

AUTOCLAVE VALIDATION SYSTEM



Features

- Enables compliance with FDA 21 CFR Part 11
- Software calculates thermal resistance in F0
- N.I.S.T. traceable calibration
- Stand alone, complete system
- No thermocouple wires
- Digital calibration through software
- Package Includes:
 - 1 or 5 HiTemp150's with N.I.S.T. certificates
 - IFC200 interface package
 - Secure Software License
 - IQ/OQ/PQ Validation Protocols
 - 1 or 5 Thermal Shield(s) rated to 250°C

The AVS150 is a complete system used to perform autoclave validations. The AVS150 consists of a N.I.S.T. traceable HiTemp150 data logger, an IP68 extended range thermal shield, an IFC200 USB cable package and MadgeTech's FDA 21 CFR Part 11 Secure Software. For larger size autoclaves or mapping projects, the AVS150-5, includes five HiTemp150's and five thermal shields.

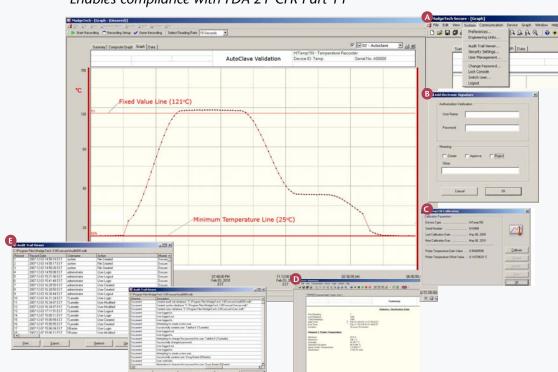


The HiTemp150 is completely submersible and can measure temperatures up to 150°C. The 2" rigid probe provides a fast response time and can record readings as fast as once per second. The HiTemp150 can be used in each autoclave cycle for verification and to provide data for validation. When used with the thermal shield the device can withstand up to 250°C (time dependent).

MadgeTech's Secure Software provides data in graphical and tabular form, and provides a summary and statistical report of the data. The software also features sterilization calculations to determine the F0 value. Furthermore the software allows for different user levels and logins, electronic signatures, an audit trail and a secure data file to stand up to auditors.

MadgeTech Secure Data Logger Software

Enables compliance with FDA 21 CFR Part 11



Key

- Administrator Settings
- **B** Electronic Signatures
- Digital Calbration
- Data Summary/Statistics
- Audit Trail View

Features & Benefits of using MadgeTech **Secure Software**

- · Install, validate and operate one software program universally
- · Compatible with all MadgeTech products
- Time and cost saving validation package, stands up to interrogation from auditors
- Data Security and audit trail is automatic
- Advanced user maintenance
- Traceability with customizable audit trails and electronic signatures
- Aids in compliance with FDA 21 CFR Part 11/820 and GxP guidelines

HITEMP150 SPECIFICATIONS*

Temperature Sensor: 100Ω Platinum RTD

Temperature Range: -40 to +150°C

Temperature Resolution: 0.05°C

Calibrated Accuracy: ±0.5°C

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Start Modes: Software Programmable

Start NowDelay Start

Memory: 32,767 readings

Reading Rates: 1 second up to 12 hours

Calibration: Digital Calibration through software

Calibration Date: Automatically recorded within

Device

Battery Type: 3.9V high-temperature lithium

battery included

Battery Life: 1 year typical

(1 minute reading rate @ 25°C)

Data Format: Date and time stamped °C, °F, K, °R

Time Accuracy: ±1 minute/month at 20°C

(RS232 cable not in use)

Computer Interface: PC serial or USB (Interface cable

required); 2,400 baud

Software: XP SP3/VIsta/Windows 7

Not Compatible with 64 bit systems

Operating Environment: -40 to +150°C, 0 to 100%RH

Dimensions (Body): 1.1" x 1.75" dia. (28mm x 45mm dia.)

Dimensions (Probe)*: 2.0" x 3/16" dia. (50mm x 5mm dia.)

*Other probe lengths available

Weight: HiTemp150: 8 oz (225g)

AVS150: 60.9oz (3.8lbs, 1.72 Kg) AVS150-5: 134.5oz (8.4lbs, 3.81Kg))

Material: 316 Stainless Steel

Approvals: CE

*SPECIFICATIONS ARE SUBJECT TO CHANGE WITHOUT NOTICE. SPE-CIFIC WARRANTY AND REMEDY LIMITATIONS APPLY. CALL 1-603-456-2011 OR GO TO WWW MADGETECH COM FOR DETAILS

WARNING: FIRE, EXPLOSION, AND SEVERE BURN HAZARD. DO NOT SHORT CIRCUIT, CHARGE, FORCE OVERDISCHARGE, DISASSEMBLE, CRUSH, PENETRATE OR INCINERATE. BATTERY MAY LEAK OR

THERMAL SHIELD SPECIFICATIONS

Operating Environment: -200 to +250°C (-328 to +482°F)

Time limited, 0 to 100% RH

IP Rating: IP68

Dimensions: 2.1" x 2.6" dia. 53.34mm x 66mm dia.

EXPLODE IF HEATED ABOVE 150° C (302° F).

Weight: .65lb

Ambient Temperature	Time In Air To Max Internal Temp (150°C / 302°F)	Time In Liquid To Max Internal Temp (150°C / 302°F)
-200°C (-328°F)	18 minutes	N/A
-180°C (-292°F)	19 minutes	N/A
-160°C (-256°F)	21 minutes	N/A
-140°C (-220°F)	24 minutes	N/A
-120°C (-184°F)	27 minutes	N/A
-100°C (-148°F)	32 minutes	N/A
-80°C(-112°F)	40 minutes	N/A
-60°C (-76°F)	55 minutes	25 minutes
-40°C to +150°C (-40°F to +302°F)	Indefinitely	Indefinitely
160°C (320°F)	75 minutes	34 minutes
170°C (338°F)	63 minutes	29 minutes
180°C (356°F)	55 minutes	26 minutes
190°C (374°F)	50 minutes	23 minutes
200°C (392°F)	45 minutes	21 minutes
210°C (410°F)	42 minutes	19 minutes
220°C (428°F)	39 minutes	18 minutes
230°C (446°F)	36 minutes	17 minutes
240°C (464°F)	34 minutes	16 minutes
250°C (482°F)	32 minutes	15 minutes

ORDERING INFORMATION

<u>Model</u>	<u>Description</u>	Price (U.S.)
AVS150	Includes (1) HiTemp150 data logger with N.I.S.T. Calibration Certificate, an extended range thermal shield, IFC200 interface cable, MadgeTech's FDA 21 CFR Part 11 Secure Software and IQ/OQ/PQ validation protocols.	\$2,085.00
AVS150-5	Includes (5) HiTemp150 data loggers with N.I.S.T. Calibration Certificate, (5) extended range thermal shields, IFC200 interface cable, MadgeTech's FDA 21 CFR Part 11 Secure Software and IQ/OQ/PQ validation protocols.	\$4,200.00
AVS150-Custom	Includes a custom number of HiTemp150 data logger with N.I.S.T. Calibration Certificate, extended range thermal shields, IFC200 interface cable, MadgeTech's FDA 21 CFR Part 11 Secure Software and IQ/OQ/PQ validation protocols.	Call For Pricing

ASK ABO	UT OUR	OTHER
DATA	RECORD	ERS

Temperature Humidity Low Level Current Low Level Voltage PH RF Transmitters Level Intrinsically Safe Shock Spectral Vibration LCD

