# Dilemmas in the clinical investigation of clinical electrical thermometers concerning the measurement method

**Célio Fraga, Flávio Sant'Ana, Rodrigo Guilherme, Rafael Farias**[1]

[1] Sefiq/Dgtec/Dimel, Inmetro, Duque de Caxias, CEP:25250-020, Brasil

chfraga@inmetro.gov.br; fwsantana@inmetro.gov.br; rffarias@inmetro.gov.br; rfguilherme@inmetro.gov.br;

**Abstract**. The clinical electrical thermometer (CET) is a measuring instrument in the health area, with metrological technical regulation approved by Inmetro Ordinance No. 325 of July 28, 2021 (MTR No. 325/21). According to this regulation, there are two types of CET's, depending on the algorithm of the manufactured model: non-predicting (thermal equilibrium) and predicting (calculating), with three possible application sites on the body: axilla, mouth (sublingual) and rectum. The type approval applicants of almost all models submitted for type evaluation were declared non-predicting. Still, while evaluating some of these models, the clinical tests submitted corresponded with the predictive method. Additionally, the aggravating factor is that the results of these clinical tests did not comply with the regulation, as the indication varied by more than 0.2°C between the moment of the alarms and after 5 minutes in most measurements.

Nonetheless, since are analyzed the clinical tests in a preliminary phase, allowing for document correction, the applicants submitted other clinical tests in the required format for non-predicting. For this measuring method, variations in CET indication are not required after finishing measurement alarms by the regulation, assuming they do not occur due to the thermometer being non-predicting. Consequently, the evaluation process could proceed normally, even with technical doubts about the actual measurement method and the understanding that the operation was inconsistent with the declared method. For a better understanding, we reviewed the literature on the physics of thermometers and human body physiology, a documentary analysis of previously approved models, and the requirements of MTR No. 325/21 to seek possible explanations for these occurrences. As a result, the need for improvements in this regulation was identified, and some changes in the type of evaluation procedures have already been implemented.

## 1. Introduction

As per item 1.6 of MTR No. 325[1], the non-predicting CET is defined as "an instrument with a part or function that monitors, during the required period, the temperature measured by a temperature probe in contact with the body, after which it indicates and maintains the maximum temperature value for a specified time or until reset by the user." On the other hand, item 1.7 of MTR No. 325/21 defines the temperature-calculated CET as "a type of thermometer that calculates the maximum temperature of the temperature probe in contact with the body without waiting for thermal equilibrium, using heat transfer data and a mathematical algorithm, and maintains the calculated maximum value for a certain period or until reset by the user."

The healthcare measurement instruments usually recommend clinical studies to evaluate the clinical accuracy[2] of the instrument in humans since laboratory tests cannot reproduce all conditions of the human body. The ABNT NBR ISO 80601-2-56 standard[3], includes a methodology for clinical accuracy validation, but MTR No. 325/2021 follows the clinical test methodology described in Recommendation OIML R-115 of 1995[4]. Furthermore, for temperature-calculated CETs, item 4.3.1 of Annex A of MTR No. 325/21 states that "after indication, the thermometer must remain in place to measure and indicate the temperature of the probe," and item 4.3.2 of this annex adds, "the total time used must be sufficient to reach thermal equilibrium." It is worth noting that there is no similar item to 4.3.1 in item 3 of Annex A, which defines the non-predicting clinical test, determining that thermometers must remain in the application location after indicating.

During the evaluation of CET models, some inconsistencies in operation caught the attention of the technical area during the stages of documentation analysis and general examination:

1- Clinical tests sent by manufacturers, defined by them as non-predicting, were presented in the format required for the predicting method, and the results showed non-compliance with item 4.3.3 of Annex A of MTR No. 325/2021, which determines that "the difference between the predicting and the obtained non-predicting temperature for 95% of volunteers cannot be greater than 0.2°C."

2- CETs are defined by manufacturers as non-predicting exhibited behavior similar to predictive ones, varying the temperature indication after visual and audible alarms, with manuals instructing to keep them in the application location for thermal stability.

3- Lack of criteria from importers and manufacturers regarding the definition of the CET measurement method, evidenced by processes where the evaluation of the same model by different applicants declared different measurement methods.

The lack of understanding about the correct way to measure temperature with the CET on different body parts is observed in society, where there is a controversy between reading the CET immediately after alarms or after keeping it in the application location for at least 5 minutes[5]. This variation in indication after the CET triggers visual and audible alarms can confuse the user, and this non-compliance disagrees with item 3.1.5 of MTR No. 325/21.

