MADGETECH
WE BUILD DATA LOGGERS

DATA LOGGING SOLUTIONS
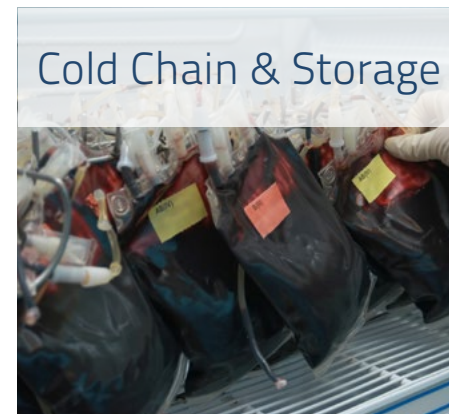# MEDICAL AND PHARMACEUTICAL

Steam Sterilization

Dry Heat Sterilization

Ethylene Oxide Sterilization

Cold Chain & Storage

Vaccine Monitoring

Lyophilization

Cryopreservation

Wireless Continuous Process Monitoring

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THE MADGETECH ADVANTAGE

Ensure safety, quality and efficiency by measuring and recording crucial data for inconsistencies that directly impact the success of a business. Our customizable data logging solutions provide real-time monitoring for applications where the slightest change in environment could be destructive. Coupled with the accuracy and reliability of our products, we also offer free software and cloud services, making compliance and validation reporting a breeze.

Why Choose MadgeTech?

At MadgeTech we take pride in maintaining meaningful relationships with our customers, going above and beyond to turn their everyday problems into new data logging solutions. To ensure the instrument's accuracy, MadgeTech offers in-house standard and customized calibration services, including ISO/IEC 17025 accredited calibrations for certain products.

Benefits:

▲ Calibration

▲ ISO/IEC 17025 Accreditation

▲ IQ/OQ/PQ On-Site Services

▲ Free Technical Support

▲ Free Software

▲ Cloud Services

▲ 21 CFR Part 11 Compliance

MadgeTech data loggers are designed, manufactured and serviced in the USA and distributed worldwide.

HEADQUARTERS
Warner, New Hampshire

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.

High Temperature Data Loggers

The **HiTemp140** 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 inch. 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-M12** is a high temperature data logger designed with a built in M12 probe connecter. 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 and mapping
- Continuous oven monitoring

Key Ring End Cap available for the HiTemp140 series data loggers

HiTemp140X2   HiTemp140-PT-1   HiTemp140-1   HiTemp140-M12   HiTemp140-FR

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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 ±0.03 Bar.

Flush Top

NPT Pressure Port Top

Luer Fitting

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

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DRY HEAT STERILIZATION AND 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 Dry Heat Sterilization.

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 Dry Heat Sterilization 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 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

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).

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.

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 Ω 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.

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.

Key Ring End Cap available for the RHTemp1000IS and Temp1000IS

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.

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 AND STORAGE

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.
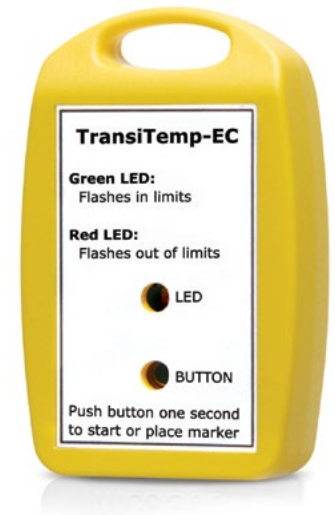
-40 °C to +80 °C Applications

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.

-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.

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.

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 °C to +75 °C (-76 °F to +167 °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.

-86 °C Cryogenic Storage & Transport

The **CryoTemp** 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.

-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.

Environmental & Process Monitoring

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_2 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.

Applications

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

Parameters

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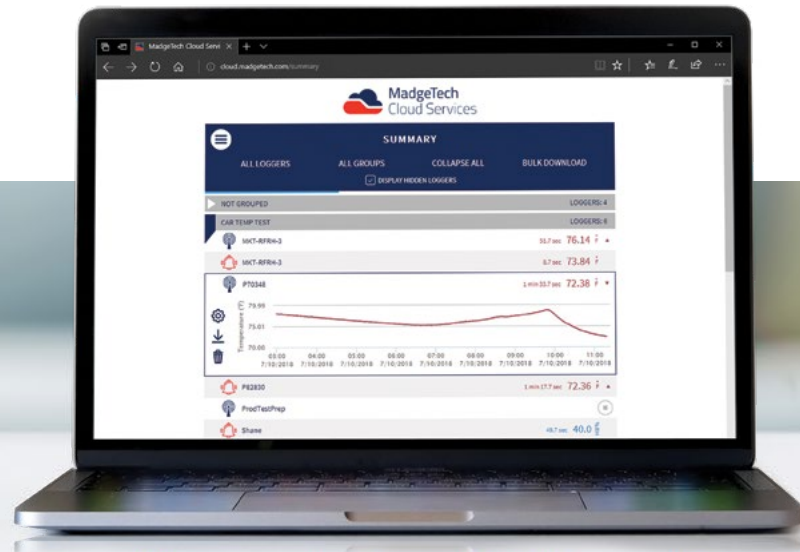- Carbon Dioxide

RFTemp2000A
Wireless Temperature Data Logger

RFRHTemp2000A
Wireless Temperature & Humidity Data Logger

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MadgeTech Cloud Services

Access Data Instantly and Securely from Anywhere in the World

The **MadgeTech Cloud** is compatible with all MadgeTech wireless data loggers, providing users with instant access to real-time data from any location. With the MadgeTech Cloud, data loggers can securely transmit data to be viewed on any Internet enabled device such as a computer, tablet or smartphone.

