Data Logging Solutions

for Ethylene Oxide (EtO) Sterilization

MADGETECH
WE BUILD DATA LOGGERS

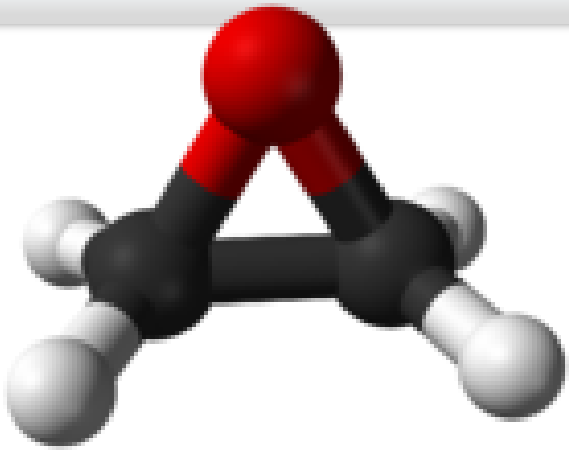
Table of Contents

About MadgeTech, Inc.

- MadgeTech, Inc. is a global company based in New England and founded on traditional principles, customer service, quality, and trust.
- MadgeTech designs and manufactures all its data loggers at its USA headquarters facility.
- MadgeTech is dedicated to providing customers with reliable, affordable products, hassle-free ordering, and excellent service, saving customers time and money.

What is Ethylene-Oxide?

Ethylene Oxide (EO) is a gas widely used for the sterilization of healthcare devices and instruments. The process involves exposing products to a gas mixture of EO and nitrogen within a vacuum-filled chamber. The EO gas acts as a surface sterilant and the vacuum environment aids the gas to reach most aspects of the device requiring sterilization.



C_2H_4O

What Needs to be Measured?

EO gas sterilization is dependent upon four parameters: EO gas concentration, temperature, humidity, and exposure time.

In accordance with ANSI/AAMI/ISO 11135, it is required by the FDA that temperature and relative humidity be monitored at different intervals during process validations on routine EO processed medical devices.

Periodic chamber mapping and cycle validations are required to be performed to ensure even distribution of temperature and humidity levels throughout the chamber.

MadgeTech data loggers can aid in:

- Facilitating Parametric Release
- Product Qualification Runs
- Chamber/Cycle Validations
- Making EO cycles more efficient

The MadgeTech Solution

- MadgeTech provides data logging solutions for temperature and humidity monitoring.
- These solutions are intrinsically safe and designed specifically for use in EO environments.
- MadgeTech data logging systems are designed to handle large numbers of data loggers, ensuring maximum efficiency.
- Free support is provided to ensure users feel comfortable and confident using the MadgeTech system.

For a complete data logging system, the following is required:

- Data loggers such as the RHTemp1000IS and Temp1000IS
- IFC400 and/or IFC406
- Computer
- MadgeTech 4 Secure Software

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RHTemp1000IS

Humidity and Temperature Data Logger

- Rated as Intrinsically Safe by FM Approvals for use in Class I, Division 1, Groups A, B, C and D and non-incendive for Class I, Division 2, groups A, B, C and D indoor and outdoor.
- Utilizes a new thermoset-polymer capacitive sensor that provides the longest operating life in an ethylene-oxide based sterilization process
- Maintains resistance against various chemical liquids and vapors like isopropyl, benzene, toluene, formaldehydes, oils and common cleaning agents

Temperature Sensor:	Resistance Temperature Detector (RTD)
Temperature Range:	-20°C to +80°C (-4°F to +176°F)
Temperature Response Time:	10 Minutes (free air)
Calibrated Accuracy:	±0.5°C (0°C to 55°C)
Humidity Sensor:	Capacitive Digital Humidity Sensor
Humidity Range:	0 to 100% RH (non-condensing)
Humidity Response Time:	τ = 2 minutes to 63% of change
Calibrated Accuracy:	±3% RH maximum ±2% RH typical at 25°C
Specified Accuracy Range:	10% RH to 90% RH; ±5°C to +55°C
Start Modes:	Software programmable immediate start or delay start up to 24 months in advance

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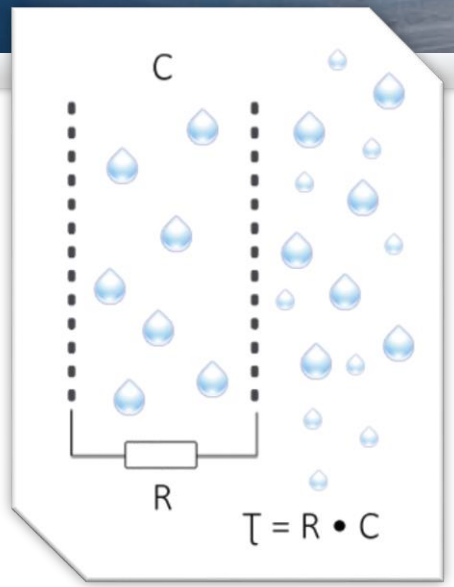
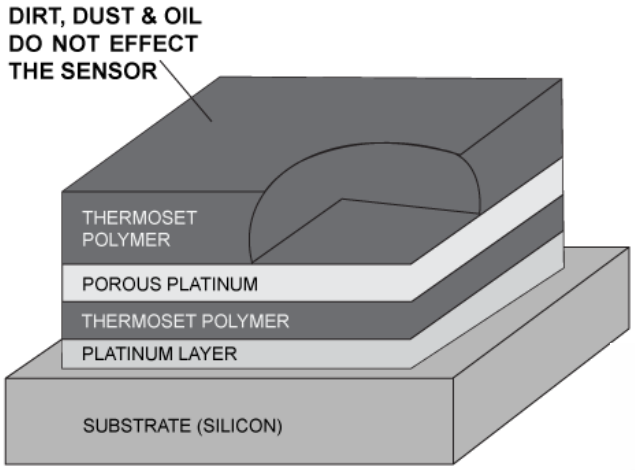
How it Measures

RHTemp1000IS

A thin ≈ 1um plastic sheet with a porous platinum or gold metalization layer on each side. Water from the environment goes into the polymer and changes the dielectricity and thus the capacitance of the sensor. When used in an oscillator, the presence of water will change the output-frequency.

