PEER REVIEWED

JVT

THE JOURNAL OF VALIDATION TECHNOLOGY

[WINTER 2008] Volume 14, Number 2

Thermistors and Thermocouples: Matching the Tool to the Task in Thermal Validation

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Validation professionals often allocate extensive amounts of time to thermal validation. Thermal validation is not only crucial for ensuring the integrity of environmental chambers, freezers, cold rooms, and warehouses, but is necessary for compliance in regulated environments.

Time spent performing pre- and post-calibrations, carefully distributing and re-distributing thermocouple wires (re-calibrating with each placement) has been considered a necessary expenditure in mapping.

Although controlling costs is a major objective for most organizations, it is imperative that cost-saving measures do not increase the risk of inaccuracy; especially when the application involves temperature-sensitive product and requires complete documentation(1).

A clear understanding of the differences between thermocouples and thermistors allows validation professionals to choose the equipment that is most efficient, accurate, and suited to the environment. Long-term calibration statistics for thermistor-equipped data recorders show that they are a viable and time-saving alternative to thermocouples. The stability of thermistors supports their use in multiple validations with the benefit of time saved by fast deployment and the reduction of nonessential pre- and post-calibrations.

THERMOCOUPLES: BASIC FUNCTION AND SOURCES OF ERROR

Thermocouple systems have long been used for thermal validation. Their function is based on the thermoelectric effect, discovered in 1821 by Thomas Seebeck. Seebeck found that when two dissimilar metals were joined and a temperature difference was present, a voltage was produced. This effect, known as the Seebeck effect, forms the basis of all thermocouples.

The modern thermocouple is composed of two high purity wires welded at the tip. Available in a variety of standard materials, Type T (Copper and Constantan) is used most often for thermal validation. However, a common source of error with thermocouples is separation at the junction point, which often occurs with repeated use. While most validation professionals have dealt with common problems like a break at the junction (See Figure 1), there are some lesser known subtleties in thermocouple function that have a large impact on their accuracy and usability in certain applications.

Any imperfections along the length of the wire also increase error. This is because the entire length of a thermocouple is a sensor. Thus, voltage is not only generated at the junction, but over the entire length of thermocouple.

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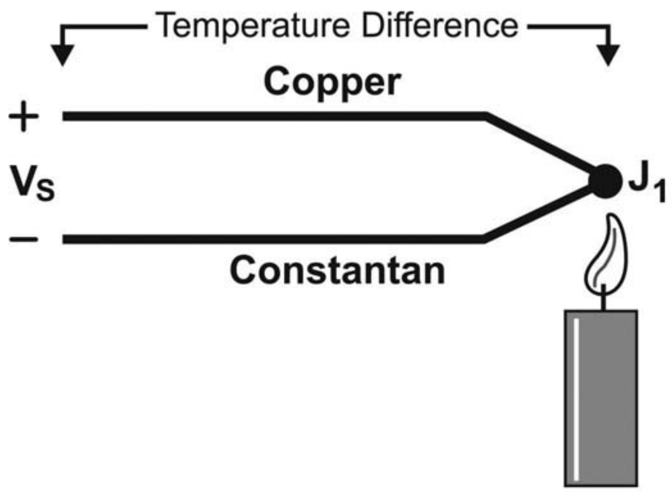
Kevin Bull has been the CEO of Veriteq Instruments for 12 years and has 30 years of experience in commercial test and measurement and designing innovative and reliable tools for measuring temperature and humidity. He is committed to developing measurement systems that improve product quality, reduce liability, safeguard assets, and protect people.

Figure 1: J1 = Junction of Cu and Constantan alloy, Vs = Seebeck Voltage produced



Imperfections in the thermocouple wire, created either at time of manufacture or during handling, will cause "micro-thermocouples" to be formed along the length of the wire.

Many applications, warehouses for instance, require long thermocouple lengths that are difficult to set out and increase the likelihood of degradation in the wire. The main issue with this is that each of these micro-thermocouples produces a slightly different voltage per °C and introduces measurement errors(2).

In addition, thermocouples typically produce a small output signal; 40uV (microvolts) per °C of temperature difference (3). Such a small output requires a high amount of signal amplification (gain) in the measuring system, which often introduces drift. These very small signals are susceptible to external noise sources, a particular problem with long wires; therefore, the longer the wire, the greater the potential noise pickup.

Every junction of dissimilar metals produces a Seebeck-voltage when a temperature difference is present. For example, a copper to copper junction that has formed an oxide will produce a voltage 10 times greater (>500uV per °C) than the intended (thermocouple) junction (See Figure 2). This can produce one of the largest sources of error, swamping the measurement of the intended junction.

Another source of error comes from the secondary cold junction temperature measurement system, which is a necessity with thermocouples. Thermocouples do not respond to an absolute temperature, but rather, to the difference in temperature across the length; no difference will result in no output voltage (4). As a result, each thermocouple measuring system must have this secondary measurement system, with its inherent sources of error.

With so much potential for error, it is understandable that thermocouple systems need continual re-calibration. Potentially unstable when shifted from one application to the next, thermocouples are often calibrated before and after every single test run (5). While thermocouples are the only option for validating extreme temperatures, there is an alternative more conducive to mapping mid-range temperatures.

THERMISTORS: AN ALTERNATIVE TO THERMOCOUPLES

At very high and very low temperatures, thermocouples are a necessary tool, but from -90°C to 130°C, thermistors are far more accurate and stable. The reason is that thermistors sense temperature by significantly changing their electrical resistance. In a thermistor-based system, a signal of 35 mV (millivolts) per °C is typical; nearly 1000 times greater than a thermocouple-based system. The large signal results in a far more stable measuring system. Also, the high resistivity of the thermistor allows a measurement lead resistance that produces a typical error of 0.05° C (6).

