

Comparison of Core Temperature Measurement from Bladder Temperature and ARC Devices InstaTemp MD

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Abstract:

This is a cross sectional observational study designed to accurately and reliably validate estimates of Core Body temperature using the naturally emitted surface body heat from the patient's forehead as measured by the ARC Devices, Ltd. InstaTemp™MD Infrared, Non-Touch thermometer. The InstaTemp™MD readings were compared to the "Gold Standard" Core Body Temperature measurement using an indwelling bladder thermometer for verification.

The results from comparative hospitalized patient measurements demonstrates that the ARC Devices, Ltd. InstaTemp™ MD Infrared, Non-Touch thermometer reliably and consistently estimates Core Body temperature in human subjects well within the range of day to day variability

Based on an extensive literature review, this is most likely the first, and perhaps the only, digital infrared, non-touch thermometer that accurately estimates Core Body temperature within a 95% Confidence Interval. The InstaTemp™MD uses a highly sensitive infrared heat sensor that does not touch the patient. It is completely harmless with no known safety concerns and no known potential for cross contamination.

This study was designed to compare the readings obtained from ARC's InstaTemp™ MD Infrared (IR) Thermometer for clinical inpatient use with Core Body temperature readings taken using an indwelling Bladder Thermometer - the "Gold Standard" in clinical thermometry. The InstaTemp™MD estimates Core Body temperature from heat emissions from the center of the forehead skin above the eyebrows, while instantly accounting for variable changes in ambient temperature. It affords reliable, accurate and safe hyperthermic fever detection as well as hypothermic determinations without direct body contact.

The study consisted of comparing patient readings using the, ARC InstaTemp™MD1-DC development device with Core General Intensive Care Unit indwelling bladder temperature readings. The InstaTemp MD1-DC unit uses sensors that are "scientific grade" black box verified to be accurate to within $\pm 0.1^{\circ}\text{C}$ versus sensors verified to be within $\pm 0.15^{\circ}\text{C}$ in the commercially available InstaTemp™ MD. The development device also provides readings to two decimal places instead of just one for greater accuracy and estimations for clinical use.

Background

In almost all clinical settings, nearly every patient is first monitored for vital signs (temperature, heart rate, blood pressure, and respiration rate) to screen for the presence or absence of a clinical condition requiring medical treatment. In the inpatient setting, vital signs are often taken 4-6 times per day or more, depending on the patient unit. Oncology units often take temperatures more frequently. In the non-surgical setting, “accurate temperature measurement is critical to the assessment and management of temperature fluctuation in the acutely ill adult.”¹

According to *Harrison's Principles of Internal Medicine* (18th ed.)², normal internal body temperature is 37.0°C (98.6°F). Oral (sublingual) temperature is approximately 0.4°F lower than Core Body with a $\pm 0.7^\circ\text{F}$ variation around the mean ($36.8\pm 0.4^\circ\text{C}$; $98.2\pm 0.7^\circ\text{F}$) compared to measurements from “the esophagus, nasopharynx or rectum”³.

Tympanic membrane thermometers are often cumbersome, may cause pain to the patient and may be difficult to get accurate placement or readings due to tortious ear canals, cerumen, otitis media, hearing aids, poor operator placement and other impediments. Many of the other instruments available for inpatient hospital temporal artery thermometry also require expensive probe covers and touch the patient. This produces medical waste and the risk of iatrogenic infection.

A recent study by *Hooper et. al.* at the Medical College of Georgia (Augusta) reviewed 223 publications and abstracts from *Medline* and *CINAHL* databases to locate published studies on temperature measurement in the adult hospitalized patient. Studies included comparisons of a tympanic, temporal artery, and/or oral non-invasive temperature measurement to Core Body temperature.

As per **Table 1** (below), studies indicate that normal Core Body temperatures are typically 0.6°F higher than oral (sublingual) temperatures in normal individuals age 18 to 65. They are 0.2°F to 0.3°F higher in patients age 66 and older. Rectal temperatures are typically higher than both Core Body temperatures since the rectal muscle tends to act as a “heat sink” trapping the heat, while axillary temperatures are typically almost 2°F to 3°F lower than Core Temperatures. Normal tympanic membrane temperatures are also typically 0.5°F to 1.6°F lower than Core Body Temperatures.

¹Hooper VD, Andrews JO (2006). Accuracy of noninvasive core temperature measurement in acutely ill adults: the state of the science. School of Nursing at the Medical College of Georgia, Augusta. Biol Res Nurs July 8: 24-34.

