Process Insights™
Premium Insights Into Process

REAL-TIME OPTICAL ABSORPTION ANALYZERS

APPLICATION NOTE

Real-time Determination of Ethylene Oxide Concentration for Sterilization Applications

Our GUIDED WAVE™ NIR-O™ full spectrum Spectrometer and our ClearView® db Photometer can be configured to provide real-time measurement of ethylene oxide (EO) gas during sterilization cycles. Ethylene oxide is commonly used in the healthcare and pharmaceutical industries as an alternative to steam sterilization or other chemical sterilization methods. For sterilization to occur, a sufficient concentration of EO must be present for an adequate length of time. The efficiency of the process is facilitated by the presence of water vapor or humidity. The concentration of EO required also depends on the temperature of the process. The higher the temperature, the lower the concentration of EO that will be necessary for sterilization to occur. The ability to measure the EO and water vapor concentrations during the complete sterilization cycle provides analytical validation that all sterilization conditions have been met.

Experimental

Near-infrared spectra of EO at 30 kPa and water vapor at 22.1 mg/l are shown in Figure 1. These spectra were measured with a our NIR-O using a 25 cm pathlength gas probe. Strong EO gas absorbance peaks at 1643 and 1693 nm are easily identified. Water vapor peaks occur at 1362 nm and 1871 nm and do not interfere significantly with the distinct EO peaks. A series of near-infrared spectra collected at varying EO pressures are shown in Figure 2.

Analysis

Routine baseline correction pre-processing was applied to the calibration data set. Regression analysis applied at the 1643 nm peak shown in Figure 3, indicates clearly how effective it is to predict EO by NIR spectroscopy. This simple one wavelength measurement produced an accuracy of ±0.15 kPa. The same methodology can be applied to the ClearView db filter photometer, which will produce similarly accurate results. The measurement of the water vapor concentration for this application is similar to the water vapor measurement performed by our GUIDED WAVE Hydrogen Peroxide Vapor (HPV) analyzer. Please contact Process Insights for more information on the measurement levels.

