

Using Thermocouples to Measure Temperatures during Retort or Autoclave Validation¹

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ABSTRACT

Thermocouples (TCs) are used almost exclusively in designing and validating the heat processes needed for sterilization of product in retorts or autoclaves. In this paper we discuss the vexing errors associated with using TCs in a hot, wet environment. Most problems seem to be associated with the action of steam and water on the TC lead wires and/or caused by temperature gradients on lead wire connectors. These errors are particularly troublesome since they are in the range of 1 to 2°C and are random in nature. The use of a pair of continuous wires that is protected or sealed from the wet retort environment, from the TC junction to the measuring instrument, is the most effective way to reduce or eliminate these problems. The hot, wet environment apparently causes electrochemical effects that produce measurable electromotive forces (EMFs) whenever bare wires come in contact with steam or water. However, the effect is greater when the wires pass through water than through steam. For containers that are nonconductors of electricity, such as plastics, grounding of the TC junction has proved necessary, particularly when processing in flowing water. We conclude that TCs can measure temperature very accurately if properly used. We emphasize that the TC system must be adequately calibrated, and that ambient temperature calibration will not compensate for high-temperature water effects and the errors caused by temperature gradients across connectors.

Temperature measurement is the largest problem area in designing and validating the heat processes used for sterilization of containers of product and hardware in retorts or autoclaves. In validating a heat process we must first determine temperature variation in the vessel and then carry out heat penetration temperature measurement in containers of product. The major problems are accuracy of measurement and calibration of the system. Because of the many problems in temperature measurement, the prudent process engineer should consider first that

temperature variations which are greater than would be expected for the specific type of system may be due to a temperature measurement error rather than a temperature deviation from a peculiar equipment phenomenon. Therefore, appropriate calibration checks should be made to be sure that there are no errors in the temperature measurement system before exhaustive experimental validation tests are carried out. Only after there have been experiments which validate the temperature measurement system and the associated calibration process can it be assumed that unique phenomena such as small floating pockets of air or superheated steam cause the temperature variation in the test vessel.

Three possible temperature sensors can be used in temperature distribution (frequently called heat distribution) testing. They are temperature measurement using thermocouples (TCs), temperature measurement using resistance temperature detectors (RTDs), or temperature measurement using thermistors. Testing done in the pharmaceutical industry has shown that all three devices can make accurate temperature measurements in sterilization applications when using proper calibration and measurement procedures and observing proper engineering applications. However, TCs seem to be the temperature sensor of choice for both temperature distribution and heat penetration studies in retorts and autoclaves. This is because TCs are primarily a more rugged sensor that can tolerate reasonably severe physical abuse, whereas RTDs and thermistors can change calibration significantly if they are dropped or bent or if they receive any other kind of minor physical abuse.

Today, in both the food and pharmaceutical industries, duplex 20-, 22-, or 24-gauge copper-constantan (Type T) TC wire with Teflon insulation on each conductor and a Teflon overwrap is almost universally used in the USA for temperature measurement.

OBJECTIVES

We attempted to obtain an overview of the temperature-measurement problems encountered in using TCs during validation of retort and autoclave processes, and we investigated those aspects of temperature measurement

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that are most troublesome. We did not include details of the theory of calibration of TC-measuring systems; these are covered very well by ASTM (1) and Kemper (9).

We concentrated on common system problems that can result in temperature-measurement errors rather than problems of inaccurate temperature measurements such as stem-conduction errors caused by heat transfer to or from the measuring junction. Heat transfer problems have already received considerable attention and numerous references exist. To mention a few, Ecklund (7) reported on studies to evaluate the effect of different types of receptacle fittings on heating rate measurement in canned foods; correction factors for conduction-heating products were included. Beverloo and Weldring (4) also studied temperature-measurement errors due to transfer of heat along TC wires in conduction-heating canned food. They apparently looked at worst-case conditions; Board (5) commented on their work and the work of others in a balanced treatment of the problems of heat transfer along TC wires. Hostetler and Dutson (8) determined the effect of the diameter of TC wire on the rate of heating by measuring temperatures in thin steaks. Packer and Gamlen (12), using an analytical heat transfer approach, developed a correction procedure for heat transfer along the TC wire when collecting heating data on convection-heating canned food products. Kemper and Harper (10) experimentally determined the temperature-measurement error in vials of pharmaceutical products by using different-sized TC probes. Berry (2) discussed the potential errors in measuring temperatures in retort pouches.

