

Temperature Assessment via the Temporal Artery: Validation of a New Method

Arterial Heat Balance Thermometry at an Exposed Skin Site: Accuracy, Comfort, and Convenience for Patient and Clinician

Abstract:

There has in the past been no method of thermometry that is considered by patients and clinicians to be comfortable, convenient, and accurate. Rectal, oral, axilla, and ear thermometry all have either significant discomfort due to the use of a body cavity, artifactual inaccuracies due to physiological/device phenomena, or both, thus making them less than desirable for the needs of both patient and clinician. The exposed skin eliminates the use of a body cavity, but an accurate method using the skin has heretofore not been demonstrated.

The superficial temporal artery demonstrates the necessary requirements for the skin thermometry method: it is easily accessible, contains no mucous membranes, and notably, it has no or very few arteriovenous anastomoses (AVA).^{1,2} Lack of AVA's means that perfusion rate is reliable under essentially all conditions, and the blood flow is relatively free of vasomotor control in response to thermoregulatory stimuli. This property is unique to the temporal artery when considering all accessible cutaneous blood vessels. The high and reliable perfusion allows accurate mathematical computations of the heat lost to the environment due to the cutaneous flow, and thus an accurate calculation of the source arterial temperature at the heart.

As a site for temperature measurement, the temporal artery presents many benefits: it poses no risk of injury for patient or clinician, eliminates any need for disrobing or unbundling, and is suitable for all ages.

Accordingly, Exergen, incorporating a patented and well-proven arterial heat balance method, developed instrumentation for non-invasive arterial temperature assessment on the skin over temporal artery. This report presents a validation of accuracy of the arterial heat balance method and of three new infrared devices, one a professional model for clinical use, one a consumer model for home use, and the other a professional model for use in neonatal intensive care.

This educational compendium has been prepared to provide you with immediate information regarding the science and technology behind a new method for noninvasive arterial temperature assessment. We are pleased to introduce this new method for your consideration and provide you with this educational material to help you in your assessment.

As it can take several years for peer reviewed studies to be published, we have chosen to present our validation of the method for your immediate consideration, for use with your patients, and so you may provide them with your considered opinion for their own thermometry needs at home.

The studies included herein are but a few examples of the comprehensive work conducted in the method over the last two decades by the scientists and clinicians of Exergen Corporation. These sample studies were conducted both by clinicians employed by the manufacturer, and independently by clinicians under the employ of the investigating hospitals.

Formal independent studies for peer review publications are currently being conducted in premier university hospitals in the United States, Canada, and Europe.

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RESULTS SUMMARY

1. Professional and consumer model temperature measurements at the temporal artery area are interchangeable (Figure 7).
2. Left temporal artery area readings vs. right temporal artery area readings are interchangeable for both the professional and consumer models (Figures 18 and 19).
3. Both professional and consumer model measurements on the skin surface over the temporal artery are interchangeable with reference arterial/oral temperatures measured via Arterial Heat Balance at the Ear (Figures 6 and 7).
4. Reproducibility of measurements for both the professional and consumer models supports interchangeability of readings between the devices (Figures 17, 18, 19).
5. Temperature measurement on the skin surface over the temporal artery is as reliable as rectal temperature measurement in detecting fevers in infants <one year old (Figure 9) and in infants and children <three years old (Figure 10).
6. Thermodynamically, temporal artery area temperature leads rectal temperature (Figures 11, 12, 13).
7. Temporal artery area temperature measurement is interchangeable with axilla and skin probe temperature measurement in neonatal intensive care units (Tables 1, 2, 3 and 4).
8. Temporal artery area temperature measurement is suitable for newborns through geriatrics (data includes patients from a few hours to 90 years old).
9. Temporal artery area temperature measurement is interchangeable with temperature measured by pulmonary artery catheters (Figure 8).
10. Temporal artery area temperature measurement is reliable for all levels of nursing skills (Figures 14, 15, 16).

Introduction

The Requirement for Improved Thermometry

Inferior thermometry increases the risk of morbidity and mortality, and increases costs. A new, superior class of thermometry has been shown to improve outcomes and reduce costs by non-invasively measuring arterial blood temperature with a degree of clinical accuracy unachievable with currently available thermometry.

Mortality from infections is increasing, requiring improved thermometry

According to a recent study from the Centers of Disease Control, mortality from septicemia has increased 83%, from infectious disease it has increased 58%, and from respiratory tract infections, the increase is 20%.³ Nosocomial (hospital-acquired) infections, largely preventable, are responsible for more than 20,000 deaths and an additional cost of \$5-\$10 billion annually.⁴ Given that fever is the first indicator of infection, early fever detection allows early intervention, resulting in significantly improved patient outcomes. An estimated 50,000 deaths per year, a number rivaling those of colon cancer, are the result of 60,000,000 bad temperatures.^{5,6} And, like deaths from nosocomial infections and colon cancer, bad temperatures are also largely preventable.

A new method based on heat transport via the circulation

The conventional core and shell descriptions of temperature distribution in human thermoregulation are not of adequate utility for conditions of metabolic or environmental thermal stress, since *core* temperatures may be 5°C (10°F) different at different sites in the same individual at the same time, and may provide conflicting indications to clinicians. A novel and surprisingly simple model was developed and shown to correctly predict observed dynamics of temperature distribution in surgery and sports medicine, examples where the conventional model fails. The governing equations are based on an original method of modeling heat transport via the circulation.⁷

Accordingly, a method of non-invasive arterial temperature assessment was developed⁸, incorporating a patented arterial heat balance (AHB) method derived from the governing equations, to measure arterial temperature at the ear applying infrared technology. For nearly a decade, the method has withstood stringent clinical investigation at multi-site academic medical centers, and during that time has been selected by many premier institutions for their hospital-wide use. Of significance, particularly with patient outcome as a benchmark, this method prevailed in all cases. It was demonstrated accurate in comparison against all invasive and non-invasive methods of temperature assessment, effectively countering the expectations of many clinicians regarding ear thermometry.

Temporal Artery: A new and potentially superior site

Recently, the temporal artery and surrounding tissue was investigated as a new, potentially more suitable site than the ear and other commonly accepted sites for temperature measurement. Physicians in particular recognize the efficacy the strong perfusion the temporal artery presents relative to temperature measurement, which is a critical attribute in terms of the measurement. For despite lying so close to the skin surface, the temporal artery perfusion, the flow of blood per unit volume of tissue, remains relatively constant, and so ensures the stability of blood flow required for the arterial heat balance method. As a temperature measurement site, the temporal artery promises many benefits not available with any other method of temperature assessment: it is readily accessible, poses no risk of injury for patient or clinician, contains no mucous membranes, would eliminate any need for disrobing or unbundling, and seemingly could become a standard temperature measurement site free from any age limitations.

Purpose of Report

The purpose of this report is three-fold:

- 1) To provide the reader a fundamental base of knowledge in the AHB method of thermometry such that further investigation or replication of the results presented may be independently accomplished on their own.
- 2) To present the validation for the accuracy claimed for three new infrared thermometers, all employing the same AHB method using the skin surface over the temporal artery as a primary site of measurement; one a professional model for clinical use, one a consumer model for home use, and the other a professional model for use in neonatal intensive care.
- 3) To present the resultant outcomes herein illustrated as validation of the arterial heat balance method of temperature measurement as a superior method of thermometry.

Method of Comparison

In order to assess a new clinical method for temperature measurement, especially since absolute values are not known because their determination would present an unwarranted risk, it is important that the new method be assessed in comparison with an established one.⁹ The two must agree sufficiently for the new to replace the old, specifically because long standing protocol for patient diagnosis and treatment is based on the established method.

Accordingly, presented in this report are comparisons upon which to assess such interchangeability, basing the comparisons on historically accepted clinical standards of temperature measurement, against both invasive and non-invasive procedures, as they relate to a well-proven method of non-invasive arterial temperature assessment at the ear, then subsequently establishing the accuracy of the measurement in the temporal artery area.

Section 2

“Don’t tell me about the labor pains, show me the baby.”
Jeanne Robertson

Validating the Accuracy of the Arterial Heat Balance Method

Introduction to the Method

Non-invasive arterial temperature assessment, contradistinctive from any other method, was introduced several years ago.¹⁰ The method originally employed only the ear, and as such, shares some similarity with tympanic thermometry. **Therefore, it is important to note that this method is not tympanic thermometry.**

The ultimate objective of using a thermometer is to accurately measure core body temperature, long recognized in medicine as an important vital sign, a key determinant of an individual’s state of health. Arguably, the best example of true core body temperature would be the temperature measured in the center of the heart. But since that would not be a measurement made without risk of injury, it would not ever be of consideration here. That said, the objective then becomes reproducing the same temperature found in the center of the heart, by a safe, gentle, simple and instantaneous means.

In this section, the focus is on validating the accuracy of the arterial heat balance method, and since the ear was the site selected for measurement, and considered optimum at the time, the following is a brief overview of arterial temperature measurement at the ear.

The arterial temperature measurement at the ear employs both patented scanning and computational procedures to produce arterial temperature, which has been demonstrated to be interchangeable with that measured concurrently by a pulmonary artery catheter (PAC). This is accomplished in part by synchronizing the temperature of the ear and ambient temperature, as ambient temperature can significantly influence the temperature of the ear.

The temperature at the outer portion of the ear canal results from the thermal energy balance between tissue warming by arterial blood and tissue cooling or warming as a result of environmental temperature. By measuring both ear and ambient temperatures, the arterial temperature necessary to maintain the ear temperature subject to the effect of the environment can be determined. The calculated heat loss or gain, the difference between the ear and ambient temperatures, is then added back to the highest temperature measured during the scan of the tissue at the outer portion of the ear canal.

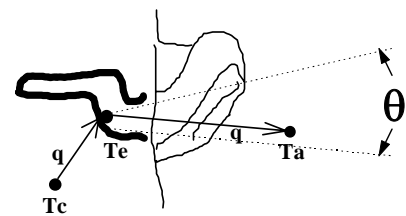


Figure 1 Thermal energy q supplied via arterial blood at temperature T_c to the ear tissue at temperature T_e is balanced by radiation loss through angle θ to ambient temperature at T_a .

Comparisons to Invasive Methods of Temperature Assessment

In the following comparisons, data were analyzed according to the recommended statistical method of Bland and Altman¹¹ for assessing agreement between two methods of clinical measurement where direct measurement without adverse effects is difficult or impossible. As the true values of the measurements are not known, indirect methods are used instead, and a new method has to be evaluated by comparison with an established technique rather than with the true quantity. If the new method agrees sufficiently well with the old, the old may be replaced.