² Harrison's principles of internal medicine. (18th Ed.). New York: McGraw-Hill. 2011. p. 142. ISBN 978-0-07-174889-6

³ Segen's Medical Dictionary. s.v. "core temperature." Retrieved February 22 2015 from <http://medical-dictionary.thefreedictionary.com/core+temperature>

Table 1. Normal Core Body Temperature Ranges

Age	0-2 years old	3-10 years old	11-65 years old	>66 years old
Core Temperature	97.5°F -100.0°F	97.5°F -100.0°F	98.2°F -100.2°F	96.6°F -98.8°F
Oral (Sublingual Pocket)	-	95.9°F - 99.5°F	97.6°F -99.6°F	96.4°F -98.5°F
Tympanic Membrane	97.5°F -100.4°F	97.0°F - 100.0°F	96.6°F -99.7°F	96.4°F -99.5°F
Rectal	97.9°F -100.4°F	97.9°F -100.4°F	98.6°F -100.6°F	97.1°F -99.2°F
Axillary	94.5°F -99.1°F	96.6°F -98.0°F	95.3°F -98.4°F	96.0°F -97.4°F

Source: Fitzgerald, E. (2003) Welch Allyn Accuracy Study for the Welch Allyn Model 692/690 SureTemp Plus Oral Adult, Axillary and Rectal Thermometer (2003), Table 2, page 4.

The recent mass screening programs around the world underscored the urgent need to develop “Non-Touch” Infrared (IR) thermometers with a high level of accuracy to:

- (a) Minimize the risk of contamination with infectious pathogens from oral (sublingual) or tympanic membrane thermometers, and;
- (b) Quickly and reliably screen large numbers of individuals for potential fever.

The mass screenings of populations focuses on early detection by screening for people with temperatures usually higher than 100.9°F (38.3°C)⁴. Hospitals and government agencies need accurate, reliable non-touch devices to safely detect fever without touching the subject. In pediatrics and inpatient settings, the ability to not wake the patient or probe the patient and instantly take a temperature via infrared temporal artery thermometry has been reported to produce “demonstrable savings in nursing time and nursing cost by 87%”⁵.

Literature Review

Research indicates that both inside and outside the hospital in non-surgical settings, a variety of methods of determining a patient’s Core Temperature are currently used. The most common methods today include Digital Oral thermometry and Infrared Tympanic Membrane thermometry.

All of these methods require touching the patient which may cause discomfort. They also represent a potential route of transmission for viral and bacterial diseases amongst patients. In contagious

⁴ Hoenen T, Groseth A, Falzarano D, Feldmann H (May 2006). "Ebola virus: unravelling pathogenesis to combat a deadly disease". Trends in Molecular Medicine 12 (5): 206–215. doi:10.1016/j.molmed.2006.03.006. PMID 16616875.

⁵ Carr E., Wilmoth M., Eliades A., Baker P., Shellestak D., Hiesroth K., Stoner K. (2011). Journal of Pediatric Nursing (26): 179-185. Comparison of Temporal Artery to Rectal Temperature Measurement in Children Up to 24 months.

disease processes, transmission occurs as a result of contact with the patients' bodily fluids. Since these other methods involve touching the patients, they endanger patients by risking transmission of infectious agents while attempting to take a measurement. When probe covers are used, potentially dangerous medical waste is produced. Therefore, Non-Touch Infrared thermometry may be the best approach to avoiding potential transmission of contagious infectious agents.

A recent global industry study (September 2013) indicated that "Improper handling [of thermometers and probe covers] by the hospital staff may result in direct contact and can lead to contamination⁶." According to this study, "current probe cover sensors carry both virulent and non-virulent microorganisms...Microorganisms deposited on these thermometers may be transmitted to other patients through the reusable probe and the electronic housing...Reusable electronic units are taken from room to room and patient-to-patient may be a means for cross [patient] contamination...Open probe cover boxes moved from one place to another may carry microorganisms...thus, probe covers may act as potential carriers of infectious disease."⁷

The study concludes that "true 'Non-Touch' Infrared units would have a much smaller chance of spreading infectious agents."⁸ Infrared units are also faster, more efficient and more convenient for nurses and physician assistants.