DISCUSSION OF THE ERROR PROBLEM

Few temperature-measurement problems arise from one failure point or condition; most are the result of the contributions of several failure points or conditions that happen to occur at the same time. Each error or failure point may occur only under a few operating conditions or cycles or during part of a heat process. In general, the problems associated with TC measurement systems, used for both retort heat distribution and heat penetration studies, can be classified as follows.

1. *Errors in the measuring system.* Both systematic and random errors that are a function of changes in ambient conditions (temperature, humidity, voltage supply, grounding, etc.) in the measuring equipment; effect of ambient conditions on systematic errors; effect of ambient conditions on random errors.

2. *Errors contributed by the sensing element* and the associated wiring and connections, effects of temperature gradients on nonhomogeneous conductors, effects of water and high temperatures on the insulation (or isolation) of the TC wire, effects of TC connectors on measurement errors.

3. *Accepted levels of temperature variation* in temperature distribution and heat penetration studies, effect of type and operation of retort or autoclave heating system, heat penetration variability attributed to product variation.

MEASURING TEMPERATURES DURING RETORT OR AUTOCLAVE VALIDATION

In retort or autoclave operation the temperature of the heating medium should be the same throughout the vessel. During validation testing, measurements of the temperature at different points in the retort or autoclave are made both with the vessel empty and under loaded conditions to determine the temperature variation.

In this report we will use as examples the following types of TCs which are commonly used for retort or autoclave validation studies.

1. *Duplex TC wire used as is*
 - a. A junction is at one end of a continuous TC wire pair that extends to the measuring instruments.
 - b. TC wire pair is not continuous from the measuring junction to the measuring instrument but is broken and then fitted with connectors either inside or outside the retort or autoclave.
2. *Duplex TC wire sealed with urethane.* A junction is at one end of a continuous wire pair that has been sealed to isolate the bare wire from the environment.
3. *Duplex TC wire totally isolated from the retort or autoclave environment.* A junction is made at one end of a continuous wire pair and the entire wire is encased in a protective hose or tubing.

Some differences between these TC wire systems are that, for example, in *1a* and *1b* the steam-water atmosphere in the retort or autoclave is in direct contact with the TC wire and from a practical standpoint will penetrate the wire at one or more places, whereas in Systems 2 and 3 a special effort is made to prevent the atmosphere in the autoclave from contacting the TC wire. In System 2 a urethane sealer is used to seal the wire against water or steam penetration and also to electrically isolate the wire from the fluid in the vessel (2,3). In System 3 a very positive approach is used to keep the water and steam atmosphere from contacting the TC wire. This is done by first making a junction at one end of the duplex TC wire and inserting and seating this junction into a stainless steel tube. The TC wire is threaded through 0.1875-in ID, 0.438-in OD Goodyear Conair utility hose [identified in ASTM Publication 1418 as Ethylene-Propylene-Diene Terpolymer (EPDM) manufactured by Goodyear Tire and Rubber Co., Industrial Products Division], which is attached to the stainless steel tube with a water-and-steam-tight connection at the measuring end and is open to the ambient atmosphere at the instrument. The hose that encloses the wire will withstand the water

and steam atmosphere and maintain the TC wire in a dry condition. This system is used primarily by the drug industry in validation of autoclaves.

It is general practice in retort and autoclave validation and also in heat penetration studies to calibrate all instruments, including the temperature-measuring system, before carrying out the tests and again after completing the tests. One method of performing temperature-measuring-system calibration tests is to place the TC-measuring junction in a well-controlled, high-temperature calibration reference that has a known temperature as measured with an accurate temperature standard with a calibration which is traceable to national standards at the National Bureau of Standards (NBS). With the proper correction for the TC reference junction temperature, the output voltage (EMF) or temperature reading from the TC-measuring instrument is determined. The steady-state difference between the measuring instrument output reading and the temperature of the TC-measuring junction is the systematic error (sometimes referred to as bias or offset) and is the correction factor at that temperature. This calibration procedure is repeated for all sensing elements. Sufficient calibration points should be used to characterize the measurement system performance over its range of use. Typical calibration points are at 10, 50, and 90% of the instrument range. However, it is recommended that calibration points be concentrated in the temperature range of the heat process.

