USER GUIDE

AVS140-1

MadgeTech

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Product User Guide

AVS140-1

Autoclave Validation Data Logging System

MADGETECH
WE BUILD DATA LOGGERS

To view the full MadgeTech product line, visit our website at **www.madgetech.com**.

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Autoclave Validation System

The AVS140-1 is a complete system used to perform autoclave validations. The AVS140-1 consists of a high temperature data logger, an IFC400 Interface and the MadgeTech 4 Secure Software providing tools to users to assist with FDA 21 CFR Part 11 compliance.

Data Logger

HiTemp140

Software

MadgeTech 4 Secure Software

IQ/OQ/PQ Validation Protocol

IQ/OQ/PQ Validation Protocol Workbook

Data Logger Interface & USB Cable

IFC400

USB Cable

Certificate of Calibration

Calibration Certificates

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.

HiTemp140-1 *HiTemp140-2* *HiTemp140-5.25* *HiTemp140-7* *HiTemp140-PT-1*

HiTemp140 Specifications

Temperature Sensor:	100 Ω Platinum RTD
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)
Temperature Resolution:	0.01 °C (0.02 °F)
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)
Reading Rate:	1 second up to once every 24 hours
Memory:	32,256 readings

Battery Life:	1 year typical (1 minute reading rate at 25 °C/77 °F)
Time Accuracy:	±1 minute/month at 20 °C to 30 °C (68 °F to 86 °F) (Stand alone mode)
Operating Environment:	-40 °C to +140 °C (-40 °F to +284 °F), 0 %RH to 100 %RH
Dimensions (Body):	1.6 in x 0.970 in dia. (40 mm x 24.6 mm dia.)
Submersible:	Yes (IP68)
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

IFC400 Product Overview

Interface Cable Package

The IFC400 is an Interface Cable Package for the HiTemp140 Data Logger. Included with the package is a USB Connection Cable and Docking Station Cradle. The IFC400 Data Logger Interface allows for a device to be connected to a PC.