10 clinical methods are typically used to measure a patient's temperature including:

1. Pulmonary Artery (Swan-Ganz Catheter)
2. Esophageal Thermistor
3. Indwelling Bladder Catheter
4. Rectal
5. Tympanic Membrane (Contact Probe and Infrared)
6. Skin Surface (Digital, Chemical and Infrared)
7. Axillary
8. Oral
9. Tracheal and
10. Nasopharynx

The Pulmonary Artery Catheter, Esophageal Thermistor and Indwelling Bladder Catheter are considered the "Gold Standard" for measuring core temperature. Both Pulmonary Artery Catheters and Esophageal Thermistors require sedation of the patient. Indwelling Bladder Catheterization methods do not require sedation and can be utilized pre-operatively, during surgery and postoperatively which was, therefore, used as the gold standard in this study. Indwelling Bladder

⁶ Temperature Monitoring Devices, A Global Strategic Business Report, September 2013, MCP3365, Global Industry Analysts, Inc. Section II – page 20

⁷ Ibid.

⁸ Ibid.

catheterization correlates closely with Pulmonary Artery Measurements^{9/10}but does not carry as much risk of the possibility of inducing infection, pneumothorax, thromboemboli, dysrhythmias and potential equipment failure as the other two methods.¹¹

While rectal temperatures were historically considered a gold standard in children less than 3 years of age¹², they have been found to offer slower responses to rapid changes in core temperatures and are typically lower than core measurements. Other studies have indicated that due to the surrounding muscle mass of the rectum, the tissue acts as a “heat reservoir” and leads to inaccurate indications of Core Body temperatures.¹³ The level of discomfort, risk of traumatic injury to the rectum and transmission of stool borne pathogens also makes rectal measurement methodologies less than ideal for both inpatient and outpatient settings.

The axillary method is often preferred by parents, children and caregivers. Yet, this method is easily affected by changes in ambient temperatures and skin perspiration.¹⁴ This leaves traditional oral thermometry methods and the newer infrared methods. Studies indicate that the oral methods can be affected by probe positioning, drinking hot or cold liquids prior to measurement and hyperventilation.¹⁵ Oral methods also pose the greatest risk of infectious agent transmission, especially in infectious agent cases. Oral and axillary temperature measurements also take considerable time to develop a stable, accurate reading ranging from 1 minute for typical digital oral thermometers to 5 minutes with axillary placement.¹⁶ This is impractical for a mass screening process at airports and other locations for contagious infectious agents.

Newer infrared thermometers are much faster and more efficient than traditional oral and axillary thermometers.¹⁷ Earlier versions of infrared thermometry were designed to be placed in the outer ear canal to measure the heat emissions of the carotid arterial branches to the hypothalamus and central nervous system. However, tympanic readings have been shown to vary by operator

⁹ Fallis WM: Monitoring urinary bladder measurements in the intensive care unit: State of the science: *American Journal of Critical Care*, (2002); 11:38-45.

¹⁰ Lefrant JY, Muller L, Coussaye JE, et. al.: Temperature measurement in the intensive care patients: Comparison of urinary bladder, esophageal, rectal, axillary, and inguinal methods vs. pulmonary artery core methods; *Intensive Care Medicine* (2003); 29: 414-418.

¹¹ Katz JD, Cronau LH, Barash,PG, et. al: Pulmonary artery flow guided catheters in the perioperative period: Indications and complications. *Journal of the American Medical Association* (1977). 237:2382-2384.

¹² Carr E., Wilmoth M., Eliades A., Baker P., Shellestak D., Hiesroth K., Stoner K. Comparison of Temporal Artery to Rectal Temperature Measurement in Children Up to 24 months. (2011) *Journal of Pediatric Nursing* (26): 179-185.

¹³ Lovoy A, et. al., Comparison of ear to rectal temperatures in infants and toddlers. (1999) *Clinical Pediatrics*. 38:463-488.

¹⁴ Erikson RS, Kirklin SK: Comparison of ear-based, bladder, oral and axillary method for core temperature measurement. *Critical Care Medicine* (1993); 21:1528-1534

¹⁵ Terndrup TE, Allegra JR, Keally JA: A comparison of oral, rectal, and tympanic membrane – derived temperature changes after ingestion of liquids and smoking. *American Journal of Emergency Medicine* (1989); 7:150-154.

¹⁶ Ibid.