The Gold Standards and the Arterial Heat Balance Method: Historically, pulmonary artery temperature, an invasive method, and rectal temperature as a somewhat less invasive method, have been accepted in clinical medicine as standards for temperature assessment. For the new method of arterial heat balance to be accepted, it must first be demonstrated interchangeable with

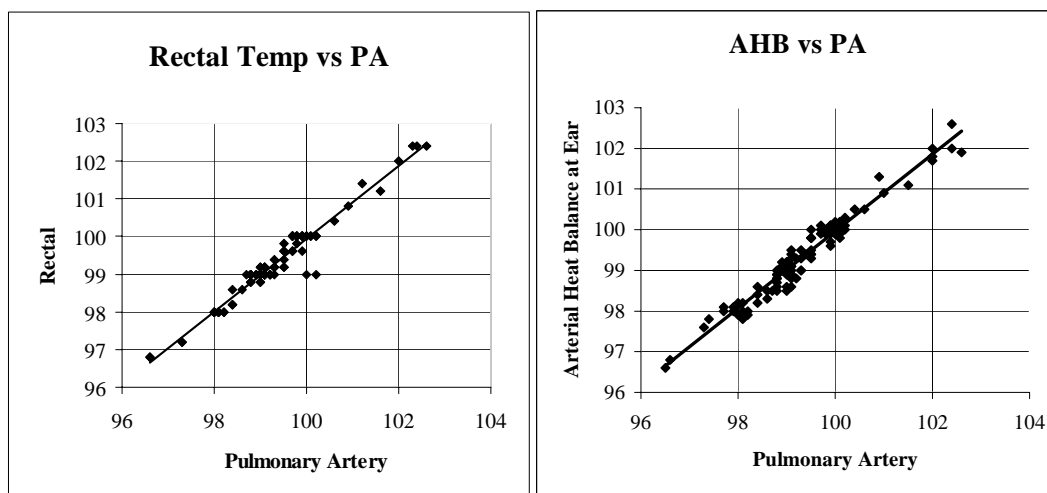


Figure 2 Comparison of Pulmonary Artery Temperature to Arterial Heat Balance at the Ear and Rectal Temperatures

the old methods.

Figure 2 is a comparison of three methods of temperature measurement, pulmonary artery, rectal and arterial temperature in the AHB method at the ear. Staff nurses simultaneously took temperatures on more than a hundred patients in the critical care unit of a large teaching hospital. The mean of the paired differences between pulmonary artery temperature and the arterial heat balance (AHB) method was 0.00°C, and the mean of the paired differences between PA and rectal temperature is -0.02°C. Standard deviation of the paired differences between pulmonary artery and AHB temperature is 0.12°C, and 0.12°C between PA and rectal. Because of the strong agreement, the Pearson correlation coefficient can be presented as meaningful, and is 0.98 for AHB, and 0.98 for rectal. The data demonstrate such strong agreement, the three methods can be considered interchangeable.

Figure 3 illustrates a comparison between esophageal temperature measurement, considered a deep core temperature normally within 0.1°C (0.2°F) of pulmonary artery temperature, and arterial temperature measured at the ear. This study was undertaken on six healthy volunteers undergoing induced temperature variations. Esophageal temperature was measured via thermistor catheters inserted into the esophagus and positioned proximal to the heart. Hospital personnel measured arterial temperature at the ear with an infrared device using the arterial heat balance method with a mean difference of -0.11°C , and a standard deviation of the differences of 0.31°C , demonstrating a very strong agreement between the two methods. Hence the Pearson correlation coefficient of 0.97 can be presented as meaningful.

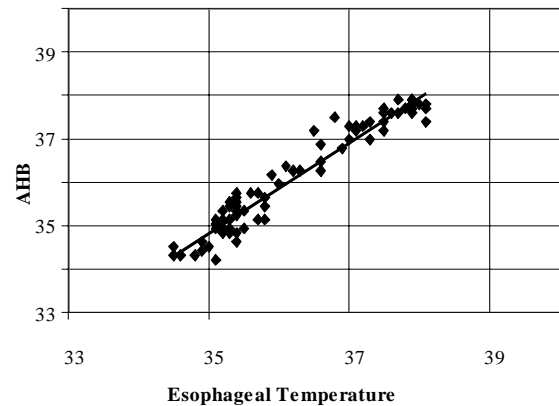


Figure 3 Comparison between esophageal temperature and Arterial Heat Balance at the ear

Comparisons to Non-Invasive Methods of Temperature Assessment

Commonly Accepted Methods and AHB: The non-invasive arterial temperature assessment method has also been demonstrated accurate against other less invasive, but also less accurate methods than the above-mentioned invasive methods. These include oral, axillary, and rectal temperatures using electronic, glass mercury and chemical strip thermometry, which were in routine use at these hospitals.¹² Hospital personnel, in accordance with the standard operating procedure for the particular thermometry being used, took all the temperature measurements.

Figure 4 illustrates a comparison between two methods, AHB at the ear, calibrated as an oral equivalent, and glass mercury thermometers used to take temperatures sublingually on eighty-two patients. The Pearson correlation coefficient, r -value = 0.90, the mean difference = 0.09°C , standard deviation of the difference = 0.39°C , all demonstrating strong agreement between the methods.

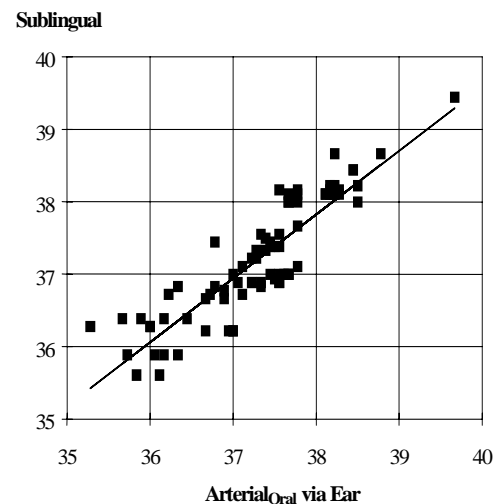


Figure 4 Comparison of temperatures, AHB at the ear Vs sublingual glass mercury thermometers.

It should be noted here that oral temperatures are known to be influenced by patient activity such as mouth breathing, eating, drinking, snoring, or talking,¹³ and therefore there is a little more scatter than with invasive methods. However, a Pearson correlation coefficient of 0.90 clearly demonstrates strong agreement between the two methods.

The Tie Breakers: In any of the cases where the temperatures using the AHB method in comparison to any other method differed by more than the expected limits of tolerance between devices,¹⁴ vital signs were always assessed, both retrospectively and prospectively, with the final verification being against patient outcome, the fundamental standard of importance.

The Prevailer: Of significance, the non-invasive arterial temperature assessment method prevailed in all cases, effectively countering the expectations of many clinicians regarding ear thermometry. By way of explanation of the clinical expectations, ear thermometry, in general, has failed to live up to original promises; most manufacturers are unable to maintain the accuracy of the products that is required for acutely ill patients,¹⁵ resulting in frequent failure to detect fever, the *raison-d'être* of any clinical thermometer. Over the past several years, there has been a profusion of journal articles on the subject of ear thermometers, notably their missed fevers, and their unacceptable sensitivity and specificity.^{16,17,18,19,20,21,22,23,24,25,26,27,28,29} And, whether review of the literature or personal experience is the origin, there are many clinicians that consider them inaccurate, preferring instead the old methods of oral, axillary and rectal thermometry.

Consumers are demanding non-invasive methods of treatment

We are currently in a time when consumers are expressing an unprecedented interest in decisions related to their health. Interestingly, the return of many clinicians to the old methods of thermometry is in direct opposition to the strong consumer demand for clinical non-invasiveness. At the same time, the popular press, as well as the peer reviewed journals are citing an alarming increase in nosocomial infections, a significant percentage of which are directly attributable to oral and rectal thermometers,^{30,31,32,33} and the same media are reporting a notable rise in antibiotic-resistant infections, especially among children.

In concordance with these market forces, Exergen undertook an extensive qualification of an even less invasive, more accessible site for temperature measurement than the ear, and one that would prove suitable for all ages. The skin over the temporal artery was the site to demonstrate the necessary requirements for the measurement, and new instrumentation was developed by Exergen to accurately measure its temperature in the arterial heat balance method.

Temporal Artery Temperature Assessment

The Temporal Artery as a Temperature Site

There are many places on the body routinely used to take temperature such as the mouth, ear, axilla, and rectum. But considering the objectives of safety, gentleness, ease and speed, the best place is actually none of these places. Consider for a moment, the temporal artery.

The objective is to reproduce the temperature found at the center of the heart. Simplistically, blood flows directly from the heart through the arteries. To replicate the source temperature, the requirement would be an artery as short a distance from the heart as possible, with a high and relatively constant blood flow, and one that is readily accessible on all individuals. In terms of accessibility, an artery such as the radial quickly comes to mind, but an artery at the extremities of the body, such as those felt as pulse points at the wrist or ankle, are highly subject to vasomotor activity. Vasoconstriction, for example, could cause a significant temperature drop at the skin surface, and although only a local artifact, the resultant temperature would not be representative of core temperature.

Given that the heart, the lungs and the brain are vital to our very existence, not surprisingly, they receive preferential treatment, especially from the circulation. The supply of blood is high to these vital organs, and continues as high as possible even though, in the face of grave illness, other areas may shut down to accommodate the additional blood flow required at the heart, lungs and brain. This now becomes the area of interest, and best understood with a short primer on anatomy.

Originating in the heart is the aorta, the main trunk of the arterial system. A direct extension of the aorta is the common carotid artery, a robust artery that runs upward in the neck and divides into the internal and external carotids. But, the carotids, even the external carotid, are at best partially embedded, and at worst completely embedded in the skull, and therefore are not accessible at the skin. Extending directly from the carotid is the temporal artery, again an artery dividing internally and externally. The focus becomes the external branch, which travels in front of the ear, and up into the soft temple area, terminating in a fork directly between the skin and the skull, adjacent to and slightly above the eyebrow.

The temporal artery area is a site with a long history of temperature measurement, actually dating back to the early centuries before Christ, and the first recorded references to palpation of the head for assessment of fever. Demonstrably, the temporal artery is easily accessible, and usually quite visible. There are no mucous membranes present; eliminating the risk of contamination, and despite lying so close to the skin surface, it presents no risk of injury from being touched. Since the temporal artery is not an anastomosing vessel, a vessel that establishes a connection between arteries, between veins, or

between lymph vessels, the perfusion remains relatively constant, thus ensuring the stability of blood flow required for the measurement method.

The Instrumentation

Infrared thermometry has compelling advantages over traditional methods of thermometry, including extraordinary speed, safety, comfort, lower cost, and potentially greater accuracy. With these advantages, the infrared system with the skin surface over the temporal artery as the measurement site has the potential to become the preferred method for clinicians as they become more familiar with and confident of its efficacy.

The issue of accuracy is of most importance. The combined accuracy of the method and particular device employed must at least equal the accuracy of conventional methods and devices. Clinically, 38.0°C (100.4°F) and 38.6°C (101.5°F) are used as fever thresholds, cutoff points for initiation of palliative treatment or investigational workup. Ideally, a thermometer will detect all temperatures elevated above the designated cutoff point in cases that are positively confirmed (sensitivity), and correctly confirm negative cases by identifying all temperatures that fall below the cutoff range (specificity).

The accuracy of an infrared thermometer can be specified with great precision when tested with a device known as a blackbody. A blackbody is a specially configured cavity, which emits a precise quantity of radiation corresponding to its temperature. It is called a blackbody because the cavity reflects nothing and indeed looks black.

An accurate infrared thermometer will produce a temperature indication matching the blackbody temperature to within a small tolerance, i.e. 0.1°C (0.2°F), over a specified range of blackbody temperatures and ambient temperatures. However, and important to note, it does not follow that just because an infrared thermometer is accurate in a blackbody that it will be accurate on the target of interest, in this case, the temporal artery area.

