Anville Instruments Ltd
Data Logging & Process Monitoring

Measurement uncertainty in thermal validation

For sterilizer and washer-disinfector validation an accurate, reliable measurement system is necessary to meet the requirements of the relevant guidelines of HTM2010, HTM2030, EN285 and EN554.

HTM2010 states that the repeatability of measurement should be ±0.25°C or better and that the combined measurement uncertainties of the complete measurement system, including sensors, should not exceed ±0.5°C. It is therefore important to use a data logger where the measurement uncertainty is known and is consistent with this required measurement capability.

Although calibration of the complete measurement system of thermocouples, data logger and computer against a UKAS reference thermometer reduces systematic and random errors at the moment of calibration it does not remove the measurement uncertainty. The measurement uncertainty is calculated using a statistical approach with a combination of quadratic summation and reporting the final value at a 95% confidence level with a Gaussian distribution. The measurement uncertainty is a function of the equipment specification and characteristics and cannot be changed by any subsequent calibration.

Calibration may improve the repeatability of measurements by reducing systematic errors such as the thermocouple error, but measurements subsequently made with the complete measurement system have to be qualified by a statement of measurement uncertainty.

System errors

In any measurement system there are two types of error: systematic errors and random errors. Systematic errors can be eliminated or reduced by careful calibration. Other errors, mainly due to the limitations of the measurement system, are random in nature and cannot be removed by calibration.

Calibration of the complete system of thermocouples, data logger and laptop against a UKAS reference thermometer each time the equipment is used reduces the systematic errors at the moment of calibration. Any measurements subsequently made with the complete measurement system have to be qualified by a statement of "measurement uncertainty". Measurement uncertainty is the statistical error in the data logger (and calibration equipment) and cannot be removed by calibration.

Data logger error

In a data logger, after calibration, the main sources of error are: difference between the thermocouple cold junction sensor temperature and the actual temperature of the input

terminals, thermal uniformity across the input terminals, input switching thermal drift error, DC amplifier thermal error and DC amplifier time drift error.

The errors are usually combined in the manufacturer's specification as 'range accuracy', 'cold junction error' and stability error due to ambient temperature'. The range accuracy is of specific importance as it cannot be improved by calibration.

These values can be obtained from the manufacturers published data sheets. These errors are random and vary with the ambient temperature of the data logger and the location of the data logger (particularly if it is near to any heat source such as an autoclave) making it essential that the effect of these errors is known to qualify the readings.

Thermocouple error

Type T thermocouples are available in two grades of thermocouple wire: class 1 and class 2. The difference between them is shown by the accuracy at 0°C. Class 1 accuracy is ±0.5°C whilst class 2 accuracy is ±1.5°C.

The systematic error in the class 1 thermocouples can be removed by calibration using a dry-block bath and an accurate UKAS calibrated reference thermometer.

Calibration equipment error

The complete system is calibrated by inserting the thermocouples into a dry-block bath and when stable measuring the temperature on an accurate UKAS calibrated reference thermometer.

The calibration measurement error is defined by the UKAS temperature reference error and the temperature dry-block bath error.

Total system error

Calibration of the complete measurement system of thermocouples, data logger and software against a UKAS reference thermometer each time the system is used reduces all errors, systematic and random, at the moment of calibration. Any measurements subsequently made with the complete measurement system have to be qualified by a statement of measurement uncertainty.