

# DATA LOGGING SOLUTIONS

# ETHYLENE OXIDE STERILIZATION



# THE MADGETECH ADVANTAGE

Ensure safety, quality and efficiency by measuring and recording crucial data for inconsistencies that directly impact the success of a business. Our customizable data logging solutions provide real-time monitoring for applications where the slightest change in environment could be destructive. Coupled with the accuracy and reliability of our products, we also offer free software and cloud services, making compliance and validation reporting a breeze.

## Why Choose MadgeTech?

At MadgeTech we take pride in maintaining meaningful relationships with our customers, going above and beyond to turn their everyday problems into new data logging solutions. To ensure the instrument's accuracy, MadgeTech offers in-house standard and customized calibration services, including ISO/IEC 17025 accredited calibrations for certain products.

### Benefits:

-  Calibration
-  ISO/IEC 17025 Accreditation
-  IQ/OQ/PQ On-Site Services
-  Free Technical Support
-  Free Software
-  Cloud Services
-  21 CFR Part 11 Compliance

MadgeTech data loggers are designed, manufactured and serviced in the USA and distributed worldwide.



**HEADQUARTERS**  
Warner, New Hampshire

# ETHYLENE OXIDE STERILIZATION

Ethylene oxide (EtO) is a gas widely used for the sterilization of healthcare devices and instruments. The process involves exposing products to a gas mixture of EtO and nitrogen within a vacuum-filled chamber. The EtO gas acts as a surface sterilant and the vacuum environment aids the gas to reach most aspects of the device requiring sterilization.

## Process

EtO sterilization involves three main phases: Preconditioning, EtO processing, and Aeration.

The effectiveness of the EtO cycle is dependent upon four physical parameters: EtO gas concentration, temperature, humidity, and exposure time. In accordance with ANSI/AAMI/ISO 11135, it is required by the FDA that temperature and relative humidity be monitored at different intervals during process validations on routine EtO processed medical devices. Periodic chamber mapping and cycle validations are required to be performed to ensure even distribution of temperature and humidity levels throughout the chamber.

## Challenges

EtO is an extremely flammable gas. This makes temperature and humidity monitoring a challenge, as equipment used to perform this is typically battery-operated. Due to the flammability, EtO processes are generally conducted in a sealed chamber, to prevent EtO gas from leaking into the atmosphere. This restricts the use of most measurement systems using external probes.

MadgeTech data loggers have been tested by SGS North America, Inc. as Intrinsically Safe for Class 1, Div 1, Groups A, B, C, and D, which allows them to be used in environments with the continuous presence of ethylene oxide. They are stand-alone and battery powered.

# SOLUTIONS

The RHTemp1000IS and Temp1000IS are MadgeTech's most robust temperature and humidity data logging solutions. FM Approved to be Intrinsically Safe for Class 1, Division 1, groups A, B, C, and D, the RHTemp1000IS and Temp1000IS are certified as safe for use in many hazardous locations where explosive gas atmospheres are present.

The **RHTemp1000IS** features a cutting-edge thermoset-polymer capacitive humidity 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 continual, long term use.

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

The RHTemp1000IS and Temp1000IS enclosures are made of 316 Stainless Steel. Their small size and sleek design allow them to be placed precisely in critical locations for temperature and humidity mapping.

Their ultra-fast communication speed allow for programming and data download in just seconds. Using the **IFC400** docking station, communications are established automatically through metal contacts and up to 6 units can be programmed simultaneously using the **IFC406** Multiplexer.



*The IFC406 Multiplexer data logger interface allows for multiple devices to be connected into one interface.*



*Key Ring End Cap available for the RHTemp1000IS and Temp1000IS*

# RHTEMP1000IS AND TEMP1000IS

## Features:

- Battery life indicator
- 6-port communication interface available
- Smaller in size than the old models
- Key Ring end cap available
- Engraved serial number and label
- FM Approved to be Intrinsically Safe for Class 1, Division 1, groups A, B, C, and D

## Benefits:

- Simply place the logger in the docking station to automatically establish communications
- Start, stop, and download from up to 6 loggers at a time by using the IFC406 Multiplexer docking station
- Small size enables it to be placed easily into product packaging
- Enhanced communication speed; download full memory in seconds

## MadgeTech data loggers can aid in:

- Facilitating parametric release
- Chamber / cycle monitoring for process validations
- Making EtO cycles more efficient



