



# Medical and Pharmaceutical Data Logging Solutions



Sterilization & Facilities Monitoring



## 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,

Founder & President



# Data Logging Solutions

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Steam Sterilization



Dry Heat Sterilization &  
Depyrogenation



Ethylene Oxide Sterilization



Lyophilization



Vaccine Temperature Monitoring



Dry Ice Shipping



Cold Chain



Real Time Continuous  
Environmental Monitoring



Service & Calibration

# 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

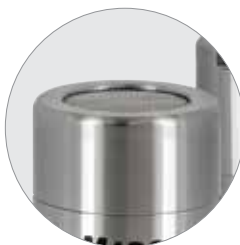
HiTemp140-FP



## 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



# Dry Heat Sterilization, Depyrogenation & 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.

## ThermoVault140-DHS

### Dry Heat Sterilization Data Logging System

The ThermoVault140-DHS is a Dry Heat Sterilization Data Logging System, designed to be used in environments up to 400 °C for dry heat applications. This system is specifically designed for use in the extreme temperatures required to adequately diminish pyrogens for the effective sterilization of goods. The ThermoVault140-DHS features the HiTemp140-M12 data logger, equipped with a high temperature detachable RTD probe and the ThermoVault140 stainless steel thermal barrier.

#### The ThermoVault140-DHS System includes:

- HiTemp140-M12 High Temperature Data Logger
- 36 inch Glass Braided RTD probe with a ceramic tip
- ThermoVault140 Thermal Barrier

## Time vs Temperature Chart

| Temperature       | Exposure Time in Air (minutes) |
|-------------------|--------------------------------|
| Ambient           | ThermoVault140-DHS             |
| -40 °C to +140 °C | Indefinitely                   |
| 150 °C            | 525                            |
| 200 °C            | 285                            |
| 250 °C            | 205                            |
| 300 °C            | 165*                           |
| 350 °C            | 140*                           |
| 400 °C            | 50*                            |

*\*Please consult the measurement range of your data logger for temperatures over 250 °C. (The thermal barrier extends the operating temperature of the data logger up to, but not exceeding the measurement range)*



# 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.



## Time vs Temperature Chart

| Temperature       | Exposure Time in Air (minutes) |
|-------------------|--------------------------------|
| Ambient           | Thermal Shield                 |
| -40 °C to +140 °C | Indefinitely                   |
| 150 °C            | 88                             |
| 200 °C            | 45                             |
| 250 °C            | 32                             |
| 300 °C            | n/a                            |
| 350 °C            | n/a                            |

*\*Please consult the measurement range of your data logger for temperatures over 250 °C. (The thermal barrier extends the operating temperature of the data logger up to, but not exceeding the measurement range)*



## 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.*

# 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  $\Omega$  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:
  - $\pm 1$  %RH, 0 %RH-90 %RH
  - $\pm 0.3$  °C, 0 °C-80 °C (special temperature accuracy of 0.05 °C @ 25.0 °C)
- Fluke Calibration 1502A Thermometer Readouts
- Accuracy of:  $\pm 0.030$  °C, -80 °C to +300 °C
- Mensor CPC 6000 Pressure Calibrator
- Accuracy of:  $\pm 0.05$  psi

### Test and Reference Equipment Subject to:

- Annual Calibration
- Annual Validation
- Annual Mapping

# Lyophilization



## LyoTemp Lyophilization Data Logger

The LyoTemp is designed to be a rugged, reliable, cost-effective solution for temperature monitoring inside lyophilizers. The ease of use and simple setup provide a significant time and cost savings over traditional thermocouple based systems.

The LyoTemp data logger is designed for use in ultra-low operating temperatures for processes such as lyophilization. The LyoTemp has an operating range of -60 °C to +75 °C, enabling the entire device to be placed inside the lyophilizer chamber. It features a hermetically sealed thermistor, offered in a 48 inch length, to allow for temperature monitoring inside vials and ampoules. The MicroDisc accessory can be fitted to the end of the thermistor, providing a solution for surface temperature monitoring for chamber mapping.

The compact size and simple operation make the LyoTemp user friendly and reliable. The LyoTemp has three LED indicators to alert or inform the user of the logging status and manual start and stop options available at the device. Other features of the LyoTemp include delayed start configuration, user configurable alarms and password protection.



*MicroDisc, surface temperature probe attachment also available*

# Vaccine Monitoring

MadgeTech's Vaccine Temperature Monitoring System (VTMS) is ideal for the continuous measurement and data logging of temperature sensitive vaccines or pharmaceuticals in refrigerators, freezers, coolers and incubators.



