



Measurement Quality and Automation

An in-depth look at using automation to calibrate a
Fluke 1595A Super-Thermometer

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Introduction

Masy BioServices utilizes Fluke's 1595A Super-Thermometers as the resistance bridge for thermometry calibrations. Easily one of the most accurate resistance bridges on the market, Masy achieves uncertainties of ± 0.70 mK at the Triple Point of Water (TPW). This whitepaper takes an in-depth look at the challenges of calibrating one of these devices as well as the benefits from automation.

Challenges

Senior Technicians have been in their roles for several years and have experience across multiple disciplines. They have the knowledge to operate and calibrate high end assets and standards without the need for additional resources. We rely on them to guide and train entry level technicians, and work on high-end equipment. However, it takes years to train an individual to the Senior level.

Calibration of the 1595A requires knowledge of electrical and thermometry disciplines. Testpoints include current, ratio, and resistance measurements. While a seasoned electrical technician may be able to calibrate this device, he or she may not understand the concept/importance of self-heating or ratio accuracy. Both are important when using a 1595A with a thermometer.

Masy ensures all calibrations are delivered with the highest quality. We realize that asking our Senior Technicians to

continuously calibrate an increasing number of devices within the same work week can lead to error, quality defects, and lost time.

The FDA states that human error *"Can be prevented by analyzing process for failure modes and increasing automation."*¹

ISO 9001:2015 states *"Control of production and service provision, states that organizations must implement production and service provision under controlled conditions, including as applicable the implementation of actions to prevent human error."*²

Automation is a great way to increase level of quality while decreasing the number of hands-on steps required to calibrate a device.

Approach

Masy uses MET/CAL[®] calibration software by Fluke Calibration to automate many processes. This flexible and procedural based software allows a Metrologist to design programs to calibrate a variety of devices, often hands-free.

MET/CAL programs mimic paper procedures, using on-screen prompts and full-color pictures. Programs are set up to communicate with most devices, configuring and retrieving measurements. This eliminates the need for a technician to remember computer or menu driven commands. Technicians

are not required to key long strings of digits to a datasheet, eliminating typing errors. Test lead type or placement are clearly displayed with on-screen pictures or diagrams.

After test leads are connected, MET/CAL can automatically retrieve all measurements until the next lead change is required. And, the technician does not need to be present while the program is running.

Quality



Automation improves quality in several ways. Thus far, we have detailed how automation can reduce procedural and typing errors, but can it provide a better measurement than a human?

Using our Fluke 1595A, the program takes a set of 12 measurements, per dataset. The highest and lowest measurements are discarded, and the remaining ten measurements are written to the certificate as the average value. The program takes the standard deviation of those

measurements, applies a Student T correction, and combines with the uncertainty. The expanded uncertainty is written to the certificate.

MET/CAL offers several additional advantages. For example, if the stimulus comes from a multifunction calibrator, such as the Fluke 5720A, it will automatically wait until the standard indicates a stable condition before proceeding with a measurement. Our 1595A program has several wait times built in, to increase settling time and reduce thermal noise. The program

will wait for the 1595A internal oven to be heated before the calibration will proceed. In contrast, during a manual calibration, a technician is required to remember these steps, while recording data by hand.

What if a connection is made incorrectly, will an automated procedure continue with an incorrect measurement? MET/CAL identifies out of tolerance measurements and gives the technician the opportunity to review and/or retest the dataset.

Creating a Program

Creating an automated program is an investment. Each program saves time and increases measurement quality, but success depends on specific steps for its creation.

Each program considers Customer, Manufacturer, and Masy requirements when creating a set of testpoints. The tolerances are agreed upon with the Customer. This falls in line with the ISO 17025:2017 requirements and our Metrology Policy. Procedural steps and communication are entered using computer programming.

Each program is executed several times to check for procedure faults, crash conditions, errors, and incorrect setup. When the program is fit for use, it is then validated. Each validation compares the program's results to a manual calibration. Masy uses NIST guidelines for the approach of comparing measurements. Each result is given an En number, which takes uncertainty into account. An $En \leq 1$ is considered a good measurement. High/Low limits and Uncertainty are also verified.

Note that a complex program, like the 1595A, takes



**INCREASE
QUALITY**

Conclusion

This discussion has demonstrated that automation can significantly decrease or even eliminate human error. An automated program allows for a greater number of measurements in a shorter period of time than possible by a technician in a typical environment. The investment in automation pays off immediately with an increase in measurement quality.



**INCREASE
EFFICIENCY**

For routine calibrations, the benefits of writing such a program are high. This mitigates measurement risk and raises the bar for quality. This also frees the technicians to complete other processes, decreasing turnaround time for this calibration process.



**DECREASE RISK &
HUMAN ERROR**

Masy is dedicated to providing the most accurate and reliable calibration services in North America. Our experienced in-house metrologists and service team members work closely with our customer service team to expertly manage your service from scheduling through documentation and delivery. Masy is accredited to ISO 17025 through NVLAP, and regularly evaluated to the highest technical standards, as well as maintaining a rigorous quality management system as an ISO 9001 certified company. Our uncertainties are among the lowest in the industry, and our calibration certificates have a 98% accuracy rate, right the first time.

To learn more about our calibration services and capabilities, you can visit us online at www.masy.com, follow us on social media @masybioservices or give one of our calibration team members a call at (978) 433-6279.

References

1. "Current Expectations for Pharmaceutical Quality Systems", U.S. Food and Drug Administration (FDA), Richard L. Friedman, 12Sept2012
2. "ISO 9001:2015 Quality management systems, section 8.5.1.g", International Organization for Standardization, Sept2015

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