Output is proportional to relative humidity, rather than moisture content





Temp1000IS

Temperature Data Logger

- Rated as Intrinsically Safe by FM Approvals for use in Class I, Division 1, Groups A, B, C and D and non-incendive for Class I, Division 2, groups A, B, C and D indoor and outdoor.
- Precision 100 ohm platinum RTD sensing element
- External RTD for fast response time

Temperature Sensor:	Resistance Temperature Detector (RTD)
Temperature Range:	-20°C to +80°C
Calibrated Accuracy:	±0.5°C (0 to 50°C)
Start Modes:	Software programmable immediate start or delay start, up to 2 years in advance
Lethality Equations:	Sterilization Units and Pasteurization Units are available in software with the click of a button

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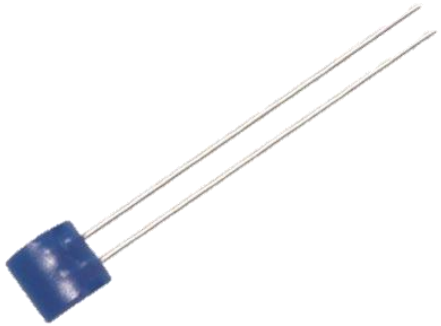
How it Measures

Temp1000IS

- High-quality RTD temperature measurement element.
- Uses 24-bit ΔΣ (*sigma delta*) ADC technology for best-in-class accuracy.
- Specific one or two point adjustment can be requested to improve accuracy over varying ranges.



Benefits of MadgeTech Data Logger Systems

Benefits

- Simply place the logger in the docking station to automatically establish communications
- Download full memory in seconds
- Multiplexer docking station allows for programming of up to 18 loggers at a time
- Small size enables it to be placed easily into product packaging
- Engraved label

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MadgeTech 4 Software

MadgeTech 4 Secure

- MadgeTech 4 Secure aids in compliance with **21 CFR Part 11** requirements.
- Full IQ/OQ/PQ validation documentation comes **included**
- Quantity discounts are available
- Don't need 21 CFR Part 11? MadgeTech has a standard version of this *same software* available for **free**.

Features

- Customizable Graphs
- Exporting
- Data Annotation
- Digital Calibration
- Automatic Statistics Calculation
- Graph Overlays, Data Summary, Reports
- Audit Trails
- Electronic Signatures
- Real time wireless alarming

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Process Overview

Data Loggers are placed where they are needed

Units are placed throughout and around the pallet or load to measure stratification

Cycles are Run

No wires – completely self-sufficient. Can record through entire sterilization cycle

Data is Downloaded

After each EO cycle to validate temperature and humidity over time using MadgeTech 4 Secure

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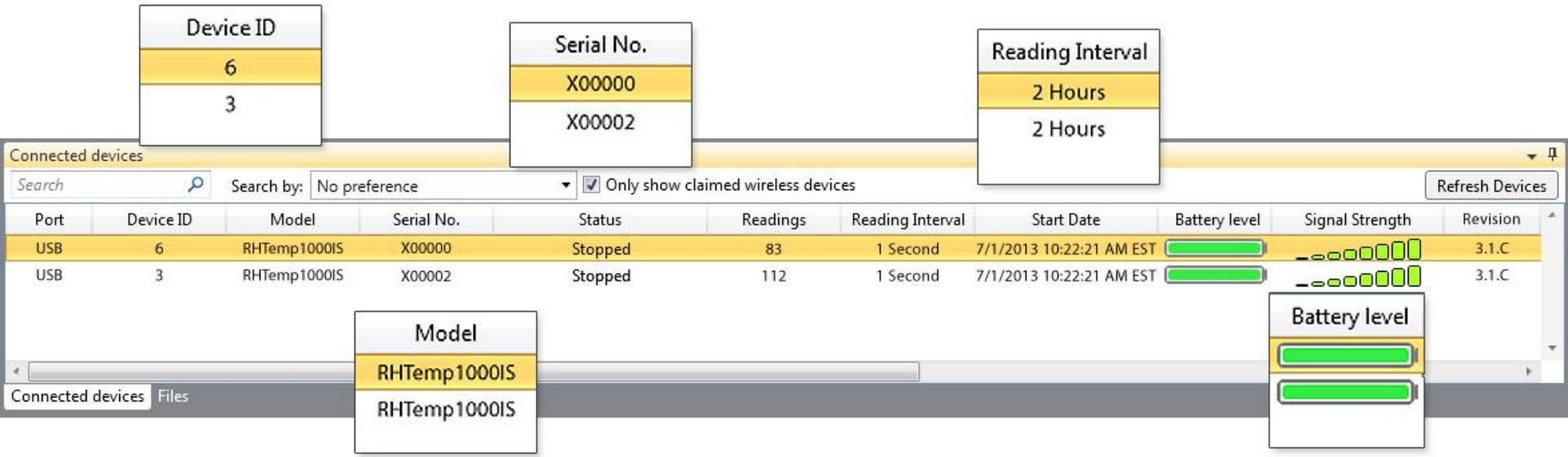
Getting Started

Communication

Simply insert the data logger into the docking station and a quick overview of device information will appear right on the main screen.