## VTMS

### Vaccine Temperature Monitoring System

With the ability to view and reset statistics manually, the VTMS data logging system provides the tools needed to comply with specific storage and handling instructions for medical observations and control mandated by the CDC.

The system includes a NIST traceable RFTCTemp2000A data logger with thermocouple probe, Glycol bottle and a power supply. Additionally, the RFTCTemp2000A data logger in the VTMS system has a convenient LCD to display the current reading, minimum, maximum and average statistics. The RFTCTemp2000A is wall mountable and capable of transmitting data wirelessly in real time to a central PC.



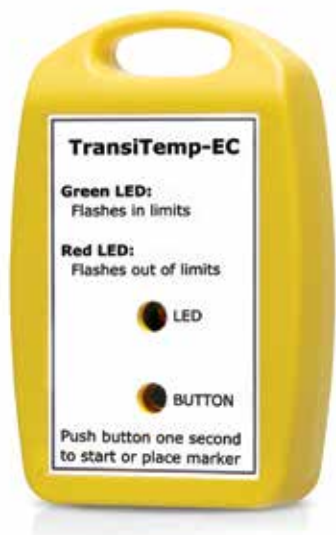
*The Thermocouple probe is detachable from the data logger*



*The VTMS mounted outside of the enclosure to be monitored*

# Shipping & Storage Data Loggers

MadgeTech's shipping and storage data loggers monitor and record the temperature of items in storage or during transit. They efficiently collect data to aid in maintaining product quality and compliance.



## TransiTemp-EC

### Cold Chain

The TransiTemp-EC temperature recorder is designed for high volume, low cost in-transit recording. It has a custom molded case with a handle for convenient attachment and comes in single and multi use versions. This compact, portable, easy to use device will measure and record up to 8,191 readings. The storage medium is non-volatile solid state memory, providing maximum data security even if the battery becomes discharged or when the device stops taking data.

## TransiTempII

### 2-8 °C Refrigerators

The TransiTempII is a low cost, splash proof temperature data logger featuring a highly precise semiconductor temperature sensor and an ABS plastic enclosure. This affordable, NIST traceable device is ideal for monitoring and recording the temperature of all types of perishable products, including food items and medical/pharmaceutical goods, both in storage and in transit.





## Cryo-Temp

### Dry Ice Shippers & Freezers

The Cryo-Temp is a stand alone, ultra low temperature logger that can measure as low as  $-86^{\circ}\text{C}$  without the need for external probes. The enclosure is designed with a handle for easy attachment and is IP64 (splash proof). It is equipped with three LED's to signify logging, indicate when user-set warning limits have been breached and when temperature alarm limits have been exceeded. The features of this device make it ideal for monitoring pharmaceutical shipments, blood-bank storage, stem-cell samples and any other substance that requires dry-ice shipments or storage.



## LNDS

### Liquid Nitrogen, $-196^{\circ}\text{C}$ Dryshipper Tanks

MadgeTech's LNDS, Liquid Nitrogen Data Logging System, is an ultra-low temperature measurement system created specifically for the monitoring of temperature sensitive substances that need to be preserved at cryogenic temperatures.

The LNDS can be mounted to the top or outside of a cryo-shipping container or freezer, and the probe sheath can be inserted into the tank. The user can then directly view the internal temperature through the LCD on the logger, in addition to minimum, maximum, and average statistics.

The LNDS system includes the TCTemp2000 data logger, type E thermocouple probe, and NIST traceable calibration at  $-196^{\circ}\text{C}$ ,  $-80^{\circ}\text{C}$  and  $0^{\circ}\text{C}$ .



# Wireless Continuous Process Monitoring

For real time continuous monitoring, MadgeTech's wireless (RF) series is a time-saving and cost effective solution for validating temperature, humidity, pressure levels and more. A selection of models are available for use in a multitude of applications.



## 2000A Series

MadgeTech's 2000A two-way wireless series of data loggers is designed for users who want an automated, reliable monitoring solution. Ideal for monitoring environments such as laboratories, warehouses, refrigerators, and freezers, a selection of models are available to meet the needs of a variety of applications. The device takes readings at user-specified intervals, with data being transmitted back to a central PC for a real time update of temperature and/or humidity readings. A local LCD display also provides instant readout of min, max, average, and current readings.

The 2000A series also includes an audible and visual alarms for users close by. If the temperature, humidity, pressure or CO<sub>2</sub> levels exceed the user defined safe range, the alarm will sound enabling the user to take immediate action. Email and text message alarms can be programmed in addition to the audible alarm, ensuring real time notifications regardless of location.