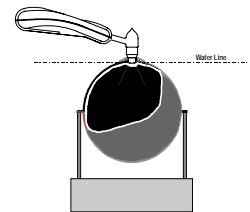
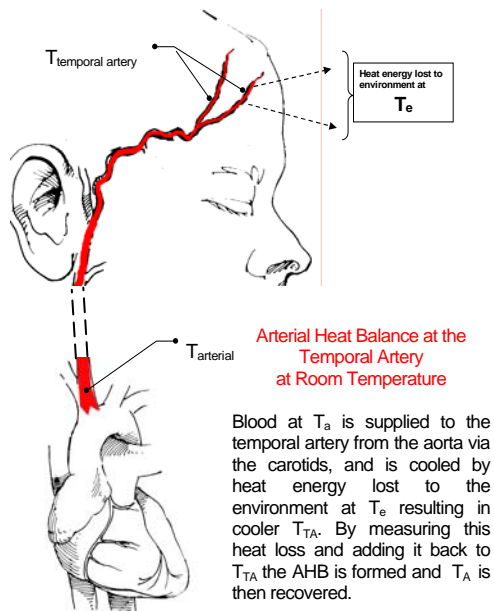


Figure 5 Certified Blackbody submerged in laboratory

The Temporal Artery and the Arterial Heat Balance Method

The absolute temperature at the outer surface of the head over the temporal artery is not the same as the arterial temperature of interest. In order for the outer surface to be at the same temperature as the temporal artery, there could be absolutely no heat loss to the environment, requiring the individual to be in an environment the same temperature as the arterial blood in the aorta. The thermal loss would then be zero, and the skin surface over the temporal artery area would be at the same temperature as the arterial blood in the aorta. But in normal ambient temperatures of about 21°C (70°F), there is a difference of nearly 17°C (30°F) between arterial temperature and ambient. Consequently, in normal ambient temperatures, there is a cooling effect at the skin surface from the radiated heat loss to the environment. If absolute temperature of the surface were to be measured in that environment, variability errors of more than 3°C (5°F) could be present.

In solution of the thermodynamics presented here, the AHB infrared thermometer accounts for the radiated heat loss by measuring ambient temperature at the same time it is measuring the absolute



temperature of the skin surface over the temporal artery. It then can compute arterial temperature by restoring the measured heat loss to the absolute peak surface temperature measurement. During each sequence, the instrument measures the two temperatures, skin and ambient, 2000 times per second. It also solves the heat balance equation multiple times per second, selects the highest of the readings and discards all others. The final temperature displayed is the solution to the algorithm, which gives the maximum reading during a particular episode.

The resultant temperature read by the instrument is arterial, free from any statistical corrections. Arterial temperature is approximately 0.4°C (0.8°F) higher than an oral temperature, close to rectal temperature, which in turn is approximately 0.5°C (1.0°F) higher than oral temperature. To allow continuation of either an oral or

rectal standard for fever reference in clinical practice, k-Factors, based on extensive published and unpublished clinical data, are programmed into the AHB instruments, the exact factor being variable depending on the site chosen for reference protocols. The calibration is not user accessible, in order to prevent accidental or unauthorized change.

Validation of Temperature Assessment at the Temporal Artery

Purpose of Validation Investigation: The purpose of this investigation was to compare two new infrared thermometers, one a professional model and one a consumer model, both of which were designed to measure human body temperature at the skin surface over the temporal artery, incorporating the aforementioned AHB method. Since the instrumentation is predicated on the much proven ear thermometers, also in the AHB method, the accuracy was expected to be the same as it related to the AHB at the ear and all other cited methods of thermometry, both invasive and non-invasive.

Timeframe and Subjects: The data as presented in this section were taken over the period from April through August 1998 at four major academic teaching hospitals in the Boston and New York City areas. It is important to note that this aspect of the report represents but a partial compilation of results from more than six years of clinical research on the temporal artery as a temperature measurement site, and nearly three thousand subjects, including premature neonates weighing less than 500 grams (1 pound), morbidly obese adults, and fragile geriatric patients. Data collection took place in multisite academic teaching hospitals. The patients represented were randomly selected from intensive care units, emergency departments, ambulatory clinics, and medical/surgical nursing floors.

Also included in the research were performing athletes in competitive events, necessary in order to validate the method under those conditions when the body is intentionally stressed to physical extremes. Normal volunteers, assumed to be healthy, were also included, whose temperature was measured under varying conditions as they went about their daily activities, in varying ambient temperatures.

Equipment: The equipment used to measure temperature at the skin surface over the temporal artery consisted of investigational devices prepared by the manufacturer for such a purpose, and included both professional and consumer models. These were microprocessor based infrared instruments incorporating the patented AHB method, and designed to measure human body temperature at the on the skin surface over the temporal artery. In functionality, the models were identical. Most of the electronics, microprocessor and components are common to both models, as is the calibration. In terms of differences, the professional model is significantly more robust in design having to survive the stringent requirements of the clinical environment.

Standards for Comparison: The standards for comparison of the temporal artery thermometers included the temperature measurements of pulmonary artery catheters, and oral and rectal temperatures using glass mercury and electronic thermometers, all of which were in routine use at the hospitals during the time of data gathering, and which were assumed to be calibrated in accordance with standard hospital policy and procedures. Also included as a standard of comparison were infrared ear thermometers incorporating the AHB method, both standard and pediatric models, and which were in daily use for patient temperature assessment at the site hospitals. Where these infrared thermometers were standard equipment for the hospital, the calibration was assumed verified according to the policy and procedure routine for that hospital. When brought to the hospital by the investigators, calibration was verified both before and after all field measurements using certified laboratory black bodies incorporating laboratory thermometers certified traceable to the standards of the National Institute for Standards and Testing (NIST).

Investigators: Three clinical professionals employed by the manufacturer, and with the permission of responsible hospital clinicians, obtained readings with the non-invasive investigational instruments. Patient temperatures were taken under routine conditions according to the protocol standard for each hospital, and compared to the method currently in use at the time by that hospital.

Comparison to Other Non-Invasive Methods of Temperature Assessment

Since the accuracy of the arterial heat balance method has previously been validated against both invasive and non-invasive methods, it can now be presented as a reference standard in the following validation against which to compare the professional and consumer models of the infrared arterial heat balance temporal artery thermometers.

Comparison of Two Professional AHB Devices: At the Ear and Temporal Artery

Figure 6 illustrates a comparison between two professional devices using the arterial heat balance method, one measuring temperature at the ear, the other at the temporal artery area. The study included forty patients, with a range of ages from two weeks through ninety years old, selected randomly from intensive care units and medical/surgical nursing floors in large acute care academic medical centers. Data demonstrate very strong agreement with a mean difference of 0.10, and standard deviation of the differences of 0.37. The Pearson correlation coefficient was 0.94, and presented in light of the strong agreement. The data support interchangeability between the two devices.

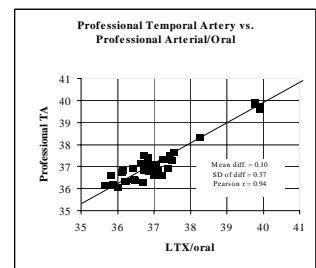


Figure 6 Comparison between two infrared thermometers, with AHB, both professional models, one measuring temperature at the ear, the other at the temporal artery.

Comparison of Two AHB Devices: Consumer at the TA and Professional at the Ear

Figure 7 illustrates a comparison between two devices both in the heat balance method, one a professional model measuring temperature at the ear, and the other a consumer model for measuring temperature at the temporal artery.

The data in Figure 7 represent the same forty patients in Figure 6, and also illustrate strong agreement between the two devices such that they could be considered interchangeable. Pearson correlation coefficient = 0.94, a mean difference of 0.07, and standard deviation of the differences of 0.35.

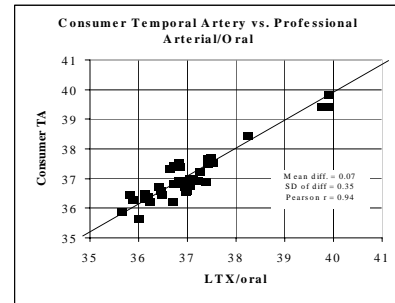


Figure 7 Comparison between two infrared thermometers incorporating AHB, one a professional model measuring temperature at the ear, the other a consumer model measuring temperature at the temporal artery.

Comparison to Invasive Methods of Temperature Assessment

Comparison of Temperatures Measured by a Noninvasive Infrared AHB Thermometer at the Temporal Artery Area and an Invasive Indwelling Pulmonary Artery Catheter

A pulmonary artery catheter (PAC) is a thin flexible tube-like device that can be passed into the heart through a vein or artery to withdraw samples of blood, measure pressures within the heart's chambers or great vessels, and inject contrast media; used mainly in the diagnosis and evaluation of congenital, rheumatic, and coronary artery lesions and to evaluate systolic and diastolic cardiac function. A PAC is also routinely used to monitor arterial temperature, but since temperature is not the primary function of the PAC, errors in temperature readings may well go unnoticed. This factor is especially important when evaluating a new thermometry method.

Normal error tolerance for a PAC is $\pm 0.3^{\circ}\text{C}$ ($\pm 0.54^{\circ}\text{F}$).³⁴ Greater inaccuracies may be from indwelling times $>48\text{h}$ due to the possibility of fibrin build-up on the catheter, the temperature of the solution used in cardiac output, calibration, etc. These may not be obvious to the clinicians since the primary purpose of a PAC is thermodilution cardiac output calculation. Accordingly, a 1°C error at normal arterial temperature may result in a cardiac output calculation error and go unnoticed. Interestingly, the AHB infrared thermometer can actually be used to verify the accuracy of an indwelling PAC.

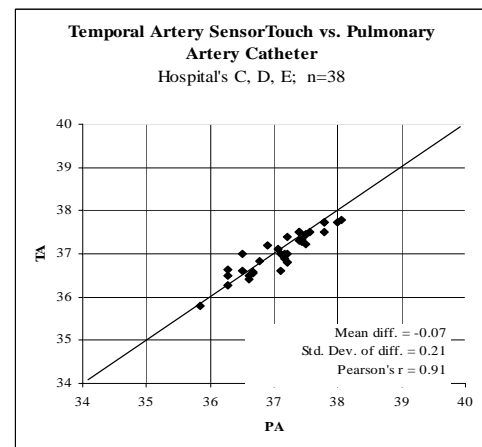


Figure 8 illustrates the results of a prospective, observational, multicenter study with data collected in the intensive care units of three teaching

Figure 8 TA vs. PAC Temperatures of 38 adult patients. Mean difference = -0.07, SD of the differences = 0.21, Pearsons correlation coefficient = 0.91.

hospitals. In a convenience sample of 38 adult patients with a PAC <48 hours post insertion, body temperatures were measured by a TA infrared scanning thermometer in the AHB method and concurrently compared to those measured by a PAC.

Data demonstrate very strong agreement between the two methods; mean difference = -0.07, standard deviation of the differences = 0.21, and Pearson's correlation coefficient = 0.91. The data on what is arguably the most invasive method of thermometry vs. the least invasive method certainly support interchangeability between the two methods, and the temporal artery method eliminates any risk to the patient.

Comparison to Rectal Temperature

A seminal study challenging the AHB method was conducted in a large university hospital.³⁵ The purpose of the study was to compare AHB ear temperature measurements to rectal temperatures in infants and children and to determine the ability of the AHB thermometer to detect fever. 1175 pairs of AHB and rectal temperature measurements were prospectively obtained from 140 infants and toddlers. Data indicated that rectal and ear temperature measurements in the AHB method were not different. Further, fever that developed in children after hospitalization was more likely to be first detected by the arterial heat balance method than by rectal measurement

With so many hospitals moving away from rectal temperature assessment, finding patients where rectal temperature was routinely used became quite a challenge. The data in Figure 9 represent the temperatures taken on 109 infants from 0 to 12 months. The temperatures were taken by hospital employed nursing assistants who were using the temporal artery thermometers for the first time. The data were gathered in an emergency room of a large university medical center. The comparisons were made using the professional model of the temporal artery thermometer incorporating the AHB method and compared to rectal temperatures. Rectal temperature was measured using electronic thermometers in the predictive mode; standard equipment and method at this patient care location.