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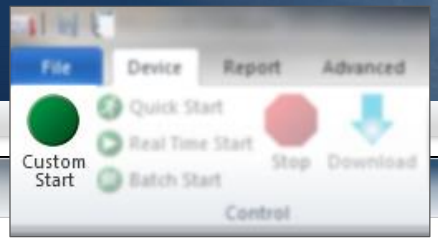
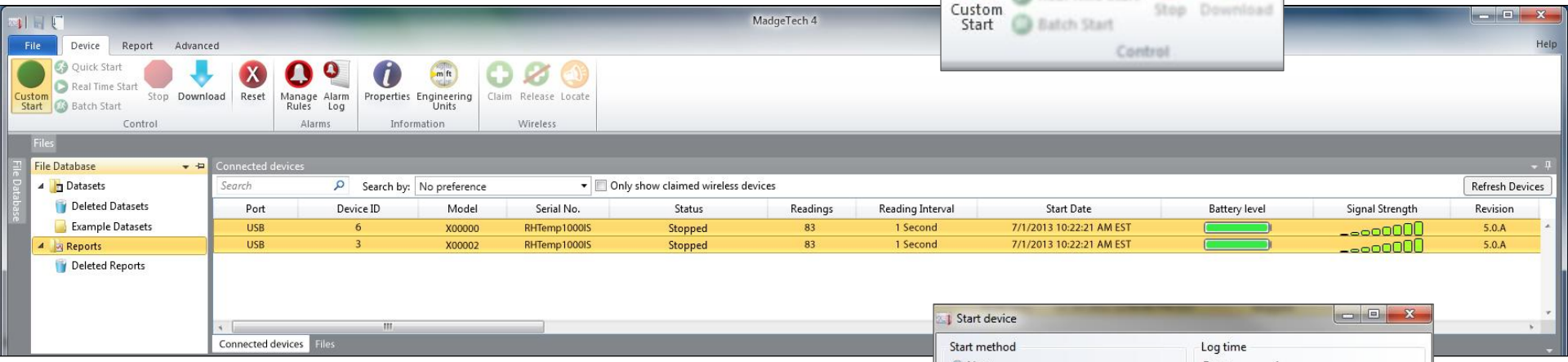
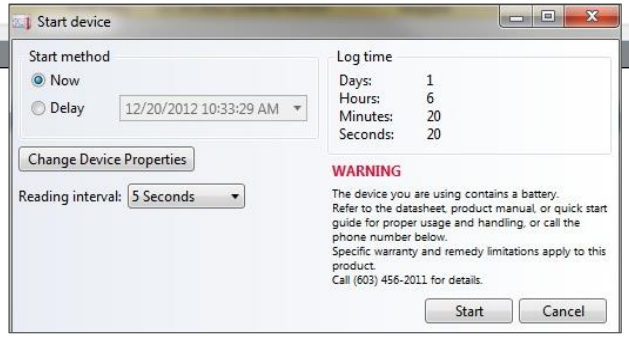
Starting the Data Loggers







1. Click to highlight loggers
2. Click ***Custom Start***
3. Program start method and reading rate
4. Click ***Start***

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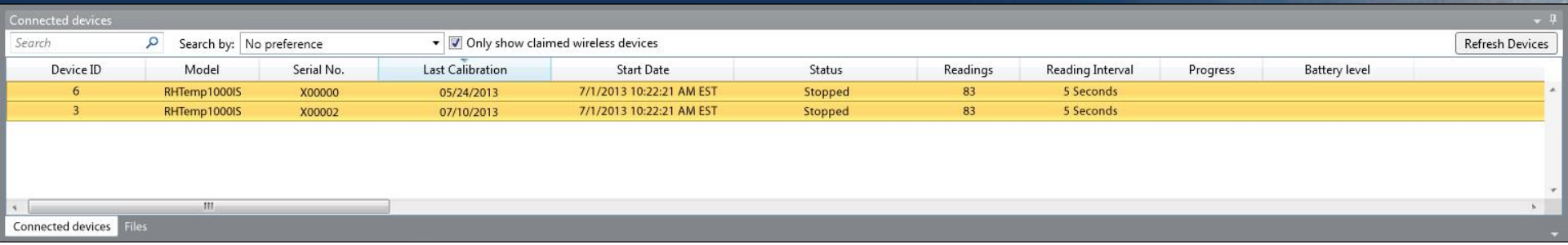
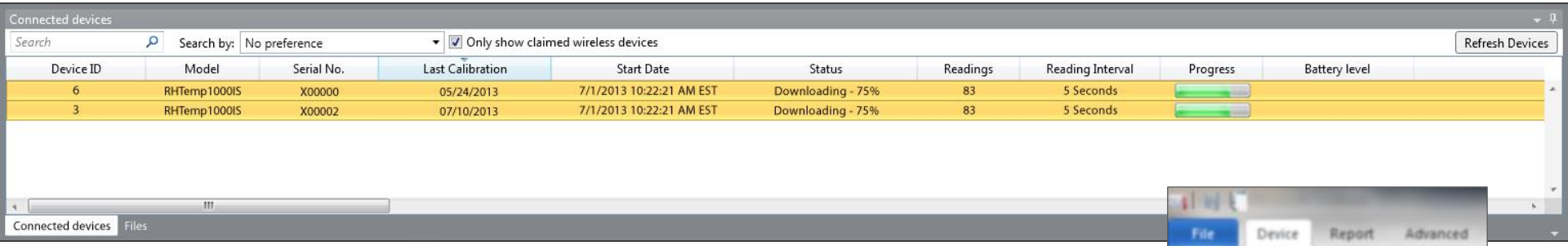
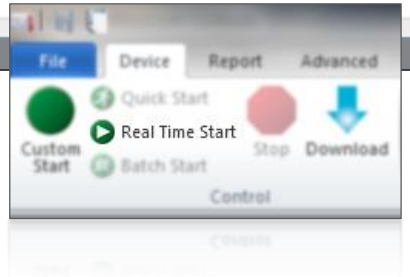
Stopping & Downloading Data Loggers







