

Use of Wireless Data Loggers for Temperature Uniformity Studies in an ISO 17025 Accreditation Program

John J. Sullivan¹; Mohammad H. Samimi²; Thanh-Thu Huynh²; Cathy Burns³; Mike Hough³; Kevin Kallander³

Abstract

Validation of controlled temperature equipment (incubators, autoclaves, water baths, ovens, refrigerators, and freezers) is an important part of an ISO 17025 accreditation program, involving temperature and/or humidity testing for uniformity and stability. For temperature, many validation studies are performed using wired, thermocouple-based systems. Setting up a wired system is time-consuming and tedious, and thermocouples are prone to failure, causing difficulty in interpreting results. An alternative to wired systems are wireless data loggers which are small, self-contained, measurement and recording devices that eliminate the disadvantages of the wired systems.

The objectives of this study were to demonstrate the utility of wireless data loggers in temperature uniformity studies of incubators and autoclaves and to develop guidelines in terms of logger placement, testing variables (such as chamber loading), and acceptance criteria.

Data loggers were placed throughout the chamber to be measured, either by themselves for empty chamber validation, or with other materials for loaded chamber validation. Generally, ten or more loggers were placed in pre-determined patterns in the chamber and data taken for 16-48 hours. After the end of the measurement period, the data were transferred to a PC for analysis.

As a result of the studies, it was determined that certain equipment had to be taken out of service because it did not meet the $\pm 2^\circ\text{C}$ uniformity criteria (e.g., 2 of the 17 incubators in one lab). Certain equipment was determined to be malfunctioning, since room temperature variations dramatically affected their interior temperatures. Additionally, guidelines were developed on loading of incubators and autoclaves, based on temperature measurements in loaded chambers.

From this work, it is clear that wireless data loggers can be used to easily and rapidly perform temperature studies on a variety of laboratory equipment as an integral part of a lab's ISO 17025 accreditation program.

Affiliations: ¹Mesa Laboratories, Lakewood, CO; ²U.S. Food and Drug Administration, Alameda, CA; ³U.S. Food and Drug Administration, Denver, CO;

