

Data Logging Solutions For
Ethylene Oxide
(EO/EtO) Sterilization



MadgeTech Data Loggers and Software

The MadgeTech Solution

Data Loggers and Secure Software for EO/EtO Sterilization

The MadgeTech 4 Secure Software contains criteria such as electronic signatures, access codes, secure data files, and an audit trail which meet the requirements of 21 CFR Part 11 and help provide data integrity. As a requirement for good manufacturing processes, MadgeTech's Secure Software is an essential tool.

MadgeTech provides data logging solutions for temperature & humidity monitoring. These solutions are intrinsically safe and designed specifically for use in EO/EtO environments.

Free support is provided to ensure users feel comfortable and confident using the MadgeTech system.

For a complete data logging system, the following is required:

- Data loggers such as the RHTemp1000IS and Temp1000IS
- IFC400 and/or IFC406
- Computer
- MadgeTech 4 Secure Software



RHTemp1000IS

Intrinsically Safe Humidity and Temperature Data Logger

Rated as Intrinsically Safe by FM Approvals for use in Class I, Division 1, Groups A, B, C and D and non-incendive for Class I, Division 2, groups A, B, C and D indoor and outdoor.

Utilizes a new thermoset-polymer capacitive sensor that provides the longest operating life in an ethylene-oxide based sterilization process.

The stainless steel body with new sintered cap provide increased accuracy and more resistance to harsh environments.

Maintains resistance against various chemical liquids and vapors like isopropyl, benzene, toluene, formaldehydes, oils and common cleaning agents.

Applications:

*EO/EtO Sterilization, Environmental Studies,
Hostile Environmental Monitoring, Medical & Pharmaceutical*



RHTemp1000IS

Intrinsically Safe Humidity and Temperature Data Logger

Features & Benefits

- Temperature:
 - > Temperature Measurement Range: -20 °C to +80 °C (-4 °F to +176 °F),
 - > Temperature Sensor: Resistance Temperature Detector (RTD)
 - > Temperature Response Time: 10 minutes (free air)
 - > Calibrated Accuracy: ± 0.5 °C (0 °C to 55 °C)
- Humidity:
 - > Humidity Sensor: Capacitive Digital Humidity Sensor
 - > Humidity Response Time: $\tau = 2$ minutes to 63% of change
 - > Calibrated Accuracy: ± 3 %RH maximum
 ± 2 %RH typical at 25°C
 - > Specified Accuracy Range: 10 %RH to 90 %RH;
 ± 5 °C to +55 °C
 - > Start Modes: Software programmable immediate start or delay start up to 24 months in advance



Temp1000IS

Intrinsically Safe Temperature Data Logger

Rated as Intrinsically Safe by FM Approvals for use in Class I, Division 1, Groups A, B, C and D and non-incendive for Class I, Division 2, groups A, B, C and D indoor and outdoor.

Precision 100 Ω (*ohm*) platinum RTD sensing element.

External RTD for fast response time.

Sterilization Units and Pasteurization Units are available in MadgeTech Software with the click of a button.

Applications:

EO/EtO Sterilization, Implement HACCP Programs, Food Preparation and Processing, Environmental Studies, Well Monitoring, Dishwasher Testing, Hazardous and Hostile Environment Monitoring, Medical and Pharmaceutical



Temp1000IS

Intrinsically Safe Temperature Data Logger

Features & Benefits

- Temperature:
 - > Temperature Measurement Range: -40 °C to +80 °C (-40 °F to +176 °F),
 - > Temperature Sensor: Resistance Temperature Detector (RTD)
 - > Temperature Resolution: 0.01 °C
 - > Calibrated Accuracy: ± 0.5 °C (0 °C to 55 °C)
 - > Start Modes: Software programmable immediate start or delay start, up to 2 years in advance
 - > Lethality Equations: Sterilization Units and Pasteurization Units are available in software with the click of a button



