

# Comparison of ARC InstaTemp MD® versus the Welch Allyn Braun 4000 Pro Scan Ear Thermometer measuring Clinical Bias in Geriatric Patients on Corticosteroid, Vasoactive, and Blood Pressure Medication in Normal Temperature Ranges

Mark Khachaturian<sup>2</sup>, PhD, Dr. Steven Reznick, MD<sup>1</sup>, Mary Ann Greenawalt<sup>2</sup>, Liz Gross<sup>2</sup>

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## **Abstract:**

*This is a cross sectional clinical observational study designed to compare the accuracy of the ARC Connected Health ARC InstaTemp MD® Non-Touch Infrared Digital Thermometer versus a current industry standard Welch Allyn Braun 4000 Pro Scan Ear Thermometer. The study was performed at S. Reznick MD PA in Boca Raton, FL and aimed at geriatric patients in normal temperature ranges who were on at least one of the following types of medication: corticosteroid, vasoactive, or blood pressure medication. The purpose of the study was to assess the impact of these types of medication on the ARC InstaTemp MD® body core measurements compared to a tympanic standard.*

*The results demonstrate that the ARC Connected Health ARC InstaTemp MD® Non-Touch Infrared Digital Thermometer accurately estimates core body temperature in geriatric patients in normal temperature ranges who are on corticosteroid, vasoactive, and blood pressure medication to within 0.17 [°C] compared to Welch Allyn Braun 4000 Pro Scan Ear Thermometer that is in widespread use in hospital practice both in the US and EU.*

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## **Background:**

The ARC Connected Health ARC InstaTempMD ® Non-Touch Infrared Digital Thermometer estimates core body temperature<sup>1</sup> from heat emissions from the patient's skin surface in the center of the forehead above the eyebrows. It affords reliable, accurate and safe hyperthermic fever detection as well as hypothermic determinations without direct body contact. This was an independent research study conducted by S. Reznick MD PA in Boca Raton, FL.

## **Methodology:**

S. Reznick MD PA, under the supervision of Dr. Steven Reznick, MD conducted this cross-sectional, clinical investigation to quantify accuracy of body temperature estimated from emitted surface body heat as measured by the ARC Connected Health ARC InstaTemp MD® Non-Touch Infrared Digital Thermometer (referred to herein as ARC InstaTemp MD®). The study was funded by ARC Connected Health; the independent research team was led by Dr. Steven Reznick, MD.

Temperature readings using the ARC InstaTemp MD® were compared in 45 patients to concurrent measurements obtained using Reference Clinical Thermometry units commonly used by hospitals,

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clinics, ambulatory surgical centers, physicians' offices and other clinical locations in both the United States and in Europe (the Welch Allyn Braun 4000 Pro Scan Ear Thermometer).

Patient consent was obtained verbally at the time care was provided during a routine examination. Full editorial power over the final analysis and report remained with the study team.

## **Study Procedures:**

Subjects who were being treated with (a) cooling blankets, (b) fans, (d) thyroxine replacement therapy, (e) barbiturates, (f) had eaten or ingested fluids in the previous 15 minutes, (h) were unable to expose their forehead, (i) had bilateral in-situ hearing aids, or (j) had active infection or inflammation at the proposed measurement site were excluded. Having obtained informed consent, a unique numerical identifier was applied to the patient's data. This tracking number was used exclusively as the identifier on study case report forms.

Patient temperatures were measured as per the manufacturer's instructions using (1) the *ARC InstaTemp MD®* and (2) the CE marked Welch Allyn Braun 4000 Pro Scan Ear Thermometer.

The *ARC InstaTemp MD®* was provided direct from ARC Connected Health from a validated product manufacturing line. The Welch Allyn Braun 4000 Pro Scan Ear Thermometers were property of the University of Medical Associates facility.

Measurements were stopped for any patient who became distressed or who did not wish to continue for any reason.

## **Avoiding Bias:**

All temperatures were recorded in Fahrenheit. A subject was considered febrile if at least 2 readings using the method in routine hospital use, (i.e. tympanic) were  $\geq 100.4^{\circ}\text{F}$ . There were no febrile patients in this study. Data was recorded doubly both written on the patient record and entered into a spreadsheet with any discrepancies reconciled against the manually recorded value.