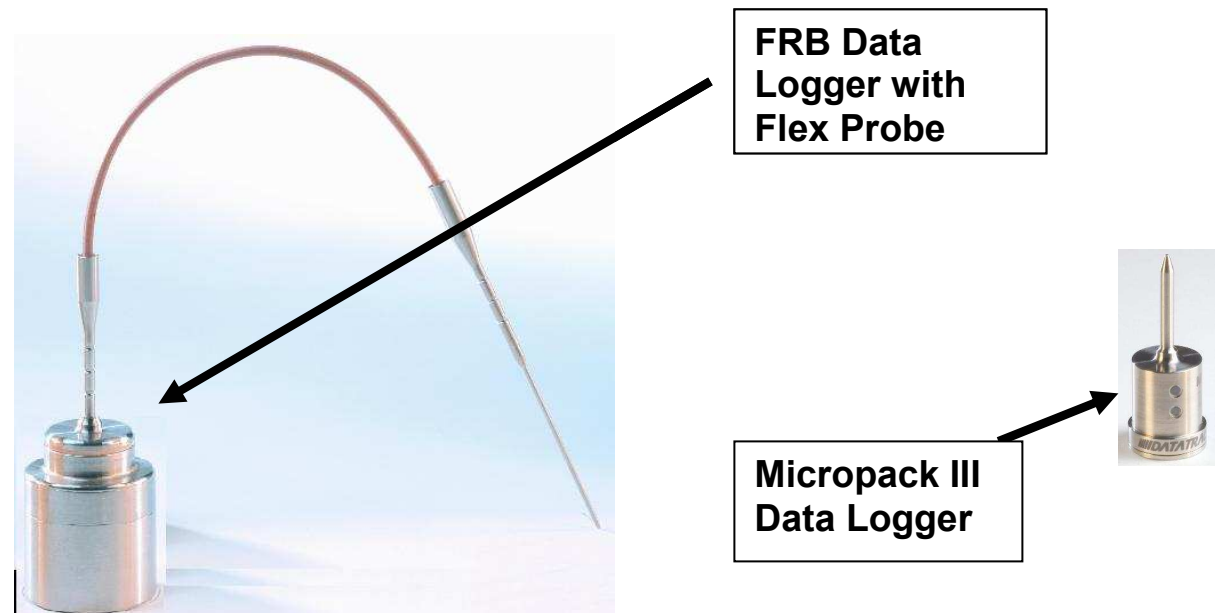
Background

As a part of their ISO 17025 accreditation programs, the Denver and San Francisco District Laboratories of the U.S. Food and Drug Administration obtained wireless data logger systems to perform validation studies on their temperature controlled chambers. The wireless equipment was chosen, rather than thermocouple-wire based measurement systems, due to the numerous problems associated with the latter, including unstable calibration, wire breakage and the difficulty of installing the wires in the chambers. Wireless, thermistor-based, data loggers are much more suited for validation studies, as they are rugged, easy to install and they hold their calibration for 1 year, or more. In this study, we demonstrate the utility of wireless data loggers for validation of incubators and autoclaves in these 2 different FDA laboratories.

There are a myriad of guidelines and regulations covering the validation of laboratory equipment, dating back to the 1980's. Some are very general in nature and others contain specific procedures on performing the testing. For this work, the AOAC International Guidelines¹ were utilized, as they apply specifically to laboratories seeking accreditation to the ISO 17025 standard. The AOAC guidelines describe a generalized equipment validation scheme, including the types of equipment that need to be validated and the validation frequency, but they do not recommend acceptance criteria for the various types of equipment. For this, criteria were established for each equipment type by each lab and these are illustrated in the table below. In general, long-term temperature mapping was performed on incubators, and, on autoclaves, both heat distribution (mapping) and heat penetration studies were performed to determine the effectiveness of sterilization.

Methods and Equipment

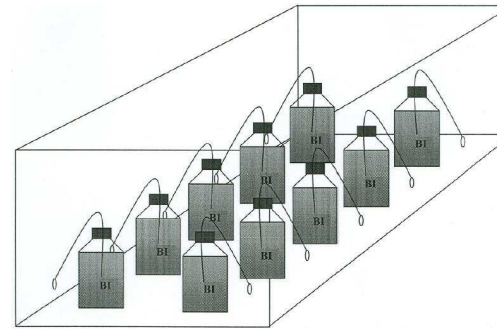
The DataTrace® data logger system from Mesa Laboratories, Inc. (www.mesalabs.com) was used for all temperature measurements in this study. This system is comprised of individual temperature data loggers (tracers), a PC interface system and software for data storage and analysis. The data loggers are self-contained measurement and data recording devices that have sufficient range and accuracy for validation of incubators and autoclaves. Although their temperature calibration was checked routinely using appropriate controlled temperature baths and reference thermometers, the individual data loggers generally hold their calibration to $\pm 0.1^{\circ}\text{C}$ for 1 year, or more. The 2 styles of data loggers used in this work are illustrated here and a generalized equipment validation process is illustrated below.



Typical Validation Study Process – Wireless Data Loggers



Program 5 to 15 Loggers



Place Loggers in Chamber



Run Process

DATA TRACE Profile Data Report

Mesa Laboratories

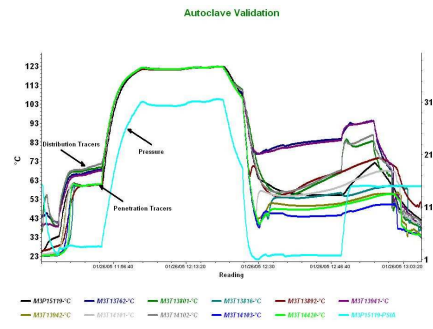
Title: Temperature Mapping
 Protocol: Incubator
 Vessel: Incubator
 Located By: John Sullivan
 Prepared By: John Doe
 Comments: Study conducted according to SOP # BX-346-2
 Fo: 121.1111 Z: 10.0000 Threshold: 100.0000

Serial Number	Serial	Start Time	Interval	# Points Collected	Data Validation	Comments
M3T12006	DT101	12/20/04 09:34:00	00:00:00:05	100	All Collected	
M3T14089	DT102	12/20/04 09:34:00	00:00:00:05	100	All Collected	
M3T12438	DT100	12/20/04 09:34:00	00:00:00:05	100	All Collected	

