



# Medical and Pharmaceutical Data Logging Solutions



Sterilization & Facilities Monitoring



## Simplifying How the World Measures & Records Data

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



Steam Sterilization



Dry Heat Sterilization & Depyrogenation



Ethylene Oxide Sterilization



Cold Chain



Vaccine Temperature Monitoring



Dry Ice Shipping



Lyophilization



Cryopreservation



Real-Time Continuous Environmental Monitoring

# 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). 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 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



## PR140

### Pressure Data Logger for High Temperatures

The **PR140** is a pressure data logger that can withstand pressures up to 5 Bar and temperatures up to +140 °C (+284 °F). This rugged device is completely submersible. The PR140 is built with a precision pressure sensor, offering a calibrated accuracy of  $\pm 0.03$  Bar.



Flush Top



NPT Pressure Port Top



Luer Fitting

## AVS

### Autoclave Validation Data Logging System

MadgeTech offers the **AVS** Autoclave Validation System, which provides all of the tools needed to validate, map and monitor autoclaves and washer-disinfectors. 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 Calibration Certificates
- (1) PR140 Pressure Data Logger with 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.

## DHS Data Logging System

### Dry Heat Sterilization Data Logging System

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

- 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 for 60 minutes, allowing it to record throughout the entire depyrogenation or dry heat sterilization 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.

## ThermoVault Max

### Compatible Data Loggers:

- HiTemp140-PT Data Logger
- HiTemp140-FP Data Logger (Max 260 °C)
- HiTemp140-M12 Data Logger



*ThermoVault Max available separately*

# HiTemp140-M12

## High Temperature Data Logger with an M12 Probe Connector

The **HiTemp140-M12** features the same rugged stainless steel body as the other HiTemp140 data loggers in the series, but offers interchangeable probe options using an M12 type connector. The M12 connectivity makes this versatile data logger compatible with the large variety of M12 RTD probes available today. The HiTemp140-M12 is capable of measuring and recording temperatures from -200 °C to +850 °C (-328 °F to +1562 °F) (probe dependent).



# 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.



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.

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 **RHTemp1000IS** is MadgeTech's most robust temperature and humidity data logging solution and 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. Its small size and sleek design allows it to be placed precisely in critical locations for temperature and humidity mapping.

# Temp1000IS

## Intrinsically Safe Temperature Data Logger

The **Temp1000IS** provides an Intrinsically Safe solution for temperature monitoring in hazardous locations and 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.

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

# Cold Chain & Storage Data Loggers

MadgeTech's cold chain 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.



## TransiTempII

-40 °C to +80 °C Applications

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 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.

## TransiTemp-EC

-20 °C to +70 °C Applications

The **TransiTemp-EC** temperature data logger 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.



# 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 an RFTCTemp2000A data logger with thermocouple probe, glycol bottle and calibration certificate. 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*

# Lyophilization

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.



## LyoTemp Lyophilization Data Logger

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  $-60\text{ }^{\circ}\text{C}$  to  $+75\text{ }^{\circ}\text{C}$  ( $-76\text{ }^{\circ}\text{F}$  to  $+167\text{ }^{\circ}\text{F}$ ), 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*

# Cryopreservation

MadgeTech's cryogenic data loggers monitor and record the temperature of items in storage or during transit providing the necessary quality control to maintain effective standards of service.



## Cryo-Temp

-86 °C Cryogenic Storage & Transport

The **Cryo-Temp** is a stand alone, ultra low temperature logger that can measure as low as -86 °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

-196 °C Liquid Nitrogen-based Applications

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:

- TCTemp2000 Data Logger
- Type E Thermocouple Probe
- 3-Point Calibration at -196 °C, -80 °C and 0 °C
- Certificate of Calibration



# 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 an instant readout of min, max, average, and current readings.

The 2000A series also includes 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 Environmental & Process 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



# MadgeTech Cloud Services

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.



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

**Scalable Solution with Limitless Applications:** MadgeTech Cloud Services is perfect for applications requiring anywhere from a single data logger, to networks of hundreds of loggers in multiple locations.

**Monitoring and Logging Continuously:** The MadgeTech Cloud allows for instant access to real-time data in the palm of your hand and 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.

## Real-Time Data can be Transmitted in Two Ways:

- **Wirelessly to the PC and recorded in the MadgeTech Software.** From there, data is sent to the MadgeTech Cloud where it can be viewed on any internet or data enabled device such as a computer, tablet or cell phone.
- **With the RFC1000 Cloud Relay data logging hub that communicates via Ethernet, live data is transmitted directly to the MadgeTech Cloud Services platform.** This allows users to remotely monitor and manage groups of data loggers, throughout a large facility or multiple locations without the need of a central PC.