- Data in Figure 9 demonstrate very strong agreement between the two methods. The mean difference = -0.15 and the standard deviation of the difference = 0.39. The data support interchangeability between the temperature measurement on the skin surface over the temporal artery using the AHB thermometer and the rectal temperature measurement using the electronic thermometers.

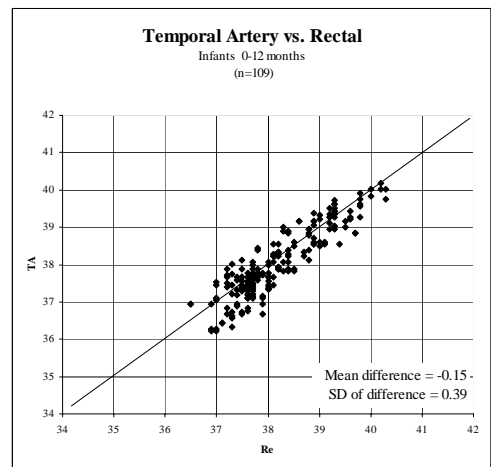


Figure 9 Paired readings of rectal vs. TA temperatures of 109 infants 0-12 months. Mean difference = -0.15, and SD of the differences = 0.39

- **Limits of Agreement:** Specific methods used for temperature assessment do not necessarily provide an unequivocally correct measurement. Therefore, it is the agreement between the methods that is of importance. Figure 10 presents 128 paired readings of rectal temperature and temperature on the skin surface over the temporal artery on infants and toddlers 0-36 months. All temperatures were taken by the same registered nurse in a busy emergency room of a large university hospital.

In determining the limits of agreement, analysis clearly illustrates excellent agreement between the two methods, and in fact, supports the interchangeability of rectal temperatures and temperatures on the skin surface over the temporal artery taken on this very young population. The mean difference between the two methods was -0.03 , with a standard deviation of the differences of 0.27 .

Time-Temperature Phasing: Figure 11 illustrates what could be interpreted as discrepancies between TA and rectal temperatures if using a simple linear regression analysis. However, what we are seeing instead is the speed with which the TA responds following the administration of acetaminophen, providing a mechanism for real-time monitoring of the effectiveness of treatment. Retrospective analysis of patient records for each of the outlined measurements in which the temperature at the skin surface over the temporal artery differed from the rectal temperature indicated an antipyretic had been administered prior to the initial measurement, and patient outcomes confirmed temporal artery as being the correct determinant of the actual thermal status of each individual patient investigated.

Differences Make the Difference: Figure 12 is a paired reading with a difference of 1.2°C between rectal and temporal artery area temperatures, a clinically significant difference. And while initially one might consider this to be a discrepancy between the two readings, like the readings in Figure 11, this was definitely not the case. The triage nurse confirmed that a parent prior to presenting in the emergency room had administered an antipyretic.

At the time of subsequent temperatures an hour later, both rectal and temporal artery area temperatures had converged. Antipyretic therapy had resulted in defervescence, and as illustrated, the temporal artery area temperature led rectal temperature in response time.

A New Gold Standard?

TA temperature is currently being investigated as to its possible role as a prognosticator of the thermal dynamics of fever and defervescence. It has long been recognized that rectal temperature exhibits an inertia, a sluggish response to changes in heat input and loss, and follows rather than leads thermoregulatory reactions.^{36,37,38,39,40,41} Accordingly, it is hypothesized that the temporal artery leads all other temperature

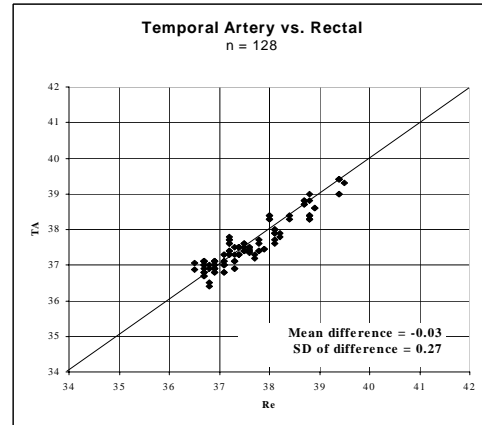


Figure 10. 128 paired readings of rectal and TA temperatures taken on infants & toddlers 0-36 months. Mean difference = -0.03 , SD of the differences = 0.27 .

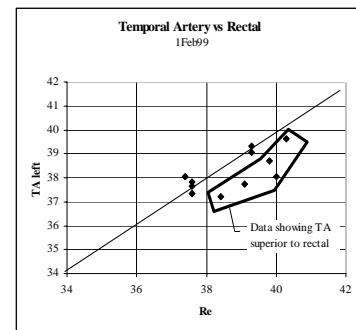


Figure 11 TA AHB temperatures vs. rectal temperatures – discrepancies, or is TA a quicker, better method?

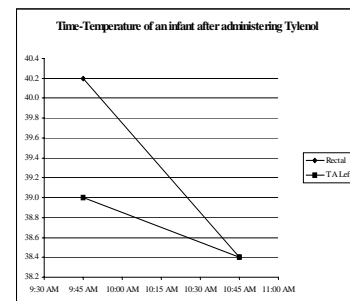


Figure 12 Time-temperature following antipyretic therapy TA

monitoring sites, and thus accounting for the differences as illustrated in Figures 11. and 12.

While Figure 12 illustrates the dynamics of defervescence, Figure 13 presents a complete picture of the thermal dynamics involved in both temperature elevation as well as the resultant defervescence following antipyretic therapy. This data was taken on an adult male with fever of rapid onset. The bottom line on the graph represents oral temperatures, which were taken with a standard hospital model electronic thermometer in a predictive mode setting. The middle line represents ear temperatures taken with an ear thermometer in the AHB method, and the top line represents the temperatures taken with a temporal artery thermometer, also in the AHB method.

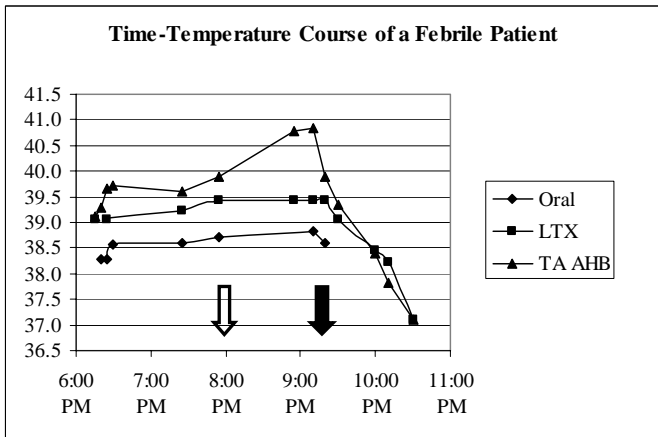


Figure 13 Comparison of 3 methods of thermometry on a febrile patient, the open arrow represents initiation of antipyretic therapy; the solid arrow is the onset of diaphoresis.

The open arrow indicates initiation of antipyretic therapy (ibuprofen 600mgs) at 8:00 PM. Temperature at the temporal artery area at that time was 39.9°C (103.8°F), ear was 39.4°C (102.9°F), but oral temperature was measured at only 38.7 (101.7°F), affected by the patient’s obvious tachypnea. The fever continued escalating to 40.8°C (105.5°F) as measured by the TA shortly after 9:00 PM. Ear was 39.4°C (102.9°F), and oral was 38.8 (101.8°F).

The solid arrow indicates the onset of profuse sweating shortly after 9:15 PM, following which time the temperature began a rapid fall. By 10:30 PM, the patient was 37.2°C (99°F) at both the ear and temporal artery area. Interestingly, at 40.8°C (105.5°F), the patient was experiencing cognitive difficulties consistent with the high temperature, which began to improve immediately following the onset of diaphoresis. Remnants of the febrile episode included multiple fever blisters and extreme fatigue lasting over several days. The patient reported at the diaphoretic onset that he suddenly felt much better, despite the still elevated temperature. Following defervescence, in a discussion of the symptomatology, he professed a belief that the 40.8°C (105.5°F) was indeed correct, as despite rare febrile experiences in the past, this was something he had never experienced. It should be noted that the patient was a scientist, who throughout his debilitation maintained an active interest in the entire episode.

Variability Assessment: Users

Interuser Variability Assessment: The accuracy of a device should be relatively independent of the technique used in order to provide for widespread clinical acceptability. Accurate temperature determination is essential, but the readings of any given thermometer are inextricably linked to the skill of the user. And although manufacturers strive to eliminate this variable in their devices, citing the many

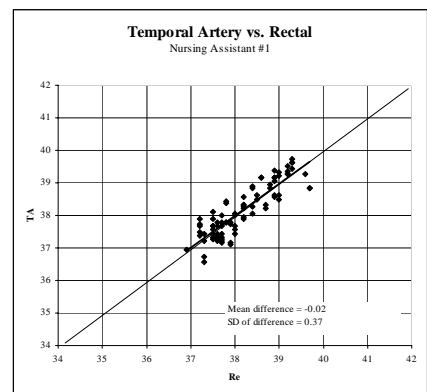


Figure 14 Paired readings of rectal and TA temperatures of 86 infants and toddlers. Mean difference = -0.02, standard deviation of the differences = 0.37.

negative studies of ear thermometers, some clearly fail in their mission.

Figure 14 represents 86 paired readings of rectal and temporal artery area temperature measurements taken on infants and toddlers by a nursing assistant. The nursing assistant was a first time user, newly employed by the hospital. Training on the temporal artery thermometer was brief; he had previous training on the rectal thermometer. The data illustrate a mean difference of -0.02 , and standard deviation of the differences of 0.37 , clinically demonstrating excellent correlation between the two methods, and a confirmation of skills quickly mastered by even a first time user.

Because thermometers using the arterial heat balance method have consistently demonstrated solid reproducibility, both to a repeat measurement of the same target and to measurements side-to-side, user variability can be assessed by analysis of the differences. The data in Figures 15 and 16 have been presented in a slightly different manner. Both of these figures represent the same measurements taken by the same user, and illustrate 78 paired readings of rectal and temporal artery area temperature taken on infants and toddlers under three years of age.

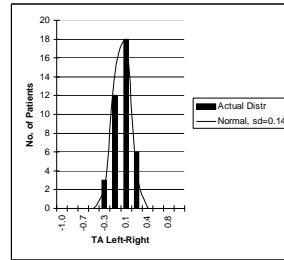


Figure 15 Frequency distribution of Left Right Temperature Differences

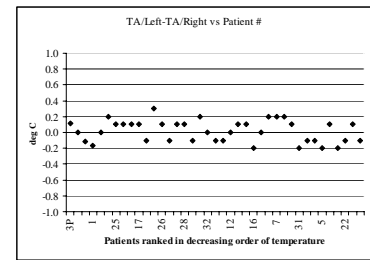


Figure 16 Left-right TA differences vs. descending order of temperatures

Figure 15 is a histogram representing the frequency distribution of the differences between left and right temporal artery area temperatures vs. the number of patients. The bars represent the actual data; the bell curve represents the anticipated normal distribution. In Figure 16, the left-right differences are presented vs. descending order of temperatures to systematically rule out any possibility of bias based on the height of the fever. The differences between left and right temporal artery area temperatures taken by this user, a registered nurse, yielded a standard deviation of 0.13 , illustrating a very tight agreement.