## 2. Theoretical basis

For a better understanding of CET operation, aiming to comprehend the inconsistencies observed in the type evaluation processes and, initially, seeking a procedure capable of identifying the accurate measurement method of each model (non-predicting or predicting), it was conducted a literature review of the physical and physiological phenomena occurring in the thermometer and the human body, respectively. It also evaluated the documents of all approved CET processes, observing the measurement method indicated in the manuals and the results of clinical tests through the database of the process system.[6]

### *2.1. Thermodynamics*

Thermodynamics deals with phenomena associated with the concepts of temperature and heat. The nature of thermodynamics is very different from mechanics, applying to many particles. That is, it is always a macroscopic description, being described statistically. Historically, the laws of thermodynamics were obtained empirically, and only later, with the formulation of the kinetic theory of gases, was the microscopic explanation of the laws of thermodynamics sought.[7]

### *2.2. Thermal Equilibrium*

A thermodynamic system generally consists of a certain amount of matter contained within a container, where the nature of the container wall affects the interaction between the system and the external environment surrounding it. Perfect thermal insulation occurs when the container wall is adiabatic (for example, thermos or thick wooden wall), while a non-adiabatic wall is defined as diathermic (for example, thin metal wall). When a diathermic wall separates two systems, they are in thermal contact, while a system contained in an adiabatic wall container is in an isolated system. In an isolated system, no macroscopic variables change with time. It is said to be in thermal equilibrium. The Zeroth law of thermodynamics states that two systems in thermal equilibrium with a third are in thermal equilibrium with each other.[7]

### *2.3. Temperature and Thermometers*

A simple thermodynamic system consists of a homogeneous fluid inside a container. In thermal equilibrium, the laws of fluid statics apply, and the pressure exerted on the walls of the container is the same at any point in the fluid. A glass thermometer consists of a fluid (thermometric liquid) inside a container (glass tube). The state of this fluid in thermal equilibrium is entirely characterized by its pressure and volume. Changing one of these variables also changes the other when the system reaches a new thermal equilibrium. The different sets of points (P, V) in thermal equilibrium are represented by a continuous curve called the isotherm of the system.

The definition of the Celsius temperature scale was associated with choosing two fixed points corresponding to the thermal equilibrium of ice in water saturated with air at a pressure of 1 atmosphere (ice point) and the equilibrium of pure water vapor at 1 atm.[7]

### *2.4. Quantity of heat*

The quantity of heat can be defined as the energy required to change the temperature of a given volume or mass in a given period. The quantity of heat required to raise the temperature of 1 g of a substance by 1°C is called the specific heat.

$$\Delta Q = m.c.\Delta T \qquad (1)$$

Where “Q” is the quantity of heat, “m” is the substance mass, “c” is the specific heat, and “T” is the temperature. Thermal capacity “C” is defined as the product of the mass and the specific heat, like this:

$$\Delta Q = C.\Delta T \qquad (2)$$

According to this equation, a system of thermal capacity “C” undergoes a temperature change ΔT due to transferring a quantity of heat “ΔQ”. Increasing the mass sufficiently, “ΔT” becomes relatively small, which constitutes the so-called thermal reservoir. The ocean and the atmosphere are examples, and for practical purposes, any adequately sized container containing a fluid in thermal equilibrium can be considered a thermal reservoir. An example is the thermostatic water bath (TWB) we used in type evaluation tests and initial verifications of CETs.[7]

### *2.5. Heat transfer*

Heat transfer is dominant in practically all energy conservation and production devices. For personal computers, heat sinks are manufactured from materials with high thermal conductivity, and small fans are used to induce forced convection. Heat transfer is also essential in nature; temperature regulates and triggers biological responses and marks the boundary between disease and health. Two common examples are hypothermia, resulting from excessive cooling of the human body, and thermal shock, which is triggered in hot and humid environments. Both are lethal and are associated with body temperatures that exceed physiological limits and are directly linked to the processes of conduction, convection, and radiation occurring on the body surface, as well as heat and metabolic energy transport inside the body.[8]

Heat transfer from one point to another within a medium occurs through three different processes: convection, radiation, and conduction. Convection occurs in a fluid where heat is transferred by the fluid, constituting a convection current. These currents occur in a fluid heated by variations in density and consequent gravitational effect, but they can also be produced with pumps or fans. Radiation transfers heat from one point to another through electromagnetic radiation. Thermal radiation is emitted by a heated body and converted into heat in the absorbing body. Solar heating is an example of utilizing radiation to produce heat. Heat conduction can only occur through a material medium but, unlike convection, without movement of the medium itself. It can occur in both fluids and solids, driven by temperature differences.[7]

When placing a pot with water over a flame, heat is transmitted through the metal wall of the pot by conduction. This pot example illustrates all the fundamental laws of heat conduction. Heat always flows from a higher to a lower temperature (a). The amount of heat transported $\Delta Q$ in a time interval $\Delta t$ is proportional to the temperature difference $\Delta T$ (b), inversely proportional to the thickness of the bottom of the pot $\Delta x$ (c), proportional to the area A (bottom of the pot) through which heat is flowing (d), and proportional to the time interval $\Delta t$ (e).