IFC406

Multiplexer Data Logger Interface

Features & Benefits

- Simply place the loggers in the docking station to automatically establish communication with the PC.
- Each IFC406 allows for 6 data loggers to be connected and up to 3 IFC406 units can be daisy-chained together for communication with a total of 18 devices through 1 USB port.
- Engraved Label
- LED Indicators:
 - > Blue: Indicates unit has power
 - > Amber: Channel is busy or searching for a device
 - > Green: Operation successful or complete
- Dimensions:
 - > 9.5 in x 1.95 in x 1.75 in (241 mm x 49.5 mm x 44.5 mm)
- Weight:
 - > 1.65 lb (750 g)





Data Logger Software

MadgeTech 4 Secure Data Logger Software

- MadgeTech4 Secure aids in compliance with **21 CFR Part 11** requirements.
- Full IQ/OQ/PQ validation documentation comes **included**.
- Quantity discounts are available.
- Don't need 21 CFR Part 11? MadgeTech has a standard version of this *same software* available for **free**.



Features

- Customizable Graphs
- Exporting
- Data Annotation
- Digital Calibration
- Automatic Statistics Calculation
- Graph Overlays, Data Summary, Reports
- Audit Trails
- Electronic Signatures
- Real time wireless alarming

Data Analysis

Graphs, Statistics & Tabular Data

The MadgeTech Software provides powerful data analysis and reporting tools to aid in sterilization validation and compliance.



Graph

The table displays the same data as the graph, but in a tabular format. The columns are Date, Time, Time Zone, Delta, X00019 Temperature (°C), X00019 Humidity (% RH), and X00019 Absolute Pressure. The data is sorted by Time, showing a sequence of measurements from 8:54:57 AM to 8:57:17 AM.

| Date | Time | Time Zone | Delta | X00019 Temperature (°C) | X00019 Humidity (% RH) | X00019 Absolute Pressure |
|-----------|------------|-----------|--------|-------------------------|------------------------|--------------------------|
| 3/20/2014 | 8:54:57 AM | -0400 | -00:00 | 27.0 | 35.0 | 986.82 |
| 3/20/2014 | 8:55:02 AM | -0400 | +00:05 | 21.09 | 35.0 | 986.82 |
| 3/20/2014 | 8:55:07 AM | -0400 | +00:10 | 21.09 | 33.0 | 986.82 |
| 3/20/2014 | 8:55:12 AM | -0400 | +00:15 | 21.10 | 34.2 | 986.82 |
| 3/20/2014 | 8:55:17 AM | -0400 | +00:20 | 21.13 | 35.8 | 986.82 |
| 3/20/2014 | 8:55:22 AM | -0400 | +00:25 | 21.16 | 43.0 | 986.82 |
| 3/20/2014 | 8:55:27 AM | -0400 | +00:30 | 21.18 | 45.6 | 986.82 |
| 3/20/2014 | 8:55:32 AM | -0400 | +00:35 | 21.20 | 50.0 | 986.82 |
| 3/20/2014 | 8:55:37 AM | -0400 | +00:40 | 21.23 | 53.6 | 986.82 |
| 3/20/2014 | 8:55:42 AM | -0400 | +00:45 | 21.26 | 57.2 | 986.82 |
| 3/20/2014 | 8:55:47 AM | -0400 | +00:50 | 21.27 | 59.4 | 986.82 |
| 3/20/2014 | 8:55:52 AM | -0400 | +00:55 | 21.26 | 50.2 | 986.82 |
| 3/20/2014 | 8:55:57 AM | -0400 | +01:00 | 21.26 | 42.1 | 986.82 |
| 3/20/2014 | 8:56:02 AM | -0400 | +01:05 | 21.25 | 37.6 | 986.82 |
| 3/20/2014 | 8:56:07 AM | -0400 | +01:10 | 21.24 | 35.0 | 986.82 |
| 3/20/2014 | 8:56:12 AM | -0400 | +01:15 | 21.22 | 33.2 | 986.82 |
| 3/20/2014 | 8:56:17 AM | -0400 | +01:20 | 21.21 | 31.8 | 986.82 |
| 3/20/2014 | 8:56:22 AM | -0400 | +01:25 | 21.19 | 30.7 | 986.82 |
| 3/20/2014 | 8:56:27 AM | -0400 | +01:30 | 21.19 | 30.2 | 986.82 |
| 3/20/2014 | 8:56:32 AM | -0400 | +01:35 | 21.19 | 30.0 | 986.82 |
| 3/20/2014 | 8:56:37 AM | -0400 | +01:40 | 21.17 | 29.8 | 986.82 |
| 3/20/2014 | 8:56:42 AM | -0400 | +01:45 | 21.16 | 29.6 | 986.82 |
| 3/20/2014 | 8:56:47 AM | -0400 | +01:50 | 21.15 | 29.5 | 986.82 |
| 3/20/2014 | 8:56:53 AM | -0400 | +01:56 | 21.16 | 29.5 | 986.82 |
| 3/20/2014 | 8:56:57 AM | -0400 | +02:00 | 21.15 | 29.3 | 986.82 |
| 3/20/2014 | 8:57:02 AM | -0400 | +02:05 | 21.14 | 29.3 | 986.82 |
| 3/20/2014 | 8:57:07 AM | -0400 | ... | 21.13 | 29.2 | 986.82 |
| 3/20/2014 | 8:57:12 AM | -0400 | ... | 21.13 | 29.2 | 986.82 |
| 3/20/2014 | 8:57:17 AM | -0400 | ... | 21.13 | 29.2 | 986.82 |