1. Highlight the Devices and Click ***Stop***
2. Click ***Download***

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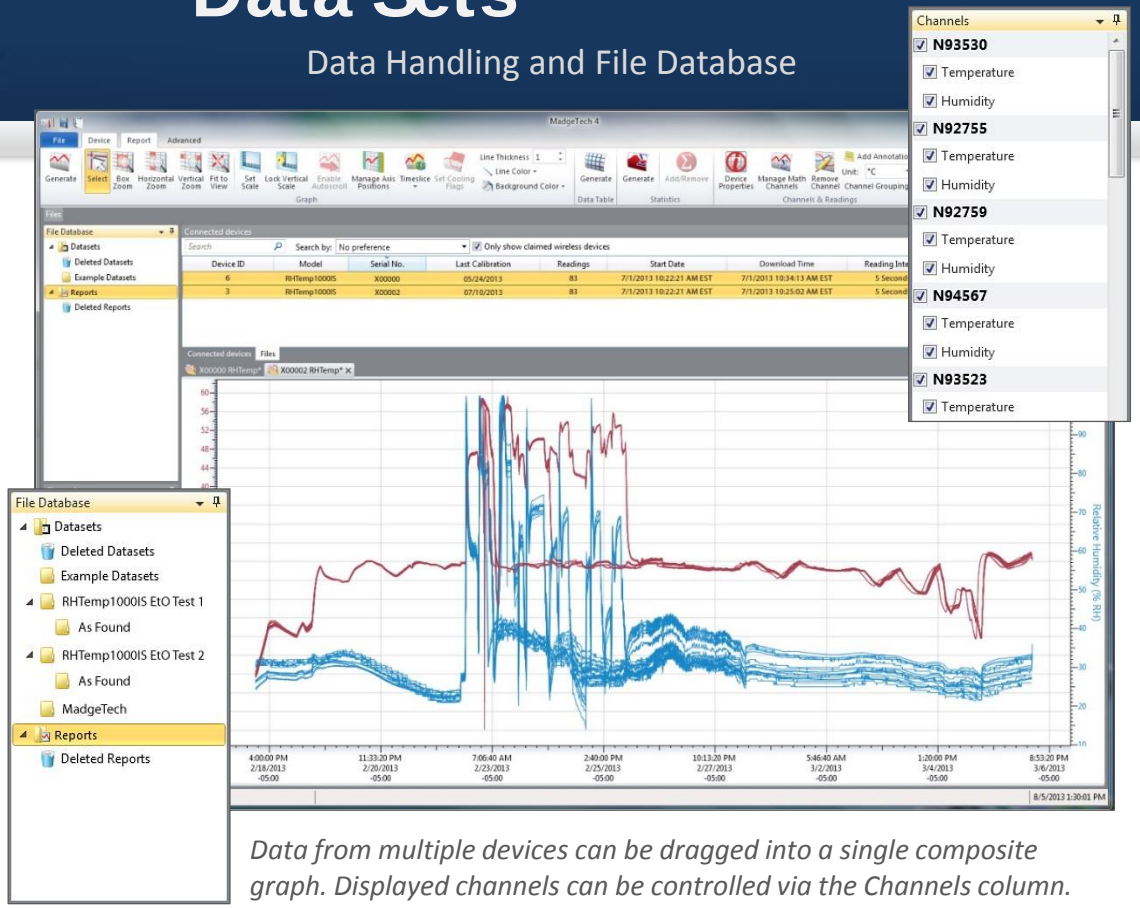
Data Sets

Data Handling and File Database



Data from multiple devices can be dragged into a single composite graph. Displayed channels can be controlled via the Channels column.

- All downloaded data is automatically saved to the ***Datasets*** folder. A graph will automatically be generated from the downloaded data.
- The software is designed with a built-in database for automatic storage of downloaded files.
- The look and feel is organized in comparison to standard email programs to aid in user friendliness and ease of use.
  - ***Original records*** for all downloaded data are automatically saved to the Datasets Folder.
  - Compiled and edited data is saved in the ***Reports Folder***.

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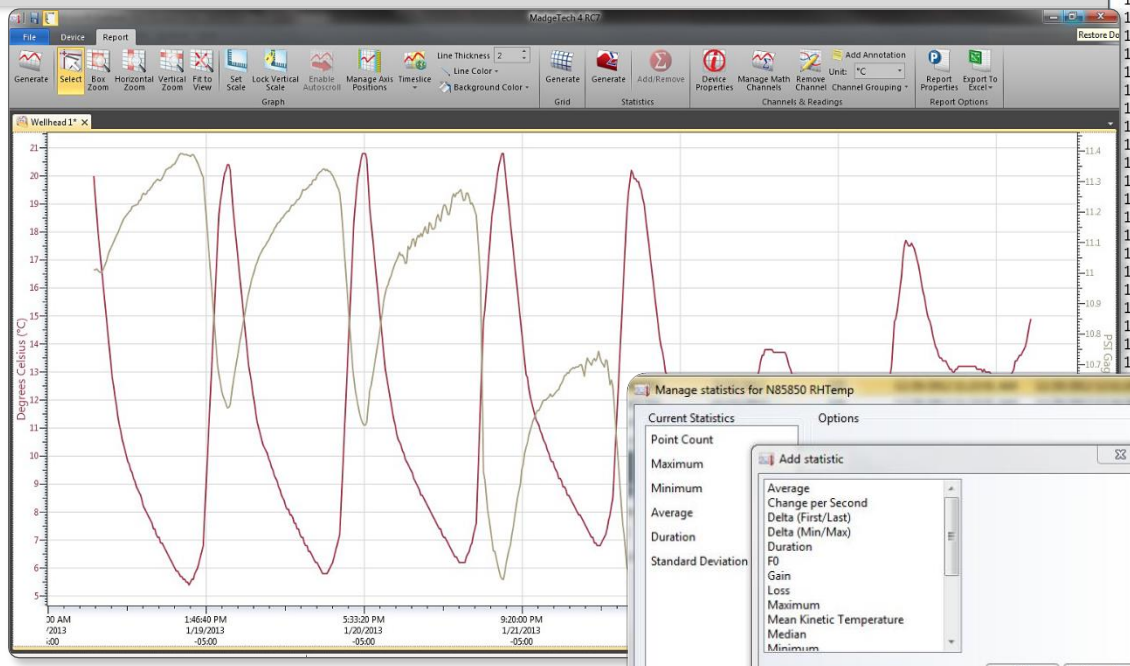
Reports