¹⁷ Carr E., Wilmoth M., Eliades A., Baker P., Shellestak D., Hiesroth K., Stoner K. Comparison of Temporal Artery to Rectal Temperature Measurement in Children Up to 24 months. (2011) *Journal of Pediatric Nursing* (26): 179-185.

placement, crying patients, ambient temperature, facial cooling, curvature of the ear canal and presence of cerumen in the ear.¹⁸ In the pediatric population, it is hard to place a thermometer in the patient's ear for an extended period of time. In the geriatric population, one often needs to remove a hearing aid which has the risk of getting lost and may be expensive to replace.

Tympanic thermometers also require expensive probe covers. One 673 bed U.S. hospital claims it spends \$15,000-\$20,000 per year on tympanic membrane probe covers, plus the added cost of removing the medical waste. This cost is based on only one tympanic membrane thermometer per nursing station or per unit (i.e., ICU, CCU, PICU).

The newest types of infrared thermometers have highly sensitive sensors measure the infrared heat emissions from a patient. These emissions can be recorded from any surface on the body (e.g., forehead, axillary, etc.). It provides an instant reading and is far less intrusive than a normal thermometer. It is quick and easy. A reading can be taken without coming into physical contact with the patient, thus virtually eliminating the risk of iatrogenic infection. It is consequently more likely to be tolerated by a subject.

*Cultu et al. (2008)*¹⁹ states that the “the ease of use and short calibration time for reading are advantageous for these thermometers.” The Horizon Scan Report (2012)²⁰ brings together the most reliable recent literature on this subject and suggests that the use of an infrared thermometer may lead to “long-term cost savings in terms of reduced staff costs (less time to obtain readings than axillary thermometry) and material costs.”

Study Design – Sample and Setting

This study is designed to accurately match the reading of ARC's InstaTemp™MD1-DC from heat emissions via the forehead skin to the Core Body temperature, while incorporating changes in ambient temperature for afebrile, febrile and hypothermic patients in an ICU setting.

The testing was performed at Cork University Hospital Clinical Research Facility-Cork, UCC HRB Clinical Research Facility Cork. Surface temperature readings were taken from the patient's forehead's and compared to simultaneous readings generated by the indwelling bladder catheter. A scientific grade thermometer was utilized to measure the ambient temperature of the room.

¹⁸ Ibid.

¹⁹ Cultu O., Yildirim I., Ceyhan M., Korkmaz A., Yurdakok M., Karaagaoglu E., Secmeer G. Comparing body temperature measurements by mothers and physicians using mercury-in-glass, digital mercury and infrared tympanic membrane thermometers in healthy newborn babies. *Turkish Journal of Pediatrics*, 2008, vol./is. 50/4(354-358), 0041-4301.

²⁰ Horizon Scan Report 00251. Non-contact infrared thermometers Clinical Question(s): What is the accuracy and utility of non-contact infrared thermometers compared to other methods of measuring temperature in children? (November 2012)

The agreement of the measured temperature with the gold standard bladder temperature was examined and the mean bias was calculated. The results were examined using Pearson's correlation, using a type I error rate of 0.05.

Data Collection

A reliable statistical sample of (267) readings were obtained in the General ICU ward validating the relationship between measurements calculated by the InstaTemp™ MD1-DC vs. temperature measured by the in-dwelling bladder catheter. The testing was performed by Prof. Joe Eustace and colleagues in the HRB Clinical Research Facility (CRF-C) at Cork University Hospital, a government funded clinical research agency.

A sub-agency of the Health Research Board of Ireland, the CRF-C is a center of excellence research facility serving multi-national medical device and pharma companies in the design, execution, and analysis of breakthrough clinical research. Cork University Hospital is a large academic teaching hospital in Cork, Ireland. The research was undertaken independently of the study sponsors and was approved by the hospital research ethics committee.

The sensor and units used for patient testing were tested by the sponsor against a scientific grade black box to determine accuracy, and were found to be accurate to within 0.1°C. The bladder temperature is found to be slightly greater than the Pulmonary Artery temperature, and often cited as a reference Core Body temperature.