Process Cycle

#	Sample Date/Time	M3T12006		M3T14089		M3T12438		T	T	T	M3T12006	M3T14089
		T	T	T	T	T	Wet					
61	12/20/04 09:39:00	62.9	63.5	61.7	61.7	63.5	62.7	47	14.2			
62	12/20/04 09:39:05	62.9	63.5	61.7	61.7	63.5	62.7	47	14.1			
63	12/20/04 09:39:10	62.9	63.5	61.7	61.7	63.5	62.7	47	14.1			
64	12/20/04 09:39:15	63.0	63.5	61.7	61.7	63.5	62.7	47	14.1			
65	12/20/04 09:39:20	63.0	63.5	61.7	61.7	63.5	62.7	47	14.1			
66	12/20/04 09:39:25	62.9	63.5	61.7	61.7	63.5	62.7	47	14.1			
67	12/20/04 09:39:30	63.0	63.4	61.8	61.8	63.4	62.7	47	14.1			
68	12/20/04 09:39:35	62.9	63.4	61.8	61.8	63.4	62.7	47	14.1			
69	12/20/04 09:39:40	62.9	63.4	61.8	61.8	63.4	62.7	47	14.1			
70	12/20/04 09:39:45	62.9	63.4	61.7	61.7	63.4	62.6	47	14.2			
71	12/20/04 09:39:50	62.9	63.4	61.7	61.7	63.4	62.6	47	14.1			

Data Analysis - Prepare Graphics and Tabular Reports



Read Loggers into PC

Placement of Data Loggers



Autoclaves



Incubators



Acceptance Criteria

Incubators

Distribution Studies

Penetration Studies

Temperature Accuracy	+/- 2°C from set point	+/- 2°C from set point
Temperature Stability	+/- 2°C	+/- 2°C
Temperature Uniformity	+/- 2°C	+/- 2°C