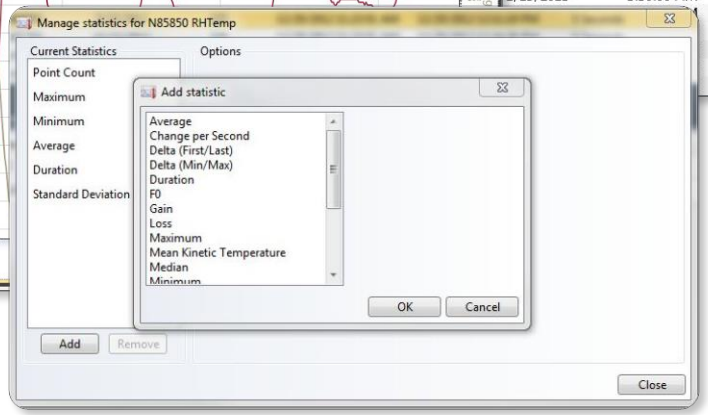
Graph, Grid, and Statistics View



Graph

Date	Time	Delta	N97631 Temperature (°C)	N97631 Gage Pressure (psi)
	6:00:00 PM	-0:00:00:00	20.0	11.012
	6:15:00 PM	+0:00:15:00	19.2	11.010
	6:30:00 PM	+0:00:30:00	18.5	11.014
	6:45:00 PM	+0:00:45:00	18.0	11.008
	7:00:00 PM	+0:01:00:00	17.6	11.004
	7:15:00 PM	+0:01:15:00	17.1	11.002
	7:30:00 PM	+0:01:30:00	16.5	11.006
	7:45:00 PM	+0:01:45:00	15.9	11.016
	8:00:00 PM	+0:02:00:00	15.4	11.028
	8:15:00 PM	+0:02:15:00	14.8	11.040
	8:30:00 PM	+0:02:30:00	14.2	11.058
	8:45:00 PM	+0:02:45:00	13.8	11.072
1/18/2013	9:00:00 PM	+0:03:00:00	13.2	11.082
1/18/2013	9:15:00 PM	+0:03:15:00	12.8	11.092
1/18/2013	9:30:00 PM	+0:03:30:00	12.5	11.102
1/18/2013	9:45:00 PM	+0:03:45:00	12.1	11.114
1/18/2013	10:00:00 PM	+0:04:00:00	11.8	11.124
1/18/2013	10:15:00 PM	+0:04:15:00	11.4	11.132
1/18/2013	10:30:00 PM	+0:04:30:00	11.1	11.144
1/18/2013	10:45:00 PM	+0:04:45:00	10.9	11.156
1/18/2013	11:00:00 PM	+0:05:00:00	10.6	11.166
1/18/2013	11:15:00 PM	+0:05:15:00	10.4	11.178
1/18/2013	11:30:00 PM	+0:05:30:00	10.2	11.184
1/18/2013	11:45:00 PM	+0:05:45:00	10.0	11.190
1/19/2013	12:00:00 AM	+0:06:00:00	9.8	11.196
1/19/2013	12:15:00 AM	+0:06:15:00	9.7	11.202
1/19/2013	12:30:00 AM	+0:06:30:00	9.5	11.206
1/19/2013	12:45:00 AM	+0:06:45:00	9.4	11.218
1/19/2013	1:00:00 AM	+0:07:00:00	9.2	11.220
1/19/2013	1:15:00 AM	+0:07:15:00	9.1	11.222
1/19/2013	1:30:00 AM	+0:07:30:00	8.9	11.224
1/19/2013	1:45:00 AM	+0:07:45:00	8.8	11.226
1/19/2013	2:00:00 AM	+0:08:00:00	8.7	11.238
1/19/2013	2:15:00 AM	+0:08:15:00	8.6	11.240
1/19/2013	2:30:00 AM	+0:08:30:00	8.4	11.256
1/19/2013	2:45:00 AM	+0:08:45:00	8.2	11.262
1/19/2013	3:00:00 AM	+0:09:00:00	8.1	11.258
1/19/2013	3:15:00 AM	+0:09:15:00	8.0	11.260
1/19/2013	3:30:00 AM	+0:09:30:00	7.9	11.270
		+0:09:45:00	7.8	11.272
		+0:10:00:00	7.7	11.280
		+0:10:15:00	7.6	11.284
		+0:10:30:00	7.4	11.294
		+0:10:45:00	7.4	11.298

Grid



Statistics

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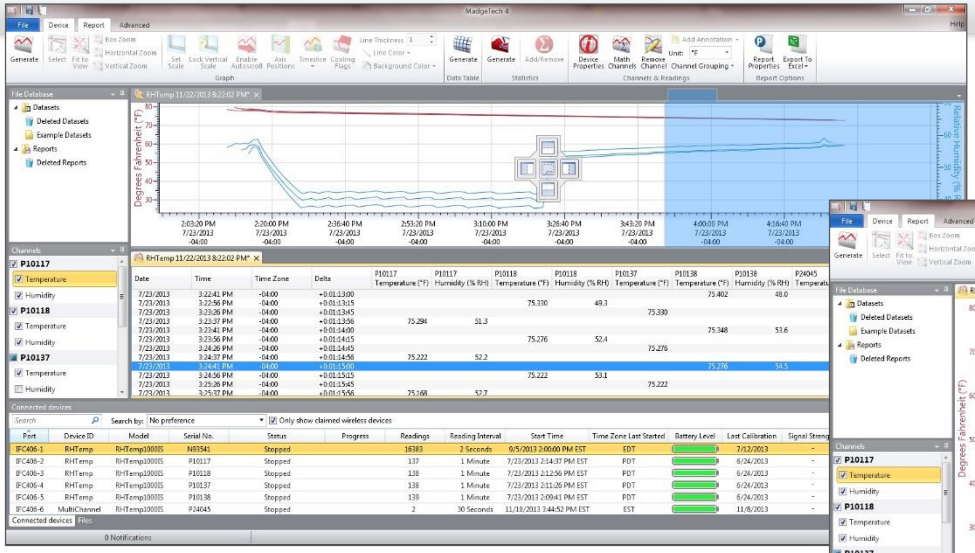
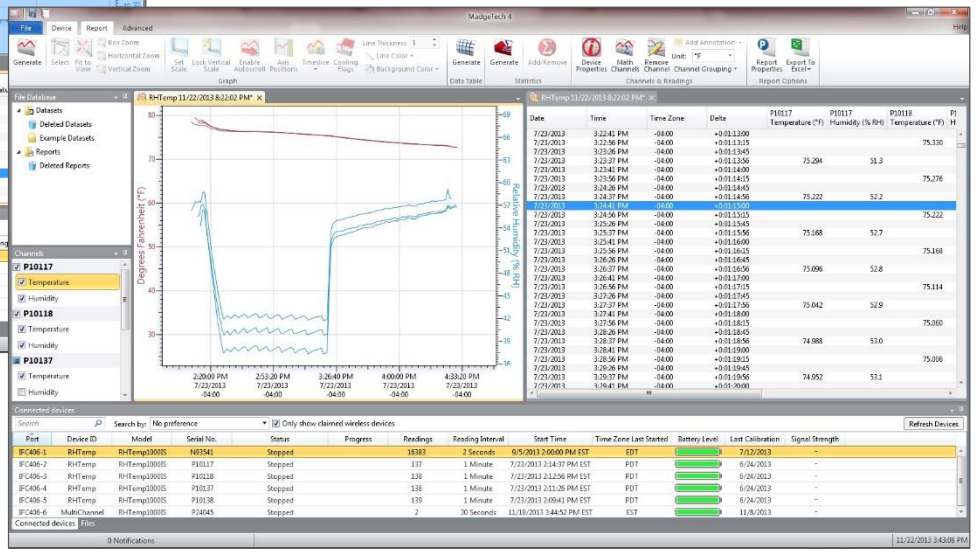
Data Analysis

Customizable Interface



Layout 1

To increase efficiency, MadgeTech allows users to customize the layout of the screen interface to better suit their needs.



