# Product User Guide



## AVS140-1 Autoclave Validation Data Logging System





# Table of Contents

Autoclave Validation Data Logging System3
Hardware 4-5
Software

IQ/OQ/PQ Validation Protocol8
System Installation9
Maintenance10-11

# 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.



## 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  $\pm 0.1$  °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

Memory: 32,256 readings

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

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).

## **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

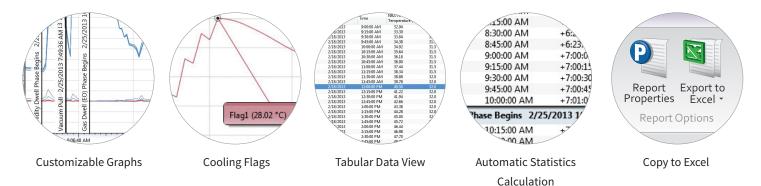
## MadgeTech 4 Secure Software

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.



at   🖥 🦲	Statement and the statement of the state		-	-	and the same	MadgeTech 4		-	-		-	-		- 0 ×
File Devie	ce Report													🗢 Helj
Connected devic	es Files													
EtO Cycle Ph	nases* X													
150-								Date	Time	Delta	N93546	N93546	N93547	N93547
140	1						100					Humidity (% RH)	Temperature (°F)	Humidity (% RF
130		_	1				· · ·		ell Phase Begins 2/					^
120			$\sim$				90	2/25/2013	5:30:00 AM	+6:20:30:00	107.514	20.1	107.514	22.1
120		$\sim$		1	~	E E		2/25/2013	5:45:00 AM	+6:20:45:00 +6:21:00:00	103.320 110.790	23.1 51.6	103.500	25.4 59.8
110-5							80	2/25/2013 2/25/2013	6:00:00 AM 6:15:00 AM	+6:21:00:00	110.790	52.1	109.404 114.102	59.2
A MA				Σd		-		2/25/2015	6:30:00 AM	+6:21:30:00	114.752	54.1	114.102	57.:
100	12 AN			5			70	2/25/2013	6:45:00 AM	+6:21:45:00	117.594	54.4	117.756	55.5
(°F) 8 06 5:20:5	7:44:42		٨	10:56:1			Re	2/25/2013	7:00:00 AM	+6:22:00:00	117.936	55.5	118.134	56.
1 1 10	444		N	1.1			50 0	2/25/2013	7:15:00 AM	+6:22:15:00	117.918	56.6	118.116	57.3
-08 H				1 9			50 lativ	2/25/2013	7:30:00 AM	+6:22:30:00	117.864	57.3	117.990	58.:
201	- G - E			V 00	A	- NA	б 50 т	Humidity Dwe	ell Phase Ends 2/25	/2013 7:44:42 AM				
1 . T . D	36 AM 13 7	4	-	201	V L	8:49	umid	2/25/2013	7:45:00 AM	+6:22:45:00	117.432	55.7	117.558	56.
Pah 2/2	19 10	LP	V	Ends 2/75/7	6 ~~		ib 04	Vacuum Pull	2/25/2013 7:49:36	AM				
vn 50			V	15			Ť	2/25/2013	8:00:00 AM	+6:23:00:00	112.842	41.8	113.328	39.8
Degrees	013 7:49 Begins	V	1	50		m 上	30 😠	2/25/2013	8:15:00 AM	+6:23:15:00	108.594	30.8	109.530	31.1
5 40 5				7 00		5		2/25/2013	8:30:00 AM	+6:23:30:00	111.690	94.3	111.672	99.4
	Be 15 1					- 5	RH)	2/25/2013	8:45:00 AM	+6:23:45:00	120.510	78.1	119.934	81.1
20 Log	//25/2013			/2013		2/26/201	20	2/25/2013 2/25/2013	9:00:00 AM	+7:00:00:00	123.948 125.460	72.8 70.4	123.912 125.730	74.
20	ha 25			10			22	2/25/2013	9:15:00 AM 9:30:00 AM	+7:00:15:00 +7:00:30:00	125.460	67.6	125.730	71.4
10 -				120	· · · · · · · · · · · · · · · · · · ·	v -	10	2/25/2013	9:45:00 AM	+7:00:30:00	125.334	58.8	125.892	57.0
			A	2/25/		~~ · · · · · · · · · · · · · · · · · ·		2/25/2013	10:00:00 AM	+7:01:00:00	124.668	59.0	125.226	58.
						Begins	D	Gas Dwell (EO	) Phase Begins 2/2	5/2013 10:13:22 A	м			
-10 -	Dwell			Dwell		- 5	_	2/25/2013	10:15:00 AM	+7:01:15:00	124.776	62.0	125.100	61.5
lic lic	D R			ć. <u></u>		-ĕ	-10	2/25/2013	10:30:00 AM	+7:01:30:00	125.244	64.2	125.388	64.3
-10 AipimnH	Vacuum Gas Dwe			Gas Dwol Rinsings		Aeration		2/25/2013	10:45:00 AM	+7:01:45:00	125.802	65.6	125.874	65.8
-30 -				04	L	<	-20	2/25/2013	11:00:00 AM	+7:02:00:00	126.306	66.3	126.342	66.
) AM	9:06:40 AM	2:40:00 PM	8-1	3:20 PM	1:46:40 AM	7:20:00 AM		2/25/2013	11:15:00 AM	+7:02:15:00	126.720	66.8	126.774	67.
2013	2/25/2013	2/25/2013		25/2013	2/26/2013	2/26/2013		2/25/2013 2/25/2013	11:30:00 AM 11:45:00 AM	+7:02:30:00 +7:02:45:00	127.062 127.332	67.1 67.3	127.116 127.404	67.1 67.1
00	-05:00	-05:00		05:00	-05:00	-05:00		2/25/2013	12:00:00 PM	+7:02:45:00 +7:03:00:00	127.332	67.5	127.638	68.0
70								2/25/2013	12:00:00 PM	+7:03:00:00	127.500	67.6	127.800	68.
EtO Cycle Ph	nases: Statistics* ×							2/25/2013	12:30:00 PM	+7:03:30:00	127.872	67.7	127.944	68.
Serial No.	Channel	Minimum Maximur	n Average	Standard Deviat	ion Delta (Min/Max)	+		2/25/2013	12:45:00 PM	+7:03:45:00	127.998	67.8	128.052	68.3
	- Contraction of the second seco		-			2.50		2/25/2013	1:00:00 PM	+7:04:00:00	126.486	58.8	126.666	57.5
Math Channels	Max Channel	31.842 °F 138.024 '	F 79.582 *F	22.131 °F	106.182 °F		-	2/25/2013	1:15:00 PM	+7:04:15:00	121.086	50.5	121.716	50.:
Math Channels	Min Channel	31.500 °F 137.772 °	F 79.249 °F	22.0176 °F	106.272 °F		=	2/25/2013 2/25/2013	1:30:00 PM 1:45:00 PM	+7:04:30:00 +7:04:45:00	117.720 117.648	49.3 44.0	117.954 117.594	50.( 44.4
Math Channels	Delta Channel	0.000 °F 3.564 °F	0.333 °F	0.405708 °F	3.564 °F		-1	2/25/2013	2:00:00 PM	+7:05:00:00	117.378	45.0	117.180	46.3
Math Channels	Average Channel	21.3 % RH 98.8 % R	H 37.1 % RH	14.14 % RH	77.5 % RH			2/25/2013 2/25/2013	2:15:00 PM 2:30:00 PM	+7:05:15:00 +7:05:30:00	116.964 118.512	38.5 38.1	117.108 118.458	39.9 39.1
Math Channels		20.1 % RH 97.9 % R		13.96 % RH	77.8 % RH		-11	2/25/2013	2:30:00 PM 2:45:00 PM	+7:05:30:00	118.512	38.1	118.458	39.
							- 11	2/25/2013	3:00:00 PM	+7:06:00:00	120.438	35.1	120.618	36.5
Math Channels	Delta Channel	0.0 % RH 11.9 % R	H 1.2 % RH	1.057 % RH	11.9 % RH			2/25/2013	3:15:00 PM	+7:06:15:00	117.468	30.1	117.648	31.(
Math Channels	Standard Deviation Channel	0.0 % RH 4.9 % RH	0.5 % RH	0.4473 % RH	4.9 % RH		-	2/25/2013	3:30:00 PM	+7:06:30:00	117.000	36.1	117.414	39.1 *
							1000							