User Variability of Other Methods:

To provide a perspective for the user variability and temperature differences of other methods of thermometry, excerpts from a multi-faceted study, rather complicated study, conducted at a university children's hospital⁴² are included as a frame of reference. Data analyses comparing temperature readings at three different sites, oral,

axillary and rectal, and using four different types of thermometers, glass mercury, both off-the-shelf and water-bathed, electronic, and chemical dot, with the temperatures taken by nurses with levels of in-service education varying from none to intense, revealed surprisingly different results. Based on the instruments, user variability, and sites used in the study, the authors concluded that *a temperature does not equal a temperature*.

Table 1 Differences in Sets of Temperature Readings by Measurement Instrument

	Electronic	Chemical	Off the Shelf Glass	Water Bathed Glass
Child #1	95.8°F	98.8°F	97.4°F	98.2°F
Child #2	96.4°F	99.7°F	96.2°F	97.2°F
One set of oral temperatures on another child were:				
Child #3	102.1°F	99.8°F	100.8°F	101.2°F
Conclusion by the authors: <i>A temperature does not equal a temperature</i>				

A table taken from this study does an excellent job of illustrating the differences. It is of particular interest given that oral temperature is by far the most common temperature taken in hospitals, other medical facilities such as clinics and private practices, and in the home. The data in Table 1 reveal a difference of $\geq 3^{\circ}\text{F}$ on the same site (the mouth) in the same child, depending on the type of thermometer and the user. Clinically, this is certainly a significant difference, especially since patient treatment and investigatory workups would vary considerably based on the temperatures.

Missing a fever as evidenced by the chemical thermometer used on Child 3 can be catastrophic, as can missing the indication for an investigatory workup. Clinically, a temperature of 101°F (38.4°C) or 101.5°F (38.6°C) would generally initiate a workup, which would have been missed not only by the chemical thermometer, but by the off-the-shelf glass thermometer as well. Unfortunately, inaccurate information can result in unjustifiable risk, pain, and expense for the patient and the family members, as well as the hospital and caregivers.

Variability Assessment: Devices

Comparison Between Professional and Consumer Devices Reading Temporal Artery Area Temperature

Figure 17 illustrates a comparison between two thermometers both with AHB, one a professional and one a consumer model. The data demonstrate strong agreement between the two devices, mean of the differences = 0.04, and the standard deviation of the differences = 0.20, and support interchangeability between the two devices.

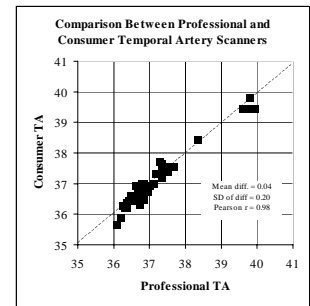


Figure 17 Comparison between measurements made with professional and consumer AHB models at the TA.

Reproducibility

Reproducibility is the hallmark of reliability; therefore, reproducibility of temperature readings should be strong if a device is to be deemed reliable. The following data, both for the professional model, Figure 18 and consumer model, Figure 19, serve to confirm the reliability of the readings.

- ❑ **Professional Model:** The data in Figure 18 illustrate strong reproducibility between left and right sides with the professional model incorporating the arterial heat balance at the temporal artery. The mean of the differences = 0.04, and standard deviation of the differences = 0.14.
- ❑ **Consumer Model:** The data in Figure 19 illustrate strong reproducibility between left and right sides with the consumer model incorporating the arterial heat balance method at the temporal artery. The mean of the differences = 0.08, standard deviation of the differences = 0.18.

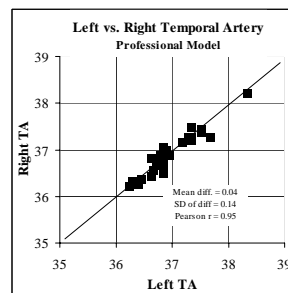


Figure 18 Comparison of side-to-side readings made by the professional model of the AHB TA thermometer.

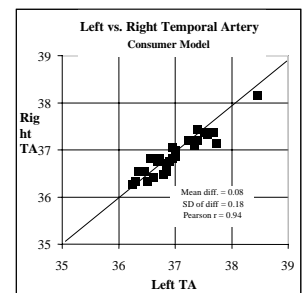


Figure 19 Comparison of side-to-side readings made by the consumer model of the AHB TA thermometer.

*Before you start to touch and feel, see if the baby likes the deal.
Touching is not the thing to do if touch makes falls in PO₂
It might be good to build a fence to keep some infant bonders hence
Until the infant makes it clear he means to live a life out here.
Pray, oh Power, that you redeem us from messing with babies in extremis.
P. Perlstein, MD*

ARTERIAL TEMPERATURE ASSESSMENT IN THE NEONATAL INTENSIVE CARE UNIT

Special Patients Have Special Requirements

An area of intensive caring identified as requiring special attention during the development of the instruments in the method of arterial temperature assessment was, not unexpectedly, the neonatal population in the intensive care unit. The specific challenges, mainly environmental in nature, presented a significant problem to overcome if the arterial method were to prevail for all patients. But the inherent benefits promised for these most fragile patients by arterial temperature assessment were compelling enough to diligently persevere toward the solution.

Thermoregulation and the Neonate

Thermoregulation is immature during the first few weeks of life; neonates are incapable of maintaining their own body temperature. Skin perfusion rates are very high, and the infant rapidly loses heat to the environment by conduction, convection, radiation, and evaporation. Heat is transferred from the interior of the body to the skin (conduction and convection from circulating blood) and from the body to the external environment (conduction, convection, radiation, and evaporation). Heat losses from convection, radiation, and evaporation in the newborn are disproportionately large as compared to an adult. The smaller and more immature the infant, the greater the relative losses. And so delicate is the balance, heat loss can occur with each perturbation to the infant. Even a diaper change exacts a price in lost BTU's (calories).

The Importance of Thermal Management

It has been well established that in response to a drop in body temperature, the metabolic rate is increased, even by the small premature infants^{43,44,45} but the resultant oxygen consumption exacts a price. In as much as caloric intake is limited by the small capacity of the stomach, and any available energy is first directed to thermogenesis rather than nutrition and growth, the resulting deficit can adversely impact optimal neurologic and physical development of the infant. Unfortunately, the consequences for low birth weight infants can be dire, as they often have inadequate metabolic fuel for oxidation as well as impaired thermogenic capacities⁴⁶ Failure to avoid thermal stress, particularly cold, by appropriate management of the environment may be decisive in terms of survival and the avoidance of subsequent morbidity.⁴⁷

The cornerstone of modern neonatology was demonstrating that thermal support markedly improves long-term survival.⁴⁸ Accordingly, thermal management requires an accurate, fast, non-invasive method of core temperature measurement.

Rectal temperature was historically considered the gold standard in the nursery. Though still occasionally used in some nurseries, rectal temperature assessment in current neonatal care is mainly avoided due to the potential risks, including vagal stimulation, which could lead to cardiac arrhythmia, bradycardia, or rectal perforation⁴⁹

Over 125 years ago, Carl Wunderlich, a German physician pioneering the study of applying thermometry to the human body,⁵⁰ used the axilla exclusively for measuring body temperature. Even that long ago, the mouth was considered unsatisfactory, and the rectum indecent. The axillary site is preferred in the nurseries of most hospitals, primarily due to the inherent safety and long established efficacy of the method, supported by many published studies demonstrating the validity of axillary temperature in the neonate population as an excellent measurement of core temperature,⁵¹ and its high correlation to rectal,^{52,53,54,55,56,57,58,59} prone chest, and femoral temperatures.⁶⁰ The uniformity of the thermal information provided by measuring the temperature of the various sites reflects the high surface perfusion of the infant.

The Challenge: Overcoming the Environmental Issues

Environmental temperatures fluctuate dramatically throughout the nursery; the dynamics of which are unlike any other area in the hospital. Already a warmer-than-normal environment, the ambient temperature in the nursery may be increased even further from the spurious output of heat from incubators, thermal transport devices, radiant heaters, warming pads, phototherapeutic lamps, etc.

Given the fragility of its thermoregulatory system, the body temperature of the newborn can be strongly influenced by the surrounding environment, warm or cold. To provide a thermally neutral environment for the infant, incubators and radiant heaters are often maintained at body temperature. And, therein lies the root of the challenge faced when using the arterial heat balance method.

The Instrument

The arterial heat balance (AHB) method synthesizes two temperatures: the patient and the environment. Because each incubator is independently controlled according to the thermal requirements of the infant, the ambient temperatures of the incubators can be very different from each other and from the nursery's ambient temperature. For example, normal ambient temperature in the nursery is $\approx 24^{\circ}\text{C}$ (75°F) compared to the temperature in an incubator or radiant warmer, which can be $\approx 38^{\circ}\text{C}$ (100°F). In order for the AHB technique to work correctly, the instrument must be at the same ambient temperature as that of the infant. With a delta of 14°C (25°F) between the ambient of the nursery and the inside of an incubator or warmer, an AHB thermometer would require time to acclimate to the warmer environment, about fifteen minutes, and clearly an impractical wait for busy nursing staff. But, if equilibration of the instrument did not occur, the thermometer would calculate based on the lower ambient temperature it had just left, and the infant's temperature would be measured erroneously high.

The Solution

Further investigation demonstrated that storing one AHB thermometer in each incubator or radiant warmer could immediately solve the problem. But the standard professional temporal artery thermometer was too large to be easily manipulated given the constraints presented by the support equipment typically surrounding and attached to the infant. In addition, the cost of the instrument would make installation in individual isolettes impractical and expensive. The solution was the design of a special model in the AHB method, and resulted in a dedicated instrument, small enough to unobtrusively remain in close proximity to the infant, robust enough to withstand terminal cleaning, cost-effective enough for one per bed, and specifically configured to address the constraints of the ever-present support equipment.

A Choice of Sites: The skin surface over the temporal artery is an ideal site to measure temperature on infants and adults for all the stated reasons of perfusion, convenience, and comfort. But in the NICU, it was soon discovered that nursing staff was somewhat less than enthusiastic about placing the probe on the head of their tiny charges. Another issue was navigating the ever-present support apparatus, only to be prevented access to the forehead by the tape holding a device in place. Even

something as innocuous as hats and blinders presented a challenge as they interfere with heat dissipation, resulting in local heat retention at the forehead area. Heat retention, while beneficial for the infant, interferes with the AHB calculations, which assumes the skin is in equilibrium with the ambient.

And so, with the assistance of clinical staff, it was ultimately determined that the preferred site for measuring the temperature of these special patients was on the neck area just behind the ear lobe. Measurements at this site were perceived as very gentle, and because of the high perfusion of the area, the measurement maintained all the original benefits of the AHB method, eliminated the issues, and markedly reduced the level of negative tactile stimulation of any other site.

While the temporal artery area is clearly a viable site if exposed and dry, of significance in the selection of the neck area was the elimination of the effect of evaporative cooling at the forehead from sweating. Diaphoresis is a condition not uncommon with premature infants.⁶¹ A compilation of data on neonatal sweating supports the conclusion that the earliest sweating is detected on the forehead, followed by the chest, upper arm, and later, more caudal areas.⁶² Accordingly, the integrity of the neck area required for the AHB measurement is maintained.

