

Independent Assessments of Temporal Artery Thermometry

An Executive Summary

Prepared by M. Pompei, Chief Clinical Scientist, Exergen Corporation

<p>Historical, physiological, and clinical evidence supporting temperature measurement at the temporal artery, starting with Hippocrates.</p>	<p>Historically, records referencing the use of the forehead for detection of fever date back to the Egyptians well over 4000 years ago, supported even 2500 years ago, in the writings of Hippocrates linking fever felt at the forehead to the presence of disease.¹ Fever was quantified by referring to the accompanying heart rate being “as fast as a gazelle, or as slow as a turtle”.</p> <p>More recently, several studies continue to demonstrate the value of fever detection by palpation at the forehead by parents^{2,3,4} and even by untrained clinicians.⁵ Another study⁶ demonstrates deep-forehead temperature as having excellent accuracy compared to pulmonary artery temperature, a conclusion strongly supportive of the validity of the temporal artery method of temperature assessment.</p> <p>Physiologically, the superficial temporal artery at the lateral aspect of the forehead demonstrates the necessary requirements for the skin thermometry method: it is easily accessible, contains no mucous membranes, and most importantly, it has no or very few arteriovenous anastomoses (AVA).^{7,8} 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.</p> <p>Clinically, 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.</p>
<p>Pediatric patients 0-1 years in an emergency care setting:</p> <p>Greenes D and Fleisher G. Accuracy of a noninvasive temporal artery thermometer for use in infants. Arch Pediatr Adolesc Med: March 2001; Vol 155; 376-381.</p>	<p>A recently published study from Children’s Hospital in Boston⁹ (n = 304 infants <one year old) found the Exergen TA thermometer to be: a) significantly more accurate than the tympanic thermometer (Sherwood Genius) for predicting rectal temperature in infants, 2) significantly more sensitive than the tympanic thermometer for the detection of rectal fever in infants, and 3) better tolerated by patients than the rectal thermometer.</p> <p>In those cases where there was a significant difference between TA and rectal temperature, the authors questioned the absolute accuracy of rectal temperature, supported by other studies also suggesting a lag between instantaneous changes in core body temperature and more delayed changes in rectal temperature^{10,11} and hypothesized that the TA may be correctly reflecting a rapid change in core body temperature, whereas the rectal temperature is lagging behind. For instance, if antipyretics had been given several minutes before the temperatures were measured, the TA temperature might accurately reflect a lowered core body temperature, while the rectal temperature still reflects the preceding fever. Phase 2 of the initial study evaluating the changes in TA and rectal temperatures in response to changes in core body temperature is nearing completion.</p>
<p>Febrile infants <12 months in an emergency care setting:</p> <p>Comparing rectal and TA temperature to determine if rectal temperature lags in defervescence.</p> <p>Greenes D, Fleisher G, Division of Emergency Medicine, Children’s Hospital, Harvard Medical</p>	<p>Many consider rectal thermometry the standard for non-invasive clinical thermometry. However, some data suggest that rectal temperature responds slowly to changes in body temperature, when compared with simultaneous arterial temperature measurements. If so, rectal thermometry may be an inaccurate measure of body temperature in some situations.</p> <p>The objective of this study was to test the hypothesis that rectal temp defervesces more slowly than temperature measured by a non-invasive temporal artery (TA) thermometer in febrile infants given an antipyretic drug. 51 febrile infants < 12 months of age presenting to a pediatric emergency department were enrolled in the study. Eligible subjects had both initial rectal and TA temperatures $\geq 38.5^{\circ}\text{C}$. Subjects were excluded if they had had any antipyretic drug within the past 2 hours. Acetaminophen (15 mg/kg) or ibuprofen (10 mg/kg) were given by standard nursing protocol.</p> <p>Rectal and TA temperatures were measured 30, 60, and 90 minutes after the antipyretic drug was given. Both TA and rectal temp dropped significantly at each interval measurement ($p < .001$ for all comparisons). Defervescence from baseline temp was greater with TA than rectal thermometers at 60</p>

