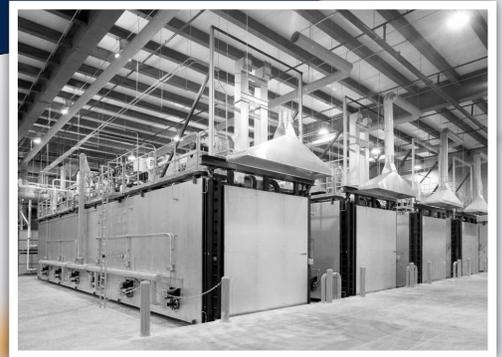


# Sterilization

Data Logging Solutions





## Simplifying How the World Measures & Records Data

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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,

A handwritten signature in black ink, appearing to read "Norman E. Carlson".

Founder & President

# Data Logging Solutions for Applications in the Sterilization Industry

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MadgeTech specializes in data loggers for a variety of sterilization methods and applications. Products and complete systems are available for EO sterilization, Dry Heat sterilization or Depyrogenation, as well as Steam sterilization including the software and tools for autoclave validation.



EtO Sterilization



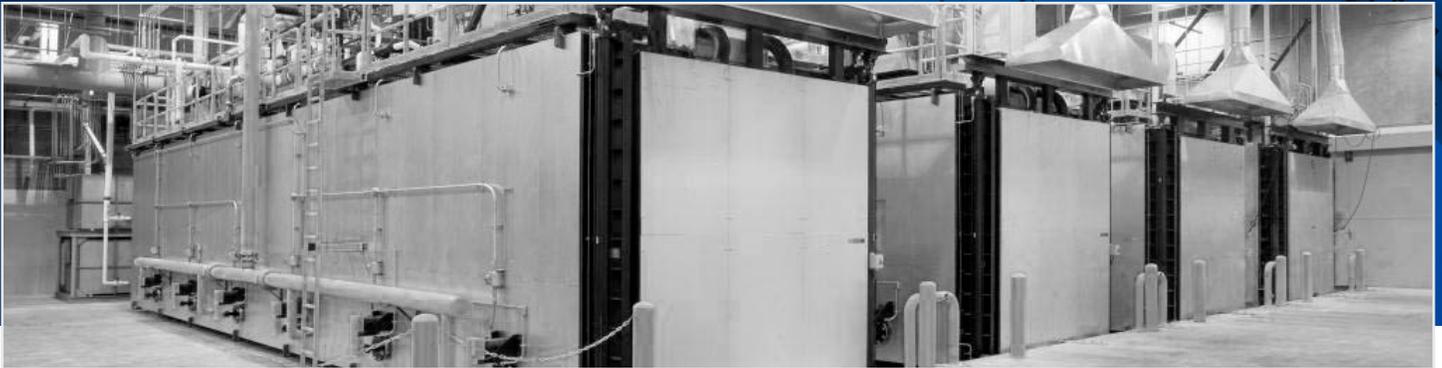
Steam Sterilization



Depyrogenation & Dry Heat Sterilization

# Ethylene Oxide Sterilization (EtO/EO)

In accordance with ANSI/AAMI/ISO 11135, it is required for temperature and humidity levels to be monitored 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  $\Omega$  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 accommodates 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

# Steam Sterilization

MadgeTech has designed a series of data loggers specifically for validating temperature and pressure within autoclaves. These rugged, stand-alone, fully-submersible devices can be placed directly inside the autoclave with the product(s), providing an overall temperature and pressure profile to validate the entire sterilization cycle.



## HiTemp140

### Data Logger for High Temperatures

The **HiTemp140** and **HiTemp140-PT** series data loggers are MadgeTech's solution for precise high temperature monitoring. These data loggers can indefinitely withstand temperatures of up to 140 °C (284 °F) and have an accuracy of  $\pm 0.1$  °C. The HiTemp140 features a rigid external RTD probe capable of measuring extended temperatures, up to 260 °C (500 °F). Varied probe lengths are available up to 7 inches. The HiTemp140-PT features a 24 inch flexible steel RTD probe capable of measuring extended temperatures, up to 350 °C (662 °F).

The **HiTemp140X2** series of dual probe high temperature data loggers offer extreme flexibility for high temperature monitoring applications. This product is ideal for applications such as autoclave validation, sterilization processes and much more.

The **HiTemp140-FR** is a high temperature data logger with an ultra-fast response time, to record temperature during rapidly changing thermal processes. This high temperature data logger is capable of recording as fast as 4 Hz.

The **HiTemp140-FP** probe design is narrow and lightweight making it ideal for placement within small vials, test tubes and other small diameter or delicate applications. The flexible lightweight probe minimizes the risks of breakage (both vial and probe) and makes placement of the probe is easy to manipulate.

