

# Product User Guide



## AVS140-6 Autoclave Validation Data Logging System



# Autoclave Validation System

The AVS140-6 is a complete system used to perform autoclave validations. The AVS140-6 consists of six 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.

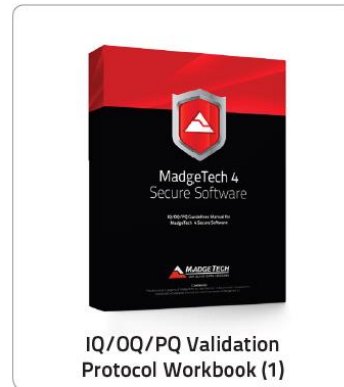
## Data Loggers



## 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  $\pm 0.1$  °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

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

# Hardware

## PR140 Product Overview

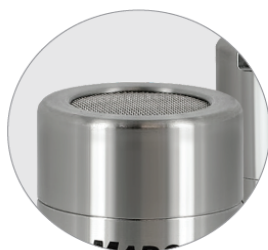
### Pressure Data Logger

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  $\pm 0.03$  Bar ( $\pm 0.435$  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

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

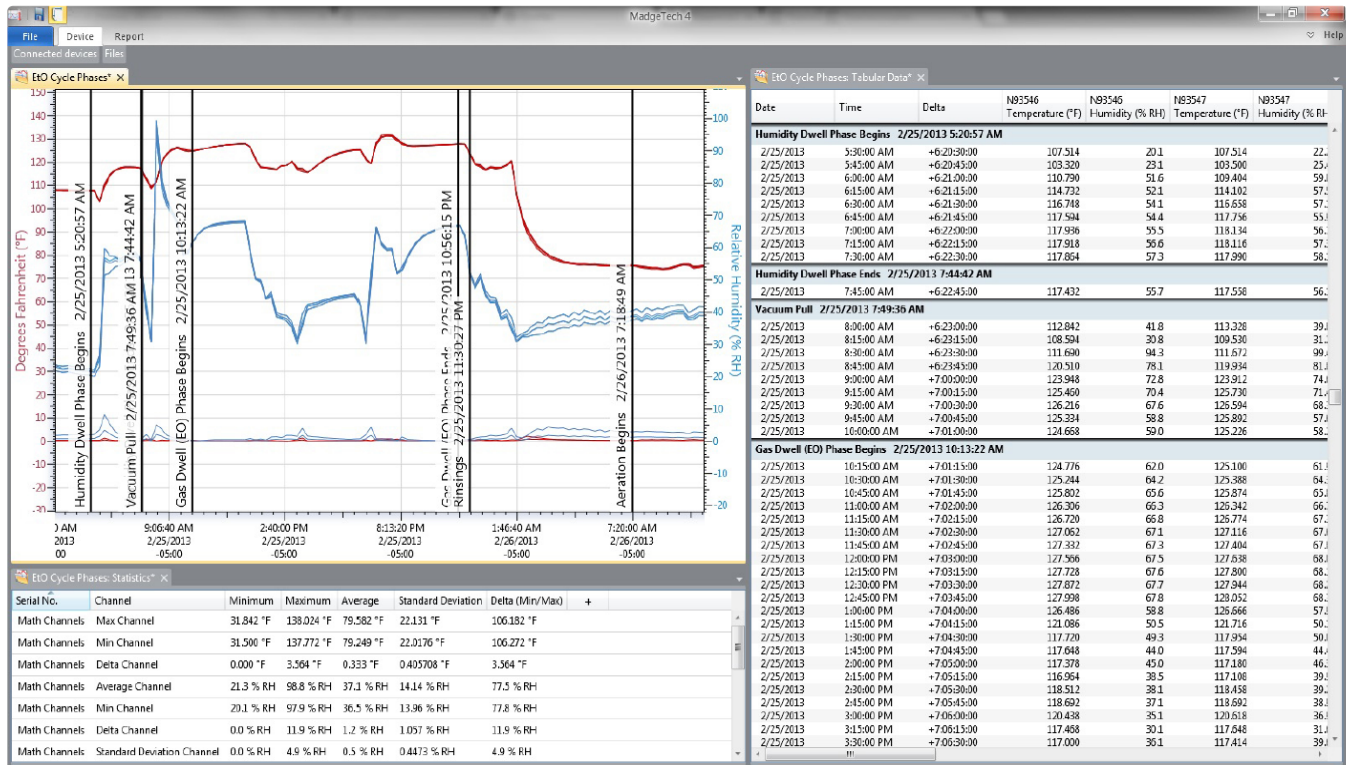
**Green:** Operation successful or complete