<p>School, Boston, MA When Body Temperature Changes, Does Rectal Temperature Lag Behind? Pediatric Academic Societies (American Pediatric Society, Society for Pediatric Research, Ambulatory Pediatric Association) Annual Meeting, Poster Section, Poster 520, Baltimore Convention Center, Baltimore MD, May 4-7, 2002.</p>	<p>minutes (mean TA-rectal difference 0.34°C [95% CI 0.11,0.57])(p=.005) and at 90 minutes (mean TA-rectal difference 0.28°C [95% CI 0.06, 0.50])(p=.013). The calculated area under the curve of temperature defervescence over the 90 minute observation period was greater for TA than rectal temp (p=0.023).</p> <p>Conclusion: Rectal temperature defervesces less than TA temp 60 and 90 minutes after an antipyretic drug is given. These data support the theory that changes in rectal temperature lag behind changes in core body temperature and raise questions about whether rectal thermometry should be the standard for non-invasive clinical thermometry.</p>
<p>Febrile pediatric patients in the emergency care setting:</p> <p>Comparison of the arterial heat balance temporal artery, aural and rectal thermometry in children in the emergency department.</p> <p>Schuh S, Komar L, Stephens D, Chu L, Read S, Allen U. Presented at the University of Toronto Emergency Medicine Research Academics Day, October 30, 2001.</p>	<p>A recently presented study abstract by physicians from The Hospital for Sick Children and the University of Toronto, Divisions of Emergency, Clinical Epidemiology, and Infectious Diseases was presented at the University's Emergency Medicine Research Academics Day.</p> <p>The purpose of the study was to evaluate agreement among temperature measurements by the AHB temporal artery thermometer, the AHB ear thermometer, and rectal thermometers, to determine their ability to detect fever. Arterial Heat Balance is a patented method inherent in both the temporal artery and ear thermometers.</p> <p>The study included 327 infants less than two years old, 205 of who had fevers by at least one method. The data demonstrated that the AHB temporal artery thermometer detected 84.4% of the fevers, the AHB ear thermometer detected 65.7% of the fevers, while the rectal thermometer detected 66.7% of the fevers.</p> <p>Conclusion: Based on the findings, the investigators concluded the AHB thermometers to be at least as accurate as rectal temperature in detecting fevers in the Emergency Department.</p>
<p>Pediatric patients in ambulatory care and inpatient settings:</p> <p>Dutko Fioravanti I, et al. Poster Section, Pediatric Nursing Conference sponsored by the Advanced Practice Nurses at the University of Rochester Medical Center, Children's Hospital at Strong, April 27, 2001.</p>	<p>The results of a pilot study¹² conducted at the University of Rochester Medical Center were presented at the Pediatric Nursing Conference sponsored by the Advanced Practice Nurses at the Children's Hospital at Strong on April 27, 2001.</p> <p>This was a study undertaken in the Children's Hospital to compare temporal artery thermometry (Exergen) to their current method of rectal temperature, in both the inpatient (n=2400) and ambulatory care (n=300) units.</p> <p>Results: 2700 paired readings identified differences between rectal and temporal artery temperatures to be less than 4%.</p> <p>Conclusion: The investigators determined temporal artery thermometry to be sufficiently accurate and precise for routine use on this patient population.</p>
<p>Adult patients in intensive care settings:</p> <p>Carroll DL, Finn C, Gill S, Sawyer J, Judge B. A Comparison of Measurements from a Temporal Artery Thermometer and a Pulmonary Artery Catheter Thermistor – National Conference of Clinical</p>	<p>From Massachusetts General Hospital, Boston, MA, preliminary findings of an ongoing study involving 300 adult patients were presented at the National Conference of Clinical Nurse Specialists, Poster Section, March 14-16, 2002.</p> <p>Pulmonary artery (PA) temperatures are generally considered to be true measures of core body temperature, and since they are obtainable on patients with previously inserted PA catheters, can be used to verify other methods of temperature measurement.</p> <p>Preliminary findings involved 130 adult patients with a mean age of 65 years, 64% male. In various stages of warming and diaphoresis in the Coronary Care Unit and the Cardiac Surgical Intensive Care Unit¹³</p> <p>Conclusion: The data demonstrated TA temperature to be as accurate as PA temperature measured by</p>