Combining (b) and (c), it follows that $\Delta Q$ is proportional to $\Delta T/\Delta x$ (temperature gradient). Combining this result with (d) and (e), it can be seen that $\Delta Q$ is proportional to $A.\Delta t.(\Delta T/\Delta x)$. For heat conduction through an infinitesimal thickness dx of a medium during a time dt:[7]

$$dQ/dt = -k.A.dT/dx \qquad (3)$$

Where k is a constant characteristic of the conducting medium called the material's thermal conductivity. The minus sign (-) expresses that heat flows from higher to lower temperatures (a).

Equation 3 can be compared to Ohm's first law, where $i = dq/dt = V/R$, and Ohm's second law, $R = \sigma.A/l$, resulting in:

$$dq/dt = \sigma.A.V/l \qquad (4)$$

*2.6. Thermal systems and the equation of the thermometer in a thermostatic water bath (TWB)*

From equation 3, heat transfer by conduction or convection is defined as:

$$q = dQ/dt = K.\Delta T \qquad (5)$$

The conduction coefficient K (kcal/s °C) is given by:

$$K = k.A/\Delta x \qquad (6)$$

The thermal resistance R for heat transfer between two substances can be defined as:

$$R = d(\Delta T)/dq = 1/K \qquad (7)$$

The thermal capacitance C is defined in item 2.4 as thermal capacity.

Considering a system formed by a glass thermometer (thin glass wall), as shown in figure 1.

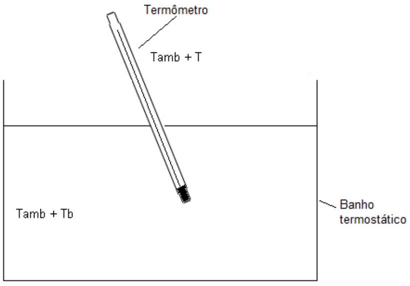


Figure 1 - Liquid-in-glass thermometer in a TWB

Assuming that the thermometer is at a uniform temperature Tamb (ambient temperature), and t = 0, it is immersed in a bath whose temperature is Tamb + Tb, where Tb is the bath temperature (which can be constant or variable), measured from the ambient temperature Tamb. It is defining the instantaneous thermometer temperature as Tamb + T so that T is the temperature variation of the thermometer satisfying the condition $T(0) = 0$. The mathematical model for this system can be deduced considering the thermal balance: the heat entering the thermometer during dt seconds is q dt, where q is the heat flux entering the thermometer. This heat is stored in the thermal capacitance C of the thermometer, thus raising the temperature by dT. Therefore, the heat balance equation is:[9]

$$C\, dT = q\, dt \qquad (8)$$

For heat transfer by conduction or convection, the heat flux "q" can be given in terms of the constant "K" (equation 5) and thermal resistance "R" (equation 7):

$$q = \Delta T/R = [(Tamb + Tb) - (Tamb + T)] / R = (Tb - T) / R \quad (9)$$

Thus, combining (8) and (9), we have C.dT/dt = (Tb - T)/R, or:

$$R.C.dT/dt + T = Tb \quad (10)$$

Equation 10 is a mathematical model of the thermometer system. By replacing "Tb" with "Vi" and "T" with "Vo", the electrical analog is obtained where "R" is the resistance of a resistor and "C" is the capacitance of a capacitor, as shown in figure 2. In this case, the first-order differential equation is given in the equation 11:[10]

$$R.C.dVo/dt + Vo = Vi \quad (11)$$

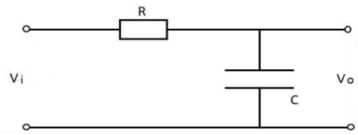


Figure 2 – RC electrical circuit

The solution to the first-order differential equation for the system with the thermometer in the TWB, from equation 10, is as follows:[9]

$$T = Tb.(1 - e^{-t/RC}) \quad (12)$$

The temperature in the thermometer varies exponentially, tending to equal the bath temperature "Tb". For an elapsed time corresponding to a time constant "τ" equal to RC, the value of the temperature "T" is equal to 63.2% of "Tb," whereas for t = 5τ, the value of "T" corresponds to 99.3% of the value of "Tb" (figure 3)

