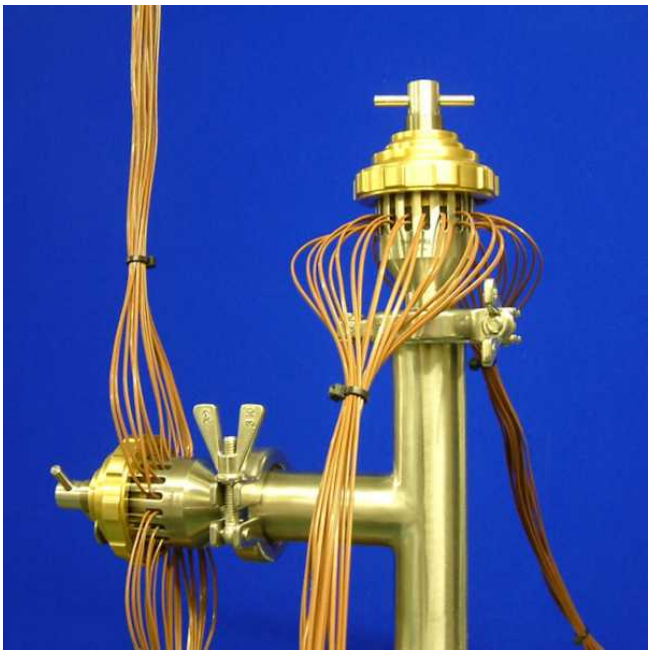

SELECTION OF VALIDATION THERMOCOUPLES

ABSTRACT

Thermal Detection has 30 years of experience in the manufacture and supply of validation thermocouples to the Pharmaceutical industry. The following paper outlines the key considerations for successful temperature validation.

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Selection of Validation Thermocouples

Introduction

Regulatory requirements for Pharmaceutical sterilisation processes such as autoclaves and lyophilisors, requires frequent and rigorous temperature validation to be performed.

The mainstay of such an exercise is the Type T validation thermocouple wire, which provides accurate temperature measurement in difficult to reach areas, and allows data collection over long distances, up to 50M in some cases.

The following article explains the main selection criteria to consider when specifying validation thermocouples, and also showcases a range of useful accessories provided by Thermal Detection, to assist the engineer.

Links to the Thermal Detection website are highlighted throughout the report, where further information can be obtained, and also a Product Enquiry Form is available to receive pricing and availability.

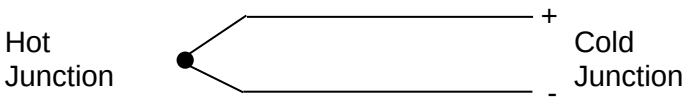
Keywords

Type T thermocouple, hot junction, encapsulation, wire format, thermocouple entry gland

Principle of Measurement

The thermocouple is a simple and effective method of temperature measurement which is based on the Seebeck effect discovered by the German physicist Thomas Johann Seebeck in 1821.

A thermocouple consists of two conductors of dissimilar metals which are joined together at one end (the hot junction). A difference in temperature between the hot junction and the other end of the conductors (cold junction) generates a small electromotive force proportional to the temperature difference.



By careful selection of materials, the change in electromotive force with temperature can be used to infer an accurate temperature measurement.

Thermocouple properties and tolerances are described in BS EN 60584-1:2013 standard.

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Validation Type T Thermocouple Tolerance

There are many standard thermocouple types, however the Type T thermocouple is recognised as providing very accurate and stable measurement over the range -50 to 350°C, which covers the majority of Pharmaceutical, BioMed and Healthcare processes that require frequent temperature validation.

Type T thermocouples are constructed with copper on the positive leg and a nickel copper alloy known as Constantan® on the negative leg.

For the purposes of temperature validation, it is recommended that only Class 1 material is used. This will give a measurement tolerance of:

Range -40 to +350°C: greater of ±0.5°C or 0.004t
Where t = temperature °C

Thermal Detection only supply Class 1 type T thermocouples for validation.

Validation Thermocouple Wire Construction

The main criteria for consideration are the conductor size, and type of wire insulation.

Conductor size.

The most common size used in validation applications is a pair of single solid conductors of 0.3mm diameter, described as 1/0.3mm.

Although it offers good value, long or complicated wire runs can be prone to damage.

Therefore, where long or complicated wire runs are expected, a multi stranded wire consisting of seven 0.2mm conductors twisted together may be preferable, described as 7/02mm.

A range of other conductor sizes are also available:
1/0.2mm
1/0.5mm
3/0.2mm
13/0.2mm

Wire Insulation

Individual conductors are typically insulated with Teflon. The most common outer insulation is an extruded PFA outer insulation jacket. This can be used up to 250°C and has a smooth and easy to clean surface, and due to the manufacturing process is an economical choice.

An alternative is an outer PTFE lapped insulation. PTFE tape is tightly wound around the conductors which reduces capillary action when used in steam autoclaves, where steam is

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drawn into the wire and condensate forms and travels along the wires. It is a more expensive product however, and can be difficult to work with.

For higher temperature applications, such as hot air tunnel sterilisers, Kapton® insulated conductors with a Kapton® outer insulation jacket can be used for up to 300°C, and 350°C for short periods. Kapton® is a polyimide material manufactured by DuPont.

Hot Junction Preparation

A well-formed hot junction is essential for successful temperature measurement.