Autoclaves

Distribution Studies

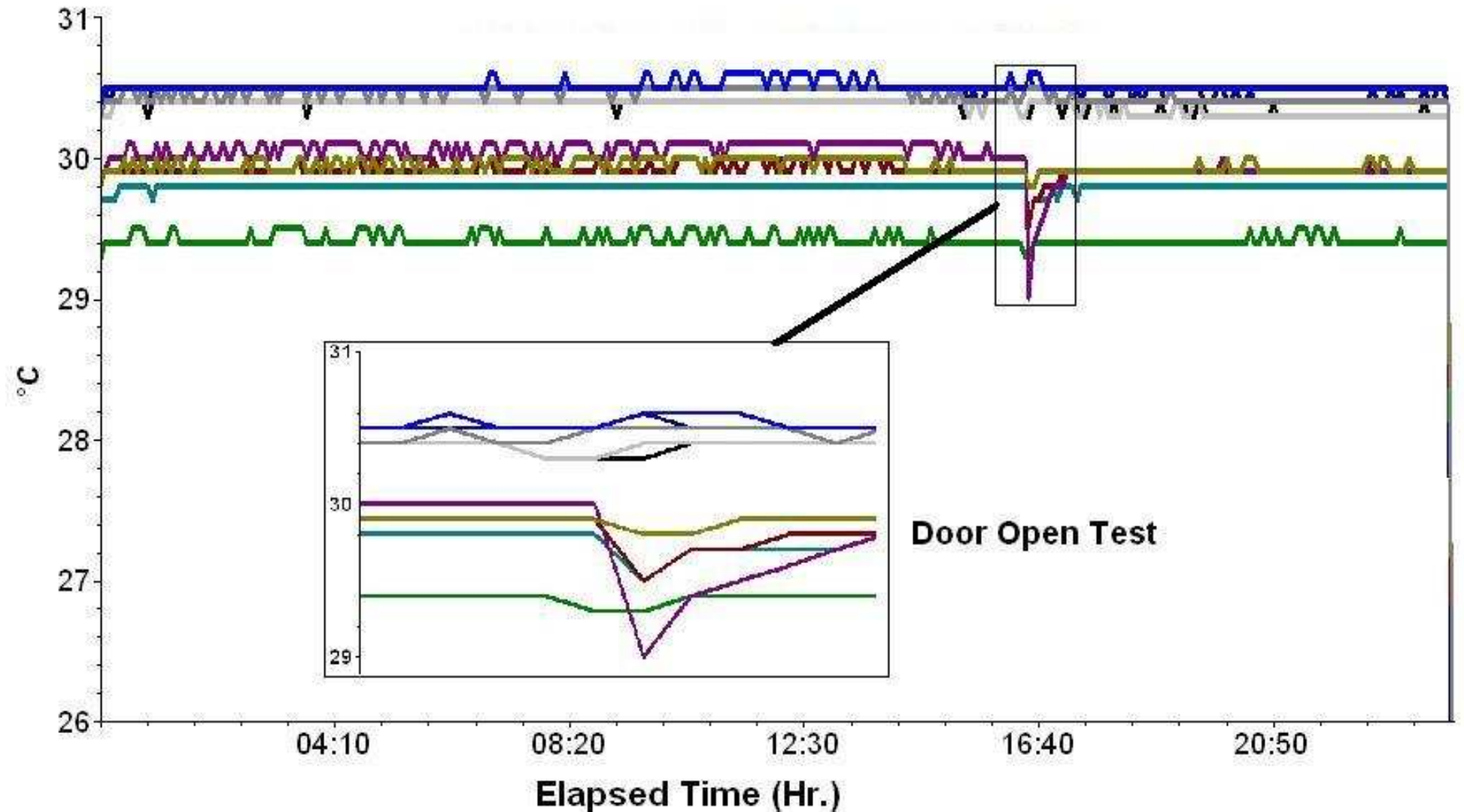
Penetration Studies

Temperature Accuracy	+ 3°C ¹ from set point	+ 3°C ¹ from setpoint
Temperature Stability	+/- 1°C	+/- 1°C
Temperature Uniformity	+/- 2°C	+/- 2°C
Biological Indicators	NA	No Growth
Fo Value	NA	>12

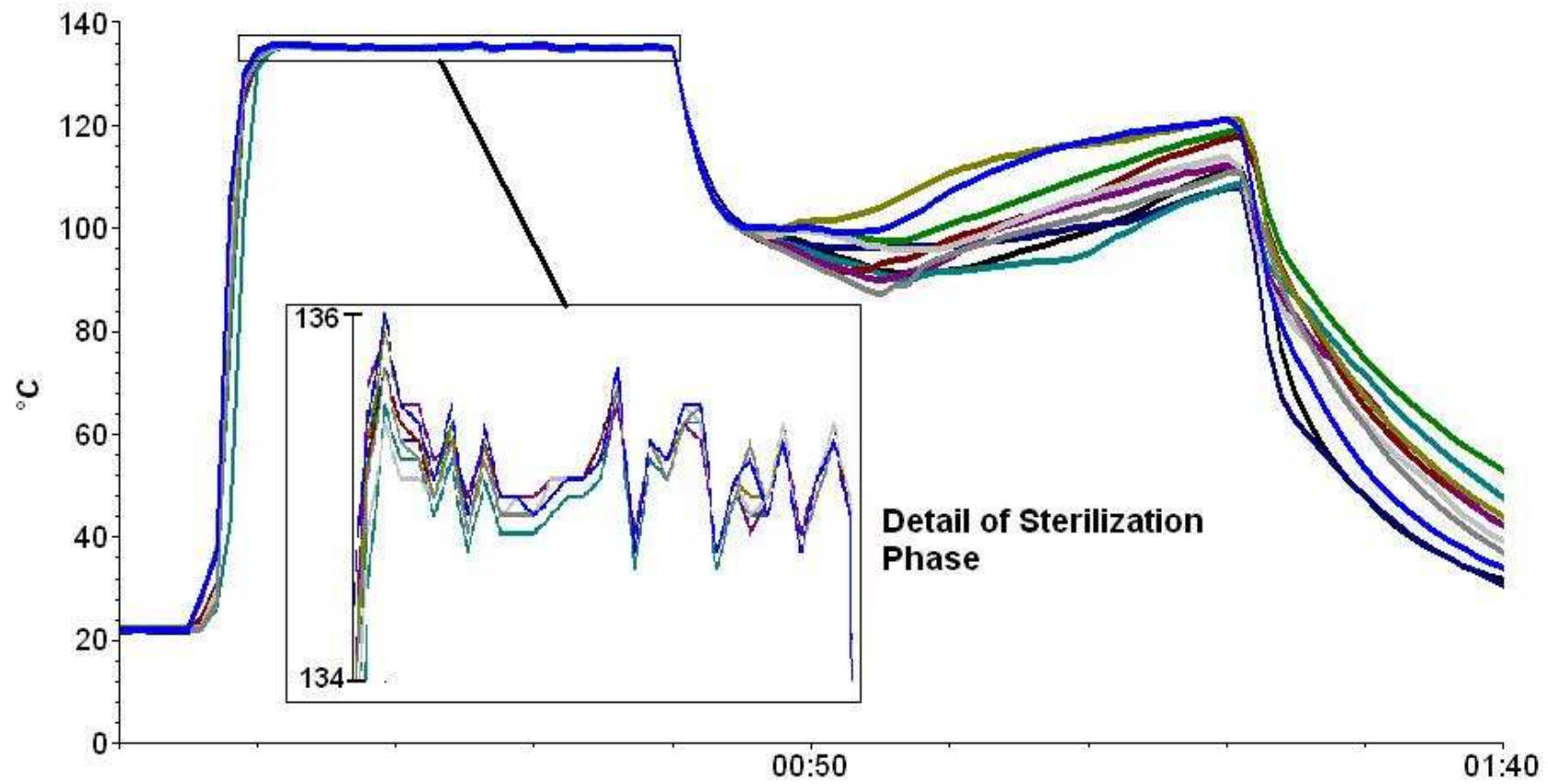
¹ San Francisco District Lab uses +/- 1.5°C from set point