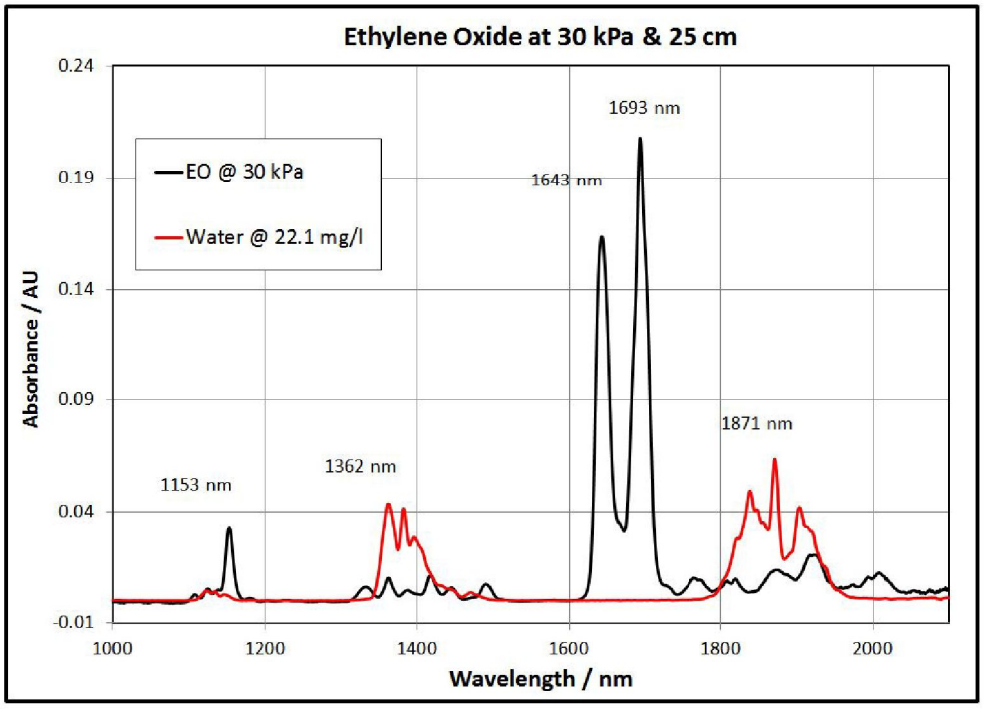

Figure 1: Ethylene Oxide and Water Spectra

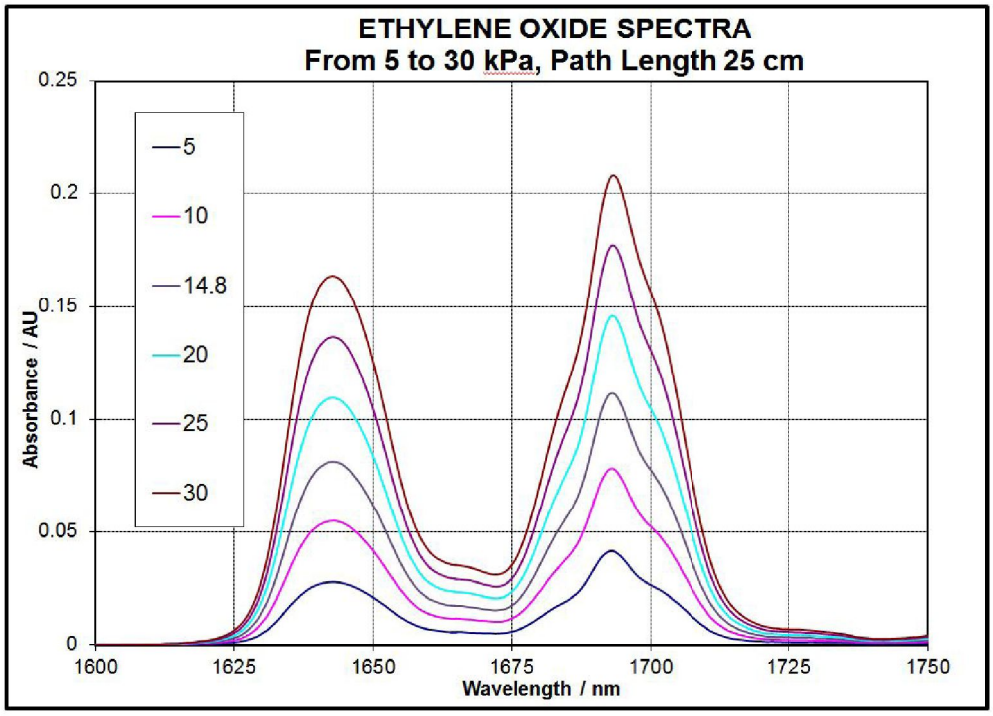

Figure 2: Ethylene Oxide - varying pressures

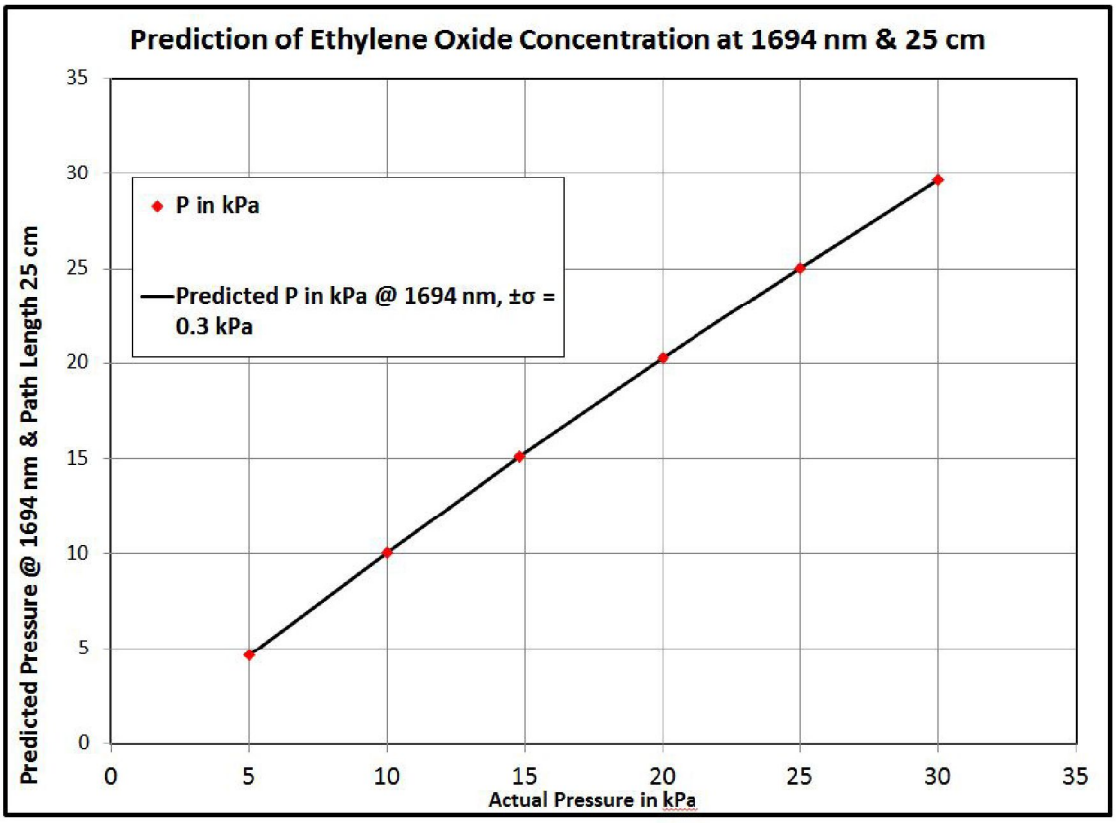

Figure 3: Regression Results - NIR-O

Conclusion

Both analyzer instrument technologies, spectrometer or photometer, can provide accurate and reliable insitu measurement of ethylene oxide concentration during sterilization. The use of fiber optics to deploy the optical gas sensor allows for remote, and thus safe continuous measurements to occur, both under vacuum conditions or in explosive environments. The differentiating factor for choosing one analyzer system over the other is typically the measurement environment and other measurement parameters that are of interest.

The NIR-O full spectrum analyzer can more easily perform under varying conditions including interfering gas species. The ClearView db is better suited for single or binary component gas mixtures. Both analyzer systems will produce similar signal-to-noise ratios and accurate results for both water vapor and ethylene oxide. Both units can provide the confidence and documentation required to meet regulatory compliance in your sterilization application. Contact Process Insights for additional help in choosing the right analyzer.

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REAL-TIME OPTICAL ABSORPTION ANALYZERS

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