## RFTemp2000A & RFRHTemp2000A

For Ambient Environmental Monitoring



**RFTemp2000A**

*Wireless Temperature Data Logger*



**RFRHTemp2000A**

*Wireless Temperature & Humidity Data Logger*

### Applications

- Laboratory Monitoring
- Warehouse Monitoring
- Incubators
- Stability Chambers
- Clean Rooms
- Environmental Mapping
- Refrigerators and Freezers

### Parameters

- Temperature
- Humidity
- Pressure
- Current
- Voltage
- Pulse
- Carbon Dioxide

# RFCO<sub>2</sub>RHTemp2000A

For CO<sub>2</sub>, Humidity & Temperature Monitoring

## Applications

- Incubator Monitoring
- Building Monitoring
- HVAC Testing
- Agricultural Monitoring



## Benefits

- Immediate notification of parameter breaches with the use of audible, email, on-screen or text message alarms
- Data is automatically saved as it is transmitted
- Automatic update of graph, grid, and statistics reports within the software
- Customizable alarm capabilities
- Up to a 3 year battery life, user-replaceable
- Visual verification of min, max, average and current readings via local LCD
- Wall or surface mount options



All MadgeTech Wireless Data Loggers are compatible with MadgeTech Cloud Services.

See page 18 for details.