Although it is possible to form a hot junction on site by twisting the conductor ends together by hand, it is not good practice and should be avoided. Contamination from grease imparted by the fingers and a lack of mechanical soundness will impact on the stability and accuracy of the measurement.

The recommended method for forming the hot junction is by welding the two conductors together to form a small uniform ball whilst in an inert atmosphere. This procedure is usually carried out using a TIG (tungsten inert gas) or capacitance type welding machine, in both cases using Argon to flood the weld area.

Thermal Detection use a capacitance welder for the quick and precise formation of hot junctions.

To further protect the hot junction from oxidisation, Thermal Detection use Type T material with a silver-plated copper leg.

Hot Junction Encapsulation

A consequence of using a thermocouple with a bare hot junction for autoclave validation, is that under chamber pressure, steam (or water in a water cycle autoclave) will be forced up the inside of the thermocouple outer jacket. Capillary action assists this and when reaching the cooler side of the chamber the steam condenses and can be seen by a constant drip of condensate at the thermocouple terminals.

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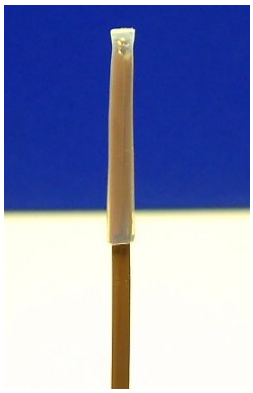
To prevent this, the hot junction can be encapsulated within a Teflon cap which forms a permanent seal, thus preventing steam or water penetrating the thermocouple jacket. The cap also gives mechanical protection to the hot junction and reduces the effects of oxidisation.



In addition to tip encapsulation a small slit in the wire insulation can be made to form a weep hole, which allows any condensate to fall out of the insulation before it reaches the terminals.

Validation Thermocouple Looms

The placement and installation of many long flexible wire thermocouples into a confined space such as an autoclave, can be a challenging and frustrating task.

To make this task easier, Thermal Detection can make a 'loom' of thermocouple wires, which is where the required number of thermocouples, pre-prepared to the required length, are bundled and secured together with cable ties. Each thermocouple in the loom is identified at both ends.

The loom can be placed into position without the individual thermocouple wires becoming tangled together. Once in place, the cable ties can be snipped away allowing placement of the individual thermocouples in the required locations. As each thermocouple is already identified at each end, matching thermocouples to measurement positions becomes a much easier task.

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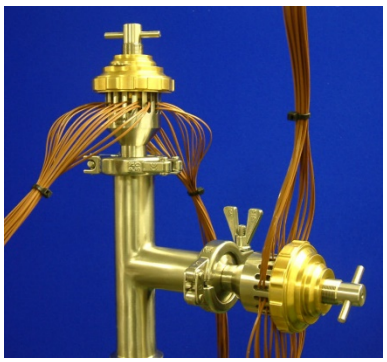
Thermocouple Entry Glands

Validation thermocouples often need to be fed into an autoclave through a limited number of entry ports. In addition, steam leakage from the port must be within the maximum chamber leakage permitted by the regulatory authorities.

The Thermocouple Entry Gland (TCEG) was designed by Thermal Detection to assist with the feedthrough of thermocouples through one port.

Up to 36 thermocouples can be fed through the gland, and sealed with silicone gaskets to ensure minimal steam leakage from the port.

By combining two TCEG's together with a Tee piece, up to 72 thermocouples can be fed through one autoclave port.



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Products to Assist with Temperature Validation of Product Loads

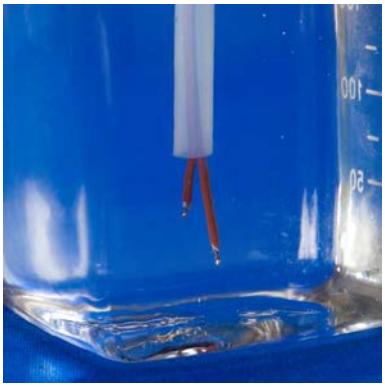
Thermal Detection has developed a range of products that allows the accurate placement of validation thermocouples within liquid product loads that are undergoing validation.

Liquid Loads in Bottles

The key to successful validation is to measure the temperature at the point of slowest temperature response.

The thermocouple mounting bottle cap GL45-1 assists with this by allowing the accurate placement and securing of thermocouple wires inside a bottle.

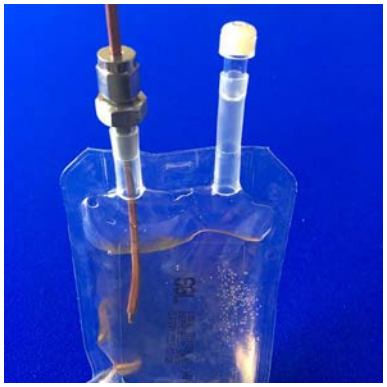
It comprises of a silicone seal within a stainless steel fitting, and it can be combined with most laboratory bottle designs.



Liquid Loads in Pouches

As with loads in bottles, the key to successful validation is accurate positioning of the thermocouple wire inside the pouch.

The bag pouch thermocouple holder uses a similar arrangement to the bottle cap gland to position and secure the thermocouple in the correct position.



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Conclusions

The type T thermocouple is a valuable tool for accurate temperature validation in processes operating in the temperature range -50 to 350°C.

Thermal Detection has over 30 years' experience in assisting customers to choose the correct materials, and has also developed a range of complimentary products to ensure successful validation.

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