The **HiTemp140-M12** is a high temperature data logger designed with a built in M12 probe connector. This logger is compatible with dozens of M12 RTD probes and capable of measuring up to 850 °C (probe dependent).

## Applications

- Steam sterilization cycle validation
- Autoclave chamber mapping
- Blood plasma sample monitoring
- Refrigerator/freezer monitoring & mapping
- Continuous oven monitoring



HiTemp140X2

HiTemp140-PT-1

HiTemp140-1

HiTemp140-M12

HiTemp140-FR

HiTemp140-FP



## PRTemp140

### High Temperature and Pressure Data Logger

The PRTemp140 is a data logger designed to validate if appropriate temperature and pressure levels have been achieved during the steam sterilization cycle. It is built with a precision stainless steel pressure gauge. The data logger has an accuracy of  $\pm 0.1$  °C and  $\pm 0.03$  Bar ( $\pm 0.435$  PSI), which can be achieved over a wide temperature range, from +20 °C to +140 °C (+68 °F to +284 °F). The PRTemp140 is available in either a Flush Top or NPT Pressure Port Top design, with an optional female luer fitting accessory.



Flush Top



NPT Pressure Port Top



Luer Fitting

## AVS

### Autoclave Validation Data Logging System

MadgeTech offers the **AVS** Autoclave Validation System to satisfy demanding autoclave needs. This system comes with five HiTemp140, High Temperature Data Loggers and one PRTemp140 Temperature and Pressure Data Logger, all loggers with NIST certified calibration. The IFC406 Multiplexer Interface and one MadgeTech Secure Software License with IQ/OQ/PQ validation workbook are also included with this system. The AVS comes with all components securely packaged in a sleek and protective aluminum briefcase, ideal for storage or transporting the system to multiple facilities or locations.

The AVS kit can be custom configured with any combination of HiTemp140 data loggers offering a wide variety of probe lengths to choose from.

#### The AVS kit includes (Standard Package):

- (5) HiTemp140 High Temperature Data Loggers with 1 inch probe, all with NIST Calibration Certificates
- (1) PRTemp140 High Temperature and Pressure Data Logger with an NPT port, with NIST Calibration Certificate
- IFC406 Multiplexer interface
- MadgeTech Secure Data Logger Software, with IQ/OQ/PQ validation protocols and workbook
- Aluminum Storage Briefcase



# Depyrogenation, Dry Heat Sterilization & Extreme Temperature Validation

For applications that require extended exposure to high heat, MadgeTech has developed a line of thermal enclosures for use with the HiTemp140 series data loggers. These thermal shields and barriers expand the capabilities of the HiTemp140 series, making an ideal solution for monitoring the extreme temperatures and exposure time required for effective Depyrogenation or Dry Heat Sterilization.

## DHS Data Logging System Dry Heat Sterilization Data Logging System

The DHS Data Logging System for Dry Heat Sterilization is an all in one depyrogenation solution that comes equipped with:

### The ThermoVault Max System:

- HiTemp140-M12, High Temperature Data Logger
- 36 inch Glass Braided RTD depyrogenation probe with M12 connector and flat probe tip
- ThermoVault Max, Extreme Temperature Thermal Barrier

This system is capable of withstanding and measuring temperatures up to 400 °C, allowing it to record throughout the entire depyrogenation process. The HiTemp140-M12 data logger features the popular rugged steel body design of the HiTemp140 data logger series with the flexibility to utilize dozens of RTD probe options with M12 connection compatibility.

The MadgeTech software allows for fast and easy data logger configuration. Simply insert the data logger into the IFC400 or IFC406 docking station (sold separately), choose either immediate or delay start and the desired reading rate. Insert the data logger onto the ThermoVault Max enclosure and screw the cap back on securely. The device is ready to be deployed.



# HiTemp140-M12

## High Temperature Data Logger with an M12 Probe Connector

The HiTemp140-M12 is a high temperature data logger featuring an M12 probe connector. Compatible with a wide variety of M12 RTD probe styles, this logger is capable of measuring up to 850 °C. (probe dependant)

All MadgeTech HiTemp140 series of data loggers are designed out of food grade stainless steel and can be placed in environments as high as 140 °C (284 °F).

The device records and stores up to 43,690 time stamped readings and is equipped with non-volatile solid state memory which retains data even if the battery becomes discharged.