Layout 2

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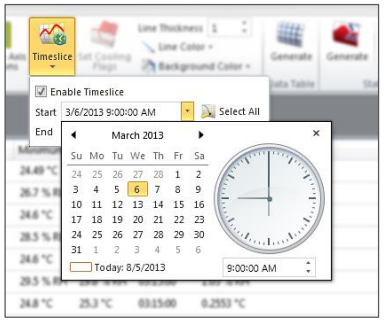
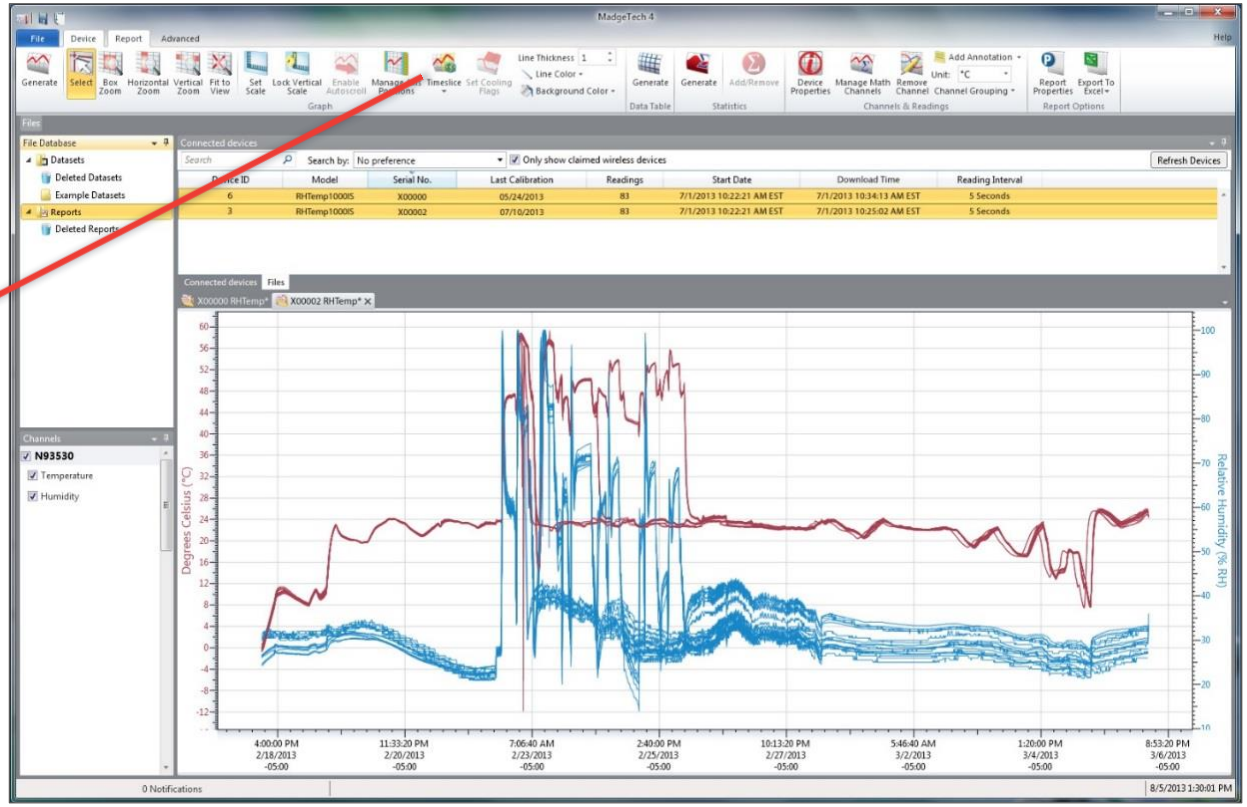
Data Analysis

Timeslice

- The ***Timeslice*** feature enables users to view statistics for user-selectable sections of data.
- Statistics report will update and recalculate based on the ***Timeslice*** selection.





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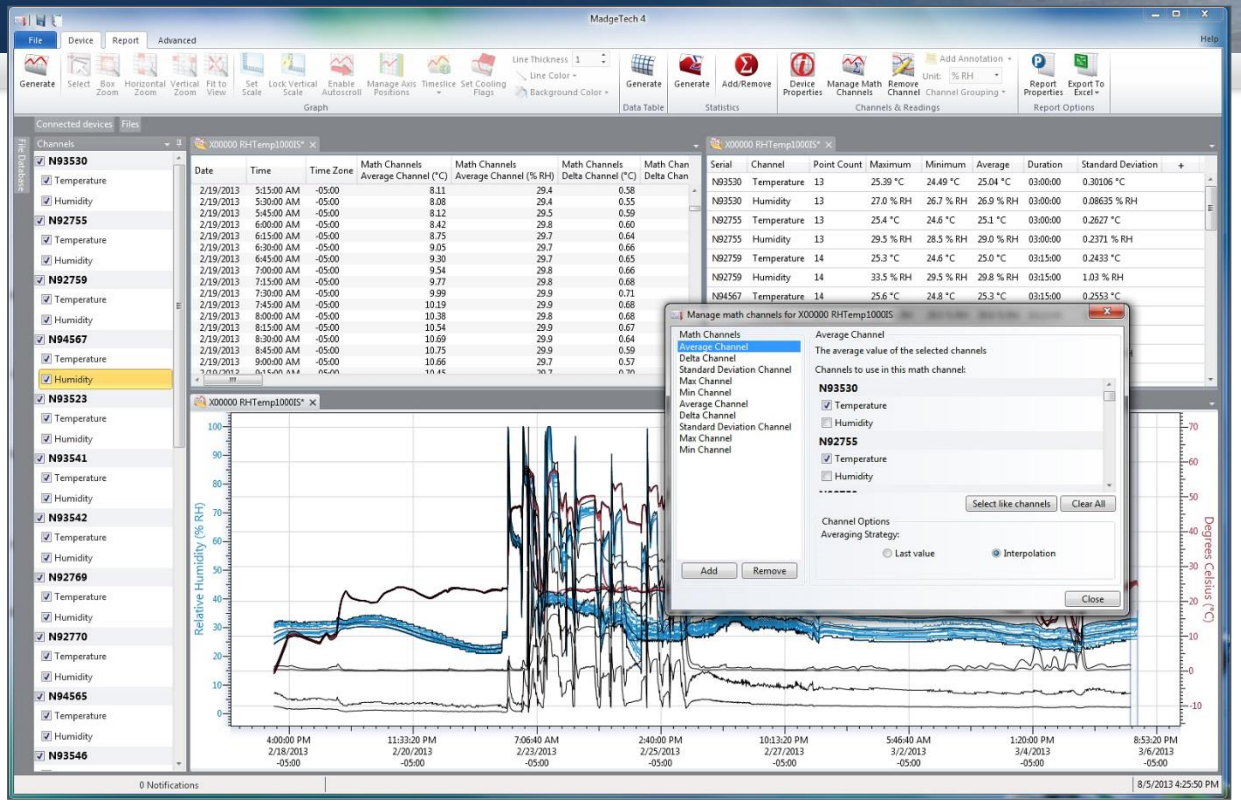
Data Analysis