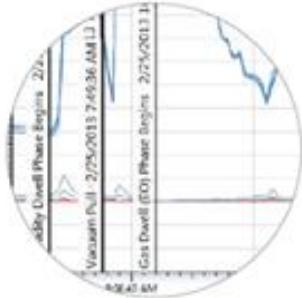
# Software

## 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.

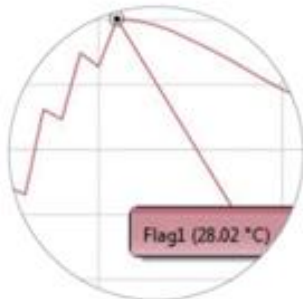




Customizable Graphs

Time	Temperature
2/25/2013 8:00:00 AM	22.00
2/25/2013 8:15:00 AM	22.00
2/25/2013 8:30:00 AM	22.00
2/25/2013 8:45:00 AM	24.00
2/25/2013 9:00:00 AM	26.00
2/25/2013 9:15:00 AM	28.00
2/25/2013 9:30:00 AM	28.00
2/25/2013 9:45:00 AM	28.00
2/25/2013 10:00:00 AM	28.00
2/25/2013 10:15:00 AM	28.00
2/25/2013 10:30:00 AM	28.00
2/25/2013 10:45:00 AM	28.00
2/25/2013 11:00:00 AM	28.00
2/25/2013 11:15:00 AM	28.00
2/25/2013 11:30:00 AM	28.00
2/25/2013 11:45:00 AM	28.00
2/25/2013 12:00:00 PM	28.00
2/25/2013 12:15:00 PM	28.00
2/25/2013 12:30:00 PM	28.00
2/25/2013 12:45:00 PM	28.00
2/25/2013 1:00:00 PM	28.00
2/25/2013 1:15:00 PM	28.00
2/25/2013 1:30:00 PM	28.00
2/25/2013 1:45:00 PM	28.00
2/25/2013 2:00:00 PM	28.00
2/25/2013 2:15:00 PM	28.00
2/25/2013 2:30:00 PM	28.00
2/25/2013 2:45:00 PM	28.00
2/25/2013 3:00:00 PM	28.00
2/25/2013 3:15:00 PM	28.00
2/25/2013 3:30:00 PM	28.00
2/25/2013 3:45:00 PM	28.00
2/25/2013 4:00:00 PM	28.00
2/25/2013 4:15:00 PM	28.00
2/25/2013 4:30:00 PM	28.00
2/25/2013 4:45:00 PM	28.00
2/25/2013 5:00:00 PM	28.00

Tabular Data View



Cooling Flags

8:15:00 AM	
8:30:00 AM	+6:23
8:45:00 AM	+6:23
9:00:00 AM	+7:00:00
9:15:00 AM	+7:00:15
9:30:00 AM	+7:00:30
9:45:00 AM	+7:00:45
10:00:00 AM	+7:01:00
<b>Phase Begins 2/25/2013 10:00:00 AM</b>	
10:15:00 AM	+7:01:15
10:30:00 AM	+7:01:30
10:45:00 AM	+7:01:45
11:00:00 AM	+7:02:00
11:15:00 AM	+7:02:15
11:30:00 AM	+7:02:30
11:45:00 AM	+7:02:45
12:00:00 PM	+7:03:00

Automatic Statistics Calculation



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