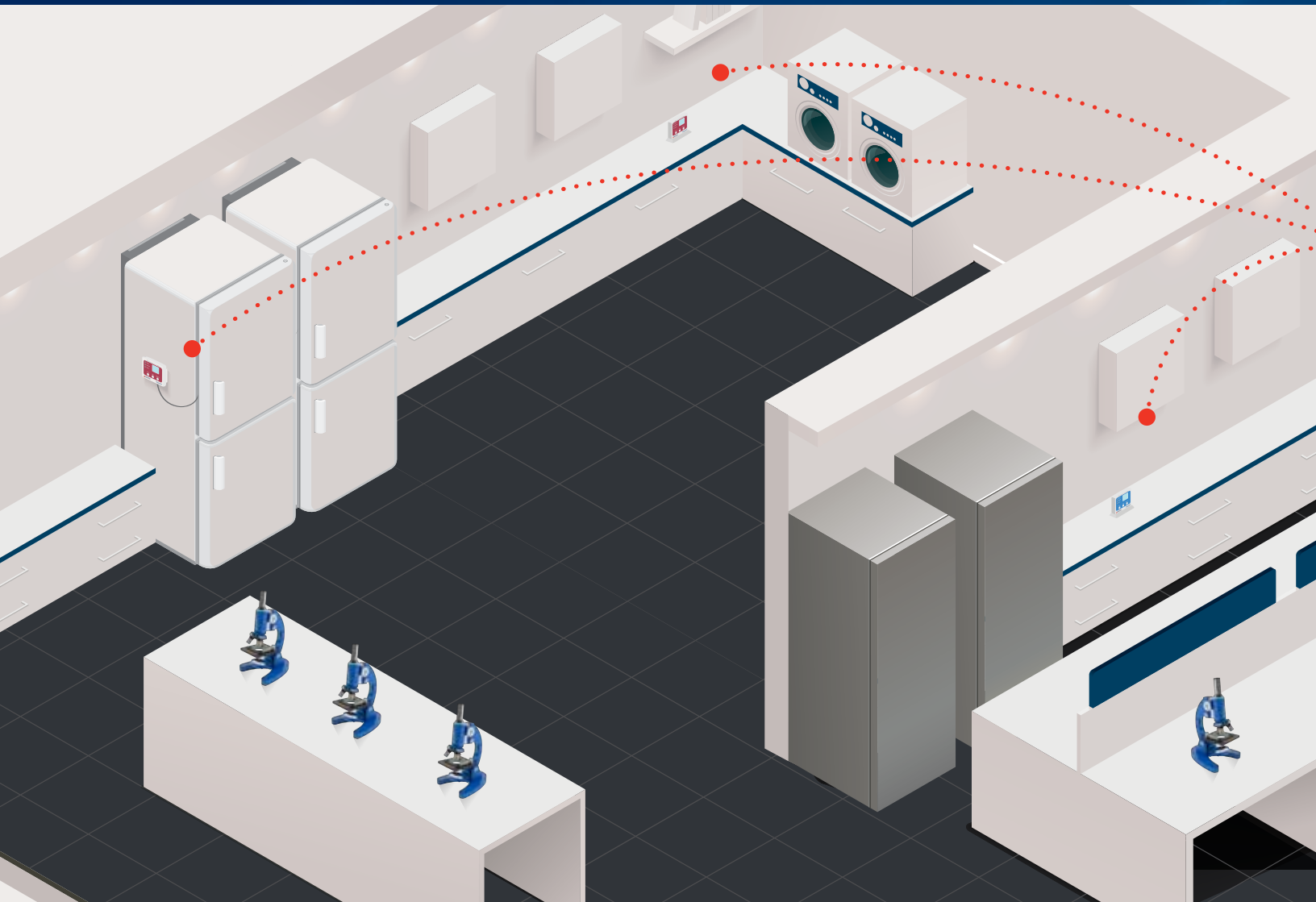
## RFC1000

Wireless Transceiver

MadgeTech's RFC1000 is a high powered transceiver that has a substantially long transmission range, providing enhanced performance in occluded environments (ovens, refrigerators, etc.). The RFC1000 also features an external antenna, allowing more flexibility with mounting positions in both orientation and proximity to metal walls. The device may be used as a repeater, or directly plugged into the Windows PC.



# Wireless Continuous Monitoring System



Data Loggers to Transceiver

Transceiver to Base Station PC



**VTMS**

Vaccine Temperature  
Monitoring System

**RFTemp2000A**

Wireless Temperature  
Data Logger

**RFRHTemp2000A**

Wireless Temperature &  
Humidity Data Logger

**RFC1000**

Wireless Transceiver

**RFCO<sub>2</sub>RHTemp2000A**

Wireless CO<sub>2</sub>, Humidity and  
Temperature Data Logger

**Base Station PC**

With Plugged in Transceiver

Connect any Data Logger directly to Base Station



## Wireless Temperature & Humidity Alarming System Overview

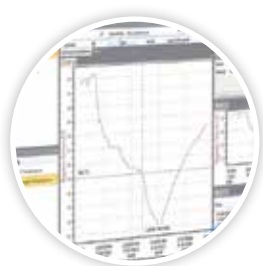
Setup and installation of MadgeTech wireless data loggers is quick and easy. Little to no manual programming is necessary, as loggers and repeaters are designed to communicate with each other as soon as they are turned on.



1. Deploy the data loggers



2. Wirelessly start the loggers at the main PC



3. Data is instantly transmitted to the main PC for real time monitoring

### Alarm Notifications:

- Email
- Text Message
- On-screen
- LED Visual on Logger



# MadgeTech Cloud Services

*Measure, Log, Monitor and Manage Your Data*

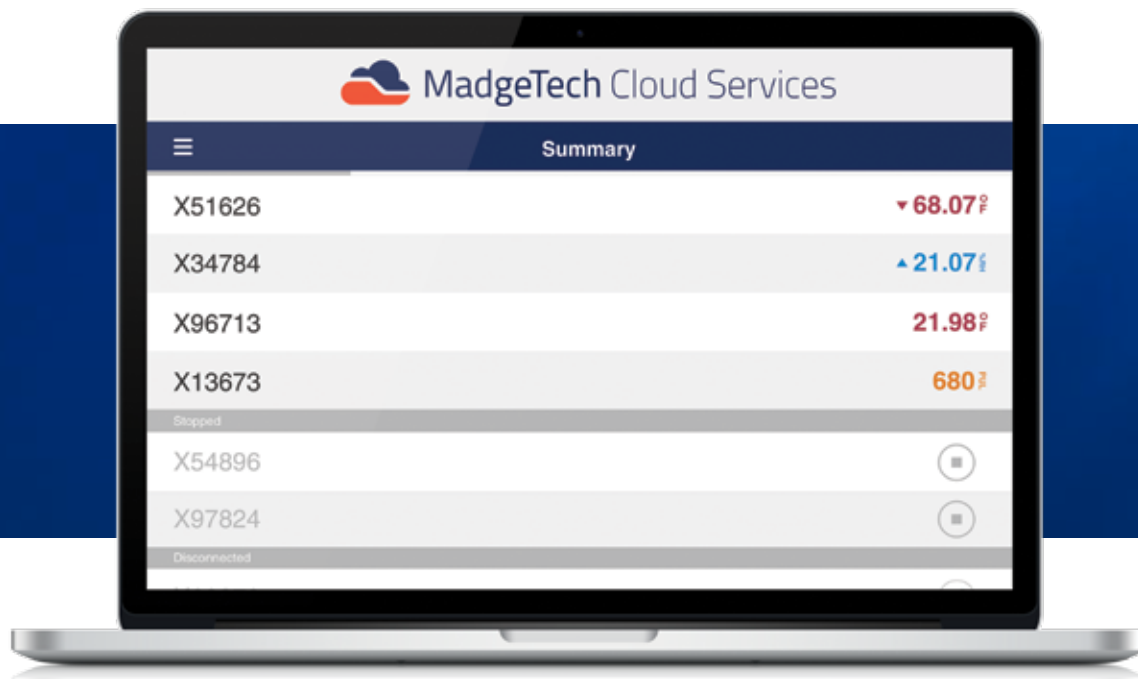
**MadgeTech Cloud Services provides instant access to temperature, humidity, pressure data and more from any internet enabled device!**