IFC400 Specifications

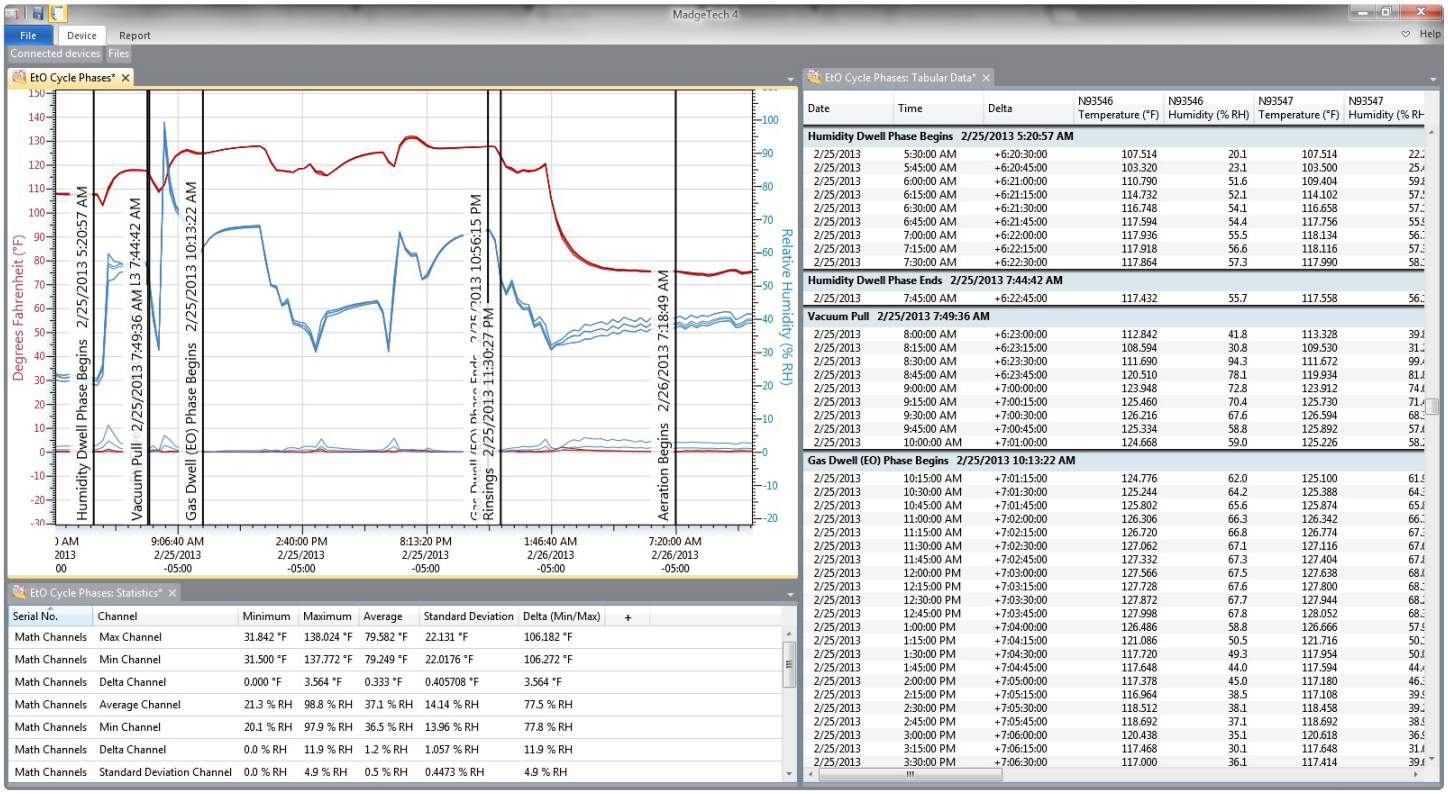
Operating Environment:	-20 °C to +50 °C (-4 °F to +122 °F) 0 %RH to 95 %RH non-condensing
Connection Type:	USB (to PC)
Weight:	0.3 lb (140 g)
Material:	Acetal Copolymer
Dimensions:	1.95 in x 2.39 in x 1.5 in (49.3 mm x 60.7 mm x 38.1 mm)
Approval:	CE
Battery:	This device does not use a battery

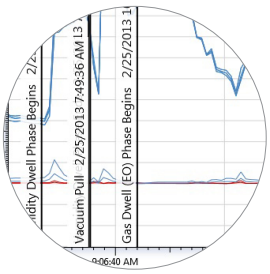
Software

MadgeTech 4 Secure Software

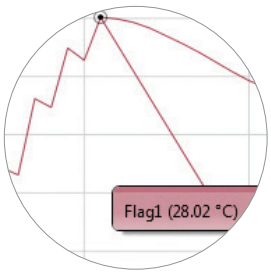
The MadgeTech 4 Secure Software aids customers in compliance with 21 CFR Part 11 requirements. The software ensures standards in which electronic files are considered equivalent to paper records, saving time and effort. MadgeTech 4 Secure Software contains criteria such as electronic signatures, access 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.

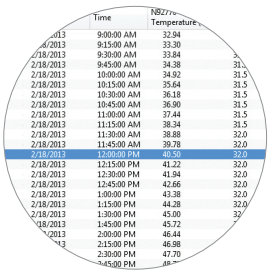




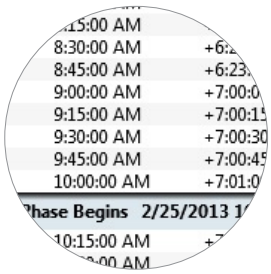
Customizable Graphs



Cooling Flags



Tabular Data View



Automatic Statistics Calculation

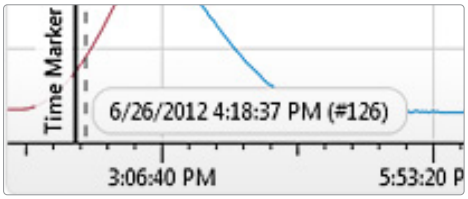
Copy to Excel

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:

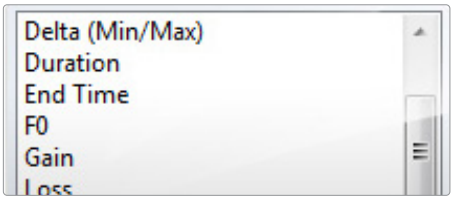
Workflows

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

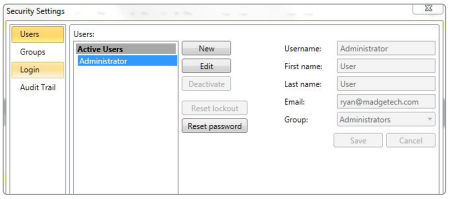
Easily mark a desired point in time on any report using Time Markers. Time Markers appear as a vertical line in a graph or a colored row in a data table, Time Markers can help to organize different stages or cycles within your process or any reference points critical to interpreting your data as desired.



Advanced Statistics

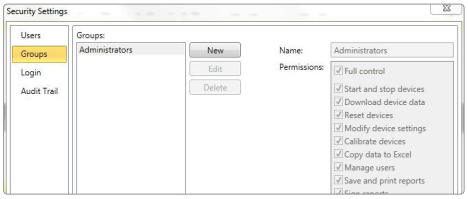
MadgeTech 4 Secure Software has expanded to offer more options and statistics available for data analysis.

- 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.

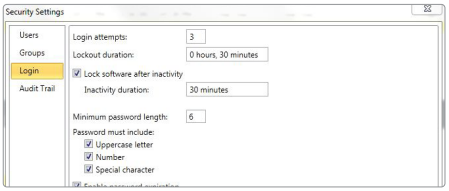


Groups

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

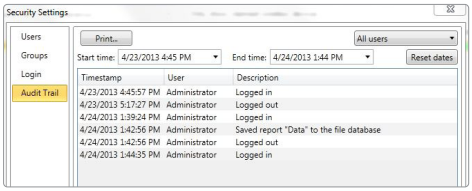
Electronic Signature

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 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.

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 IFC400.
3. Connect the other end to a USB port on your PC. When the IFC400 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.

Data Logger Maintenance

Battery Replacement

Materials needed: **ER14250-SM Lithium Battery**

Battery Replacement Procedure:

1. Unscrew the end cap of the data logger to expose the battery.
2. Remove the battery.
3. Place the new battery into the data logger. Note the polarity of the battery.
4. Tightly screw the data logger back together until the O-Rings are no longer visible.

BATTERY WARNING: DISCARD USED BATTERY PROMPTLY. KEEP OUT OF REACH OF CHILDREN. DO NOT DISPOSE OF IN FIRE, RECHARGE, PUT IN BACKWARDS, DISASSEMBLE, OR MIX WITH OTHER BATTERY TYPES. MAY EXPLODE, FLAME, OR LEAK AND CAUSE PERSONAL INJURY.

Recalibration

Recalibration is recommended annually for all MadgeTech data loggers. The **Properties** window in the MadgeTech 4 Secure Software displays the date of the last calibration and the date that the device is next due for calibration. The MadgeTech 4 Secure Software can also be configured to send an on screen notification prior to the calibration due date for each device. By default this is set to seven days prior to calibration due date and can be changed by the user by going to the **File** tab in the MadgeTech 4 Secure Software and clicking on **Options**. Select **Device** and check "**Display popup notification when a device nears its next calibration date**". The user can then select the number of days before calibration due date to notify.

HiTemp140 Standard Calibrations Points: 2 points at 30 °C and 140 °C.