Absolute calibration to national standards is always desirable but often not practical for field applications. The best second choice is to perform a relative calibration where the temperature-measuring system is compared to a temperature-indicating device of known accuracy, such as the vessel Hg-in-glass thermometer or RTD or other device indicating the heating medium temperature in the vessel. Relative correction factors are only useful for indicating differences among sensing elements and are only as accurate as the temperature-indicating device used to indicate vessel temperature.

ORIGIN OF TEMPERATURE ERRORS

Two types of errors in TC temperature measurements are well documented: (a) those produced by the action of steam and water at autoclave temperatures on the TC lead wires, and (b) those that may be produced by temperature gradients from hot autoclave conditions to ambient conditions, imposed on lead wire connectors or junction points. The source of both of these errors is the high-temperature wet condition that exists inside the autoclave during operation.

It is a basic principal that measurement system calibration should be carried out under the same conditions that exist during use. Applied to autoclaves and retorts, this means filled with steam or water at a temperature above 100°C. Since it is not easy to calibrate under these conditions, measuring systems are normally calibrated with the vessel at room temperature. When a temperature-measur-

ing system is calibrated with the autoclave or retort cold, errors induced by the high temperature will not exist at the time of calibration; therefore, they cannot be compensated for in the calibration adjustment. Consequently, the high-temperature wet conditions described above may produce errors that may lead to erroneous variations in the temperatures measured during the validation tests. The magnitude of these errors will not be constant but will vary from one TC to another, so the result will be variable temperatures which often may be interpreted as hot and cold zones in the retort or autoclave - fictitious hot and cold zones.

We do not know why the action of high-temperature flowing water on Teflon-insulated TC wire produces temperature measurement error. The errors do not appear to be as great in steam. The effects may be similar to those of high-temperature water on nylon-insulated TC wire, observed by Pflug et al. (16); they may be electrochemical in nature. Middlehurst et al. (11), in their report on the electrochemical effects on TC-measurement-system voltages, state, "Any moisture bridging the two wires can lead to the generation of a chemical EMF, some part of which will appear across the output terminals of the TC and give an erroneous temperature reading." They developed a theory to explain the magnitude of the voltage error that can be generated electrochemically and they then verified the theory experimentally. They concluded that the magnitude of the electrochemical effect is surprisingly large - perhaps as much as 1°C in aerated, distilled water and even higher in water containing an electrolyte - and that, in general, errors must be anticipated whenever TC wires are wet.

In a TC-measuring system the net EMF is a function of the TC junction, lead-wire connectors, and intermediate lead wires. All parts of the system can contribute to errors; therefore, the intact TC-measuring system should be calibrated under conditions of operation and in the configuration in which it will be used. The TC junction itself is only a connection point in the circuit. The objective is to have a small, simple, low-resistance TC junction; the method of making the junction (i.e., twisting, soldering, or welding) is not critical so long as there is a low-resistance connection between the two wires.

It is well known that a nonhomogeneous TC connector or a dissimilar TC wire in the circuit, where there is a temperature difference at the connection points, produces errors. These errors are predicted by the law of the effect of intermediate metals in the TC measurement circuit (1,9). Briefly, this law states that if any intermediate metal exists in the TC circuit, whether it be a connector or a third-metal conductor, and if all parts of the connector or conductor are at the same temperature, there will be no error. However, if the junction points are at different temperatures, there will be an error. It is important to note that items such as a screw on a connector or a solder joint represent a third metal in a TC circuit and that whenever a temperature difference exists across the third metal junction points, these two new TCs that are

