Ethylene Oxide Sterilization
Data Logging Solutions
MadgeTech, Inc. is a global company, based in New England and founded on old-fashioned principles, customer service, quality, and trust. MadgeTech’s President, Norman Carlson, started the company in 1996 and charted the growth of the product lines and services while maintaining those solid core principles.

Our Can Do team of engineers and technical staff consistently incorporate new and innovative ideas into our data loggers. In short, we push the envelope, raising the bar in innovation and quality. Our competitors have praised us by adopting many of our ideas as their own. Over time, MadgeTech has become the industry standard in the data logger market.

MadgeTech continuously develops new, cutting-edge products, creating solutions for our customers around the world in industries across the board. Our growing network of distributors has expanded our presence to markets far beyond our home-headquarters in New Hampshire, our products are now sold in over 100 countries around the world.

Our employees are committed to quality and customer satisfaction. Behind the full range of MadgeTech’s products and services is the cumulative expertise of experienced engineers, manufacturing and electronic professionals and technicians. Our knowledgeable sales team can offer technical advice to assist in selecting the right product for each application, as well as providing after-sales support.

MadgeTech is dedicated to providing customers with reliable, affordable products, hassle-free ordering, and excellent service, saving customers time and money. It is our goal to earn your trust in meeting your needs and providing innovative solutions. The products and services that bear the MadgeTech name come with quality assurance and the best support in the industry today.

Norman E. Carlson,
Founder & President
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 FM Approvals 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.

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.

Application

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.
The new 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’ enclosure 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 18 units can be programmed simultaneously using the IFC406 Multiplexer.

RHTemp1000IS & Temp1000IS

Features
- Battery life indicator
- 6-port communication interface available
- Smaller in size than the old models
- Key Ring bottom 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 18 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 & 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:** 16,350 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

Key Ring End Cap available for the RHTemp1000IS and Temp1000IS

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**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:** 32,767 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

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**IFC406**
Multiplexer Data Logger Interface

The IFC406 Multiplexer Data Logger Interface allows for multiple devices to be connected into one interface. Each IFC406 allows for 6 data loggers to be connected. Up to 3 IFC406 units may be daisychained 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.

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### Features & Benefits

Aids in complaints with FDA 21 CFR Part 11/820 and GxP guidelines. Features additional security benefits such as:

- 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
- Sophisticated user management
- Traceability with customizable electronic signatures

Meeting compliance with regulations for the FDAs 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)
- 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
Reporting Features

Customizable Graphs
- Cycle Phases
- Composite Graphs
- Data Annotation

Automatic Statistics Calculation
- Cycle Phases
- Composite Graphs
- Data Annotation

Export to Excel

Export Options
- Automatic Statistics Calculation
- Cycle Phases
- Composite Graphs
- Data Annotation