Results and Discussion

Since 2001, when the first wireless data loggers were put into use by the FDA lab in Denver, they have been used by the 2 laboratories in this study to perform many validations on incubators and autoclaves. Illustrated here are typical temperature profiles for a 24 hour incubator temperature mapping study and an autoclave validation.



24 Hour Incubator Temperature Mapping Study Using 10 Data Loggers



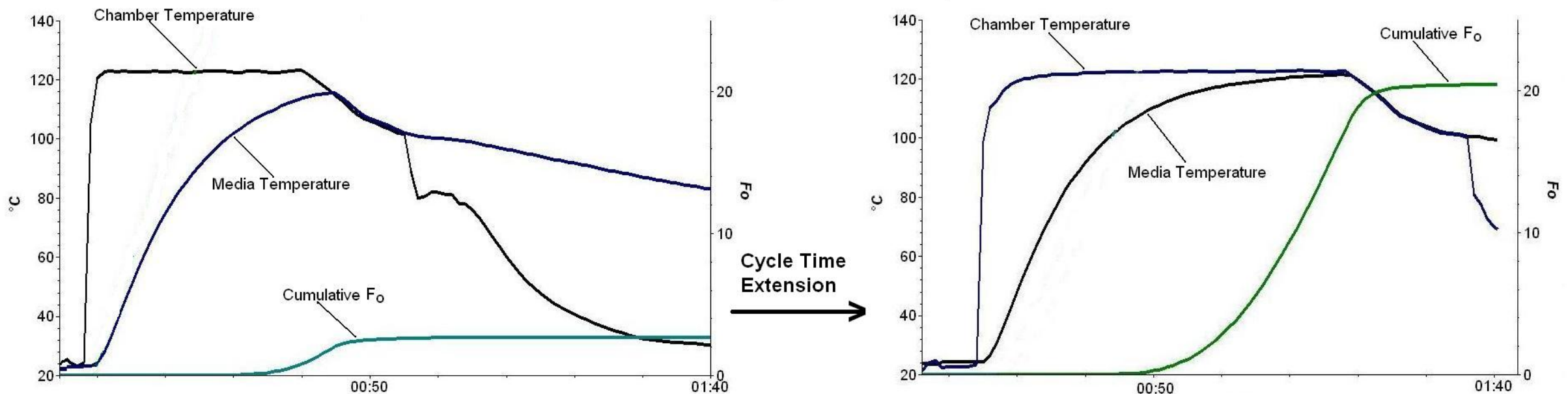
Typical Autoclave Temperature Mapping Study Using 10 Data Loggers

Generally, most equipment met its acceptance criteria during its initial validation and at each annual re-certification. Occasionally however, it was found that certain pieces of equipment either needed to be modified, their controls needed to be adjusted or the laboratory's procedures for use needed to be changed in order to meet certain of the acceptance criteria. It is beyond the scope of this presentation to detail all of the results collected during the past 4 years, but 2 examples will be cited and a summary of the overall results are presented below.