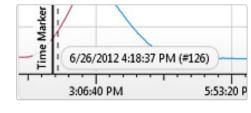




### **Great New Features**

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.

Delta (Min/Max)	*
Duration	
End Time	(T-1)
FO	1.00
Gain	=
Loss	

### **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

Jsers	Users:			
Groups	Active Users	New	Username:	Administrator
ogin	Administrator	Edit	First name:	User
Audit Trail		Deactivate	Last name:	User
		Reset lockout	Email:	ryan@madgetech.com
		Reset password	Group:	Administrators *
		· · · · · · · · · · · · · · · · · · ·		Save Cancel

### 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.

Users	Groups:			
Groups	Administrators	New	Name:	Administrators
Login		Edit	Permissions:	Full control
Audit Trail		Delete		Start and stop devices
				Download device data
				Reset devices
				Modify device settings
				Copy data to Excel
				Manage users
				Save and print reports

#### Groups

52

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

Username:	User	
Password:	•••••	
	Sign	Cancel

### **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.

Users	Login attempts:	3	
Groups	Lockout duration:	0 hours, 30 minutes	
Login	Lock software after inactivi	ity	
Audit Trail	Inactivity duration:	30 minutes	
	Minimum password length:	6	
	Password must include:		
	Uppercase letter		
	Special character		

#### 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



## 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.



MadgeTech 4 Secure Software
MadgeTech Installer Options
MadgeTech Secure Software Install components for MadgeTech Data Logger Secure Software Install USB Interface Driver Installs Windows device drivers for the MadgeTech USB Interface cable
Exit      O View Contents     MadgeTech We suite DATA Loggers

#### 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!

## 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.

# 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<sup>®</sup> 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



■Tel:+86 755-8420 0058 ■Fax:+86 755-2822 5583 ■E-mail:sales@eofirm.com ■http://www.eofirm.com