The MadgeTech Cloud Hosted data logging platform provides continuous logging and monitoring of temperature, pressure, and humidity data while giving users instant access from any location. With MadgeTech Cloud Services, data loggers can securely transmit data in real time to be viewed on any internet or data enabled device such as a computer, tablet, or cell phone.

## Benefits

- Scalable Solution with Limitless Applications
- Quick and Easy Setup
- Monitoring and Logging Continuously
- Access Data Instantly from Anywhere in the World
- Email & Text Message Alarm Notifications
- Powerful, Customizable User Interface
- Data Dashboard Overview
- World Class Support



# Features

## Access Data Instantly and Securely from Anywhere in the World

Because data is sent to the cloud, data can be made available for viewing from any internet enabled location around the world.

## Scalable Solution with Limitless Applications

With MadgeTech Cloud Services, this system is dynamically designed to perfectly fit applications requiring anywhere from a single data logger, to networks of hundreds of loggers in multiple locations. The MadgeTech Cloud platform provides facilities on-demand data supervision offering peace of mind and flexibility like never before.

## Monitoring and Logging Continuously

As a monitoring system, the MadgeTech Cloud allows for instant access to real time data in the palm of your hand. As a logging solution, recorded data is buffered and saved to the device's internal memory. This provides uninterrupted continuous monitoring even in the event of a power loss or network failure.

## Email & Text Message Alarm Notifications

The MadgeTech Cloud platform allows users to configure alarms to custom fit their needs. Notifications can be sent via email or text message the moment a threshold is exceeded. Notifications are also available on screen as well as audible and visual alerts directly on the device. When an alarm is triggered, users get immediate notifications via text message or email and have instant access to review the situation within seconds.



