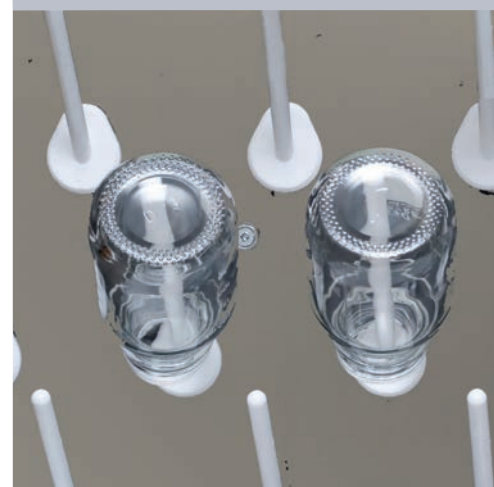
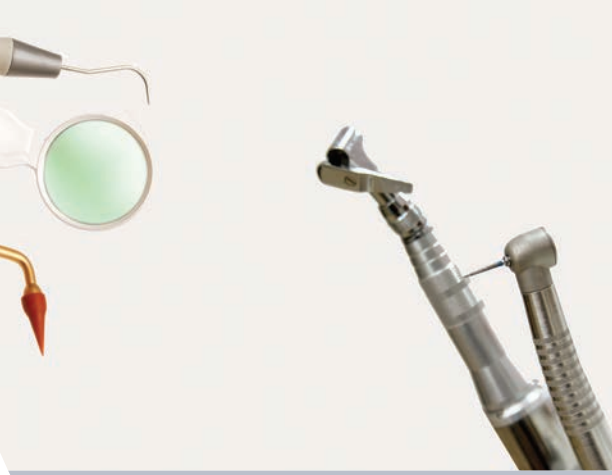


# DATA LOGGING SOLUTIONS



For

STEAM STERILIZATION  
DRY HEAT STERILIZATION  
AND OTHER THERMAL PROCESSES



## SPECIFICATIONS

A MadgeTech line of data loggers has been developed exclusively to validate the entire Sterilization cycle. The **HiTemp150**, **HiTemp150FP**, **Temp1000S** and **Temp1000FP** data loggers measure temperatures up to 150°C, enduring the high pressure found in sterilizers. All the devices record measurements at periodic time intervals, validating the entire sterilization cycle. Their stand alone operation and compact size permits the recorders to fit easily into the sterilization chamber with the product load.

As federal regulations mandate records for each sterilization cycle, the MadgeTech software makes it simple to maintain records validating each successful sterilization cycle.

MadgeTech Data Loggers have become the data loggers of choice in the sterilization industry.

## FEATURES

- Extended Temperature Range
- Submersible
- Rugged
- Reusable
- Programable Start Time
- NIST Traceable
- CE Compliant
- Real Time Operation
- Low Cost



\* The minimum bending radius of the probe is 2", bending only once. Avoid bending the probe anywhere along its first 2.5" from the tip.

Part Number	HiTemp150	HiTemp150FP	Temp1000S	Temp1000FP
Temperature Sensor	Integral 2" probe 100Ω Platinum RTD	4" Probe 100Ω Platinum RTD	Integral 1" probe 100Ω Platinum RTD	Integral 10.8" flexible probe 100Ω Platinum RTD
Temperature Range	-40 to +150°C	-40 to +150°C	-40 to +150°C	-40 to +150°C
Temperature Resolution	0.05°C	0.05°C	0.05°C	0.05°C
Temperature Accuracy	±0.5°C	±0.5°C	±0.5°C	±0.5°C
Memory	32,767 readings	32,767 readings	32,767 readings	32,767 readings
Sample Rate	1 reading every second to 1 every 12 hours	1 reading every second to 1 every 12 hours	1 reading every second to 1 every 12 hours	2 seconds up to 12 hours
Delayed Start	0 - 180 days	0 - 180 days	0 - 180 days	0 - 180 days
Required Interface Package	IFC110 or IFC200	IFC110 or IFC200	IFC110 or IFC200	IFC110 or IFC200
Typical Battery Life	1 year	1 year	1 year	1 year
Operating Environment	-40 to +150°C 0 to 100%RH	-40 to +150°C 0 to 100%RH	-40 to +150°C 0 to 100%RH	40 to +150°C 0 to 100%RH
Materials	316 stainless steel	316 stainless steel	303 stainless steel	303 stainless steel body 304 stainless steel probe
Submersible	Yes	Yes	Yes	Yes
Dimensions Body	1.1" x 1.75" dia (28mm x 45mm dia.)	1.1" x 1.75" dia (28mm x 45mm dia.)	4.8" x 1.0" dia (122mm x 26mm dia.)	5.7" x 1.25" dia (145mm x 32mm dia.)
Dimensions Probe	2.0" x 3/16" dia (51mm x 5mm dia.)	4" x 1/8" dia. (102mm x 4mm dia.)	1.0" x 3/16" dia (26mm x 5mm dia.)	10.8" x 1/8" dia (275mm x 4mm dia.)
Approvals	CE	CE	CE	CE
NIST Certificates	Yes	Yes	Yes	Yes