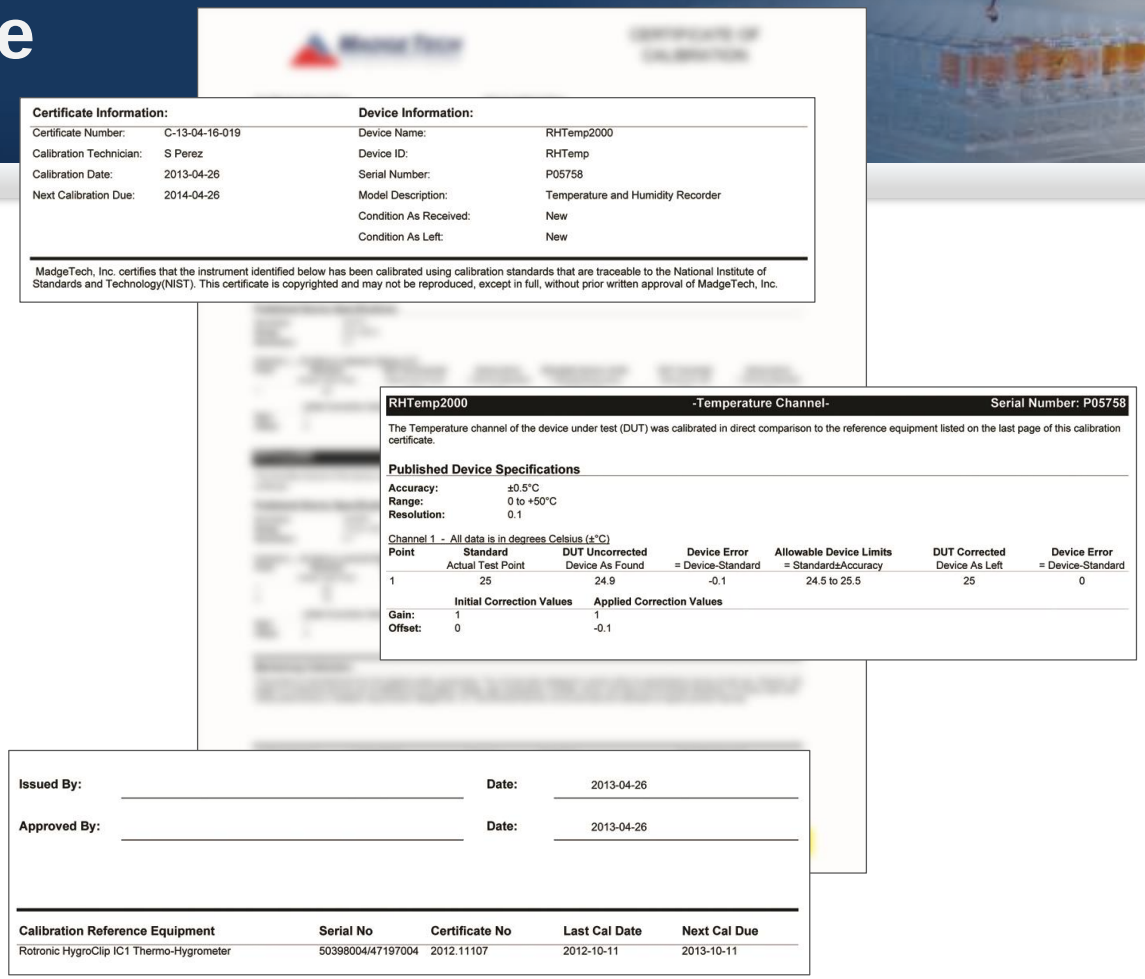
Math Channels

- Minimize analysis time by using ***Math Channels***. Math Channels is a tool for displaying data as a calculation of other channels.
- Can be used to display point-by-point calculations based on two or more reading channels.
- Rather than having to analyze each dataset individually, use Math Channels to consolidate the view to only the minimum, maximum, and average readings
- Appears as a separate channel in graphical, tabular, and statistic reports



NIST Certificate

- Certificate header displays details specific to the calibration being performed and the DUT information such as ***Device ID*** and ***Model***.
- Calibration section lists device specifications and calibration results.
- ***As Found*** and ***As Left*** data is displayed side by side for quick and easy identification
- ***Issued By*** and ***Approved By*** signatures stand up to auditor scrutiny
- Calibration Reference Equipment information is always listed. Full calibration certificates are available upon request.



Certificate Information:

Certificate Number:	C-13-04-16-019
Calibration Technician:	S Perez
Calibration Date:	2013-04-26
Next Calibration Due:	2014-04-26

Device Information:

Device Name:	RHTemp2000
Device ID:	RHTemp
Serial Number:	P05758
Model Description:	Temperature and Humidity Recorder
Condition As Received:	New
Condition As Left:	New

MadgeTech, Inc. certifies that the instrument identified below has been calibrated using calibration standards that are traceable to the National Institute of Standards and Technology(NIST). This certificate is copyrighted and may not be reproduced, except in full, without prior written approval of MadgeTech, Inc.

RHTemp2000 -Temperature Channel- Serial Number: P05758

The Temperature channel of the device under test (DUT) was calibrated in direct comparison to the reference equipment listed on the last page of this calibration certificate.