formed will lead to an error. For example, with Type T TCs, solder has a higher electrical conductivity than constantan and because of the affinity for the current to flow through the solder, a new constantan/solder TC is formed at each end of a solder joint on the constantan wire. This does not occur for copper since its conductivity is greater than solder. If the solder joint is thermally insulated to any degree, there will be a temperature differential across it and the two "new" TCs formed will be producing slightly different EMFs. The effect is usually manifested as transient peaks or valleys lasting from a few to several seconds (depending on how well the solder joint is insulated) when a change in the temperature of the solder junction occurs, e.g., at steam-on or when cooling water is introduced into the retort. This may be the cause of the "spike" often observed in the heat penetration data for conduction-heating products at the start of cooling. A simple laboratory experiment to illustrate this effect can be done by passing a flame over a solder connection (or a portion of constantan wire that has been coated with solder) other than the TC junction in a TC circuit. Instantaneous peaks as high as 25°C can be produced. The use of a homogeneous conductor from the sensing element to the measuring unit, of course, eliminates the problem of an intermediate metal.

In validation studies, it would be ideal if we were confident that all our TCs were accurate to $\pm 0.1^\circ\text{C}$, for example, as determined by calibration tests using NBS traceable standards. If the test system is such that this is not possible, then we must devise a test procedure that will ensure that all TCs in the autoclave or retort validation test will provide measurement with an uncertainty no greater than $\pm 0.1^\circ\text{C}$ when subjected to the same steam or hot-water temperature.

In evaluating the results of a retort or autoclave validation test in which temperature variations have been observed between points in the autoclave, usually the first reaction is to assume that if the temperatures measured at different points are different and if the TCs were calibrated before use, these temperature differences are real. However, if, as discussed previously, the TCs were calibrated with the wires and connectors at ambient conditions of temperature and humidity, and if, for example, Teflon-covered TC wires were used and there were connectors in the system, there is no way of knowing whether all or part of the temperature difference is real or there is an error caused by the steam and hot water acting on the TC wire plus the effect of possible temperature gradients across connectors. Consequently, we do not know if the observed temperature variation actually existed in the vessel. We can only establish that an observed test result of a hot or cold zone is true and not fictitious if we have validation data for the measuring system for conditions identical to those seen by the instrument, connectors, and wire during the test.

It is necessary that we use both a calibration process and measurement systems which have been properly designed and validated for the specific application. Proceed-

ing in this way and using good technical judgement in performing the measurement process, it is possible to measure temperatures in autoclaves where the uncertainties do not exceed $\pm 0.1^\circ\text{C}$. It would be desirable that the final temperature calibration of the measuring system be made in the vessel at operating conditions, ideally to absolute standards, or, if this is not economically or physically possible, then the best we can do is calibrate on a relative basis. Calibrating inside an autoclave at 120°C is difficult; we have found that bunching all the TCs together at a central location in the heating medium in the hot autoclave is a practical way to proceed. The calibration factors determined under these conditions are a measure of the difference between the temperature indicated by the TCs and a reference TC (or other temperature indicator located at the same point in the vessel). Only when the temperature-measuring system is calibrated under actual use conditions are the calibration factors directly applicable to the temperature measurements made during the temperature distribution or heat penetration test.

MINIMIZING TEMPERATURE-MEASUREMENT ERRORS

Continuous water-protected TC wires

When the TC wire is continuous from the measuring instrument to the sensing element and isolated from the steam-and-water environment, the probability of an error caused by water or by a connector is very small since there are no connectors and water is excluded.

One system that protects the TC wire from the wet environment of the retort or autoclave has been described previously (i.e., encasing the wire in a rubber tube). Another method of isolating the TC wire from the wet environment uses a urethane sealer and was developed by Berry (2) for heat penetration measurements in flexible pouches. The sealer not only prevented water from flowing along the wires under the insulation because of the pressure differential between the inside and outside of the retort, but the urethane also electrically insulated the bare portions of the wires from stray EMFs. The wires were installed in the retort through a stuffing box made from pipe flanges with soft rubber gaskets (14). The TC junctions were submerged to cover the ends of the Teflon insulation in a beaker of liquid urethane (Insulator Seal Coat 02049, CRC Chemicals, Warminster, PA). The retort was pressurized with air (20 psi) until urethane was forced out of the ends of the wires outside the retort and the wires were dried in place overnight. Then several coats of urethane were sprayed on the junctions to seal them and protect them from abrasion.