<p>Nurse Specialists, Poster Section, Atlanta, GA March, 2002</p>	<p>a pulmonary artery catheter.</p> <p>Further, the findings demonstrated <i>no correlation</i> between PA temperature and oral temperature.</p>
<p>Premature neonates, 25-34 week gestation, in an intensive care setting:</p> <p>Vladimir F. Burdjalov, Adrienne Combs, Sharon Nachman, Stephen Baumgart. Non-invasive temperature assessment of the temporal artery for core temperature determination in premature neonates. American Pediatric Society and the Society for Pediatric Research, May 1, 2001.</p>	<p>Accurate serial measurements of body core temperature in critically ill premature neonates is vital for providing safe re-warming and incubation, particularly in cold stressed, very low birth weight neonates. Deep rectal or esophageal probes require insertion at five or more centimeters to accurately reflect core temperature, and may result in visceral erosion or perforation. More superficial probe placement, or axillary temperatures may be considerably cooler than the true core. Tympanic membrane infrared thermometry in tiny preterm babies is also notably inaccurate. Application of a novel, non-invasive infrared scanning device applied over the temporal artery in preterm infants may provide a better alternative for assessing and regulating core temperature.</p> <p>The results of a pilot study¹⁴ presented May 1, 2001 at the American Pediatric Society and the Society for Pediatric Research by Steve Baumgart, MD and colleagues, Neonatal & Infectious Disease Divisions, Departments of Pediatrics and Nursing, State University of New York at Stony Brook, compares routine clinical temperature assessments by axillary thermistor (IVAC) to infrared thermometry scanned over the temporal artery (Exergen) in premature neonates, gestation 25-34 weeks, birth weight 575-2,540 grams, who were assessed in air temperature controlled (N=6), and skin temperature servo controlled (N=6) convection warmed incubators.</p> <p>The investigators concluded that infrared scanned temperature over the temporal artery (Exergen) “better reflects true core temperature in premature babies, and is less invasive than deep rectal or esophageal temperature monitoring. Moreover, serial temperature assessments during re-warming and incubation are easy to perform.”</p>
<p>Other Formal Studies</p>	<p>There are currently additional formal studies also conducted at major university hospitals in North America that have been completed and have either been submitted for publication, or are in the process of being submitted. None can be cited here, but it is permissible to state that all of these studies are highly supportive of the temporal artery method.</p>
<p>Gary Fleisher, MD, Professor of Pediatrics, Harvard Medical School, Director Emergency Medicine, Children’s Hospital, Boston.</p> <p>Keith Powell, MD, Professor of Pediatrics, Northeast Ohio Universities College of Medicine, Physician-in-Chief Children’s Hospital Akron.</p> <p>David Greenes, MD, Pediatrician, Emergency Medicine, Children’s Hospital and Harvard Medical School</p>	<ol style="list-style-type: none"> 1. "There really is a need for something that is quick, accurate, noninvasive and nonirritating," says Dr. Gary Fleisher, a temperature expert at Children’s Hospital, Professor at Harvard Medical School, and the lead author of the new study. Despite the popularity of tympanic thermometers, Dr. Fleisher said, “Their accuracy is less than desirable, and if people are currently using an ear thermometer, the temporal artery thermometer is more accurate and easy to use.” <i>High Fever, Meet High-Tech Thermometer</i>, Shari Roan, Los k, April 9, 2001. 2. The new technology (TA thermometry) "has been carefully thought out, and it's going to be useful," says Dr. Keith Powell, chairman of the Department of Pediatrics at Northeast Ohio Universities College of Medicine, and Physician-in-Chief, Children’s Hospital, Akron, Ohio. <i>High Fever, Meet High-Tech Thermometer</i>, Shari Roan, Los Angeles Times, Monday, April 9, 2001. 3. In an interview on National Public Radio on the program “<i>All Things Considered</i>” commenting on accurate temperatures, Dr. David Greenes, a pediatrician specializing in Emergency Medicine at Children’s Hospital and Harvard Medical School said, “Essentially we found that by every measure that we used, the temporal artery thermometer was more accurate than the tympanic. The under the tongue method is probably the one that is most commonly used by patients and their families for older children and for adults, and I think, if done carefully, if you leave the thermometer in for several minutes, it can be reasonably accurate. And, similarly, with the under the arm method, under ideal circumstances it can be OK, but you have to be very careful. So for routine measurements, we don’t find either the oral or the under the arm method to be so reliable.” <p>When asked for what age patients the TA thermometer would be recommended, Dr. Greenes recommended it’s use on “infants in the first couple of months, and even the first couple of years”. Dr Greenes is also one of the scientific investigators in the above-stated Children’s Hospital study. This segment is from the Wednesday, April 11, 2001 All Things Considered, syndicated on National Public Radio.</p>

