# TempTrak calibration programs and processes

# Copeland Policy Statement TempTrak System Calibration

The design and components used in TempTrak products are of the highest quality. Under normal use conditions, TempTrak instruments and probes experience insignificant drift and maintain stated accuracy, even over extended time periods. However, thermal, physical and in some cases, environmental conditions will cause temperature instruments and probes to drift over time. Therefore, annual periodic system calibration of TempTrak instruments and probes, or any manufacturer's products is a sound and recommended practice. Periodic system calibration is also required by many industry standards and regulations. The only way to be absolutely certain an instrument is accurate is to perform annual periodic calibration.

Copeland recommends annual periodic system calibration of instruments and probes against known, traceable standards with measurements traceable to an international unit of measure

Measurement results obtained through calibration should be traceable to the National Institute of Standards and Technology (NIST) or other recognized international standards organization. Calibration procedures should follow accepted metrology practices. Calibration test points should simulate the expected measurement range.

In addition to formal calibrations, users may also elect to perform routine verification of instrument accuracy using working standards maintained within their own facility. Incorporating a routine process such as this does not replace the need for formal calibration but can provide further assurance of instrument accuracy. If in-house verification is performed, variables such as probe type (e.g. air, glycol product simulator, liquid probe, humidity) and location within the monitored space should be consistent with the probe being verified.

If system calibration results demonstrate out of tolerance conditions for a TempTrak transmitter and probe, the equipment should be replaced.

System calibrated, transmitters and probes offered by Copeland are provided with a factory certificate of calibration and NIST traceable measurements results. The certificate of calibration states the date that the system (probe and transmitter) were calibrated at the Copeland facility. Proper system calibration involves testing both the transmitter and probe together as a single unit, where the accuracy of both the probe and transmitter are used to determine any calibration variance.



It should be noted that while annual calibration of equipment is recommended for a probe and transmitter that has been put into use, re-calibration of a new, unused, factory received temperature probe and transmitter is not required under most circumstances prior to installation. This also applies to any previously used temperature probe and transmitter that has been calibrated but not returned to service (in storage).

Under typical ambient storage conditions, the accuracy of a temperature probe or transmitter will not experience significant drift in accuracy over time. It is therefore suggested that the initial re-calibration date be established in relation to the date the probe and transmitter is placed into service, as these devices are system calibrated as a single unit. Other types of probes & instruments (humidity, pressure,  $O_2$ ,  $CO_2$ ) may experience slight drift when stored and not in use. The recalibration date for these should be established in relation to the original factory calibration. Future system calibrations, in accordance with generally accepted metrology practice, should be performed annually from this date according to the use conditions (i.e. conditions noted above) and criticality of the application.



### TempTrak On-site Calibration Services

#### TempTrak Original Factory Calibraton

TempTrak now provides electronic storage of Certificates of Calibration when calibration services are performed by a Copeland certified trained technician. During a regulatory inspection, you can pull up the necessary calibration records from within TempTrak to demonstrate compliance in real-time. In addition to providing immediate access to electronic copies of the Certificates of Calibration, this feature also provides notice to customers about upcoming calibration needs based on past calibration history. This ensures that customers are informed about calibration schedules and helps them remain in compliance in the future.

#### **Temperature Calibration**

The TempTrak Calibration process, was designed to monitor the accuracy of a previously installed TempTrak transmitter and its solid simulator probe connected, measured as a unit, and in place within the use environment. The solid simulator incorporates a secondary hole in the opposite end from where the thermistor sensor is inserted into the solid simulator. This secondary hole is used to place an insertion probe in the vicinity of the simulator's thermistor sensor.

Calibration of the transmitter and solid simulator is achieved by comparing the documented readings from the transmitter and solid simulator with the reading from the reference standard. As an example, the Total System Accuracy (TSA) of the SysCal thermocouple reference device is  $\pm 0.5\,^{\circ}\text{F}$  ( $\pm 0.3\,^{\circ}\text{C}$ ). This accuracy will provide a Test Uncertainty Ratio (TUR) of 4:1 when used as the reference standard for the TempTrak transmitter and Solid Product Simulator.

#### **Humidity Calibration**

TempTrak temperature/humidity transmitters can also be calibrated on-site and in place within the use environment.

Calibration of the temperature/humidity transmitter is achieved by comparing the documented readings from the transmitter to the readings of a calibrated humidity standard.

As an example, the Total System Accuracy of the SysCal reference device is  $\pm 0.8\%$ RH. This accuracy will provide a sufficient Test Uncertainty Ratio (TUR) when used as the reference standard for the TempTrak transmitter.

## Calibration Acceptance Tolerances

	On-site Humidity	On-site Temperature	Factory Humidity	Factory Temperature
Tolerance	±6% RH	±2°F(1°C)	±3% RH	±1°F(0.5°C)

Temperature or temperature/humidity equipment replacement is no longer necessary as long as the calibration process yields an accuracy within the stated range, and the calibration process is performed within the actual in-use environment. If any calibration results demonstrate out of tolerance conditions for a TempTrak transmitter or probe, the equipment will need to be replaced (refer to current price schedule).



# ISO/IEC 17025:2005 Compliant Calibration for Vaccines for Children Products

The Centers for Disease Control (CDC) provides guidance on appropriate vaccine storage and handling practices and publishes a Vaccine Storage & Handling Toolkit.

This guidance is intended as the approved standard of care for all public and private sector vaccine providers.

The CDC recommends that monitoring devices measuring temperature in the storage units should be calibrated to conform to ISO17025 standards, with an uncertainty of  $\pm 1^{\circ} \text{F}~(\pm 0.5^{\circ} \text{C})$ . Copeland offers a VFC (Vaccine for Children) monitoring solution that meets the vaccine monitoring requirements of CDC for uncertainty of monitoring  $\pm 1^{\circ} \text{F}~(\pm 0.5^{\circ} \text{C})$  and annual recertification in-situ. Calibration of transmitter and probe is performed by our technicians on-site, with no requirement to send back the probe for calibration.

#### Benefits of ISO/IEC 17025 Compliant Calibration

- System calibration process uses a written, controlled document
- Technicians performing system calibrations have been trained to perform the calibrations as stated by the system calibration control document
- The total uncertainty associated with the accuracy and variation of the device under test, the reference device(s) used in the calibration, repeatability of the test and any error inherent in the documented calibration process itself, is less than the stated accuracy of the device as used in its intended application
- Copeland retains the calibration record/certificate of the device under test

For further information or assistance call your local TempTrak sales representative **833-409-7505** or email **I-Care@copeland.com** 