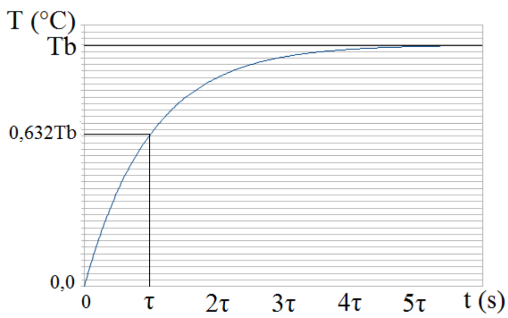


**Figure 3 –** Graph of the thermometer temperature as a function of time

2.7 *Body Temperature and Thermal Regulation*

The core body temperature (CBT) corresponds to the temperature of the body's deep tissues, remaining almost constant, with variations of ±0.6 ºC, even with exposure to ambient temperatures between 13 and 70 ºC, only varying beyond this in case of fever. Body temperature is controlled by the balance between heat production (metabolism) and heat loss (transfer from internal organs to the skin and from there to the environment).[11]

Heat is transferred from the skin to the environment through radiation, conduction, and evaporation. Heat transfer by radiation occurs under infrared waves and accounts for approximately 60% of heat loss. The body transfers heat by conduction to objects in contact, which corresponds to only 3% of the total, while the conduction of heat to the air represents a measurable portion of the organism's thermal loss (15%). Heat removal by convection occurs after heat is conducted from the skin to the air and then transported through air currents (22%).[11]

In dry air between 15.5 ºC and 54.5 ºC, the naked body can maintain the standard internal temperature between 36.6 and 37.6 ºC. The body's temperature control system functions similarly to a control system used in automation. The area of the anterior preoptic hypothalamus contains many neurons sensitive to heat and cold, which function as thermal sensors. These signals are transmitted to the posterior hypothalamus area, combined with signals from the body periphery to trigger reactions to control body temperature. When the skin is cooled, reflexes arise to increase temperature, such as shivering stimuli, inhibition of sweating, and cutaneous vasoconstriction to reduce heat transfer. When the body temperature is too hot, vasodilation, sweating, and decreased heat production occur through mechanisms such as inhibition of shivering and chemical thermogenesis.[11]

## 3. Experiments carried out with CETs in the laboratory and the results

Initially, several experiments were conducted to reproduce a procedure capable of identifying the method of measurement used by the CETs in the laboratory. This would evaluate whether the manufacturer's declaration was consistent with the model's functioning. The first idea was to use the equations defined in section 2.7 to relate the time constant of the CET in the TWB to its behavior when applied to the axilla. The results showed that, according to the theoretical model, the time constant changed depending on the value of "R", as "C" remains constant in this case. According to equations 6 and 7, the value of "R" only changes based on the probe's contact area "A" with the medium. In the bath, the CET's probe maintains a total contact area, but in the axilla, only a percentage of the probe is in contact with the skin. However, the results did not present uniformity among the tested models. At this point, we had not yet correlated the effects described in section 2.8, as we considered that the axilla behaved like the TWB, that is, with a stabilized temperature. In reality, during the heat transfer from the axilla to the CET, the axilla's temperature was not constant but also varied exponentially with the time constant of the body-to-axilla heat transfer, leading to a high standard deviation.

A second experimental idea to evaluate the CET's measurement method was to place them in a TWB with a variable temperature. Therefore, some CET models, declared as non-predicting types, with a measuring range of 32.0°C to 42.9°C, were tested. Since a TWB model with temperature ramp programming was not available, the procedure was carried out as follows: the models were first stabilized at room temperature, then inserted into the bath with an initial temperature of 32.5°C, and at that moment, the set point was changed to 42.4°C. It was observed that the models triggered the alarm before the bath reached the set point temperature, meaning that the CETs did not wait for the water temperature in the TWB to stabilize before indicating the measurement results through the visual and auditory alarms. However, this procedure was still unable to confirm the measurement method, as the early alarm could also be due to an inadequate thermal stability criterion in the algorithm.

Upon consulting the documentation of approved CET model processes6, it was noticed that almost all processes were declared as non-predicting types. However, they behaved similarly, continuing to vary the indication after the visual and auditory alarms were activated, similar to the behavior defined for predicting types. For the non-predicting types, the expected behavior would be to end the measurement, indicated by the visual and auditory alarms, and maintain the result for a sufficient time for the user to read it. It was also noticed that the instructions for measurement, in most manuals, were to turn on the CET, wait for the "Lo" indication (temperature below the measurement range) on the display, and then immediately insert it into the axilla, pressing the forearm against the body to ensure better contact of the thermometer.