<p>Barry McCraw, MD, Pediatrician, St. Mary's Hospital, Russellville, AR.</p> <p>Shari Roan, Syndicated Health Writer, Times News Publications</p>	<p>4. Dr. Barry McCraw, a Pediatrician at St. Mary's Hospital, Russellville, AR, uses TA thermometry throughout his practice and said, "It is much easier to use than the ear temp probes; no handling of the ear, which typically scares a child, is a great benefit. I have been very impressed with the accuracy of the unit. I would highly recommend it to anyone."</p> <p>5. "The method works well, researchers say, because the temporal artery, located in the forehead, is directly connected to the heart through the carotid artery. The temporal artery is also close to the skin's surface." Reported by Shari Roan, Syndicated Health Writer, Times News Publications, High Fever, Meet High-Tech Thermometer, Shari Roan, Los Angeles Times, Monday, April 9, 2001</p>
<p>Consumer Reports, Front Lines: Product Test Report, August 2000</p>	<p>Engineers at the headquarters for the magazine <i>Consumer Reports</i> tested the home version of the TA thermometer in their laboratory, and reported: "...it works".¹⁵</p> <p>The home model was then tested in the home setting by a small group of parents, who attested to it's ease of use, and who unanimously voiced their preference for the TA thermometer over glass mercury and electronic digital thermometers. <i>Consumer Reports</i>, August 2000.</p>
<p>Regulatory Approval</p>	<p>Food and Drug Administration (FDA) Acceptance; European CE Mark, 0197, TUV, Declaration of Conformity-ISO 9003/08.94; Health Canada, Canadian Therapeutic Products Directorate, Medical Devices Bureau, License 36469, Class II Devices/Instruments; National Institute for Standards and Technology (NIST) certifiable traceable calibrations; Meets or exceeds all American Society for Testing and Materials (ASTM) and Medical Device Directive (MDD) 93/42/EEC standards for radiation thermometers; Underwriters Laboratories (UL) Mark for product safety testing certification.</p>
<p>Patents</p>	<p>Protected by one or more of the following US patents: 6056435, 6047205, 6045257, 5893833, 5874736, 5653238, 5628323, 5445158, 5381796, 5325863, 5199436, 5017019, 5012813, 4993419, 4874253, 4636091, RE035554, D03708. Other US and foreign patents pending.</p>

References

- 1 Coar T. The Aphorisms of Hippocrates with a Translation into Latin and English, pub AJ Valpy, London 1822.
- 2 Graneto JW, Soglin DF. Maternal screening of childhood fever by palpation. *Pediatr Emerg Care* 1996 Jun; 12(3): 183-4.
- 3 Banco L, Veltri D. Ability of mothers to subjectively assess the presence of fever in their children. *Am J Dis Child* 1984 Oct; 138 (10): 976-8.
- 4 Singhi S, Sood V. Reliability of subjective assessment of fever by mothers. *Indian Pediatr* 1990 Aug; 27(8): 811-5.
- 5 Bergeson PS, Steinfield HJ: How dependable is palpation as a screening method for fever. *Clin Pediatr* 13:350, 1974.
- 6 Harioka T, Matsukawa T, et al. Deep-forehead temperature correlates well with blood temperature. *Can J Anaesth* 2000 Oct; 47(10): 980-3.
- 7 Bergersen TK. A search for arteriovenous anastomoses in human skin using ultrasound Doppler. *Acta Physiol Scand* 1993 Feb; 147(2): 195-201.
- 8 Takehiko I, Sessler et al. Influence of thermoregulatory vasomotion and ambient temperature variation on the accuracy of core-temperature estimates by cutaneous liquid-crystal thermometers, *Anesthesiology*, V 86, No 3, Mar 1997.
- 9 Greenes D and Fleisher G. Accuracy of a noninvasive temporal artery thermometer for use in infants. *Arch Pediatr Adolesc Med*: March 2001; Vol 155; 376-381.
- 10 Gerbrandy J, Snell E, Cranston W. Oral, rectal, and oesophageal temperatures in relation to central temperature control in man. *Clin Sci (Colch)*. 1954, 13:615-624.
- 11 Molnar G, Read R. Studies during open-heart surgery on the special characteristics of rectal temperature. *J Appl Physiol*.1974; 36:333-336.
- 12 Dutko Fioravanti I, et al. Poster Section, Pediatric Nursing Conference sponsored by the Advanced Practice Nurses at the University of Rochester Medical Center, Children's Hospital at Strong, April 27, 2001.
- 13 Carroll DL, Finn C, Gill S, Sawyer J, Judge B. A Comparison of Measurements from a Temporal Artery Thermometer and a Pulmonary Artery Catheter Thermistor - Preliminary Results, April, 2001.
- 14 Vladimir F. Burdjalov, Adrienne Combs, Sharon Nachman, Stephen Baumgart. Non-invasive temperature assessment of the temporal artery for core temperature determination in premature neonates. *American Pediatric Society and the Society for Pediatric Research*, May 1, 2001.
- 15 Pittle RD, Sr. Vice President and Technical Director. Front Lines, Product Test: Feeling flush? *Consumer Reports*, Vol 65, No. 8: 10, August 2000.