\* Specifications subject to limits or conditions. Consult product data sheet.

# SOFTWARE VALIDATION MADE SIMPLE

## ASSISTS WITH MEETING REGULATORY REQUIREMENTS

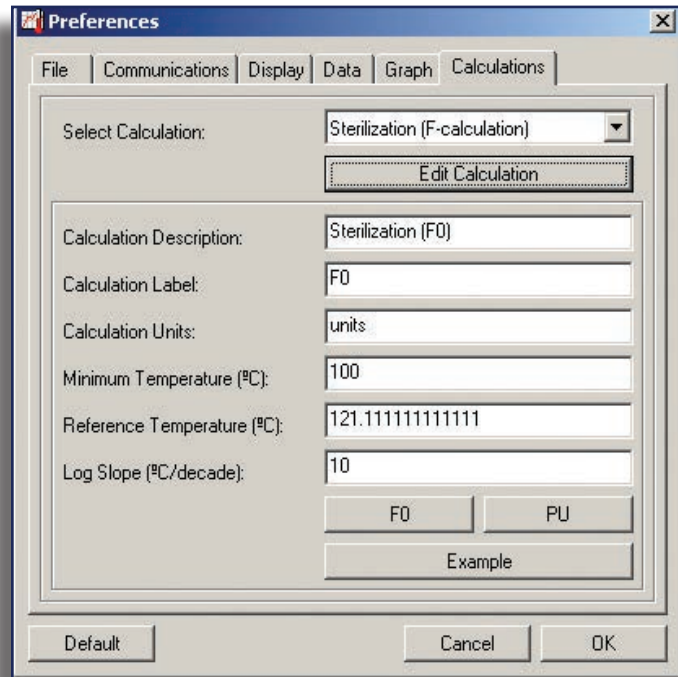
Meeting compliance regulations for the FDA's *Good Manufacturing Practices*, or those set forth in Quality Plans, has become increasingly complex. MadgeTech has simplified this process by offering IQ/OQ/PQ protocols for its standard and secure (21 CFR part 11) software.

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 (SVW) to help the user verify the functionality of the software. The workbook is not required to meet cGMP or FDA requirements. Contact MadgeTech for details.

## LETHALITY & PASTEURIZATION EQUATION

Madgetech's powerful software comes with built-in tools to dynamically re-calculate Sterilization (F0) as the user changes the data view. Additionally, specific variables (eg. Reference Temperature, Log Slope) in the equations can be changed to accommodate individual needs.



For further information, please consult our Sterilization Application Note at: [www.madgetech.com](http://www.madgetech.com).

## ON-SITE TRAINING SERVICES

A MadgeTech technician will visit your facility to assist with the installation, training and perform the validation process.



## CALIBRATION

### CALIBRATION LABORATORY AND N.I.S.T. CERTIFICATION

MadgeTech's state-of-the-art calibration laboratory offers standard and customized calibration services. Temperature and humidity calibrations are performed using only N.I.S.T. traceable equipment and highly trained personnel to ensure quality and consistency. Specific procedures are carefully followed as required by our Quality Plan. The Temp1000FP, Temp1000S, HiTemp150 and HiTemp150FP data loggers are calibrated and supplied with N.I.S.T. traceable certificates upon request.

### RECALIBRATION SERVICES

Recalibration, battery replacement and refurbishment services are offered at reasonable prices.