Quick &  
Easy Setup



View Data From  
Anywhere



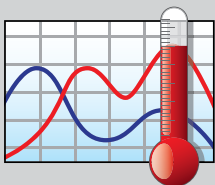
Access Data  
Instantly



Secure  
Solution



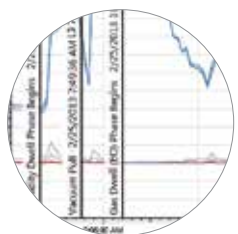
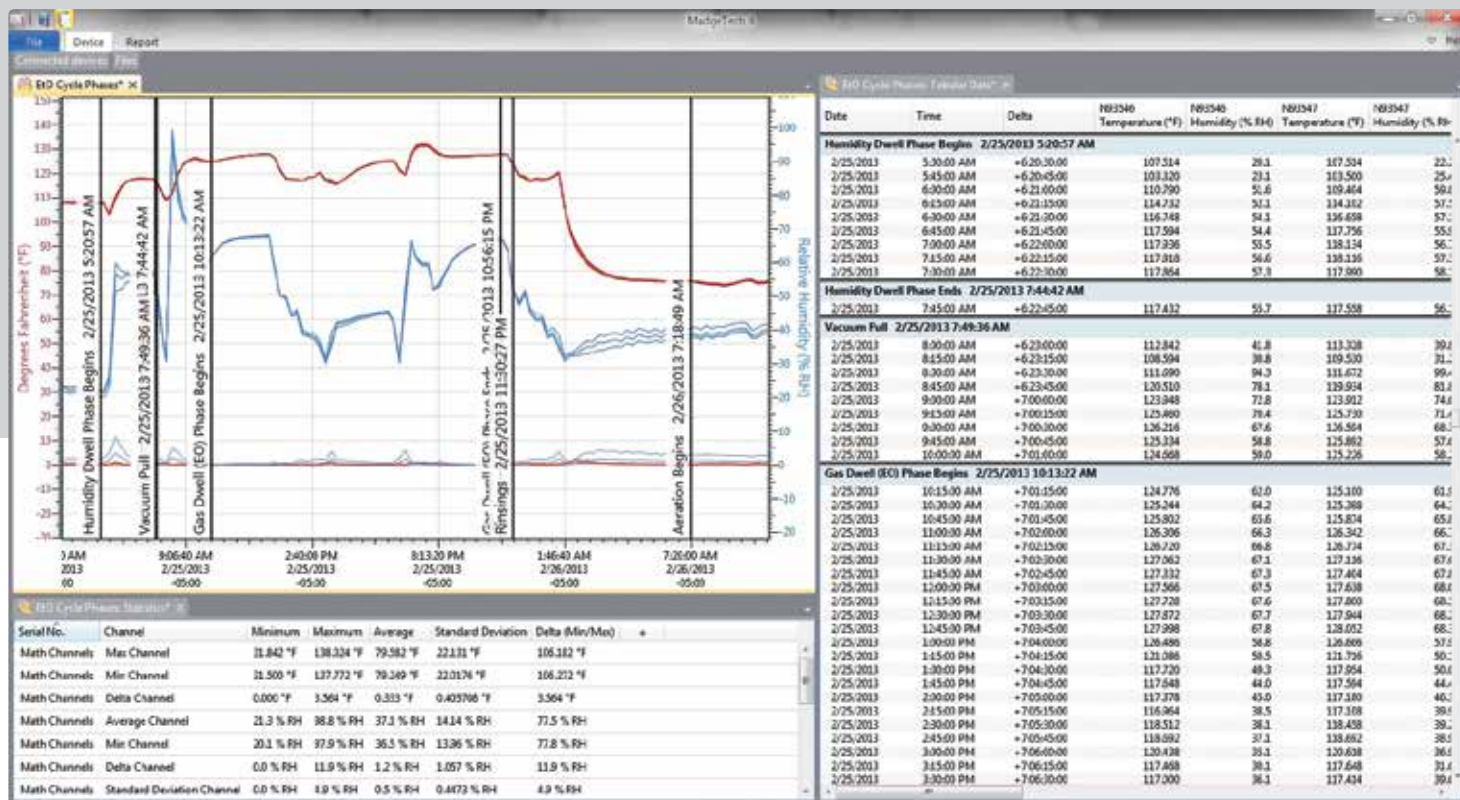
Email & Text  
Notifications



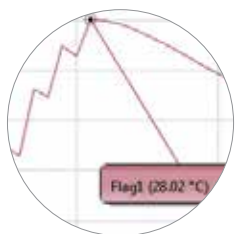
# MadgeTech Data Logger Software

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. This software can be downloaded for free from the MadgeTech website.

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



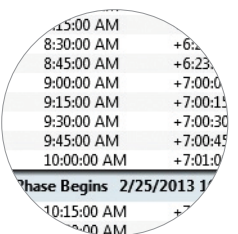
Customizable Graphs



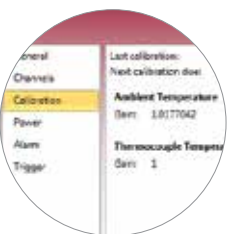
Cooling Flaps



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
- Cooling Flaps
- 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
- Sophisticated user management
- 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

