

Product User Guide



AVS140-6 Autoclave Validation Data Logging System



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Autoclave Validation System

The AVS140-6 is a complete system used to perform autoclave validations. The AVS140-6 consists of six NIST traceable high temperature and pressure data loggers, an IFC406 Multiplexer Interface and the MadgeTech 4 Secure Software providing tools to users to assist with FDA 21 CFR Part 11 compliance.

Data Loggers



Software



IQ/OQ/PQ Validation Protocol



Data Logger Interface & USB Cable



Certificate of Calibration



Hardware

HiTemp140 Product Overview

High Temperature Data Logger

The HiTemp140 data logger is MadgeTech's solution for high precision, rugged temperature monitoring. It can withstand temperatures from -40 °C to 140 °C and has an accuracy of ± 0.1 °C.

The HiTemp140 can store up to 32,700 readings, and features a rigid external probe capable of measuring extended temperatures, up to 260 °C (500 °F). Custom probe lengths up to 7 inches are available. Also available, is the HiTemp140-PT that features a 24 inch flexible stainless steel probe for measuring extended temperatures up to 350 °C (662 °F). The probe is durable and can be spiraled, bent or angled in any direction, making it easy to log temperatures within bottles, vials or other hard to reach places.



HiTemp140 Specifications

Temperature Sensor: 100 Ω Platinum RTD	Battery Life: 1 year typical (1 minute reading rate at 25 °C/77 °F)
Probe Measurement Range: HiTemp140: -200 °C to +260 °C (-328 °F to +500 °F) HiTemp140-PT: -200 °C to +350 °C (-328 °F to +662 °F)	Time Accuracy: ± 1 minute/month at 20 °C to 30 °C (68 °F to 86 °F) (Stand alone mode)
Temperature Resolution: 0.01 °C (0.02 °F)	Operating Environment: -40 °C to +140 °C (-40 °F to +284 °F), 0 %RH to 100 %RH
Calibrated Accuracy: ± 0.1 °C/ ± 0.18 °F (20 °C to +140 °C/68 °F to +284 °F) ± 0.3 °C/ ± 0.54 °F (-20 °C to +19.99 °C/-4 °F to +67.98 °F) ± 0.4 °C/ ± 0.72 °F (-40 °C to -20.01 °C/-40 °F to -4.02 °F)	Dimensions (Body): 1.6 in x 0.970 in dia. (40 mm x 24.6 mm dia.)
Reading Rate: 1 second up to once every 24 hours	Submersible: Yes (IP68)
Memory: 32,700 readings	Weight: 4.2 oz (120 g)
	Material: 316 Stainless Steel
	Approvals: CE



BATTERY WARNING: FIRE, EXPLOSION, AND SEVERE BURN HAZARD. DO NOT SHORT CIRCUIT, CHARGE, FORCE OVER DISCHARGE, CRUSH, PENETRATE, OR INCINERATE. BATTERY MAY LEAK OR EXPLODE IF HEATED ABOVE 150 °C (302 °F).

Hardware

PR140 Product Overview

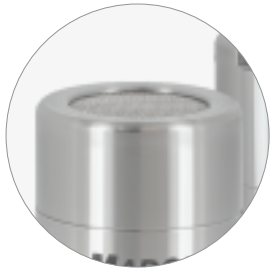
High Temperature & Pressure Data Logger

The PR140 is a data logger designed to validate if appropriate 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 ± 0.03 Bar (± 0.435 PSI), which can be achieved over a wide temperature range, from 20 °C to +140 °C (68 °F to 284 °F). The PR140 is available in either a Flush Top or NPT Pressure Port Top design, with an optional female luer fitting accessory.