By observing in more detail manuals, manufacturers informed the criteria used in their algorithms to determine the measurement result: to obtain a temperature variation less than 0.1°C within a 16-second time interval. As seen in section 2.7, as the skin constantly interacts with the environment, losing and gaining heat, some time is required to transfer heat from the body's internal organs to the axilla. A few manuals mentioned a "preheating" procedure for the axilla, keeping the forearm in contact with the body for at least 5 minutes before inserting the CET. However, conducting tests in the laboratory, even with this method, did not achieve an appropriate closeness between the indicated value when the CET triggers the alarms and the value after waiting for 5 minutes in the axilla. This fact is likely due to the "cooling" of the axilla when the arm is slightly raised to insert the CET.

In conclusion, as the part of the body is not in thermal equilibrium with the body's core temperature, the laboratory tests using a TWB with stable temperature do not simulate the actual measurement situation, where the temperature is still varying due to the mechanisms of heat transfer from the CBT to the measurement site. In these cases, it is observed that the temperature indicated after the alarms is lower than the temperature indicated after keeping the thermometer in the measurement site, with differences reaching the order of one degree Celsius when waiting for at least 5 minutes in the axilla. This non-compliance is anticipated in item 3.1.5 of the Metrological Technical Regulation (MTR), which determines that "alarms integrated into the instrument should not confuse the user".

## 4. Developments in CET-type evaluations after results

In order to promptly comply with item 3.1.5 of the MTR No. 325/21 for all CETs, it started requesting better clarification regarding the measurement procedures described in the user manuals for measurements in the armpit, which is understood to be the body part most commonly used by users. Additionally, tests were included in the armpit during the overall examination of the models to check if the model varies its reading when kept in the armpit for 1 minute after the alarms are triggered.

After reviewing the proposed procedures, the first models submitted for evaluation declared as thermal stability types did not comply because the usage guidelines for measurement provided in the manual were not in line with item 3.1.5 of the MTR No. 325/21. Some applicants chose to alter the measurement method to the predicting approach to maintain consistency with the current models' measurement method. However, in this case, the clinical test must record the indication at the moment of the alarms and after thermal stability. As a result, variations more significant than 0.2°C occurred in many cases, even after waiting for only 1 minute after the alarms since item A.4.4 allows this approach when the applicants themselves perform the clinical test.

A measurement procedure proposed by one of the applicants appeared to be the most appropriate for the currently manufactured models declared as non-predicting types: inserting the CET into the armpit while still turned off and keeping it there for 5 minutes before turning it on to ensure thermal equilibrium between the CET and the armpit concerning the body's core temperature when it is activated. This method is similar to the one used in liquid-in-glass thermometers, which seems coherent, as the time required for heat transfer from the body to the thermometer is the same regardless of the type of thermometer, and the stability criterion used by the CET manufacturers is inadequate. In this case, the measurement time was reduced to approximately 20 seconds, and temperature variations higher than 0.2°C were not recorded when the thermometer was kept at the measurement site after the alarms were triggered.

## 5. Conclusion

The thermal equilibrium criterion defined in the non-predicting CET algorithm by the manufacturers is inadequate for indicating the temperature related to the body's core temperature, as the CET and armpit are not yet in thermal equilibrium with the CBT at the time of measurement.

Manufacturers must conduct studies to adapt the CET algorithms to the measurement procedure proposed in their manuals so that users do not remain uncertain about the most appropriate temperature indication that best represents the body's core temperature.

It is also evident that even the models declared as predicting are incapable of predicting the result, meaning anticipating the expected measurement result after the CET is in thermal stability with the measurement site. They use the same stability criterion where a short time frame (e.g. 16 seconds), for variations less than or equal to 0.1°C, proves insufficient for body measurements.

As a result of this study, it began to demand that the manuals provide information on the need for "preheating" the armpit and conducting tests on the actual armpit in the overall examination. If a CET declared as a non-predicting type shows variations in indication after the alarms, it is suggested that new documentation be submitted declaring the model as predicting CET. Furthermore, the ISO is currently developing a specific standard for clinical accuracy validation of CETs, which can be used to improve metrological control in Brazil.

Concerning the types already approved, Inmetro's legal metrology must also assess the relevance of preparing a booklet, or alert, for society, informing that, regardless of the audible and visual alarms, a minimum time of 5 minutes of contact with the CET in the armpit must be awaited to read the indicated value.

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