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Inspections, Compliance, Enforcement, and Criminal Investigations

Temperature Sensors in the Regulated Industry

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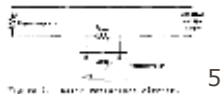
ITG SUBJECT: TEMPERATURE SENSORS IN THE REGULATED INDUSTRY

Temperature measurement can be accomplished by essentially five basic methods: (1) liquid-in-glass, (2) resistance thermometry, (3) thermoelectric thermometry, (4) optical/radiation pyrometry, and (5) bi-metal. Investigators are most familiar with the liquid (mercury or alcohol usually) -in-glass and the bi-metal (dial gauge) types. These will not be discussed in this ITG. Also, it is rare if ever that investigators will encounter the use of the optical/radiation pyrometer. This too will not be discussed. What follows will be a brief explanation of the differences between the resistance and the thermoelectric types which sometimes creates confusion or misunderstanding.

Resistance Thermometry

A resistance thermometer is a temperature-measuring instrument consisting of a sensor (an electrical circuit element whose resistance varies with temperature), a framework on which to support the sensor, a sheath by which the sensor is protected, and wires by which the sensor is connected to a measuring instrument, which is used to indicate the effect of variations in the sensor resistance. Resistance thermometers provide absolute calibration of temperatures in that no reference junctions are involved, and no special extension wires are needed between the sensor and the measuring instrument (as with thermocouples). Figure 1 is a basic resistance circuit.

[Figure 1. Basic resistant circuit.](#)⁴



(image size 8KB)⁶

The sensors can be of two types: resistance temperature detectors (RTD's) and thermistors. The RTD sensing element is formed of solid conductors (usually in wire form) wound upon an insulating core. (See [Figure 2](#))⁷ The insulating core is usually made of mica or ceramic. The conductors, which are wound in a helical coil to prevent mechanical restraints during thermal expansion, are generally made of platinum; however nickel and copper have been used. Platinum best meets the requirements because being a noble metal, it can be highly refined, it resists contamination, it is mechanically and electrically stable, and the relationship between temperature and resistance is quite linear.

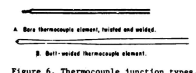
Thermistors (a contraction for "thermally sensitive resistors") are electrical circuit elements formed of solid semiconducting materials such as oxides of nickel, manganese, iron, cobalt, copper, magnesium, titanium, and other metals. The powdered metal is formed under pressure into the desired shape, usually a flat disc (See [Figure 3](#))⁸. The disc is sintered, leads are attached, and encapsulated in epoxy. The finished thermistor can also be encased in a sheath of plastic, stainless steel, copper or aluminum as shown in [Figure 2](#) for the RTD. Both the RTD and thermistor can be obtained in various configurations but generally would appear as in [Figure 4](#)⁹ in various diameters and sheath lengths.

FIG. 3¹⁰(image size 25KB)¹⁵FIG. 4¹²(image size 11KB)¹⁶

Thermoelectric Thermometry

The thermoelectric thermometer is a temperature measuring instrument consisting of two continuous, dissimilar thermocouple wires extending from a measuring junction to a reference junction with copper connecting wires to a potentiometer. Unlike the resistance types where power must be supplied to the circuit, the thermocouple circuit generates a measureable, low voltage output that is almost directly proportional to the temperature difference between the "hot" junction and the "cold" junction. A unit change in this temperature difference will produce some net change in electromotive force (emf or voltage)

Figure 5¹⁷, diagrams this circuit. Thermoelectric thermometry makes use of the known relationship between a difference in junction temperatures and the resulting emf developed by a thermocouple circuit. The temperature of one junction (reference junction, T1) is held at a constant known value. This is usually accomplished with an ice water (32 F) bath. The temperature of the other junction (measuring junction, T2) is determined by measuring the thermocouple circuit emf and referring to calibration tables for the particular thermocouple materials. (See also ITG #14, "Thermocouple Surface Pyrometers," dated 12/30/73). The thermocouple junction usually is formed by twisting and fusing the two wires together as shown in Figure 6¹⁸ or they may be butt-welded. The finished element may be used bare or enclosed in a sheath as shown in Figure 4¹⁹ for the resistance type sensors.

FIG. 5²⁰(image size 21KB)²³FIG. 6²²(image size 19KB)²⁴

Throughout the regulated industry, the investigator will at one time or another be exposed to any or all forms of the temperature measuring devices mentioned heretofore. It is important that they be recognized, their operation understood, and suitability for each application be evaluated.

Of the types discussed, by far the most accurate, sensitive, and stable is the RTD. Because of cost, it is used primarily as a standard or reference for other temperature sensors; however, increasing industrial usage include inputs to indicators, recorders, controllers, scanners, data-loggers and computers. In many instances it is taking the place of the accurate but breakable mercury-in-glass (MIG) thermometer as the prime monitor for sterilizer temperature particularly in the drug or medical device industry. (The Bureau of Foods has for now denied a petition for the use of the RTD as an alternate to the MIG for thermal processing of LACF on the grounds that insufficient evidence exists to show reliability and accuracy.) Some firms are using them as they would thermocouples in heat studies of sterilizers.

The thermistor is closely allied to the RTD in usefulness as a reference or for direct temperature measurement. One problem in the past has been a lack of electrical and chemical stability, but with newer materials and manufacturing processes, this problem is being minimized.

The thermocouple is widely utilized in most applications for temperature measurement, especially for sterilizer heat validation studies. It is a simple device being only two wires joined together at the measuring end. The thermocouple can be made large or small depending on the life expectancy, drift, and response time. It may be flexible, rugged, and generally easy to handle and install. A thermocouple covers a wide range of temperatures but linearity can be a problem. Although the voltage generated by the junction is

proportional to the measuring junction temperature, it is non-linear requiring a set of tables to make the translation or a built-in linearizer in test and control readout instruments. Unlike the resistance type sensors, the thermocouples is not subject to self-heating problems. Also, thermocouples of the same type are interchangeable within specified limits of error. It is important that where sets of thermocouples are used to perform critical heat validation studies, they should be purchased or manufactured from wire of one manufacturer's lot. This would provide almost identical performance characteristics for all in the set.

References:

1. Benedict, Robert P., "Fundamentals of Temperature, Pressure, and Flow Measurements," John Wiley & Sons, 2nd Edition. 1977.
2. Kallen, Howard P., "Handbook of Instrumentation and Controls," McGraw-Hill, 1961.

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