PR140 Specifications

Pressure Sensor: Semiconductor (Strain Gauge)	Time Accuracy: ± 1 minutes/month at 20 °C
Pressure Range: 0 to 5 Bar (0 to 72.5 PSIA)	Operating Environment: -20 °C to +140 °C (-4 °F to +284 °F), 0 %RH to 100 %RH <i>Note: The PR140 may be used above 60 °C for up to 8 hours, per 24 hour period.</i>
Pressure Resolution: 0.1m Bar (0.0015 PSIA)	Dimensions: 2.3 in x 1.0 in dia. (58.2 mm x 25.4 mm dia.)
Calibrated Accuracy: ± 0.03 Bar (± 0.435 PSI) (20 °C to +140 °C/68 °F to 284 °F)	Submersible: Yes (IP68)
Response Time: 0.1 ms (10 %FSR to 90 %FSR)	Weight: 3 oz (85 g)
Reading Rate: 1 second up to once every 24 hours	Material: Stainless Steel
Memory: 32,700 readings	Approvals: CE
Battery Life: 2 years typical, 1 minute reading rate at 25 °C (77 °F)	



Flush Top



NPT Pressure Port Top



Luer Fitting



BATTERY WARNING: FIRE, EXPLOSION, AND SEVERE BURN HAZARD. DO NOT SHORT CIRCUIT, CHARGE, FORCE OVER DISCHARGE, DISASSEMBLE, CRUSH, PENETRATE OR INCINERATE. BATTERY MAY LEAK OR EXPLODE IF HEATED ABOVE 140 °C (284 °F).

Hardware

IFC406 Product Overview

Multiplexer Data Logger Interface

The IFC406 Multiplexer Data Logger Interface allows for multiple devices to be connected into one interface. Each IFC406 allows for 6 data loggers to be connected. 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.



IFC406 Specifications

Operating Environment: +10 °C to +35 °C; 0 %RH to 95 %RH non-condensing

Connection Type: USB (to PC)

Weight: 1.65 lb (750 g)

Material: 6061 Aluminum (PTFE impregnated hard anodized coating), ABS Plastic

Dimensions: 9.5 in x 1.95 in x 1.75 in (241.3 mm x 49.5 mm x 44.5 mm)

Maximum Input Voltage: 6 Volts (V)

Approval: CE

Battery: This device does not use a battery

LED Indicators

Blue: Indicates unit has power.

Amber: Channel is busy or searching for a device

Green: Operation successful or complete

Dust Cover

Be sure to remove the dust cover from the spring pin contacts to ensure the devices communicate properly.



To connect multiple IFC406 Interfaces together, simply join the units side by side, making sure the spring pin contacts are connected and magnetically joined. And optional AC Power adapter is included, recommended for three or more daisy-chained IFC406 Interfaces.