Procedure

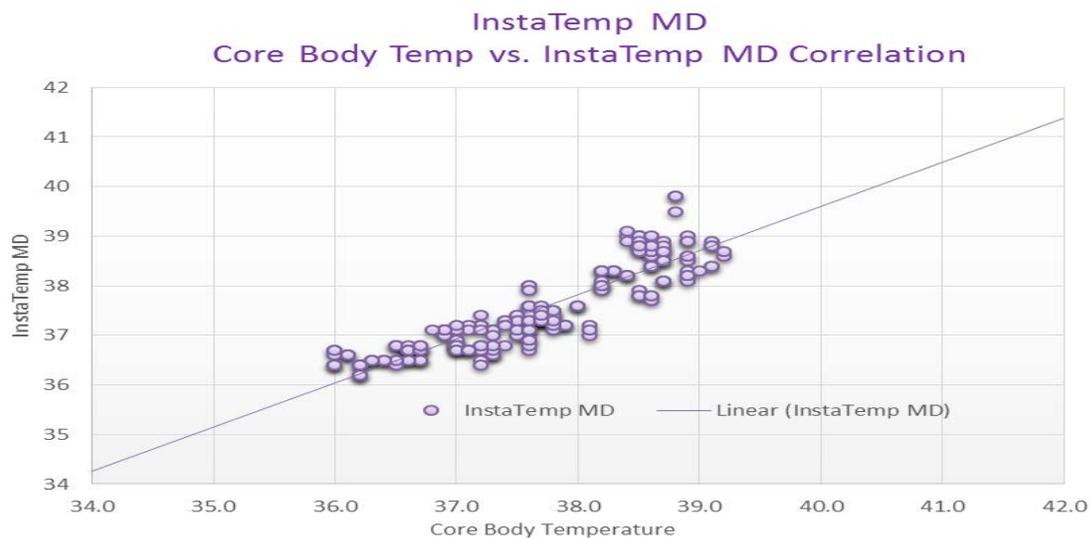
To avoid potential errors in methodology by multiple researchers, a single PhD researcher collected the data using a consistent methodology. The procedure was designed to measure the emitted surface body heat of the patient at multiple points in time (**without touching the patient**) and compare these readings to the Core Temperature of the patient as routinely measured in the ICU setting. The researcher took the temperature of the patient using the InstaTemp™ MD1-DC by pointing the sensor at the patient's forehead from a distance of approximately 2.5 cm. This reading was recorded and simultaneously compared by the Anesthesiologist from the patient's forehead to the routine instrument readings from an indwelling bladder catheter thermistor.

The procedure was repeated at least three times for each subject. The number of times a patient's temperature was taken and at what intervals was left to the discretion of the researcher based on the setting in which the patient is and the condition of the patient. The ambient temperature was recorded during the study to ensure it is between the recommended operating temperatures. The ICU patients provided accurate sampling due to the variety of septic febrile patients, afebrile patients and post-surgical hypothermic patients across the general range of human Core Body temperature readings.

Results

The relationship between the InstaTemp™ and the Core Body temperature measurements is shown in **Figure 1**. The results provide a Pearson's correlation coefficient of $r=0.89$, $p=0.001$.

Figure 1: The relationship of InstaTemp™ MD-DC measurements relative to the bladder temperature in 267 duplicate measurements. The diagonal line shows the line of identity representing perfect agreement.



The mean (SE) overall difference for all 267 InstaTemp™ MD1-DC measurements relative to the bladder temperature was -0.19 (0.03), with 95% confidence interval for the mean difference being -0.24 to -0.14 . The standard deviation for the difference between the 2 techniques was 0.4 .

Discussion

The relationship between Core Body temperature and peripheral temperature is complex and varies both within and between subjects. Since Core Body temperature, by its nature, is difficult to access outside of the Operating Room, accurate estimations can be obtained using Non-Contact Infrared thermometry.

In-vitro testing of the InstaTemp™MD1-DC device confirms that it accurately and precisely measures surface temperature. Our study demonstrates that in clinical use it reliably reflects the change in Core Body temperature with high correlated with each other and can be used in the clinical setting to reflect and effectively signal the presence of an underlying fever. The average

absolute difference is relatively modest with a mean value of -0.19 and is well within the range of day to day variability in Core Body temperature.

