

Technical Note

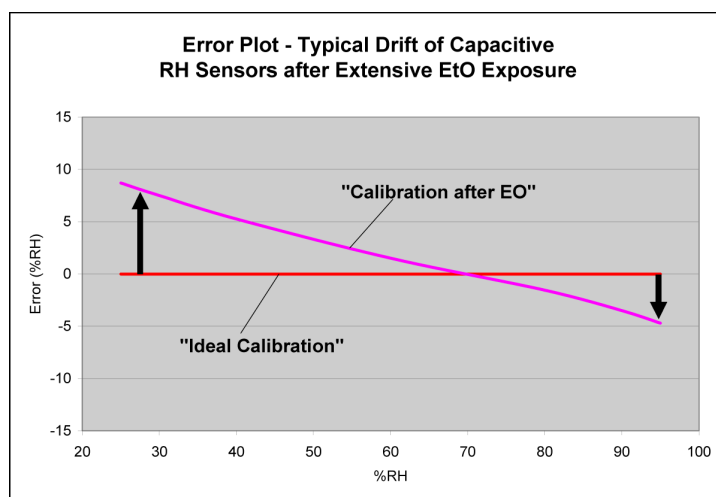
Date: October 15, 2009

Subject: Considerations in the Use of DataTrace RH Data Loggers for Monitoring Ethylene Oxide Sterilization Processes

Data loggers that measure relative humidity (RH) and temperature are routinely used in Ethylene Oxide (EO) sterilization processes for validation and routine monitoring. An understanding of the effects of EO exposure on the sensing element of the RH data logger is critical to the successful application of these devices in this application.

First, a brief explanation of the RH sensor technology is required. The newest data loggers, such as the Micropack III (MP-III) and Micropack RF use a Capacitive RH sensor in which water vapor migrating into a thin polymeric film changes the capacitance of the sensor element. Older devices, such as the DataTrace FRB loggers use a similar device, except that a resistance change is measured upon exposure to water vapor. Both of these sensors rely on the water absorption properties of an organic polymer as the basis for their RH measurement.

Unfortunately, EO is a very reactive compound and can oxidize a wide variety of substances. When either resistive or capacitance RH sensors are exposed to EO, subtle change can occur in the water absorption properties of the polymeric coating. This manifests itself as a shift in the calibration of the data logger. The degree of shift is somewhat proportional to the duration of EO exposure, although there are likely other unknown factors that influence the speed and degree of calibration shift. Illustrated below is the typical change in calibration of a MP-III data logger fitted with a capacitive RH sensor after extensive exposure to EO.



The "Error Plot" above illustrates the degree of calibration error as a function of the absolute RH. Typically, at low RH levels, the calibration shifts above the ideal curve and the logger reads higher than the actual humidity. At high RH levels the opposite is true and the logger reads lower than the true humidity.

It is important to note that, in the primary range of interest in EO sterilization processes, typically 40% to 85% RH, the shift in calibration is less severe and generally within tolerances established by most standard operating procedures (SOP). This means that the MPIII data logger is still providing accurate RH results in the range of interest for the sterilization process, even after extensive exposure to EO gas.

There are several considerations and recommendations that can be made based on the behavior of RH data loggers exposed to EO, as follows:

- To successfully utilize data loggers for monitoring EO processes, it is important to routinely monitor their accuracy through periodic calibration checks. The duration between calibration checks depends on usage, but generally is between 3 months and 12 months. It is always safest to start at 3 months and only extend the time between checks after a history of stability is established.
- It is important only that the calibration is accurate between the RH levels of interest in EO sterilization (typically 40% to 85%). Inaccuracies outside of the area of interest are generally not important and can be ignored.
- When evaluating calibration accuracy, use an acceptance criteria established by standard EO protocols at your facility. Even though the loggers are calibrated to an accuracy of +/- 2% RH at the factory, it is unlikely that they will maintain this accuracy following EO exposure. An accuracy specification of between +/- 5% and +/- 10% is more appropriate for RH sensors that have been exposed to EO.
- For the best accuracy, perform a calibration check at the typical EO sterilization temperature of approximately 55^o C. The drift in calibration is less severe at 55^o C than it is at 25^o C, where many data loggers are checked and calibrated.
- There are a number of RH calibration chambers available on the market for checking the accuracy of data loggers. While salt solutions can sometimes be used successfully, they are somewhat cumbersome and prone to errors. Alternately, the data loggers can be returned to the factory for calibration checks.
- If loggers are found to be out of calibration in the range of interest, they can be recalibrated using the DataTrace software. To successfully perform recalibrations, choose 2 points that span the range of interest (i.e. 40% and 85%) and follow the instructions in the DataTrace SOP which can be found online at www.mesalabs.com/datatrace-documents-and-downloads/
- It has been noted that calibration inaccuracies have a tendency to "self-correct" if the data loggers are outside of the EO environment for a period of time (1-2 days). It is a good idea to let loggers sit for this period of time prior to performing a calibration check. Elevated temperatures (60^oC) may help the loggers return to a calibrated state more rapidly.
- The Resistive Sensor used in the older Micropack FRB loggers undergoes a shift in calibration that is more severe in the mid-RH range, less predictable, and non-linear in nature. More frequent calibration checks are generally called for if these older loggers are used.
- Most RH sensors are adversely affected if liquid water forms on their surface. Under these "condensing" conditions a shift in calibration can occur. EO process cycles should be designed, and loggers should be placed in the chamber, to avoid the possibility of water condensing on the logger.

Mesa Laboratories stands ready to assist its customers in developing an effective quality control program for their RH data loggers. We can recommend the type of equipment required to perform calibration checks, or we can perform these checks in our calibration laboratory. Simply contact your sales representative or the factory directly for assistance with this or any other data logger application.