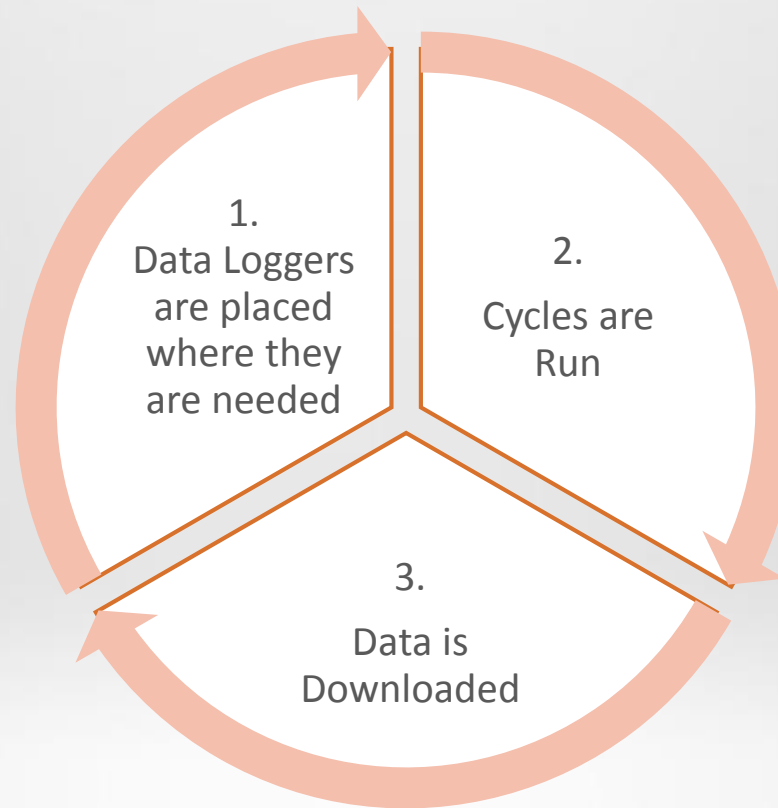
Tabular Data

Statistics

The MadgeTech Solution

Process Overview

Units are placed throughout and around the pallet or load to measure stratification



No wires – Completely self-sufficient. Loggers can record through the entire sterilization cycle

After each EO cycle, data is retrieved to validate temperature and humidity over time using MadgeTech 4 Secure Software

Servicing and Maintenance

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 recommend 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 & 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

Calibration & Servicing

To combat the effects of Ethylene Oxide

- To successfully utilize data loggers for monitoring EO/EtO processes, it is imperative to routinely verify accuracy through periodic calibration checks and servicing.
- It is recommended to start at a 6 month interval and only to extend the duration between checks after a history of stability is established.
- MadgeTech offers professional calibration services for all MadgeTech data loggers. Traceable to NIST for temperature, humidity, pressure, voltage, and current. Standard servicing plans for EO/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
- Custom calibration options available