Table 2 Data taken at a Neonatal Intensive Care Unit Large University Teaching Hospital	Mean Temp	Mean of Paired Differences in Temperature	SD of Paired Differences in Temperature
Isolettes Group (n=61)			
IR Axilla, Exergen	36.68		
Glass/Hg Axilla	36.71		
ServoControl on Abdomen	36.80		
IR Temporal Artery	36.70		
IR Axillary vs gl/Hg Axillary		-0.03	0.28
ServoControl on Abdomen vs gl/Hg Axillary		0.07	0.23
IR Axillary vs ServoControl on Abdomen		-0.07	0.30
IR Temporal Artery vs ServoControl on Abdomen		-0.03	0.20
Radiant Warmers Group (n=48)			
IR Axilla, Exergen	36.78		
Glass/Mercury Axilla	36.72		
ServoControl on Abdomen	36.69		
IR AHB	36.83		
IR Axillary vs gl/Hg Axillary		0.06	0.30
ServoControl on Abdomen vs gl/Hg Axillary		0.01	0.21
IR Axillary vs ServoControl on Abdomen		0.06	0.34
IR AHB vs ServoControl on Abdomen		0.06	0.30

The Accuracy: Table 2 is a comparison of temperatures taken by various methods on various sites on 109 infants in the neonatal intensive care unit of a large university hospital. Because the temperatures are all within a very narrow range, graphical presentations tend to be meaningless, hence the table presentation. Data were collected using an infrared thermometer in the method of AHB at the temporal artery or neck area, a glass mercury thermometer and an infrared thermometer for measuring axillary temperature⁶³, and the standard servocontrol of the incubator or radiant heater was used to measure the temperature of the anterior abdominal wall.

In both the incubators and the radiant warmers, both in superheated ambient and normal nursery ambient, the data illustrate such strong agreement among the four methods employed that the methods can most assuredly be considered interchangeable. Further, the infrared arterial measurement provides additional benefits over the other methods of thermal assessment: no perturbation, no disrobing, and increased convenience for nursing staff. And, because the instrument remains with

one infant from admission to discharge, and is terminally cleaned with the rest of the equipment in the incubator, the requirement for disposable covers is eliminated, resulting in a significant reduction in cost, as well as elimination of the risk of cross-contamination by device.

Table 3 is of particular interest in that the data were reluctantly gathered at another teaching hospital by nursing staff not wanting to make a change from their current system of disposable digital electronic thermometers. The mean of both temperatures is identical at 37.0, the mean of paired differences is 0.00, and the standard deviation of paired differences is 0.12, all demonstrating interchangeability between the two methods. Of further interest here, the standard deviation of the differences between the AHB thermometer and the hospital's disposable electronic thermometer was significantly tighter than the frequently referenced standard deviation in other more familiar site-pair differences such as rectal-axillary (0.47) and rectal-abdomen (0.76).⁶⁴

Table 3: NICU data taken on the TA in isolettes

Equipment Used	Mean	Mean of Paired Differences	SD of Paired Differences
Isolette: n = 23 premature infants			
Axillary w/disposable electronic thermometer	37.0		
Temporal artery AHB thermometer	37.0		
Temporal artery AHB thermometer vs axillary w/disposable electronic thermometer		0.00	0.12

Radiant warmers present more of a challenge than isolettes.⁶⁵ Two conditions inherent to the radiant warmer are potential contraindications if not stringently controlled: (1) environmental radiation, (2) irradiation of the skin surface, both of which can spuriously affect the measurement. Activating and deactivating the instrument only on the skin surface accomplish control of the environmental radiation. Control of the irradiated skin surface is accomplished by avoidance. Heat radiation travels in waves the same way as light. The heat waves themselves are not hot, but when they are stopped and absorbed by something, that something will get quite hot; in this case, that something is the skin of the infant. The method used in a radiant warmer is best understood by use of an analogy. An individual asleep on a beach under the noonday sun will be burned red on exposed horizontal surfaces, while the perpendicular surfaces remain white. As such, it is the perpendicular surfaces required for the AHB measurement.

Table 4: NICU data taken in radiant warmers

Equipment Used	Mean Temp	Mean of Paired Differences	SD of Paired Differences
N = 50 premature infants			
Servocontrol sensor	36.94		
IR thermometer behind ear	36.93		
Behind ear vs servocontrol		0.04	0.14

The data in Table 4 were taken on 50 premature infants in radiant warmers in the neonatal intensive care unit of another large university hospital. The object was to assess the interchangeability of the servocontrol probe attached to the anterior wall of the abdomen and the temperature taken behind the ear or other shaded area perpendicular to the radiation with the AHB thermometer. The mean temperatures of both methods are identical at 36.94, the mean of the paired differences is 0.04, and the standard deviation of the paired differences is 0.14. The data support the conclusion that the two methods are interchangeable. Further, particularly because of the fragility and cost involved with the servocontrol probe, ABH was selected as a better method.

An Overview of Body Temperature

Defining Body Temperature

The term *core temperature* has traditionally been used to designate clinically meaningful temperatures on which to base patient assessment. However, there is general ambiguity to its meaning, since it is used variously to describe temperatures taken in the oral cavity, rectum, axillae, esophagus, bladder, etc.; all of which should be more properly described as *core temperature approximations*.

Textbook references to core temperature describe it as "the temperature of the deep tissues of the body"⁶⁷ or "the central core includes the contents of the skull, thorax, and abdomen, i.e. most of the vital organs, and a variable amount of the deep tissue of the limbs."⁶⁸ Another concept of core temperature arises from consideration of the *hypothalamic thermostat* as the primary thermoregulatory center.

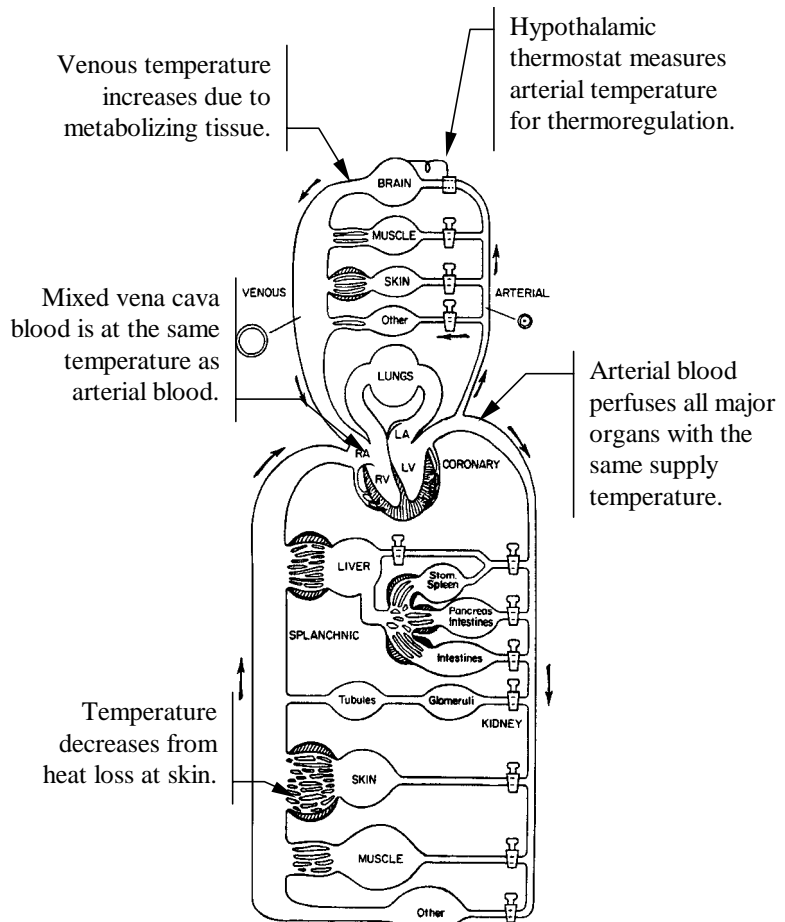


Figure 20. Illustration of circulation transport of thermal energy.⁶⁶

A core temperature definition aptly suited for clinical efficacy, physiological clarity, and thermophysical accuracy, and one that can be easily tested empirically, is arterial temperature: the temperature of the blood flowing in the great vessels. The specific arterial location to be referenced is the pulmonary artery (PA), since PA catheterization is common and the measured PA temperature can be used as a reference.⁶⁹ Temperature changes in the great vessels are negligible under widely varying conditions of heat loss and heat gain, and therefore all major organs, including the brain, are perfused by blood at arterial temperature.

All thermoregulatory responses which influence core temperature (vasomotor activity, shivering, diaphoresis) start with changes in arterial temperature via the mixing of venous return from metabolizing tissue (raises temperature) and skin and peripheral tissue (lowers temperature). Accordingly, arterial temperature is properly viewed as causal to all other core temperatures within the body. Mathematically, the relationship between arterial and other core sites may be represented as arterial temperature plus local heating via metabolism, minus local cooling via conduction; with varying time lags from the causal arterial change to the resultant local change.

As depicted in Figure 20, the temperature of thermoregulatory receptors in the hypothalamus, and of all other deep central nervous system thermoregulatory receptors, is controlled by the arterial supply temperature, which in turn provides the essential feedback for accurate stable thermoregulation.

Since arterial temperature immediately responds to thermoregulatory perturbation via changes in venous mixed mean temperature, including pyrogenic influence on the hypothalamic thermostat, it is the direct indicator of all core temperature changes. All other commonly used core temperature approximations are resultants of inferior accuracy and reliability, relative to the causal arterial change. But despite the fact that arterial temperature is arguably the best representation of core body temperature, its measurement is grossly invasive, and certainly not a consideration for routine clinical measurement. Accordingly, alternative sites are explored for their suitability as a determinant of arterial temperature.

Normal Body Temperature

Normal body temperature is expressed not by a single number, but by a range of values. Contrary to popular belief, recent data show that only 8% of the population has a “normal” temperature of 37°C (98.6°F), and strongly support abandoning the age old concept of 37°C, replacing it instead with 37.2°C (98.9°F) in the early morning and 37.7°C (99.9°F) overall as the upper limit of the normal oral temperature range in healthy adults aged 40 years or younger.⁷⁰

Temperatures vary with age, and older is colder. A high temperature may develop in the newborn infant in the absence of disease due to marked instability of the

vasomotor system. Conversely, however, a “normal” temperature in the elderly may be the first, and at times, the only manifestation of a potentially lethal infection.⁷¹

All mammals, including man, have an extensively developed heat regulating system with thermostat-like action existing in the hypothalamus. This control mechanism for balancing heat production, skin blood flow, sweating, and respiration enables the maintenance, under any ordinary conditions, of a remarkably constant body temperature regardless of the temperature of the surrounding environment. In fact, so elegant is the control of this remarkable system, that with the exception of an occasional illness or in response to intense exercise, the body temperature stays within 1°C (2°F) of baseline temperature over the entire course of one’s lifetime.

It is precisely because we are capable of maintaining a rather constant temperature that deviations from that temperature can be used to determine the pathophysiology of the individual. There is diagnostic significance to be found in the mere presence or absence of a fever, and since fever may be the first and only sign of infection in certain patient populations, an undetected fever can be of serious consequence. Accordingly, the actual height of the fever is often of no great importance, and most physicians have no particular concerns with whether a temperature is 38.3 or 39.2°C (101°F or 102.5°F), but rather whether the temperature is 36.7 or 38.3°C (98°F or 101°F).⁷²

Temperature Comparison under Normal Conditions

Figure 21 illustrates the range of variations from arterial temperature at different temperature measurement sites including the site artifacts at steady state. It also illustrates the reasoning behind the cutoff points for initiation of palliative treatment or investigatory workup selected as standard protocol in most medical centers.