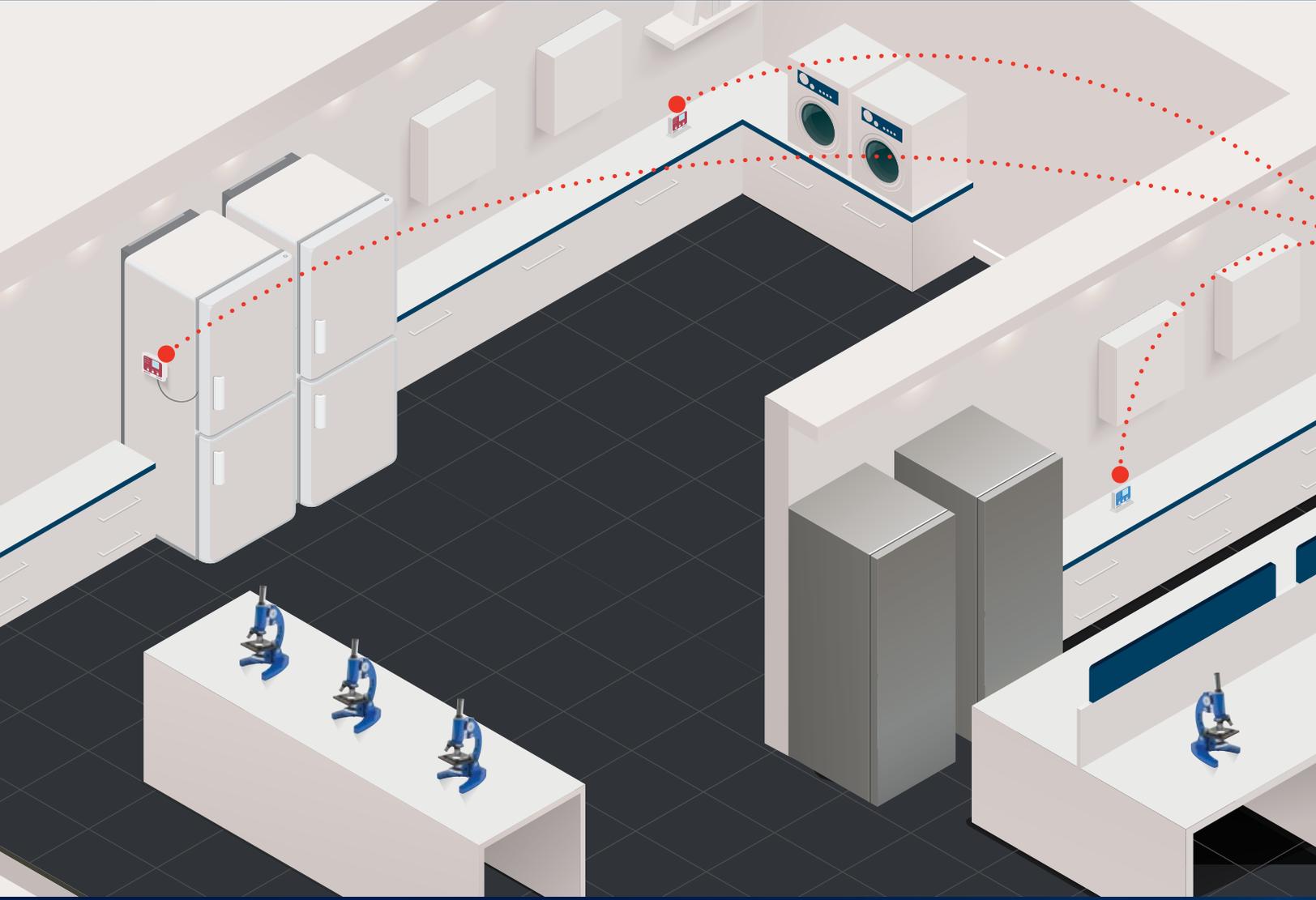
## RFC1000 Cloud Relay Data Logging Hub

The **RFC1000 Cloud Relay** is a data logging hub that communicates via Ethernet to transmit live data directly to the MadgeTech Cloud Services platform. This allows users to remotely monitor and manage groups of data loggers, throughout a large facility without the need of a central PC.



Set user access permissions, configure text or email alerts all from a smartphone, tablet or PC. Live data is sent to the MadgeTech Cloud for instant access and all recorded data is available to download as a CSV file for your records or further analysis.

# 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



**Base Station PC**  
With Plugged in Transceiver

Connect any Data Logger directly to Base Station



## Wireless Temperature & Humidity Monitoring Overview

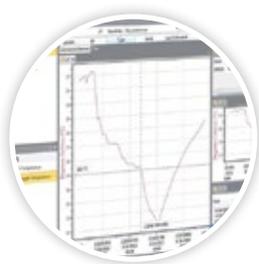
Setup and installation of MadgeTech wireless data loggers is quick and easy. Little to no manual programming is necessary, as loggers and repeaters are designed to communicate with each other as soon as they are turned on.



1. Deploy the data loggers



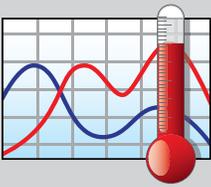
2. Wirelessly start the loggers at the main PC



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

### Alarm Notifications:

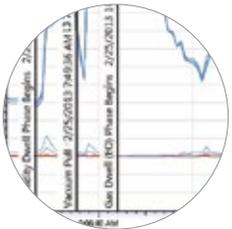
- Email
- Text Message
- On-screen
- LED Visual on Logger



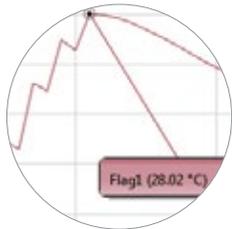
# MadgeTech Data Logger Software

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



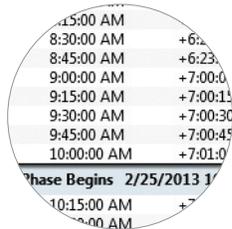
Customizable Graphs



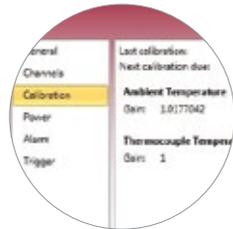
Cooling Flags



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 Flags
- 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 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) 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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