Scalable Solution

The MadgeTech Cloud is designed to support organizations of any size. From a single data logger to a network consisting of hundreds of loggers, the MadgeTech Cloud provides facilities with on-demand data supervision, attainable results, and flexibility like never before. The MadgeTech Cloud gives users the power to have control of all their critical data right in the palm of their hand.

Cloud Capabilities

All wireless MadgeTech data loggers can transmit data to the MadgeTech Cloud to be saved, viewed and controlled. The data is available for viewing from any Internet enabled device anywhere in the world. Equipped with many features, the MadgeTech Cloud is flexible enough to adapt to any data logging needs.

New Logger Groups

Assembling data loggers is easier than ever thanks to the MadgeTech Cloud's Logger Groups. Users have the ability to organize data loggers into groups and subgroups, making all data easily accessible from one central location.

Email & Text Message Alerts

The MadgeTech Cloud allows users to configure alarms to alert for no readings, channel thresholds or battery level. When an alarm is triggered, text message or email notifications are instantly sent, giving users the ability to view the data and assess the situation immediately.

Quick and Easy Setup
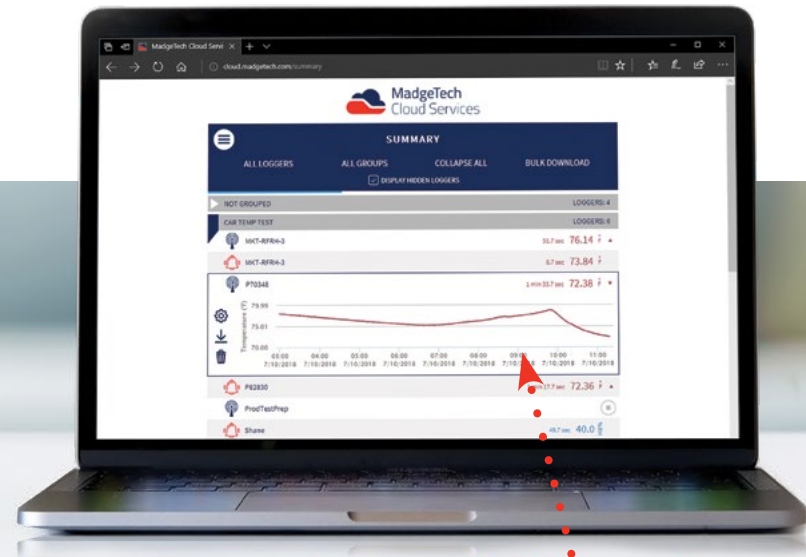
View Data From Anywhere

Access Data Instantly

Email and Text Notifications

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MadgeTech
Cloud Services

Transmit Data to the MadgeTech Cloud with the RFC1000 Cloud Relay

Taking cloud data logging to a whole new level! The **RFC1000 Cloud Relay** is a data logging hub that connects to the Internet via Ethernet and transmits data directly to the MadgeTech Cloud. 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.

The RFC1000 Cloud Relay has the ability to transmit data for up to 64 data loggers with no limit on the number of cloud relays that can be connected to a cloud account. This provides users with the ability to obtain information from a single data logger to many data loggers in multiple locations.

Relay Data Directly to the MadgeTech Cloud

Long Distance Wireless Transmission

LED Indicators

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MADGETECH 4 SOFTWARE

The 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.

MadgeTech 4 Software Customizable Features and Options

MadgeTech 4 Software can communicate with multiple loggers through multiple interface cables. Capable of simultaneous start, stop and download of over 100 devices, this software serves as your virtual command center for large scale facilities and small. Display your data in graphs, with tabbed views and multi-monitor support. Utilize the infinite graphing flexibility by combining channels and datasets as desired. All graphing makes use of accelerated graphics hardware for real-time updating and high performance visuals.

MadgeTech 4 Software is designed with a built-in database for automatic storage of downloaded data. The look and feel is organized much like standard email programs to aid in user friendliness and ease of use. MadgeTech 4 Software also offers extensive alarming options across multiple devices, wireless and non-wireless. Alarm output options include email, on-screen, text message and run-a-program alerts.
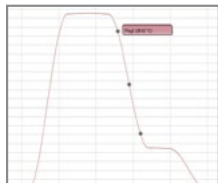
MadgeTech 4 Software has a powerful and comprehensive statistics system that allows the user to customize and view statistics as desired. Another feature is customizable engineering units. This enables users to support and program devices with many different unit types as well as the ability to display them as an alternate unit if desired.
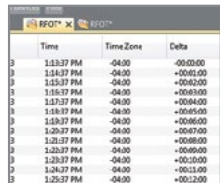
Software Features
- Multiple Graph Overlay
- Statistics
- Digital Calibration
- Zoom In / Zoom Out
- Cooling Flags
- Lethality Equations (F0, PU)
- Mean Kinetic Temperature
- Full Time Zone Support
- Data Annotation
- User Friendly File Management
- Min. / Max. / Average Lines
- Timeslice
- Data Table View
- Automatic Report Generation
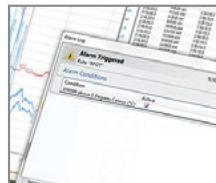- Summary View
- Workflows / Automation
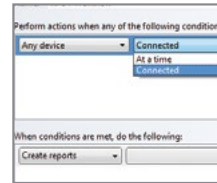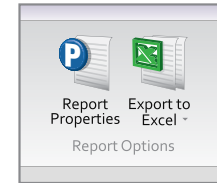
| Cooling Flags | Graph View | Tabular Data View | Alarm Notifications | Automation | Export to Excel |

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.

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.

Features and Benefits

- 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

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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