO emission rate constant was found to be  $x.xx E^{-x}$  (confidential).

Four disposable units were tested.