Published Device Specifications

Accuracy:	±0.5°C
Range:	0 to +50°C
Resolution:	0.1

Channel 1 - All data is in degrees Celsius (±°C)

Point	Standard Actual Test Point	DUT Uncorrected Device As Found	Device Error = Device-Standard	Allowable Device Limits = Standard±Accuracy	DUT Corrected Device As Left	Device Error = Device-Standard
1	25	24.9	-0.1	24.5 to 25.5	25	0

	Initial Correction Values	Applied Correction Values
Gain:	1	1
Offset:	0	-0.1

Issued By: _____ **Date:** 2013-04-26

Approved By: _____ **Date:** 2013-04-26

Calibration Reference Equipment	Serial No	Certificate No	Last Cal Date	Next Cal Due
Rotronic HygroClip IC1 Thermo-Hygrometer	50398004/47197004	2012.11107	2012-10-11	2013-10-11

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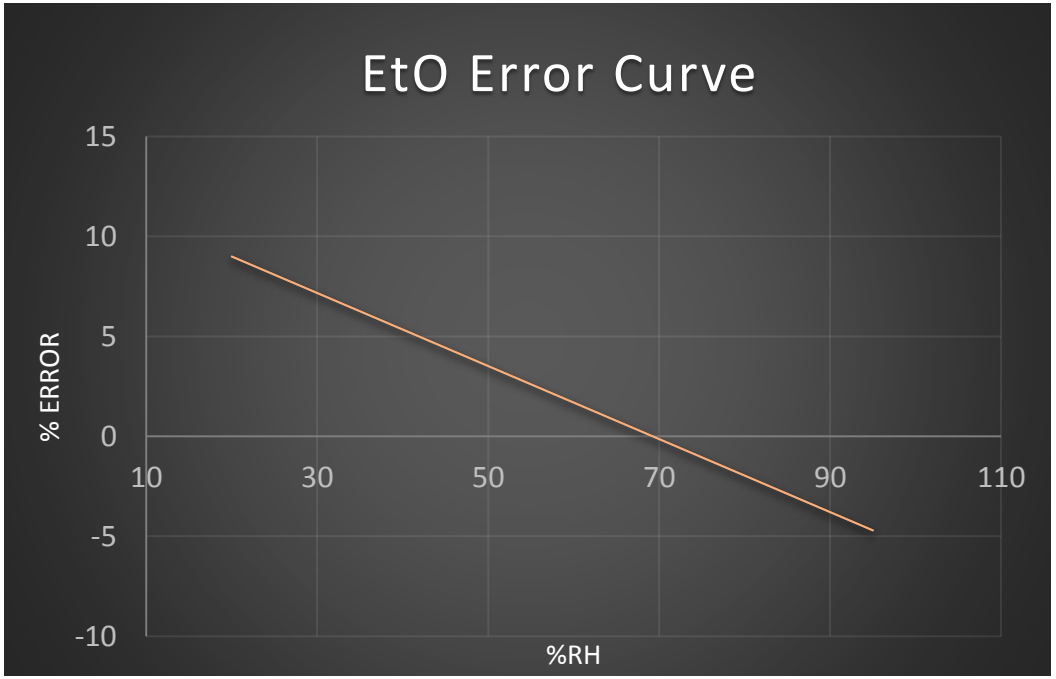
The EtO Effect

All RH sensors are affected by Ethylene Oxide. Over time, particles can become embedded in the sensor substrate, which can cause a drift in the calibration.

When using resistive or capacitive RH sensors in an EtO environment, additional error will be created by the reactive effects of the compound.

The chart indicates the typical error induced in a capacitive sensor by prolonged exposure to EtO. Error for resistive sensors tends to be non-linear.

EtO sterilization is primarily concerned with accuracy <40-85% range, where error is typically >5%



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Maintenance

To combat the effects of Ethylene Oxide

To combat the detrimental effects of EtO on the RH sensors, it is highly recommend that a standard maintenance protocol is implemented. MadgeTech can assist clients in developing maintenance procedures based on their specific usage of the devices as well as in-house capability.

MadgeTech Recommends - *Daily or Weekly*

Reconditioning

- The negative impact of the EtO on the RH sensor can be lessened by letting the units sit for a few days (*1-2*) after exposure, bringing the sensor back to a more "***calibrated state***."
- This can be accelerated in a higher temperature, drier environment: 55C, 35%RH for 24 hours
- This is referred to as "reconditioning" the sensor. A reconditioning procedure should be implemented after each EtO cycle to ensure best performance out of the sensor.

Tolerance Verification

- Calibration or verification in a controlled environment with NIST traceable reference equipment
  - Temperature & Humidity Chamber
  - Incubator
  - Saturated Salt Solution
- Comparison against another data logger standard, such as a logger that has not been exposed to EtO
  - Software report
    - Display minimum and maximum values
    - Verify that all are within % to standard

MadgeTech EtO Servicing

To combat the effects of Ethylene Oxide

- To successfully utilize data loggers for monitoring EtO processes, it is imperative to routinely verify accuracy through periodic calibration checks and servicing.
- It is recommended to start at a 6 month interval and only to extend the duration between checks after a history of stability is established.
- MadgeTech offers professional calibration services for all MadgeTech data loggers. Traceable to NIST for temperature, humidity, pressure, voltage, and current. Standard servicing plans for EtO processing include:
    - Free device evaluation
    - As Found data collection
    - RH sensor replacement
    - O-Ring replacement
    - Battery replacement
    - Calibration and adjustment at standard or custom points

MadgeTech EtO Servicing

Calibration Test Equipment

Test Equipment

- (2) PGC Temperature and Humidity Stability Chambers
- Various Circulating Baths
- Pressure Calibrator

Reference Equipment

- Rotronic hygrometers
  - Accuracy of:
    - ±1%RH, 0-90%RH
    - ±0.3°C, 0-80°C (special temperature accuracy of 0.05°C @ 25.0°C)
- Fluke Calibration 1502A Thermometer Readouts
  - Accuracy of:
    - ±0.030°C, -80.00 to +300.00°C
- Mensor CPC 6000 Pressure Calibrator
  - Accuracy of:
    - ±0.05PSI

Test and Reference Equipment Subject to:

- Annual Calibration
- Annual Validation
- Annual Mapping

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MadgeTech Customer Support

We are here for you

MadgeTech data loggers come with a one year manufacturers warranty.

Free support available for the lifetime of the product

Contact Information:

Phone: 603-456-2011

Fax: 603-456-2012

Email: info@madgetech.com