References

1. Nimah MM, Bshesh K, Callahan JD, Jacobs BR. *Pediatric Critical Care Med.* 2006 Jan;7(1):48-55. Infrared tympanic thermometry in comparison with other temperature measurement techniques in febrile children.
2. Xiaojiang Xu, Anthony J. Karis, Mark J. Buller, William R. Santee. *European Journal of Applied Physiology.* DOI 10.1007/s00421-013-2674-z. Relationship between core temperature, skin temperature, and heat flux during exercise in heat.
3. Fitzgerald E. (2003). Welch Allyn. Accuracy Study for the Welch Allyn SureTemp Model 692/690 SureTemp Plus Oral, Adult Axillary and Rectal Thermometer.
4. Carr E., Wilmoth M., Eliades A., Baker P., Shellestak D., Hiesroth K., Stoner K. (2011). *Journal of Pediatric Nursing* (26): 179-185. Comparison of Temporal Artery to Rectal Temperature Measurement in Children Up to 24 months.
5. Horizon Scan Report 00251. Non-contact infrared thermometers Clinical Question(s): What is the accuracy and utility of non-contact infrared thermometers compared to other methods of measuring temperature in children? (November 2012).
6. Lee JY, Nakao K, Takahashi N, Son SY, Bakri I, Tochiyama Y. Validity of infrared tympanic temperature for the evaluation of heat strain while wearing impermeable protective clothing in hot environments. *Industrial Health*, 2011, vol./is. 49/6(714-25), 0019-8366;1880-8026.
7. Masamune T, Yamauchi M, Wada K, Iwashita H, Okuyama K, Ino H, Yamakage M, Ishiyama T, Matsukawa T. The usefulness of an earphone-type infrared tympanic thermometer during cardiac surgery with cardiopulmonary bypass: clinical report. *Journal of Anesthesia*, August 2011, vol./is. 25/4(576-9), 0913-8668;1438-8359.
8. Edelu BO, Ojinnaka NC, Ikefuna AN. Fever detection in under 5 children in a tertiary health facility using the infrared tympanic thermometer in the oral mode. *Italian Journal of Pediatrics*, 2011, vol./is. 37/(8), 1720-8424;1824-7288.
9. Paes BF, Vermeulen K, Brohet RM, van der Ploeg T, de Winter JP. Accuracy of tympanic and infrared skin thermometers in children. *Archives of Disease in Childhood*, December 2010, vol./is. 95/12(974-8), 0003-9888;1468-2044.
10. Landa DC, Brasil-Neto JP, Boechat-Barros R, Uribe C. Normative study of tympanic infrared thermometry: a non-invasive index of asymmetric cerebral activity. *Arquivos de Neuro-Psiquiatria*, March 2008, vol./is. 66/1(50-2), 0004-282X;0004-282X.
11. Cultu O., Yildirim I., Ceyhan M., Korkmaz A., Yurdakok M., Karaagaoglu E., Secmeer G. Comparing body temperature measurements by mothers and physicians using mercury-in-glass, digital mercury and infrared tympanic membrane thermometers in healthy newborn babies. *Turkish Journal of Pediatrics*, 2008, vol./is. 50/4(354-358), 0041-4301.
12. Vertedor-Hurtado MV, Padín-López S, Carreira-Pastor MJ, López-Martínez JM. The tympanic thermometer in pediatrics as an alternative to the mercury-in-glass thermometer. *Enfermería Clínica*, 01 May 2009, vol./is. 19/3(115-120).

13. Duncan AL, Bell AJ, Chu K, Greenslade JH. Can a non-contact infrared thermometer be used interchangeably with other thermometers in an adult emergency department? *Australasian Emergency Nursing Journal*, 01 August 2008, vol./is. 11/3(130-134).
14. Pickersgill, J, Fowler, H, Boothman J, Thompson, K, Wilcock, S, Tanner, J. Temperature taking: children's preferences. *Paediatric Nursing*, 2003. 15:2, 22-25.
15. Barnason, S, Williams, J, Proehl, J, Brim, C, Crowley, M, Leviner, S, Lindauer, C, Naccaroto, M, Storer, A. Clinical Practice Guideline: Non-Invasive Temperature Measurement in the Emergency Department. December 2011. Emergency Nurses Association. <http://www.ena.org/practice-research/research/CPG/Documents/TemperatureMeasurementCPG.pdf>
16. CPG Evidence Table. Barnason, S, Williams, J, Proehl, J, Brim, C, Crowley, M, Leviner, S, Lindauer, C, Naccaroto, M, Storer, A. Clinical Practice Guideline: Non-Invasive Temperature Measurement in the Emergency Department. December 2011. Emergency Nurses Association. <http://www.ena.org/practiceresearch/research/CPG/Documents/TemperatureMeasurementEvidenceTable.pdf>
17. Sessler, D. Temperature Monitoring and Perioperative Thermoregulation, *Anesthesiology*. Aug 2008; 109(2): 318–338. doi: 10.1097/ALN.0b013e31817f6d76 PMID: PMC2614355. NIHMSID: NIHMS80954