Unlike thermocouples, thermistors have no other dependencies. They produce an output which is proportional to the absolute temperature. When placed inside a small data recorder, they are ideal for stand-alone operations such as thermal mapping.

Data recorders are small self-contained instruments that include memory, a long life battery, a clock, and a microprocessor. Although designed for more limited temperature ranges than thermocouples, they offer numerous advantages such as easier and faster setup, greater accuracy, long-term in-calibration performance and data redundancy. Data recorders can provide temperature accuracies to 0.1°C and some models are tamperproof and 21 CFR Part 11 compliant.

THERMISTOR-EQUIPPED DATA RECORDERS AS AN ALTERNATIVE

Pre- and post-calibrations are not only time-consuming and labor intensive, they are de rigueur in thermocouple-based testing. Aside from calibration, placing long thermocouples takes a great deal of time.

A logical and efficient approach is to look at the temperature range in the actual application and match the instrumentation to that range. Obtaining the highest achievable accuracies from -90 to 85°C is more easily accomplished with a thermistor-based data recorder in situ. Using a thermistor-based measurement—

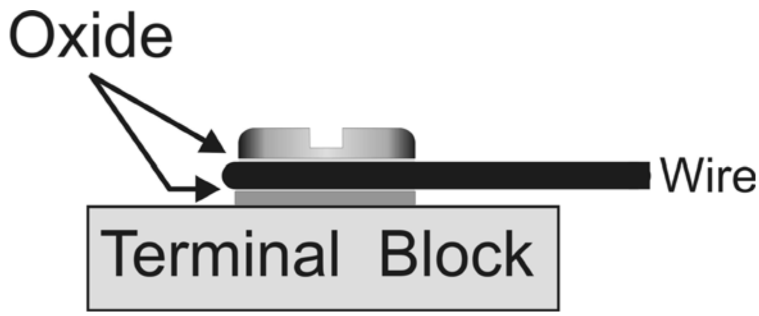


Figure 2: Mechanical Connections such as terminal blocks and connectors are prone to oxide related errors.

wherein the sensor is enclosed in a data recorder with its own power source and on-board memory—allows validation to be completed in less time and with fewer personnel. In these mid-range temperatures, the thermistor will not only measure more accurately, the lack of wiring to connect to a recording device is less intrusive to normal operations.

REDUCING THE RISKS IN VALIDATION

Using data recorders instead of thermocouples in temperature mapping need not increase risk; however, the key is the stability of the device over time. One manufacturer of thermistor-equipped data recorders reported that of the 2427 routine service calibrations they performed (in one year) on temperature recorders, 99.7% of the devices were still within published specifications after 10 to 14 months of field use. Of the failed calibrations (0.3%), none were out-of-specification by more than 0.12°C; the average out-of-specification value being 0.036°C (7). This performance is well within acceptable limits for most pharmaceutical validations.

These statistics underscore a significant finding that might have huge implications on the use of thermistor-equipped data recorders for critical environment mapping. More stable over time, and more accurate within mid-range temperatures, the recorder/thermistor combination is a safe substitute for difficult and error-prone thermocouple systems in validation. Post-calibrations are normally performed to avert product implication should the thermocouple system reveal a future calibration error. However, when a more stable thermistor-based device is used, the need for post-calibration is eliminated, which is a substantial savings in time, personnel and costs.

SKIPPING PRE-CAL. & POST-CAL.: EFFICIENT OR RECKLESS?

Still, old practices die hard, especially in regulated industries. The idea of not performing field calibrations before and after every temperature study is unthinkable to many validation professionals who have performed them for years.

When a failed calibration can potentially annul all prior validation runs, exposing an organization to increased liabilities, the risks seem to weigh in favor of extra personnel, extra time, and the interrupted operations that generally accompany pre- and post-calibration. This has long been an argument against using temperature data recorders for validation. However, a disturbing double standard is revealed when one considers that the temperature reference sensors used to field calibrate thermocouple systems are typically calibrated once a year, just like thermistor-based recorders.

EFFICIENCY AND ELEGANCE IN CALIBRATING

In any regulated environment, calibration is not optional. However, there is also no requirement for excessive calibration. The ultimate goal is to establish a routine that provides a high degree of confidence in the results, at an acceptable cost.

There are numerous guides that can help in the establishment of a prudent calibration program. A helpful source of data should be the equipment manufacturer, who should be able to provide statistical data on recommended calibration intervals, product test specifications and performance. Evaluating performance specifications on validation equipment will mitigate doubts over new equipment and protocols and justify the effort of changing over from entrenched validation methods.

As economic necessity forces regulated industries to periodically review and optimize their validation processes, eliminating waste is a constant challenge. Using data recorders equipped with thermistors for temperature mapping offers several advantages: higher accuracy in temperatures from -90°C to 85°C,(8) simple setup and operation, faster test completion, improved quality of data, and minimization of site disruptions.

The autonomy of the recorder, with its self-contained power source, sensor, and redundant recording, make it the ideal tool for both large- and small-scale thermal validation projects. But, most importantly, the long-term stability of thermistor-equipped data recorders allows validation professionals to use the device for multiple validations, without spending excessive time on pre- and post-calibrations; the result being more efficient validations, and significant savings in time and money.

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7. One-year statistics from the calibration database of Veriteq Instruments showed that 99.7% of 2,427 data recorders, having been used in a variety of environments over a period of 10 to 14 months, were still within published accuracy specifications to 0.15°C.
8. Veriteq Instruments' temperature accuracy specifications for thermistor-based data recorders are 0.15° C between the range of 20 to 30°C and 0.25°C between the range of -20 to 70°C. JVT