For more information about MadgeTech Data Loggers or to demo our software, visit us online at: [www.madgetech.com](http://www.madgetech.com)



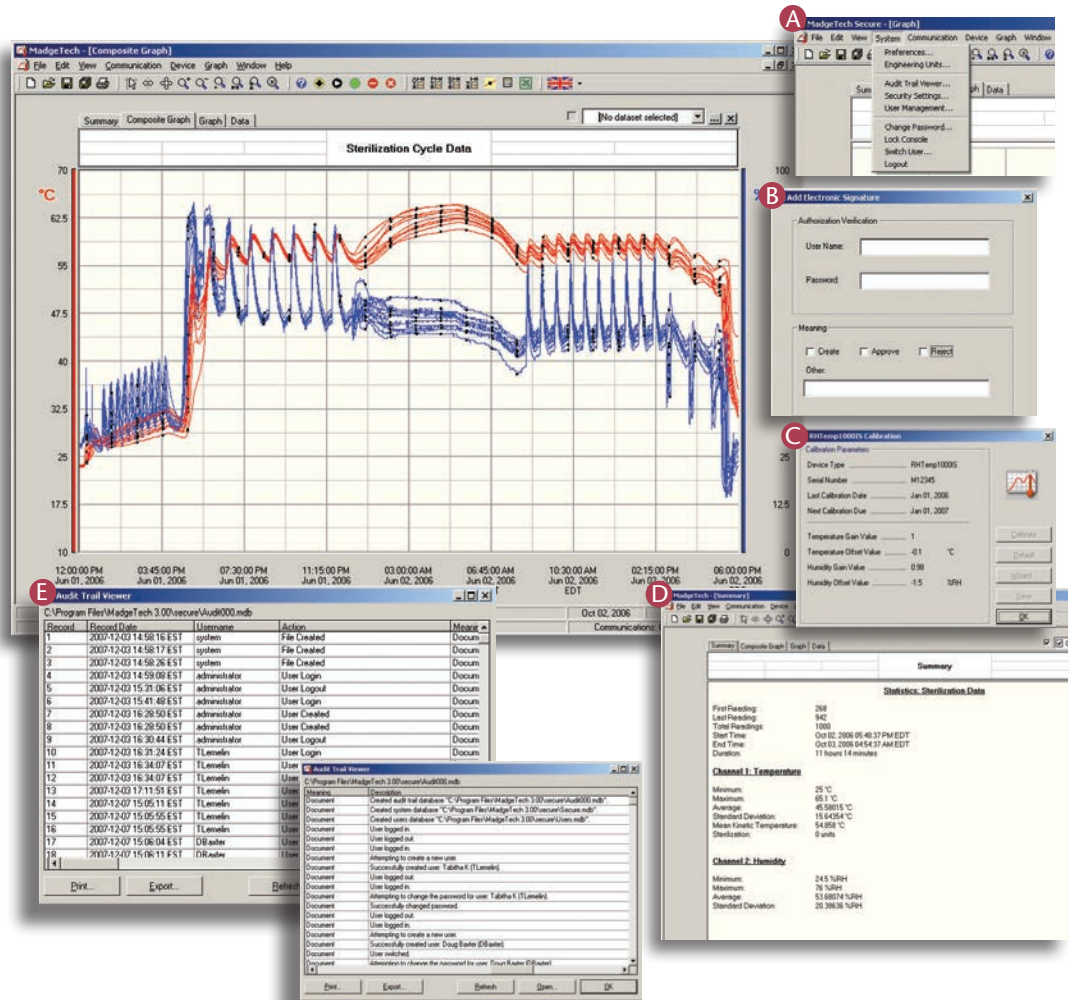
# MADGETECH DATA LOGGER SOFTWARE

## Key

- A** Administrator Settings
- B** Electronic Signatures
- C** Digital Calibration
- D** Data Summary/Statistics
- E** 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



## BASIC SOFTWARE FEATURES

- Multiple graph overlay
- Statistics calculations
- Digital calibration
- Zoom in/ zoom out
- Average line
- Lethality equations
- Full time zone support
- Data annotation
- Data table view
- MKT (Mean Kinetic Temperature)
- Automatic report generation
- Summary view

Regulations and working practices designed to ensure development and quality are kept to a very high standard and are implemented in accordance with GAMP (IQ/OQ/PQ) and enforced by the FDA and other regulatory bodies. Those that apply to environmental monitoring are addressed with MadgeTech Secure.

The software ensures standards in which electronic files are considered equivalent to paper records, saving time, and effort. MadgeTech Secure Software contains criteria such as electronic signatures, access codes, secure data file, and an audit trail which meet the requirements of 21 CFR Part 11 and helps provide data integrity.

For use with the precise and reliable MadgeTech data logging range, the MadgeTech Secure Software aids to help customers comply with 21 CFR Part 11 requirements.