Ethylene Oxide Sterilization (EtO/EO)

In accordance with ANSI/AAMI/ISO 11135, it is required for temperature and humidity levels be monitored during an EtO/EO sterilization process. MadgeTech data loggers can be used to validate these parameters to ensure an environment in which sufficient sterility levels are achieved.

MadgeTech has developed data loggers designed specifically to validate temperature and humidity requirements for EtO sterilization cycles. The **Temp1000IS** data logger measures temperature and the **RHTemp1000IS** measures both temperature and humidity. Both devices are designed to withstand harsh environments and record data at user selected time intervals, providing a complete temperature and humidity profile of each EtO cycle. The stand alone operation and compact size of these data loggers allows them to fit easily into the sterilization chamber with the product load.

As federal regulations mandate that facilities produce records for each EtO sterilization cycle, all recorded readings are automatically saved upon download and can then be included with validation documents and reports to verify a successful sterilization cycle. The MadgeTech 1000IS Series has become the data logger of choice for the EtO sterilization industry.

The Temp1000IS and RHTemp1000IS are designed to be placed directly inside the sterilization chamber and meet the required regulation equipment standards. These devices have been certified by FM Approvals as intrinsically safe for Class I, Division 1, groups A, B, C, D, and non-incendive for Class I, Division 2, groups A, B, C, D, hazardous environments.

RHTemp1000IS
Intrinsically Safe Humidity & Temperature Data Logger

The new RHTemp1000IS is MadgeTech's most robust temperature and humidity data logging solution. FM Approved to be Intrinsically Safe for Class 1, Division 1, groups A, B, C, and D and non-incendive for Class 1, Division 2, groups A, B, C, and D, the RHTemp1000IS is certified as safe for use in many hazardous locations where explosive gas atmospheres are present.

The RHTemp1000IS features a cutting-edge thermoset-polymer capacitive sensor, that provides the longest operating life in an ethylene oxide-based (EtO) sterilization process. With the ability to maintain resistance against various chemical liquids and vapors like isopropyl, benzene, toluene, formaldehydes, oils and common cleaning agents, this sensor is ideal for EtO processes, as well as continuous, long term use.

The RHTemp1000IS enclosure is made of 316 Stainless Steel. It's small size and sleek design allows it to be placed precisely in critical locations for temperature and humidity mapping.

Its ultra-fast communication speed allows for programming and data download in just seconds. Using the IFC400 docking station, communications are established automatically through metal contacts and up to 18 units can be programmed simultaneously using the IFC406 multiplexer.

Temp1000IS

Intrinsically Safe Temperature Data Logger

The Temp1000IS provides an Intrinsically Safe solution for temperature monitoring in hazardous locations. It is FM Approved to be Intrinsically Safe for Class 1, Division 1, groups A, B, C, and D and non-incendive for Class 1, Division 2, groups A, B, C, and D, certifying it safe to use in explosive acetylene, hydrogen, ethylene, and propane gas atmospheres.

The Temp1000IS features a highly accurate precision 100 Ω platinum RTD sensing element. The external 1 inch RTD probe provides a faster response time in comparison to most standard internal sensors.

The Temp1000IS comes housed in a 316 Stainless Steel enclosure. An optional key ring attachment is available for additional installation configurations.

Key Ring End Cap available for the RHTemp1000IS and Temp1000IS

IFC406

Multiplexer Data Logger Interface

The IFC406 Multiplexer Data Logger Interface allows for multiple data loggers to be connected and download data simultaneously. Each IFC406 accomodates up to 6 data loggers, up to 3 IFC406 units may be daisy-chained together to communicate with a total of 18 devices through 1 USB port.

To connect multiple IFC406 Interfaces together, simply join the units side by side, making sure the spring pin contacts are connected and magnetically joined.

MadgeTech EtO Servicing

To successfully utilize data loggers for monitoring EtO processes, it is imperative to routinely verify accuracy through periodic calibration checks and servicing.

MadgeTech offers professional calibration services for all MadgeTech data loggers. Traceable to NIST for temperature, humidity, pressure, voltage, and current.

Standard servicing plans for EtO processing include:
• Free device evaluation
• As Found data collection
• RH sensor replacement
• O-Ring replacement
• Battery replacement
• Calibration and adjustment at standard or custom points

Test Equipment
• (2) PGC Temperature and Humidity Stability Chambers
• Various Circulating Baths
• Pressure Calibrator

Reference Equipment
• Rotronic hygrometers
• Accuracy of:
  ±1 %RH, 0 %RH-90 %RH
  ±0.3 °C, 0 °C-80 °C (special temperature
  accuracy of 0.05 °C @ 25.0 °C)
• Fluke Calibration 1502A Thermometer Readouts
• Accuracy of: ±0.030 °C, -80 °C to +300 °C
• Mensor CPC 6000 Pressure Calibrator
• Accuracy of: ± 0.05 psi

Test and Reference Equipment Subject to:
• Annual Calibration
• Annual Validation
• Annual Mapping