When using a TC system that relies on protecting the TCs from the wet environment, the system should be inspected or tested at the conclusion of the data-gathering tests to make sure there has been no water leakage during the tests. For this type of system, differences between calibrations at ambient and operating conditions should be minimal.

Noncontinuous, nonprotected TC wires

Probably the most common TC-measuring system consists of noncontinuous, nonprotected TC wires. If Teflon-covered wire is used and there are connectors in the TC circuit (either inside or outside the autoclave), then a calibration in the heating medium should be carried out in which all the TCs are drawn together (at one point, if possible, near a measuring unit) and the autoclave is operated through one or more regular cycles. All TCs should show the same temperature (all the TC wires used in the test are from the same lot of quality TC wire) or at least the same variation in temperature as indicated by an ambient calibration. Any additional variation in temperature is an indication there is a calibration variation in the TCs that is due to the effect of water at a high temperature on the wires or the effect of a temperature gradient across a connector in the system.

If TCs are calibrated so there are no errors at the autoclave-operating temperature from water or connectors, the variation in the temperature in the steam at different points in the autoclave after it has reached equilibrium should be no more than 0.1 to 0.2°C. This should be true both for empty and loaded autoclaves so long as the temperature-sensing elements are measuring temperatures in the heating medium.

Other steps to eliminate or reduce errors

Grounding problems historically have been a primary concern for TC systems. We will discuss two types of grounding: (a) correct voltage (normally 115VAC) connection (neutral to ground) required by many temperature-measuring potentiometers, and (b) grounding of the thermocouple itself, which is possible when a floating-bridge voltage-measuring system is used. Potentiometers used with TC systems must have reliable, nonfluctuating voltage supplies with adequate earth grounds; otherwise, significant error in the indicated temperature can result particularly with the older types of instruments. These are normally easy errors to detect (in the range of 2 to 10°C) and they usually can be eliminated by connecting grounding straps from the instrument to a waterline or to the retort.

Of more concern is the grounding of the thermocouple junction. Often, custom-made TCs are purchased from companies specializing in their manufacture. These TCs are normally encased in 1/16- or 1/8-in. OD stainless steel sheaths with a connector. The TC junction can be ungrounded or grounded to the sheath, which effectively reduces the stray electrical potential to that of the surrounding medium. This is desirable for most applications.

Often, TCs are made from TC wire by twisting, soldering, or preferably welding the wires together. It is common practice by some workers in the food sterilization area to ground the TC junction when measuring temperatures in flexible packages or glass containers that are heated and submerged in water (14), since these types of containers electrically insulate the TC junction from the surroundings. A number of workers, including Davis

et al. (6), have found that this practice of grounding the TC junction, which results in a three-wire TC unit, will eliminate problems when TC wires are used without an extra protective covering in systems where heating is carried out with the product submerged in water. Others have found the same effect can be achieved by grounding the copper side of a Type T TC system to the measuring instrument (2). We have found grounding the TCs to be desirable for the new, unique packaging forms made from retortable plastics.

Peterson and Adams (13) reported on studies of TC grounding in retort pouches. They reported, "The best response was found with a TC shielded with a stainless-steel tube in which the measuring junction was electrically isolated from the sheath." They also observed variable f_n -values when different types of TCs were used in the same type and size of object; they did not investigate this rather unsettling observation.

Another important point is the interchangeable nature of some components of the TC system, such as lead wires, connectors, rotary contactors, or the TCs themselves. These components may or may not be interchangeable without recalibration. For this reason most workers establish elaborate numbering schemes to ensure that they are able to reconstruct the same system during operation that was in place during calibration. We have found that recalibration is necessary when lead wires must be replaced or increased in length, but that the Ecklund TCs (Ecklund Custom Thermocouples, Cape Coral, FL), normally used for heat penetration measurements in canned foods, are interchangeable.

GENERAL DISCUSSION OF THE TC TEMPERATURE-MEASUREMENT PROBLEM IN HIGH-TEMPERATURE, WET LOCATIONS

We believe that there are perhaps three or four sources of error, rather than one causative agent or action, which act singularly or together to cause the many observed TC errors. One of the sources of error is undoubtedly the electrochemical effect studied by Middlehurst et al. (11) that occurs when bare TC wire is exposed to the wet environment of a steam or water retort.