# Matrix



| Product                         | RFTemp2000A                         | RFRHTemp2000A                                                                                                   | RFCO <sub>2</sub> RHTemp2000A                                                          | VTMS                                                            | HiTemp140/<br>HiTemp140-PT                                                                             | HiTemp140-M12                                                         | HiTemp140-FR                          | Thermal Shield                                                                                         |
|---------------------------------|-------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------|
| <b>Measurement Range</b>        | -20 °C to +60 °C                    | -20 °C to +60 °C<br>0 %RH to 95 %RH                                                                             | 0 ppm to 200,000 ppm<br>0 °C to +55 °C<br>0 %RH to 95 %RH                              | -20 °C to +60 °C                                                | -200 °C to +260 °C<br>PT: -200 °C to +350 °C                                                           | -200 °C to +850 °C                                                    | -200 °C to +260 °C                    | -200 °C to +260 °C                                                                                     |
| <b>Resolution</b>               | 0.01 °C                             | 0.01 °C<br>0.1 %RH                                                                                              | 10 ppm<br>0.08 °C<br>0.08 %RH                                                          | 0.1 °C                                                          | 0.01 °C                                                                                                | 0.001 °C                                                              | 0.01 °C                               | 0.01 °C                                                                                                |
| <b>Calibrated Accuracy</b>      | ±0.5 °C<br>(0 °C to +55 °C)         | ±0.5 °C<br>(0 °C to +55 °C)<br>±3.0 %RH, ±2.0 %RH<br>typical @ +25 °C<br>(10 %RH to 90 %RH;<br>+5 °C to +55 °C) | ±70 ppm<br>±1.0 °C<br>±3.0 %RH from<br>25 %RH to 75 %RH<br>@ 25 °C, 7 %RH<br>otherwise | ±0.1 °C                                                         | ±0.1 °C<br>(+20 °C to +140 °C)<br>±0.3 °C<br>(-20 °C to +19.99 °C)<br>±0.4 °C<br>(-40 °C to -20.01 °C) | ±0.5 °C from +160 °C<br>to +400 °C<br>±1.0 °C from 0 °C to<br>+160 °C | ±0.1 °C<br>(+20 °C to +140 °C)        | ±0.1 °C<br>(+20 °C to +140 °C)<br>±0.3 °C<br>(-20 °C to +19.99 °C)<br>±0.4 °C<br>(-40 °C to -20.01 °C) |
| <b>Operating Range</b>          | -20 °C to +60 °C<br>0 %RH to 95 %RH | -20 °C to +60 °C<br>0 %RH to 95 %RH                                                                             | 0 °C to +55 °C<br>0 %RH to 95 %RH                                                      | -20 °C to +60 °C<br>0 %RH to 95 %RH                             | -40 °C to +140 °C<br>0 %RH to 100 %RH                                                                  | -40 °C to +140 °C<br>0 %RH to 100 %RH                                 | -40 °C to +140 °C<br>0 %RH to 100 %RH | -200 °C to +250 °C<br>0 %RH to 100 %RH                                                                 |
| <b>Memory</b>                   | 32,256 Readings                     | 16,128 Readings                                                                                                 | 10,752 Readings                                                                        | 16,128 Readings                                                 | 32,700 Readings                                                                                        | 43,690 Readings                                                       | 32,767 Readings                       | 32,700 Readings                                                                                        |
| <b>IP Rating</b>                | IP22                                | IP22                                                                                                            | IP22                                                                                   | IP22                                                            | IP68                                                                                                   | IP68                                                                  | IP68                                  | IP68                                                                                                   |
| <b>Material</b>                 | ABS Plastic                         | ABS Plastic                                                                                                     | ABS Plastic                                                                            | ABS Plastic                                                     | 316 Stainless Steel                                                                                    | 316 Stainless Steel                                                   | 316 Stainless Steel                   | 316 Stainless Steel<br>Enclosure: PTFE                                                                 |
| <b>Required Interface Cable</b> | RFC1000                             | RFC1000                                                                                                         | RFC1000                                                                                | RFC1000                                                         | IFC400 or IFC406                                                                                       | IFC400 or IFC406                                                      | IFC400 or IFC406                      | IFC400 or IFC406                                                                                       |
| <b>Probe</b>                    | Internal Sensor                     | Internal Sensor                                                                                                 | External Sensor                                                                        | External Thermocouple<br>Probe, Type K<br>Thermocouple Included | External RTD Probe                                                                                     | Detachable External<br>RTD Probe<br>(M12 Compatible)                  | External RTD Probe                    | External RTD Probe                                                                                     |
| <b>More Details</b>             | Refer to page 14                    | Refer to page 14                                                                                                | Refer to page 15                                                                       | Refer to page 11                                                | Refer to page 4                                                                                        | Refer to page 7                                                       | Refer to page 4                       | Refer to page 7                                                                                        |

## Data Logger Calibration

### Why Calibrate?

All physical sensors become less accurate due to the environment, usage, stress, and even time. The degree to which these changes occur varies from device to device. For example, a voltage device will drift very little over the years whereas a humidity sensor can drift significantly in several weeks if subjected to a corrosive environment.

### Calibration Certificates

The calibration certificates are generated at the end of the manufacturing process. Each certificate indicates the date and conditions of calibration. These certificates provide the documentation needed to satisfy most requirements, certifying that a product has been properly calibrated. The calibration certificate also provides traceability back to National Institute of Standards and Technology (NIST) standards on select models, non-NIST available for all other models.

### Calibration Services

MadgeTech's calibration laboratory offers a variety of standard and customized calibration services. The scope of MadgeTech's services covers the following parameters temperature, humidity, pressure, voltage, current, shock and more.