Autoclave Process Validation Example

A primary use for the wireless data loggers is sterilization validation in loaded autoclaves. For this, temperature measurements were made of the actual products being sterilized, typically microbiological media. The temperature measurement tip of the data loggers was located at the expected "cold spot" of the media and the test autoclave cycle was run. The resulting data were analyzed and F_0 values were calculated and evaluated. If inadequate sterilization was indicated, either the autoclave process or the load was to be altered. Illustrated below is an example of a sterilization validation where the calculated F_0 value was initially inadequate ($F_0 = 2$), but was increased to acceptable levels by increasing the cycle time.

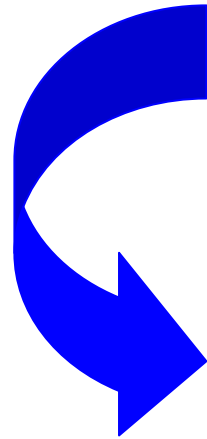
Sterilization Cycle Development



Incubator Validation Example

In this example, temperature measurements using the wireless data loggers indicated that one of the lab's incubators did not meet its +/- 2°C temperature uniformity test. The data loggers on the bottom shelf showed a significant deviation in temperature from one point to another, as illustrated in the test record on the right.

Raise bottom shelf
in incubator
approximately 3
inches



To correct the problem, the bottom shelf in the incubator was raised 3 inches to allow for better air circulation and the test was repeated, with passing results, as illustrated here.

Temperature Probe Placement:		Temperature Probe Data (°C)					Incubator Statistics (°C)																									
Top Shelf 		<table border="1"> <thead> <tr> <th>Probe SN</th> <th>MIN</th> <th>MAX</th> <th>AVG</th> <th>Pass / Fail</th> </tr> </thead> <tbody> <tr> <td>169</td> <td>36.5</td> <td>37.5</td> <td>36.79</td> <td>PASS</td> </tr> <tr> <td>170</td> <td>36.4</td> <td>37.4</td> <td>36.72</td> <td>PASS</td> </tr> <tr> <td>171</td> <td>36.6</td> <td>37.5</td> <td>36.82</td> <td>PASS</td> </tr> </tbody> </table>	Probe SN	MIN	MAX	AVG	Pass / Fail	169	36.5	37.5	36.79	PASS	170	36.4	37.4	36.72	PASS	171	36.6	37.5	36.82	PASS	<table border="1"> <tbody> <tr> <td>MINIMUM</td> <td>35.34</td> </tr> <tr> <td>MAXIMUM</td> <td>38.09</td> </tr> <tr> <td>AVERAGE</td> <td>36.66</td> </tr> <tr> <td>UNIFORMITY</td> <td>±2.8°C</td> </tr> </tbody> </table>		MINIMUM	35.34	MAXIMUM	38.09	AVERAGE	36.66	UNIFORMITY	±2.8°C
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Results of Incubator Validations

	# of Studies	% Failed	Typical Corrective Action
Denver District Lab	97	5%	Re-calibrate controls
S.F. District Lab	21	19%	Avoid hot/cold spots or take equipment out of service in 1 case

Results of Autoclave Validations

	# of Studies	% Failed	Typical Corrective Action
Denver District Lab	78	1%	Reduce media volume, increase cycle time (heat penetration study)
S.F. District Lab	10	10%	Adjust cycle time (heat penetration study)

Conclusions

As illustrated in this presentation, wireless data loggers are very useful for validation studies of temperature-controlled chambers as a part of a laboratory's ISO/IEC 17025 accreditation program. The wireless data loggers used in this study demonstrated a marked and definite improvement in accuracy and use over the other options that are available to perform temperature uniformity and stability studies. In addition, wireless data loggers maintain their stability for a longer period of time than wired systems and chambers don't need to be modified for their use, as with wired systems. Wireless data loggers have the additional advantage of being able to be placed inside the material under study in order to obtain accurate heat penetration data. They provide a "hands off" process which is not labor intensive and does not require training or additional staff time to implement. The proper operation of temperature-controlled chambers can be verified with the use of a wireless data logger system. The U.S. FDA Denver District Laboratory has successfully undergone third party accreditation and the San Francisco Lab will shortly. Their use of wireless data loggers for the temperature uniformity and stability requirement on incubators and autoclaves was accepted as a valid process to check this required equipment parameter.

References

AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025 AOAC International, Gaithersburg, MD, 2004

STANDARD OPERATING PROCEDURE For the DataTrace® SYSTEM, Mesa Laboratories, Inc., Lakewood, CO, 2005

Note: This presentation is not meant as an endorsement of any particular wireless Data Logger system