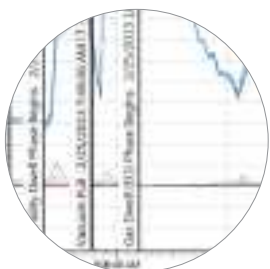
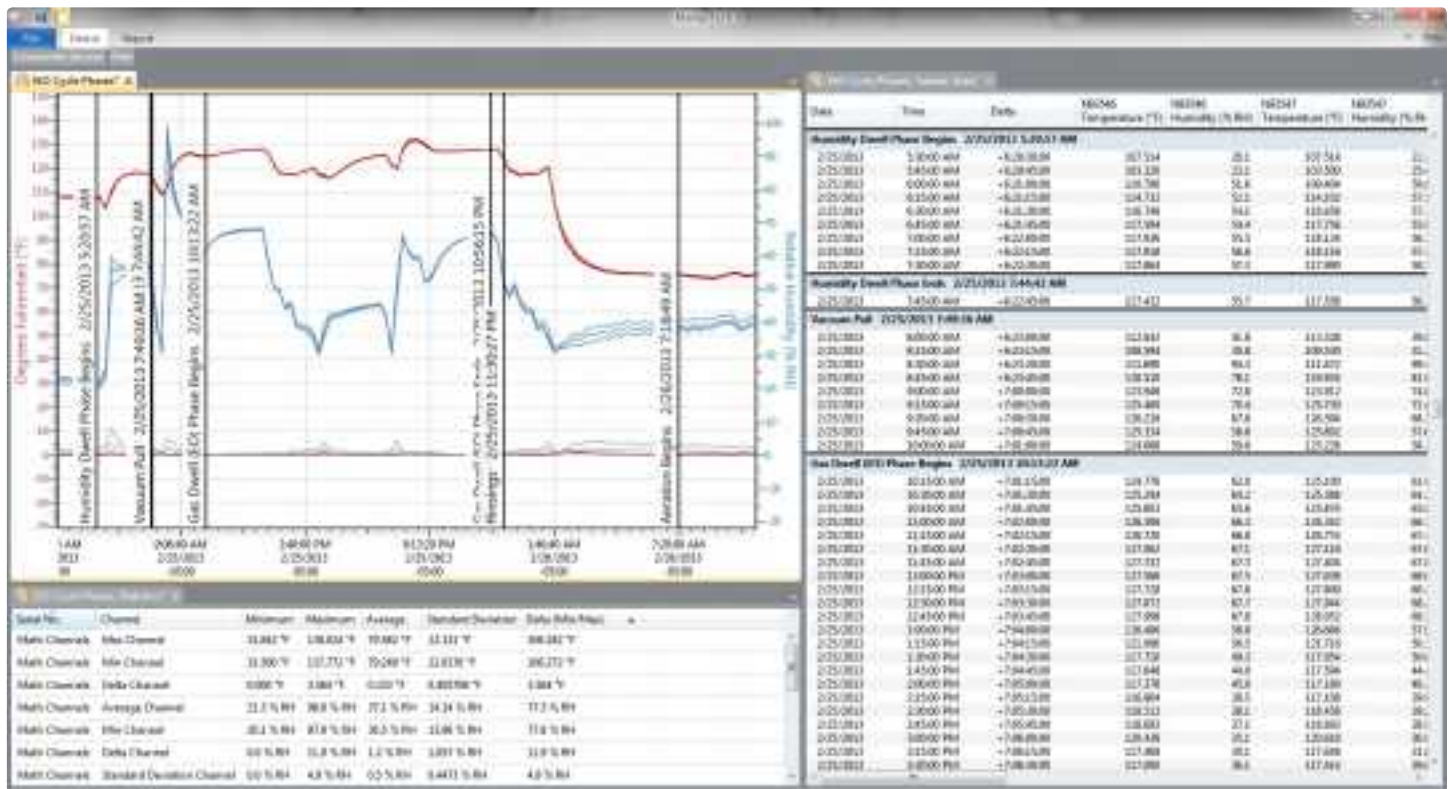


Software

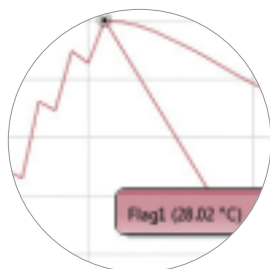
MadgeTech 4 Secure Software

The 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. MadgeTech 4 Secure Software contains criteria such as electronic signatures, access codes, secure data files, and an audit trail which meet the requirements of 21 CFR Part 11 and help provide data integrity.

MadgeTech provides on-site IQ/OQ/PQ services to help the user validate the data logging system. Our trained staff are extremely knowledgeable with the standard IQ/OQ/PQ protocols of the MadgeTech data logging system. This service is a cost-effective means to save time and ensure proper implementation of IQ/OQ/PQ of the MadgeTech data logging system with a minimal disruption to staff and operations. Get more information on our IQ/OQ/PQ On-Site Service.



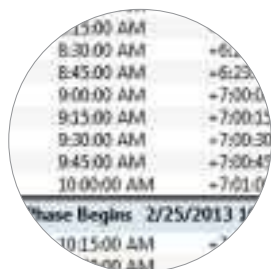
Customizable Graphs



Cooling Flags



Tabular Data View



Automatic Statistics Calculation



Copy to Excel



Great New Features

The MadgeTech 4 Secure Software is a powerful, intuitive tool containing features that are designed to save on both time and headaches. Both management and users will find MadgeTech's new software exciting: users will love the familiar interface and numerous shortcuts, while management will appreciate the increased data security and time-saving elements. Some of the most highly-anticipated new features include:



Workflows

Configure routine data logging tasks to run while you are free to do other things. The Workflows feature enables the automation of tasks such as creating reports, downloading data, starting and stopping devices or even sending email notifications!