Use the MadgeTech RMA System to submit the device for recalibration.

RMA Instructions

To send a device back in to MadgeTech, follow the instructions below to create an RMA (Return Merchandise Authorization) on the MadgeTech website:

1. Visit **www.madgetech.com**, click on the **Services** tab, and select **RMA Process.**
2. When the web page opens, please sign in. If this is the first time, select **Create an Account** and create one. Once signed in, click on the **Make New RMA** button.
3. Complete the applicable fields on the form including customer Billing and Shipping information, even if they are the same. Please see the field explanation below for a more detailed description about questions asked in the Device Information section.
4. When all of the fields are complete, click **Generate RMA**.
5. Print out the confirmation page that follows containing the RMA number and MadgeTech's address for shipping. A Return **Merchandise Authorization must be accompanied by a copy of the RMA paperwork and shipping is prepaid by the customer**. The RMA number should be clearly marked on the outside of the package.
6. Please ship the package via UPS, FedEx, TNT, or DHL to the address listed on the confirmation page. USPS will not ship MadgeTech data loggers.
7. A notification email will be automatically sent when MadgeTech has received the RMA.

Prices and specifications subject to change. See MadgeTech's terms and conditions at www.madgetech.com.
To send the devices back, visit www.madgetech.com, select Services then RMA Process.

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Data Logger Maintenance

O-Rings

O-Ring maintenance is a key factor when properly caring for the HiTemp140 and PR140. The O-Rings ensure a tight seal and prevent liquid from entering the inside of the device.

Materials needed for the HiTemp140: **HiTemp140-O-Ring**

O-Ring Replacement Procedure:
1. Unscrew the end cap from the data logger to expose the O-Ring.
2. Use a small pointed tool (knife or pick) to pry the old O-Ring out of its groove.
3. Make sure that the O-Ring groove is free of any dirt or debris.
4. Partially screw the mating parts back together leaving the O-Ring groove exposed.
5. Apply a thin coat of silicone based lubricant to the O-Ring.
6. Stretch the O-Ring over the cap and into its groove. **WARNING:** Avoid stretching the O-Ring over the threads! Sharp threads can cut the new O-Ring.
7. Tightly screw the data logger back together until the O-Rings are no longer visible.

Maintenance:
MadgeTech data loggers come directly from the factory with high quality O-Rings that have been properly installed. As a user, there are only a few things that need to be remembered to maintain a functional O-Ring seal.

DO:
- Clean them frequently (use compressed air or a soft brush to avoid abrasion).
- Lubricate regularly (if it doesn't feel slippery, it needs to be lubricated). We recommend Parker® Super-O-Lube, but any silicone based O-Ring lubricant will work. This is most important on the seals that are frequently opened and closed for communication with the logger.
- Inspect the O-Ring regularly for signs of failure.

DON'T:
- Poke, jab, pry at the O-Ring with sharp or pointed objects.
- Expose the O-Rings to harsh chemicals.
- Expose the seals to high pressure (the HiTemp140 and PR140 data loggers are rated to 60 PSIG).
- Expose the seal to high temperatures (see specification for operating temperature range).

Support

For more assistance with our products, please contant us using the information below

Phone & Fax
Sales & General Inquiries: (603) 456-2011
Fax: (603) 456-2012

E-mail
General Information: info@madgetech.com
Sales: sales@madgetech.com
Customer Support: support@madgetech.com

Mailing Address
MadgeTech, Inc
6 Warner Road
Warner, NH 03278

Hours of Operation
Monday - Friday,
8:00am - 5:00pm EST

Website
Visit our Online Knowledge Base
at ***www.madgetech.com/kbase***

MadgeTech, Inc. . 6 Warner Road . Warner, NH 03278
Tel: (603) 456-2011 . Fax: (603) 456-2012 . info@madgetech.com . www.madgetech.com

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DOC-1293-036-00 Rev3 2022.06.27