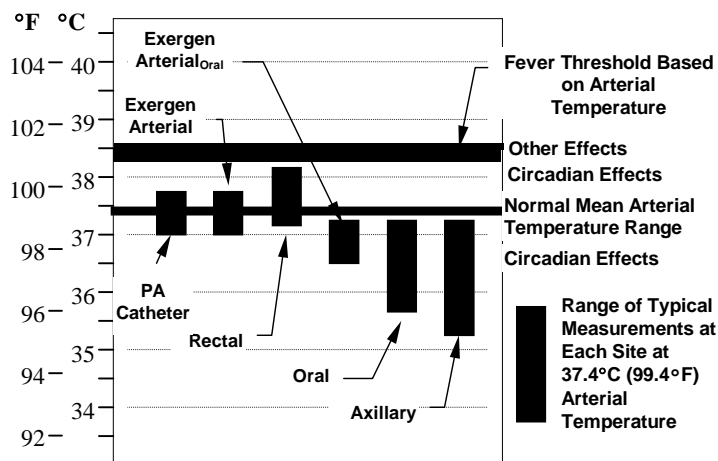


Figure 21 Temperature Comparison under Static Conditions

- ❑ Arterial fever threshold is the level above which false positives due to normal variations in arterial temperature, including range of normal mean + circadian effects + other effects (metabolic, ovulation, etc.), are unlikely.
- ❑ Range of variations from arterial temperature at different sites shows the site artifacts at steady state.
- ❑ Dynamic differences can be much larger.

Normal Elevations in Body Temperature: Fortunately, not all elevated temperatures are associated with potentially life threatening disease; for example, normal body temperature may be elevated during exercise. Unfortunately, many patients with temperature elevations, especially measured rectally, that are entirely physiologic have been subjected to potentially hazardous tests and treatments because their elevated temperatures were regarded as pathologic.

Elevated body temperature, under certain circumstances, is not abnormal and should not be viewed as disease. Body temperature can be increased up to 1°C (2°F) or more from a combination of clinically benign causes:

- ❑ Circadian Cycle
- ❑ Meals
- ❑ Ovulation
- ❑ Physical exercise
- ❑ Physical therapy
- ❑ Pathologic exercise - shaking chills, seizures
- ❑ Psychological behavior - anxiety, excitement

Since normal body temperature can realistically be termed a constant, deviations from the baseline are abnormal, and defined as hypothermia, fever, and hyperthermia.

Abnormal Body Temperature

Hypothermia: Hypothermia occurs when the normal thermoregulatory system is unable to sustain body temperature by mechanisms of heat generation and heat conservation. When body temperature falls below 35°C (95°F), the patient will be described as hypothermic. Once the normal body temperature drops approximately 6°C (11°F), the hypothalamus is disabled and can no longer regulate temperature. Significantly lower temperatures usually result in death. Some of the causes of hypothermia can be extreme environmental exposure, which treated properly has a favorable prognosis, or in less extreme environments, if the individual has any condition affecting thermal regulation such as CNS and metabolic diseases, infections, or shock.

Hyperthermia: Conditions in which core temperature rises despite the body's attempt to maintain eutheria should be referred to as hyperthermia rather than fever. Hyperthermia is a state of thermoregulatory failure in which the heat dissipation does not keep up with the heat production causing the temperature to rise. It is an elevation of body temperature above the normal range, but not a true fever, as the set point does not change. A temperature in excess of 42°C (107.6°F) makes hyperthermia a likely diagnosis because even with severe infections, such a temperature rarely occurs with fever alone. The causes, although multiple, are either physiologic or behavioral.

Heatstroke: Heatstroke is a life threatening situation, requiring immediate detection and treatment. There are two types of heatstroke: (1) classical heat stroke which most often affects very young or very old patients chronically ill from any number of causes, and (2) exertional heat stroke which typically affects healthy men between the ages of 15-45. In each, core temperatures as high as 46.6°C (116°F) have been reported.⁷³ Without cooling measures, spontaneous decline of body temperature is almost never seen in classical heat stroke, whereas in exertional heat stroke, if sweating persists, evaporation will cause a decline in body temperature.

A high body temperature tends to perpetuate itself, and when the hypothalamus becomes excessively heated, its thermoregulatory ability is depressed and sweating diminishes. When the core temperature rises approximately 6°C (11°F) above normal, the nervous system and/or the cardiac system are compromised, and unless measures are taken to reduce body heat, death may result. At body temperature above 45-46°C (113-114.8°F), the upper thermal limit for the survival of most organisms,⁷⁴ death usually results.

Fever: Fever is one of the most common signs of illness, and a reliable guide to the presence of disease and its responses to therapy. A diagnostic, prognostic, and therapeutic barometer, fever is best defined as an increase in temperature over what is normal for a given individual at that particular time of day, and not necessarily an isolated temperature greater than normal.

It is important to differentiate between fever and other types of temperature elevation. An elegant definition simply stated: *fever is that condition in which the body thermoregulates an increase in core temperature as an organized and coordinated response to a disease or other insult.*⁷⁵ Fever is a *controlled* state, all normal thermoregulation responses are maintained, but at a higher set point, whereas hyperthermia and heat stroke are thermoregulatory *failures*.

Causes of Fever:

The main causes of fever are:

- Infection
- Neoplastic Disease
- Collagen Vascular Disease
- Granulomatous Disease
- Pulmonary emboli
- Drug induced fever
- Factitious fever

Fever Detection: It's Impact on Mortality and Cost:

No diagnostic test has a longer history or has been used more often than temperature as an indicator of disease, but modern tools of stochastic modeling show that hospital mortality and costs can be significantly influenced by the fever detection method employed.

A recent study on the influence of fever detection on mortality and cost, currently in prepublication stage, demonstrated high sensitivity, the accuracy of fever

detection, to be the dominant characteristic influencing results; frequency of measurement being less important. This study was based on an intensive review of literature on non-invasive temperature detection methods, and excludes data on instruments manufactured with the arterial heat balance method to prevent biasing of results.

Indwelling rectal probes exhibited the highest sensitivity contributing to a decrease of 77,000 deaths (-9.8%) and a decrease per patient-day of \$15.00. A random number model of fever detection in which random numbers are used instead of measurements produced results that were superior to several thermometry methods in common use. Palpation as a method of fever detection was nearly as well performing as the rectal methods, and superior to all but rectal methods in reduced mortality and reduced costs.

The study concluded that the ideal fever detection method would be at least as sensitive as rectal methods (≥ 0.86), but should be non-invasive and agreeable to patient and clinician.

Temperature Comparisons in a Febrile State

Figure 22 illustrates the differing dynamics of common temperature sites compared to the causal arterial temperature in response to infection. When used correctly, the AHB method can be considered sufficiently accurate to be interchangeable with pulmonary artery temperature measurements.

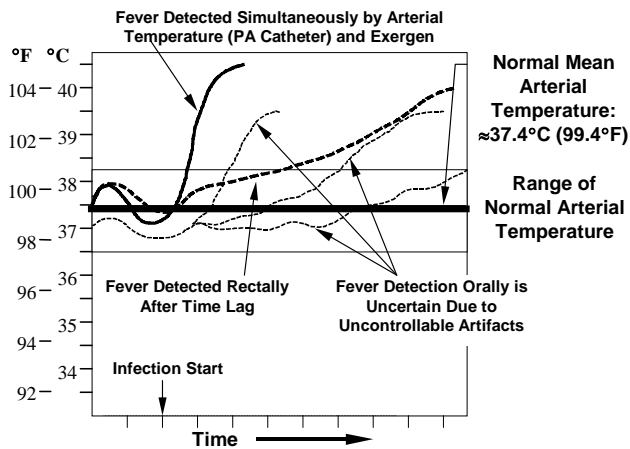


Figure 22 Temperature Comparison under Dynamic Conditions

- ❑ Arterial temperature is always the first to reach the fever threshold in response to pyrogenic agents.
- ❑ Temperature measured with the Exergen thermometer follows arterial temperature with near zero time lag.
- ❑ Oral temperature response to arterial temperature is uncertain due to artifacts.
- ❑ Rectal temperature can lag for many hours.

Body Sites for Temperature Assessment

An Overview of Temperature Measuring Sites

Oral Temperature: Oral temperature measurement is by far the most common clinical method in use today, and is responsible for masking the greatest number of fevers. Oral temperature can be misleadingly lowered by patient activity such as tachypnea, coughing, moaning, drinking, eating, mouthbreathing, snoring, talking, etc. Alarming, another cause of low oral temperatures is the fever itself. For each 0.6°C (1°F) temperature elevation, the pulse rate usually increases approximately 10 beats per minute, there is a 7% increase in oxygen consumption,⁷⁶ increasing the respiratory rate approximately 2 cycles per minute.⁷⁷ The resulting increase in respiration can further lower oral temperature sufficiently to mask a fever.

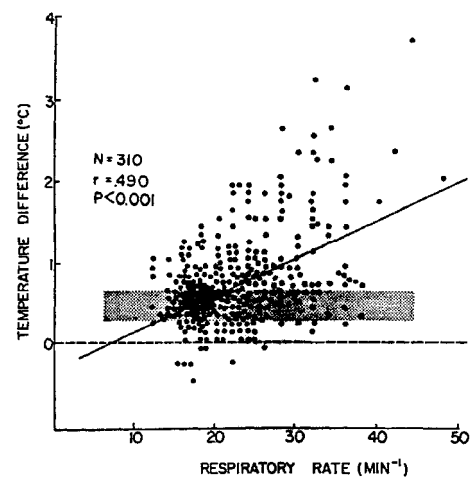


Figure 23 Temperature Difference (Rectal minus Oral) in 310 Patients with a Wide Range of Respiratory Rates. The straight line of best fit is shown. The stippled area demonstrates the traditional "normal" difference between rectal and oral temperature (0.3 to 0.65°C).⁷⁸

Figure 23 is of interest as it illustrates fever masking even when clinicians had eliminated all obvious mouthbreathers from the study. This emergency room study, presents the temperature difference (rectal minus oral) in 310 patients with a wide range of respiratory rates. The straight line of best fit is shown. The stippled area demonstrates the traditional normal difference between rectal and oral temperature (0.3°- 0.65°C). The investigators concluded, that many patients with tachypnea would have oral temperatures in the normal range despite the presence of clinical fever, seriously misleading the clinician.⁷⁸

Rectal Temperature: Generally, rectal temperature is considered an indicator of deep tissue and critical tissue temperatures, but long standing data demonstrate that rectal temperature can be a lagging and unsatisfactory index.^{79,80,81,82,83,84} Fifty years ago, Eichna et al⁸⁵ reported differences between intracardiac, intravascular and rectal temperatures on afebrile patients to be so insignificant that for all practical purposes,

the temperatures may be considered to be the same. Certainly rectal temperature is far less invasive than a pulmonary artery catheter, however, in the same study, data on febrile patients support sizeable differences.

Other comparisons between rectal, esophageal and aortic temperatures undertaken on hypothermic patients by different researchers also confirm similar differences.⁸⁶ Subsequent but equally comprehensive comparisons on healthy volunteers further confirmed not only temperature differences, but also quantified significant lags in rectal temperature vs. hypothalamic temperature by times of order one hour.⁸⁷ This is of interest since the blood as it enters and affects the critical tissue in the hypothalamus should have considerable significance in thermal homeostasis. However, this early data on hypothalamic temperature was measured by a thermocouple inserted against (and often times perforating) the tympanic membrane. With significant improvements in the methodology, more recent clinical observations show that the time constant of rectal temperature in critically ill patients may be considerably longer, and in some cases, as much as a day.⁸⁸

Under certain conditions, rectal temperature is even contraindicated; for example, severe arterial insufficiency in one or both legs might be associated with falsely low readings,⁸⁹ or in conditions affecting peripheral blood flow such as cardiogenic shock.⁹⁰ More common contraindications include neutropenia, severe hemorrhoids, and recent anorectal surgery. A less common but serious complication of rectal temperature measurement is perforation of the rectum, which has even occurred in the absence of predisposing rectal pathology.⁹¹

Rectal temperature measurement is not well tolerated, by either the patient or the caregivers, is uncomfortable and embarrassing. Rectal temperature is subject to inaccuracies of placement, environment, and time of insertion. And although it is well established that a rectal temperature requires two to five minutes or more to reach optimum measurement with a glass mercury thermometer,^{92,93,94,95} in practice many are withdrawn in just one minute, a technique responsible for misleadingly low readings.