Time Markers

Easily mark a desired point in time on any report using Time Markers. Time Markers appear as a vertical line in a graph or a colored row in a data table, Time Markers can help to organize different stages or cycles within your process or any reference points critical to interpreting your data as desired.



Advanced Statistics

MadgeTech 4 Secure Software has expanded to offer more options and statistics available for data analysis.

- Time until threshold statistics
- Sterilization Data (F0 and A0)
- Default statistic settings



Administrator & User Settings

Users can be given two levels of access, either administrator or user. Administrators have access to all the security settings, while users only have access to communicate with the data loggers and analyze data.



Groups

Users and Administrators can be assigned to Groups and can be easily maintained using a variety of permissions.



Electronic Signature

By clicking the Electronic Signature button, users and administrators can add electronic signatures. The electronic signature contains the printed name of the signer, date and time of the signing and the meaning of the signing.



Login

Login attempts and lockout duration can be assigned within the Login tab. There are numerous password and account settings for the administrator to set such as the complexity of the password and status of each user account. The user management tab is only available to administrative users.



Audit Trail

An Audit Trail is kept automatically with information such as who has logged in and out, what files were downloaded, save, printed etc. Each record is date and time stamped and includes the user information.

IQ/OQ/PQ

IQ/OQ/PQ Validation Protocol

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.

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 4 Secure 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



System Installation



A Installing the Software

1. Inserting the MadgeTech 4 Secure Software CD into the CD drive on the Windows PC.

An autorun window should appear. If the autorun does not appear, locate the drive on the computer by selecting the **Start** menu and choosing **Computer** or **My Computer**. Browse to the CD drive and select the **autorun.exe** file. For Windows 7 and Windows 8 users, a dialog box may appear with a list of options. Select **Open Folder to View Files** and select the **autorun.exe** file.



2. The MadgeTech 4 Secure Software Setup Screen will display with options as shown to the left.

3. Installing the Windows Driver

To install the drivers for the IFC406, click on the **Install USB Interface Drivers** link on the MadgeTech Installer Options window panel. A window will appear prompting for a directory and to start the installation. The default directory is **C:\Program Files\MTI-USB\Datalogger Interface**. If you choose to change the location of the install directory, select the **Change Install Location** button. Once you have the install location set click the **Install** button to start the installation.

4. Installing the .NET 4.0 Framework

If the Windows PC doesn't already have .NET 4.0 Framework, installation may be required. If you are running Windows 8, these components are already installed. To see if the .NET 4.0 Framework is already installed on the Windows PC, go to the **Windows Control Panel** and select **Programs**. "Microsoft .NET Framework 4.0" would be listed as a Windows program. If the Windows PC doesn't already have .NET 4.0 Framework, click on **MadgeTech Secure Software** and then select **Install .Net 4.0 Framework** to install.

5. Installing the MadgeTech 4 Secure Software

Click on **MadgeTech Secure Software** and then select **Install MadgeTech Secure Software**. Follow the MadgeTech 4 Secure Setup Wizard on-screen prompts to complete the installation. The installation of MadgeTech 4 Secure Software is complete!

B Connecting the Data Logger Interface

1. Remove the Warning Label on the IFC406 to expose the USB connector.
2. Connect one end of the USB cable to the USB port of the IFC406.
3. Connect the other end to a USB port on your PC. When the IFC406 is plugged in, a **New Hardware Found** message will appear in the lower right corner of your screen. The new drivers will automatically configure themselves for use with the interface cable. A message will then appear that the new hardware is installed and ready to use.
4. The installation of the USB data logger interface is complete!

C Test the Data Logger Interface Operation

To verify that the USB Interface drivers are installed properly, check to ensure the Data Logger Software can recognize a device.

1. When the interface cable is connected to the PC the blue LED power indicator light should be on.
If the indicator light is not on, unplug the interface cable, wait 5 seconds and plug it back into the PC.
2. Start the MadgeTech 4 Secure Software.
3. Your device(s) should be listed in the **Connected Devices** Panel.