## RHTemp1000IS

Intrinsically Safe Humidity and Temperature Data Logger

Range:	-40 °C to +80 °C (-40 °F to +176 °F) 0 %RH to 100 %RH (non-condensing)
Resolution:	0.01 °C (0.018 °F), 0.1 %RH
Memory:	32,768 readings
Reading Rate:	1 reading every second to 1 every 24 hours
Operating Environment:	-20 °C to +80 °C (-4 °F to +176 °F), 0 %RH to 95 %RH
Battery Life:	2 years typical at 25 °C, 15 minute reading rate

## Temp1000IS

Intrinsically Safe Temperature Data Logger

Range:	-40 °C to +80 °C (-40 °F to +176 °F)
Resolution:	0.01 °C (0.018 °F)
Memory:	65,536 readings
Reading Rate:	1 reading every 2 seconds to 1 reading every 12 hours
Operating Environment:	-40 °C to +80 °C (-40 °F to +176 °F), 0 %RH to 100 %RH
Battery Life:	2 years typical at 25 °C, 15 minute reading rate

# MAINTENANCE RECOMMENDATIONS

All RH sensors are affected by Ethylene Oxide and over time, particles can become embedded in the sensor, which can cause a drift in the calibration. To combat the detrimental effects of EO/EtO on the RH sensors, it is highly recommended that a standard maintenance protocol is implemented.

MadgeTech assists clients in developing maintenance procedures based on their specific usage of the devices as well as in-house capability. By offering calibration services at MadgeTech's facility, not only are data loggers calibrated against NIST standards, but they are also carefully inspected by the manufacturer for complete quality assurance.

## MadgeTech Recommends – Daily or Weekly

### Reconditioning

- The negative impact of the EO/EtO on the RH sensor can be lessened by letting the units sit for a few days (1-2) after exposure, bringing the sensor back to a more *calibrated state*.
- This can be accelerated in a higher temperature, drier environment: 55 °C, 35 %RH for 24 hours
- This is referred to as *reconditioning* the sensor. A reconditioning procedure should be implemented after each EO/EtO cycle to ensure best performance out of the sensor.

### Tolerance Verification

- Calibration or verification in a controlled environment with NIST traceable reference equipment
  - › Temperature and Humidity Chamber
  - › Incubator
  - › Saturated Salt Solution
- Comparison against another data logger standard, such as a logger that has not been exposed to EO/EtO
  - › Software report
    - Display minimum and maximum values
    - Verify that all are within % to standard



# MADGETECH 4 SECURE SOFTWARE

MadgeTech 4 Secure Software aids customers in compliance with 21 CFR Part 11 requirements. The software ensures standards in which electronic files are considered equivalent to paper records, saving time and effort.

Meeting compliance with regulations for the FDA's Good Manufacturing Practices, or those set forth in Quality Plans, has become increasingly complex. MadgeTech has simplified this process by including IQ/OQ/PQ protocols with its **MadgeTech 4 Secure Software** package.

This enormous time and money saving feature eliminates the need to develop in-house software validation procedures. The MadgeTech IQ/OQ/PQ protocol is in support of FDA and cGMP guidelines. In addition, MadgeTech offers a Software Validation Workbook to help the user verify the functionality of the software.

## Areas Evaluated

### Installation Qualification (IQ)

- A description of the MadgeTech system
- Verification that all MadgeTech system equipment, software and accessories are received in good condition
- A check for complete documentation
- Verification that the installation of MadgeTech equipment is completed properly
- Verification that MadgeTech software is installed properly on the target workstation
- Verification of basic communication between MadgeTech data logger(s) and the target workstation(s)

### Operational Qualification (OQ)

- Functional verification of MadgeTech data loggers
- Handling and maintenance information for the use of MadgeTech equipment
- MadgeTech operating procedures for primary functions
- Verification of proper communication between the MadgeTech data logger(s) and the workstation(s)
- Verification that the data logger hardware is operational

### Performance Qualification (PQ) Recommendation

- Additional handling precautions for maintaining the accuracy of MadgeTech equipment
- Periodic maintenance information for the use of MadgeTech equipment
- Periodic calibration verification in the field
- Comparison of the reported values to a known good standard
- Verification of acceptable performance in the target system

## Features and Benefits

- Audit Trails
- Secure data file
- Sophisticated user management
- Electronic signatures
- Time and cost saving validation package, stands up to interrogation from auditors
- Automatic data security and audit trail
- Traceability with customizable electronic signatures