We have indicated that there appears to be no temperature error in measuring the hot, wet environment in an autoclave if the TC lead wires are enclosed in a water-and-steam-impervious tubing or sealed with urethane extending from the measuring junction to outside of the autoclave. The success of these control measures suggests that it may be the water at high temperature acting on or with the polymeric insulation, or the electrochemical potential across the bare wires that causes stray EMFs and the resulting error.

Another causative agent may be moving water (not just the presence of moisture on the wires). More temperature-error problems seem to exist in systems where the measuring TC junction is in a nonconducting package of product (glass or plastic container) that is heated in agitated water. These errors may be due to stray EMFs gen-

erated by the action of the water on the lead wire and the plastic insulation or on the container itself. Any stray EMFs will not normally be neutralized because these packages are nonconducting and thus isolated from the ground, unlike metal cans, which are conductors and an extension of the ground.

Some workers have believed that grounding the TC junction would drain off any stray EMFs generated. The errors in systems that have improperly grounded TCs are usually of the magnitude of one or two degrees, and the observed temperatures can be higher or lower than the true temperature. An indicated temperature of one or two degrees above or below the actual temperature is a major problem in sterilization processes because microbial kill is an exponential function of temperature. These are truly confounding errors because they are variable both in magnitude and occurrence. As mentioned above, some engineers have found that by grounding the TC junction the problem condition has been eliminated. Although this is a lot of work, it is worth the extra effort since unexplained TC temperature deviations are dramatically reduced.

As far as we know, no one has conclusively shown what happens to produce temperature errors when Teflon-coated TC wires pass through water at high temperatures. While some workers (Pflug, University of Minnesota; Robertson, Continental Can Co.) have grounded the TC junction in various ways to eliminate the errors, others have eliminated errors by sealing the entire TC wire (Berry, FDA) or encasing it in tubing (Kaye Instruments Co.; FitzGerald, Travenol Labs) to prevent contact with water. Both approaches are expensive and time-consuming, but they have achieved success in eliminating TC errors.

Any time we use nonprotected TC lead wires, such as Teflon over Teflon, we are never able to keep water completely away from the conductors themselves. We can take rather elaborate precautions to seal the TC junction inside plastic; however, if we are running a 20-ft TC lead wire inside an autoclave, the probability approaches zero of having no water leakage in any of 20 TCs being used in an experiment! Of course, when the TCs are new and first installed, the probability of leakage is lower than after they have been used in several tests. Nevertheless, we expect that the probability of no leakage, even with new TCs, is low and that after several experiments most of the TCs will have at least microscopic breaks which will allow water to penetrate to the wire. Apparently, when TC wires pass through water, the water has a smaller effect when the TC junction is grounded.

SUMMARY

We have shown that calibration of TCs at ambient temperature will not compensate for high-temperature water effects on TC wire and insulation and for errors that occur when there are temperature gradients across connectors. At the same time we emphasize that TCs and

the companion measuring system can measure temperature very accurately if the correct system is properly used. Pflug (15) listed 10 points that, when followed, help to lead to accurate measurement of temperatures using TCs. Those who use Teflon-covered TC wire in high-temperature, wet areas should, at the minimum, calibrate the TC with the vessel and all lead wire at the operating conditions of temperature and wetness. One way to do this is to put all the TCs together at one point and operate the autoclave through a normal process cycle.

In this report we have discussed some of the special problems that occur in measuring temperatures in autoclaves and retorts. A most important problem is errors caused by the effect of high-temperature water. Several different groups of workers who encountered temperature-measurement errors when using Teflon-coated leads in high-temperature water or in "wet" locations were required to take major action to reduce the errors. To obtain reliable readings, one group of workers enclosed the Teflon-covered TC wires in a tube, a second group sealed the TC wires with urethane, and a third group grounded the TC junction. We conclude that anyone who uses Teflon-coated TC wires for measuring temperature in containers in water without protecting them from the wet environment or without grounding has a high probability of significant errors in temperature measurement. These errors will occur on an intermittent basis and will be variable in magnitude.

The TC errors that occur at high temperatures in these wet locations are to a great extent unpredictable, and, as far as we know, the causes are not well understood.

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