MADGETECH
WE BUILD DATA LOGGERS

CERTIFICATE OF CALIBRATION

| Certificate Information | | Device Information | |
|-------------------------|-----------------|--------------------|--|
| Certificate Number: | NC-13-05-30-000 | Device Name: | RFTCTemp2000A |
| Calibration Technician: | Paul Dymont | Device ID: | RFTCTEMP |
| Calibration Date: | 2013-05-30 | Serial Number: | 200421 |
| Next Calibration Due: | 2014-05-30 | Model Description: | Wireless Thermocouple Temperature Recorder |

MadgeTech, Inc. certifies that the instrument identified below has been calibrated using calibration standards that are traceable to the National Institute of Standards and Technology (NIST). This certificate is copyrighted and may not be reproduced, except in full, without prior written approval of MadgeTech, Inc.

RFTCTemp2000A - Temperature - **200421**

The Temperature channel of the device under test (DUT) was calibrated in direct comparison to the reference equipment listed on the last page of this calibration certificate.

Published Device Specifications

| | |
|----------------------------|---------------|
| Calibrated Accuracy: | ±0.50 °C |
| Calibrated Accuracy Range: | 0 °C to 50 °C |
| Resolution: | 0.01 °C |

Channel 1 - Units of °C

| Point | Standard | DUT Uncorrected | Device Error | Device Allowable Limits | DUT Corrected | Device Error |
|-------|-------------------|-----------------|---------------------|-------------------------|----------------|---------------------|
| | Actual Test Point | Device As Found | ± Device - Standard | ± Standard ± Accuracy | Device As Left | ± Device - Standard |
| 0 | 25.00 | 23.43 | -1.57 | 24.50 to 25.50 | 25.00 | 0.00 |
| 1 | 60.00 | 57.46 | -2.54 | 59.50 to 60.50 | 60.01 | 0.00 |

Initial Correction Values Applied Correction Values

| | | |
|---------|------|------------|
| Gain: | 1 | 0.97205368 |
| Offset: | 0.00 | -0.87 °C |

Maintaining Calibration:

This product is manufactured from the highest quality components. The unit has been designed to remain within its specifications during normal use. However, the length of in-tolerance service can be affected by low battery voltage, age, temperature, humidity, shock, and other environmental influences. For those users with critical performance or validation requirements, MadgeTech, Inc. recommends that the unit be serviced and calibrated at regular periodic intervals.

| Reference Equipment | Serial # | Certificate # | Last Calibration Date | Next Calibration Due |
|-----------------------|----------|---------------|-----------------------|----------------------|
| Rotronic HygroClip2-S | 61057626 | 130516-KR01 | 2013-05-06 | 2014-05-06 |

Calibration and Service:

For information regarding this calibration or to arrange factory calibration or other service for this product, contact MadgeTech, Inc. or an authorized reseller. Products shipped directly to MadgeTech, Inc. will include a Return Merchandise Authorization (RMA) number.

Issued By: *P. Dymont*

Approved By: *N. Chuma*

Certificate Number: NC-13-05-30-000
Date Created: 2013-05-30
Date Printed: 2013-05-30
Revisory Revision: 5
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MadgeTech EO/EtO Servicing

Calibration Test Equipment

Test Equipment

- (2) PGC Temperature and Humidity Stability Chambers
- Various Circulating Baths
- Pressure Calibrator

Reference Equipment

- Rotronic hygrometers
 - > Accuracy of: ± 1 %RH, 0 %RH to 90 %RH
 ± 0.3 °C, 0 °C to 80 °C (*special temperature accuracy of 0.05 °C @ 25.0 °C*)
- Fluke Calibration 1502A Thermometer Readouts
 - > Accuracy of: ± 0.030 °C, -80.00 °C to +300.00 °C
- Mensor CPC 6000 Pressure Calibrator
 - > Accuracy of: ± 0.05 PSI

All Equipment Subject to:

- Annual Calibration
- Annual Validation
- Annual Mapping



MadgeTech Customer Support



MadgeTech data loggers come with a one year manufacturers warranty.

Free support available for the lifetime of the product.

Contact Information:

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