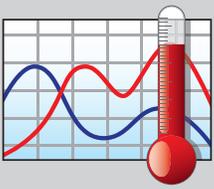


## Thermal Shield

### For Extended High Temperature Monitoring

For applications above 140 °C, a thermal shield is available for most models of the HiTemp140 and HiTemp140-PT series data loggers. The thermal shield extends the operating temperature of the data logger, allowing it to be exposed to higher temperatures for a longer amount of time. Flush and vented models are available to help provide probe protection.

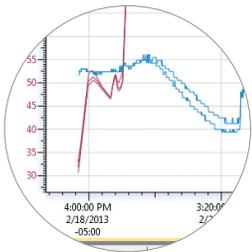
*Thermal Shields shown with HiTemp140 series data loggers.*



# MadgeTech Data Logger Software

This simple, easy-to-use, Windows-based software enables the user to effortlessly collect, display, and analyze data. A variety of powerful tools can be used to examine, export, and print professional quality reports with just a click of the mouse. The user-friendly MadgeTech software is available for free download from [www.madgetech.com](http://www.madgetech.com).

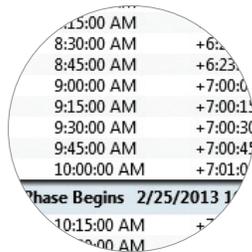
## Simple, Easy-to-use, Windows-based Software



Customizable Graphs

Time	N92770 Temperature	N93530 Temperature	N94559 Temperature
2/18/2013 9:00:00 AM	32.94	31.5	30.672
2/18/2013 9:15:00 AM	33.30	31.5	30.906
2/18/2013 9:30:00 AM	33.84	31.5	31.266
2/18/2013 9:45:00 AM	34.26	31.5	31.734
2/18/2013 10:00:00 AM	34.92	31.5	32.292
2/18/2013 10:15:00 AM	35.64	31.5	32.940
2/18/2013 10:30:00 AM	36.18	31.5	33.624
2/18/2013 10:45:00 AM	36.90	31.5	34.344
2/18/2013 11:00:00 AM	37.44	31.5	35.082
2/18/2013 11:15:00 AM	38.34	31.5	35.838
2/18/2013 11:30:00 AM	38.88	32.0	36.576
2/18/2013 11:45:00 AM	39.78	32.0	37.332
2/18/2013 12:00:00 PM	40.50	32.0	38.088
2/18/2013 12:15:00 PM	41.22	32.0	38.844
2/18/2013 12:30:00 PM	41.94	32.0	39.618
2/18/2013 12:45:00 PM	42.66	32.0	40.410
2/18/2013 1:00:00 PM	43.38	32.0	41.202
2/18/2013 1:15:00 PM	44.28	32.0	42.000
2/18/2013 1:30:00 PM	45.00	32.0	42.804
2/18/2013 1:45:00 PM	45.72	32.0	43.614
2/18/2013 2:00:00 PM	46.44	32.0	44.388
2/18/2013 2:15:00 PM	46.98	32.0	45.144
2/18/2013 2:30:00 PM	47.70	32.0	45.918
2/18/2013 2:45:00 PM	48.78	31.5	46.962
2/18/2013 3:00:00 PM	49.68	32.0	48.200
2/18/2013 3:15:00 PM	50.58	31.5	49.014
2/18/2013 3:30:00 PM	51.30	31.5	49.936
2/18/2013 3:45:00 PM	51.84	31.5	50.400
2/18/2013 4:00:00 PM	52.02	31.5	49.644
2/18/2013 4:15:00 PM	52.20	31.5	49.716
2/18/2013 4:30:00 PM	52.38	31.5	49.788
2/18/2013 4:45:00 PM	52.38	31.5	49.860
2/18/2013 5:00:00 PM	52.56	31.5	49.950
2/18/2013 5:15:00 PM	52.56	31.5	50.036
2/18/2013 5:30:00 PM	52.56	31.5	50.148
2/18/2013 5:45:00 PM	52.56	31.5	50.256
2/18/2013 6:00:00 PM	52.56	31.5	50.346
2/18/2013 6:15:00 PM	52.56	31.5	50.436
2/18/2013 6:30:00 PM	52.56	31.5	50.472
2/18/2013 6:45:00 PM	52.38	31.5	50.472

Tabular Data View



Automatic Statistics Calculation

Digital Calibration

Copy to Excel

## Software Features

- Multiple Graph Overlay
- Statistics
- Digital Calibration
- Zoom In / Zoom Out
- Timeslice
- Lethality Equations (F0, PU, Fh, Fd)
- Mean Kinetic Temperature
- Full Time Zone Support
- Data Annotation
- User Friendly File Management
- Min / Max. / Average Lines
- Data Table View
- Automatic Report Generation
- Summary View



# 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.

## Features & Benefits

Aids in compliance 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
- Traceability with customizable electronic signatures



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



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