In fact, it is difficult to attribute any thermal significance at all to the rectal area. It is not known to contain any thermoreceptive elements and its geographical location distances it from both the CNS and the crossroads of circulation at the heart, which are the vital informational elements.⁹⁶

Tympanic Membrane and Ear Temperature: A temperature site of more recent onset is the ear. It is a compelling site, accessible, free from bodily fluids, and not easily influenced by patient activity. This temperature is measured using infrared technology, and there are three types of infrared thermometers: tympanic, ear, and arterial heat balance. It has, however, become common practice to refer to any thermometer making the measurement at the ear as a tympanic thermometer. Although the terms tympanic and ear may be used interchangeably, they actually describe quite different measurements.

True Tympanic Membrane Temperatures: The tympanic membrane is deep inside the skull, and is not subject to the artifactual errors that can affect oral, rectal, axillary and ear temperatures. True tympanic thermometers provide an uncorrected, direct reading of the temperature of the tympanic membrane, and are preferred for continual

measurement during certain surgical procedures, and for use in extreme conditions such as military use, research, and sporting events.

There are two types of instruments used to make the measurement. One is a long thin thermocouple probe, usually fitted with cotton at the end, that must come in contact the tympanic membrane.⁹⁷ There is much historical data on the efficacy of tympanic thermometry using contact thermocouples, stemming originally from work done over thirty years ago^{98, 99, 100, 101, 102} However, this method never gained wide acceptance due to the risk of injury to the delicate membrane.

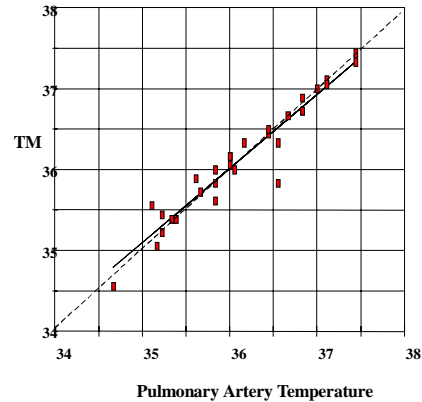


Figure 24 Comparison between a true tympanic thermometer Vs pulmonary artery catheter

Ten years ago, the advent of an infrared device¹⁰³ made the direct measurement of tympanic membrane temperature possible by non-contact means, eliminating risk of injury to the tympanic membrane. Figure 24 illustrates the strong correlation of a direct measurement of the tympanic membrane with pulmonary artery temperature obtained with this infrared device. The study was conducted in the cardiac intensive care unit of a large suburban teaching hospital. The mean differences between the measurements is 0.00°C, the standard deviation of the differences is 0.2°C, and the Pearson correlation coefficient is 0.96, all demonstrating a very strong linear correlation between tympanic temperature as measured by the infrared device and pulmonary artery temperature measured with a catheter inserted in the pulmonary outflow of the heart.

While the infrared method is certainly less invasive than the contact probe, it is still a somewhat invasive measurement, as the device must actually view the tympanic membrane, placing constraints on both device and clinician. The device requires a narrow field of view, and must be inserted past the bend in the ear canal to view around the dogleg bend. It must also scan the canal to assure viewing the TM; similar to the technique employed when conducting an otoscopic examination. Some users may not be proficient with otoscopic technique, nor wish to subject the patient to the required ear manipulation or discomfort. However, it is the preferred instrument under extreme environmental condition, and used over the past decade at such sporting events as the Olympic Games, and the Boston Marathon, and by the military for monitoring individuals suffering from heat or cold stress, especially valuable in the assessment of their mental acuity.

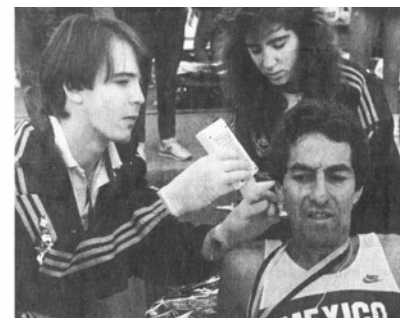


Figure 25 True tympanic thermometry is the standard at the Boston Marathon

Ear Temperature: Ear thermometry is a method of measuring the temperature of the external portion of the ear canal. For routine clinical use, ear thermometry has been preferred as a simpler, faster, and more convenient alternative to true tympanic

thermometry. The absolute temperature of the outer ear, however, is lower, and more variable than arterial temperature. It is subject to a cooling effect resulting from the body heat being radiated to the environment, and a heat balance method is required in order to produce the requisite accuracy. When combined with an arterial heat balance method, ear thermometry provides a highly accurate indication of body temperature, but those ear thermometers without it¹⁰⁴ have high rates of missed fevers.
105,106,107,108,109,110,111,112,113,114,115,116,117,118

Arterial Temperature via the Ear Canal: Arterial temperature as measured by the method of heat balance via the ear canal responds immediately to changes in the causal arterial temperature, without the delays inherent in rectal temperature; and without the uncontrollable artifacts inherent in oral temperature measurements, thus providing the means to identify a fever faster and more reliably than possible with oral or rectal methods.

Overview of Clinical Devices for Measuring Body Temperature

Non-Invasive Thermometry

Glass Mercury Thermometers: Though routinely used for over one hundred years, the accuracy of the glass mercury thermometer is less reliable than commonly assumed. In 1949, an extensive accuracy study of clinical thermometers revealed over 50% of the glass mercury thermometers failed to meet commercial standards.¹¹⁹ Fifteen years later, there was no significant improvement as evidenced in a study of 625 thermometers from 11 companies showing a 20% failure rate¹²⁰. Thirty-five years after the initial study, errors up to 0.5°C (0.9°F) in normal body temperature range and even greater errors at higher temperatures, the area of primary concern, were still not uncommon.^{121,122,123} In addition, storage time,^{124,125,126,127} instrument use¹²⁸ have been shown to change the accuracy of glass mercury thermometers. The clarity and specificity of calibration marks on glass and chemical thermometers can also affect their accuracy.^{129,130}

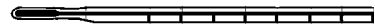


Figure 26 Glass Mercury Thermometer

Despite routine cleaning, glass mercury thermometers pose a risk as vectors for cross-contamination to both patients and staff, and when cultured, one study found 30% of the thermometers in use to have been contaminated with salmonella eimsbuettel, and responsible for infecting newborn infants, mothers, and attending staff.¹³¹ And, while glass mercury thermometers are still in widespread clinical and home use, they have already been banned in many states and foreign countries, and are on a deadline in others, because of the risk of contamination presented by the mercury contained in these thermometers. Regulatory requirements, disposal costs, training and supply costs of maintaining mercury-based products in a clinical setting are of significant impact to the facility, and health care facilities must bear the associated costs in order to meet the standards set by Occupational Safety and Health Administration (OSHA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards for the Environment of Care.

Electronic Thermometers: Electronic thermometers are generally more accurate than glass mercury or chemical thermometers,^{132,133} But unfortunately, despite the use of a disposable cover on the probe, investigators found that 80% of the probes were colonized after clinical use, and that 25% of the electronic thermometers harbor pathogens,¹³⁴ playing a significant role in spreading diarrhea-causing *Clostridium difficile*, and are well documented as major vectors for infection.^{135,136,137,138} Investigators clearly demonstrated this mode of transmission could be significant in *Salmonella* and *Shigella*, as well as viral pathogens,

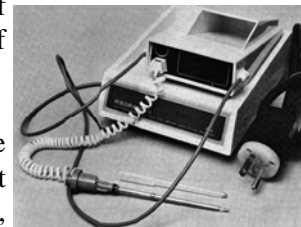


Figure 27 Electronic

strongly recommending encasement of the entire instrument in disposable sheaths as the most viable solution.

Another study in a university medical center is believed to be the first study in which electronic thermometers were positively identified as the vehicles of transmission for a nosocomial outbreak of infection due to a highly vancomycin-resistant strain of *Enterococcus*.¹³⁹ Investigators also demonstrated duration of treatment and days of hospitalization in the intensive care unit each increased three-fold as a result of the infections, leading to substantially increased costs.

There are some inconsistencies in the comparative studies using electronic probe-type thermometers on neonates. One study¹⁴⁰ demonstrates their inaccuracies when used for axillary temperature, suggesting the axilla may not be sensitive enough to determine a fever when measured with this type of thermometer. This is consistent with other findings where the electronic thermometers underrepresented and the chemical thermometers over-represented when measuring axillary temperatures.^{141,142} In the case of axillary measurements with probe-type devices, accurate readings can be obtained, but only with certain devices, and with five to eleven minutes or more insertion.^{143,144}

Other Thermometers: An alternative probe-type thermometer is a chemical thermometer. This is a paper device with heat activated chemical dots superimposed on the surface, designed to change color in accordance with the temperature sensed. They are used interchangeably with other probe type thermometers, however, as a one-use product, their primary intent is to prevent cross-contamination.



Figure 28 **Chemical Thermometer**

Occasionally considered for fever detection, especially in pediatrics, is a plastic forehead strip containing heat-sensitive liquid crystals in which the crystals change color according to body temperature. While they have been reported to work sufficiently well enough for screening in older children, in one study 57% of children with fever = 38.3°C (101°F) had a normal temperature as measured by a liquid crystal strip, an appreciable number of false-negative results.¹⁴⁵ Another study found the strips more likely to give false positive results,¹⁴⁶ and other investigators found the strips to be imprecise and often inaccurate.^{147,148,149}

Invasive Thermometry

Invasive Thermometry: Long considered the gold standards for temperature measurement, invasive thermometry methods include pulmonary artery thermal dilution catheters, esophageal temperature probes, and indwelling bladder and rectal temperature probes. The true gold standard for thermal assessment is the pulmonary artery/thermal dilution catheter, which allows continuous monitoring of the temperature of the pulmonary outflow tract of the heart.

Artifactual errors are minimized with this method, but placement, time lapse post-insertion, and calibration of the equipment are critical, and errors have been reported.¹⁵⁰ Interestingly, the requirement for clinical accuracy on pulmonary artery catheters is more tolerant than less invasive clinical thermometers. For example, the American Society of Testing and Materials (ASTM) requirement for clinical thermometers is $\pm 0.1^{\circ}\text{C}$ (0.2°F), but product specifications for a thermal dilution catheter¹⁵¹ state blood temperature accuracy in the range of 31°C to 43°C to be $\pm 0.3^{\circ}\text{C}$ ($\pm 0.54^{\circ}\text{F}$). Most probably, this is in deference to the site, and the fact that temperature monitoring with a PA catheter is secondary to cardiac output.

Esophageal temperature probes, when positioned properly, proximal to the heart, compare favorably to PA catheters, but are invasive and uncomfortable. Bladder catheters containing thermistors are also used to measure temperature, but bladder temperature is slower to respond to patient thermal responses. Tympanic temperature probes of the long thin thermocouple design, which are inserted proximal to the tympanic membrane, are also considered accurate when positioned properly. However, these are quite uncomfortable, not suitable for an awake, alert patient, and perforation of the tympanic membrane is a very real risk.¹⁵²

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