Standard calibration values and pricing can be found on the Product Information Card for each data logger. The Product Information Card can be found on the website page for that product. The standard calibration is normally a one or two point correction of the reported values, depending on the type of device being calibrated. Additional or nonstandard points incur an additional fee.



| PRTemp140                                                    | ThermoVault140-DHS                                                                                          | LyoTemp                              | RHTemp1000IS                                                | Temp1000IS                          | TransiTemp-EC                                                  | TransiTempII                         | CryoTemp                             | LNDS                                             |
|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|--------------------------------------|-------------------------------------------------------------|-------------------------------------|----------------------------------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------------------|
| 0 Bar to 5 Bar<br>(0 PSIA to 72.5 PSIA)<br>-20 °C to +140 °C | -200 °C to +850 °C                                                                                          | -60 °C to +75 °C                     | -40 °C to +80 °C<br>0 %RH to 100 %RH<br>non-condensing      | -40 °C to +80 °C                    | -20 °C to +70 °C                                               | -40 °C to +80 °C                     | -86 °C to +35 °C                     | -200 °C to +260 °C                               |
| 0.0001 Bar<br>0.01 °C                                        | 0.001 °C                                                                                                    | 0.1 °C                               | 0.01 °C<br>0.1 %RH                                          | 0.01 °C                             | 0.1 °C                                                         | 0.1 °C                               | 0.1 °C                               | 0.1 °C                                           |
| ±0.03 Bar<br>±0.1 °C                                         | ±0.5 °C from +160 °C<br>to +400 °C<br>±1.0 °C from 0 °C to<br>+160 °C                                       | ±0.5 °C                              | ±0.5 °C<br>±3 %RH maximum;<br>±2.0 %RH typical at<br>+25 °C | ±0.5 °C                             | ±0.5 °C<br>(-10 °C to +40 °C)<br>±1.0 °C<br>(-20 °C to +70 °C) | ±0.5 °C<br>(-10 °C to +40 °C)        | ±1.0 °C                              | ±0.5 °C                                          |
| -20 °C to +140 °C<br>0 %RH to 100 %RH                        | Time Dependant<br>See Chart on Page 6                                                                       | -60 °C to +75 °C<br>0 %RH to 100 %RH | -40 °C to +80 °C<br>0 %RH to 100 %RH<br>non-condensing      | -40 °C to +80 °C<br>0 %RH to 95 %RH | -20 °C to +70 °C<br>0 %RH to 90 %RH                            | -40 °C to +80 °C<br>0 %RH to 100 %RH | -86 °C to +35 °C<br>0 %RH to 100 %RH | -20 °C to +60 °C<br>0 %RH to 95 %RH              |
| 32,767 Readings                                              | 43,690 Readings                                                                                             | 32,767 Readings                      | 16,350 Readings                                             | 32,767 Readings                     | 8,191 Readings                                                 | 32,767 Readings                      | 32,767 Readingsz                     | 131,071 Readings                                 |
| IP68                                                         | IP50 (no O-Ring)<br>IP68 (with O-Ring)                                                                      | IP50                                 | Not IP Rated                                                | Not IP Rated                        | IP20                                                           | IP64                                 | IP64                                 | IP20                                             |
| 316 Stainless Steel                                          | Enclosure: 300 Series<br>Stainless Steel<br>Seals: PTFE & Silicone Rubber<br>Insulation: Dewar Flask & PTFE | ABS Plastic                          | 316 Stainless Steel                                         | 316 Stainless Steel                 | ABS Plastic                                                    | ABS Plastic                          | ABS Plastic                          | Black Anodized<br>Aluminum                       |
| IFC400 or IFC406                                             | IFC400 or IFC406                                                                                            | IFC300                               | IFC400 or IFC406                                            | IFC400 or IFC406                    | IFC103                                                         | IFC300                               | IFC300                               | IFC200                                           |
| Internal Sensor                                              | Detachable External<br>RTD Probe<br>(M12 Compatible)                                                        | External Sensor                      | Internal Sensor                                             | External RTD Probe                  | Internal Sensor                                                | Internal Sensor                      | Internal Sensor                      | External Sensor, Type E<br>Thermocouple Included |
| Refer to page 5                                              | Refer to page 6                                                                                             | Refer to page 10                     | Refer to page 8                                             | Refer to page 9                     | Refer to page 12                                               | Refer to page 12                     | Refer to page 13                     | Refer to page 13                                 |

## NIST Calibration Certificates

MadgeTech's calibration laboratory offers a variety of standard and customized calibration services.

The scope of MadgeTech's NIST Calibration Services include the following parameters:

- **Temperature**
- **Humidity**
- **Pressure**
- **Voltage**
- **Current**

A certificate of conformance is offered for the Pulse, Event and State data loggers which do not require calibration.

For details on MadgeTech's calibration services, please contact the services department.

## ISO 17025/A2LA Accredited Calibration Certification

MadgeTech can supply A2LA accredited calibrations to ISO 17025 standards. Please contact a sales representative for details on calibration abilities and pricing. Note: This certification must be requested prior to sending the device in for recalibration.



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