## **Patient Cohort Characteristics of this Study**

The patients in this study ranged from 34-97 years old with an average age of 74 (25 female, 20 male). The patient population had the following characteristics with respect to medication:

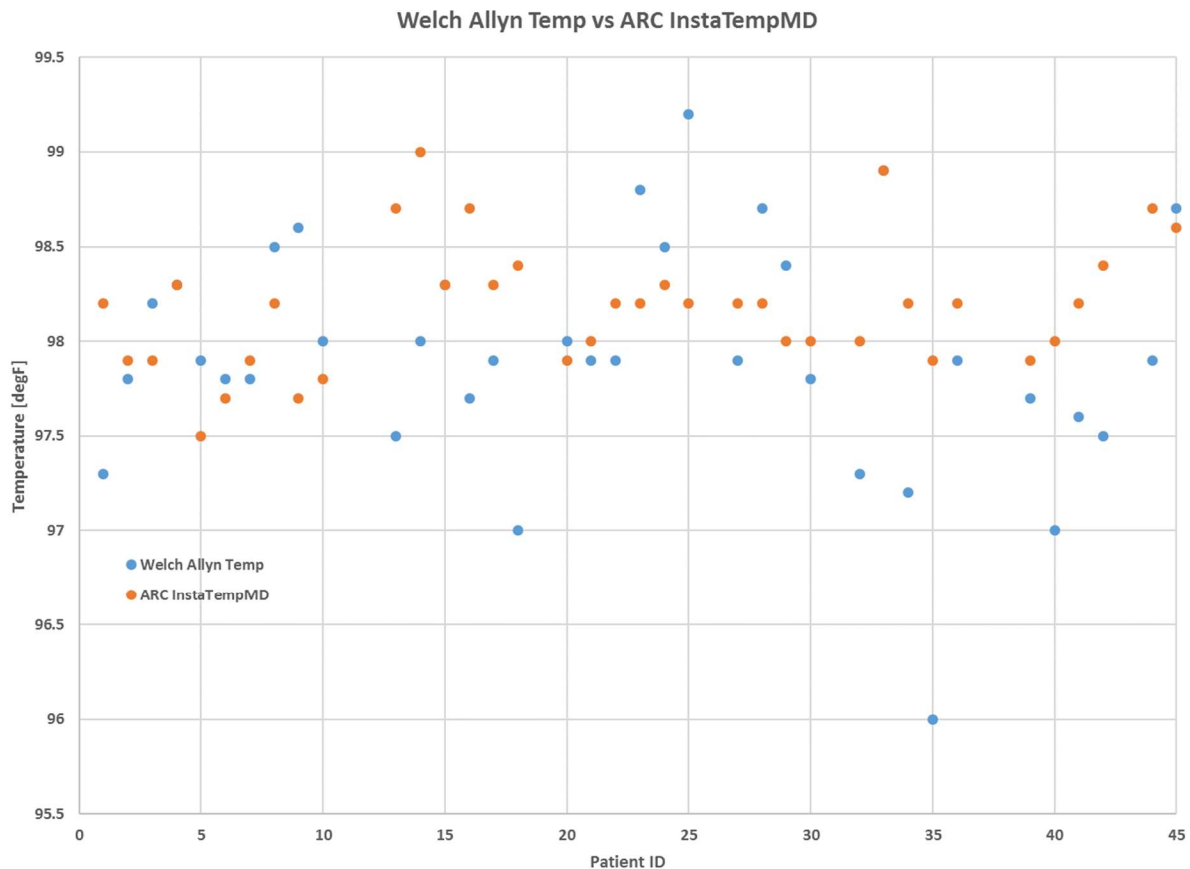
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Medication Group Cohort	Number of Patients Studied
Patients on at least one Corticosteroid, Vasoactive, and Blood Pressure Medication	4
Patients on at least one Vasoactive and Blood Pressure Medication	30
Patients on only Blood Pressure Medication	5
Patients on only Vasoactive Medication	2
Patients on only Corticosteroid Medication	4
<b>Total</b>	<b>45</b>

## Clinical Accuracy

The data from the trial was compiled in a spreadsheet and analyzed. The plot below shows the tympanic temperature measured with the Welch Allyn Braun 4000 Pro Scan Ear Thermometer versus the ARC InstaTemp MD. It should be noted that there were no febrile or hypothermic patients in the study.



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The accuracy value in the table below was derived based on calculating the standard deviation of the difference between the Welch Allyn Braun 4000 Pro Scan Ear Thermometer and the ARC InstaTemp MD.

Accuracy of InstaTemp MD® vs Welch Allyn Braun 4000 Pro Scan Ear Thermometer
< -0.3 [°F] or 0.17 [°C]

## Conclusion

The results demonstrate that the ARC Connected Health ARC InstaTemp MD® Non-Touch Infrared Digital Thermometer accurately estimates core body temperature in geriatric patients in normal temperature ranges who are on corticosteroid, vasoactive, and blood pressure medication to within 0.30 [°F] or 0.17 [°C] when compared to the Welch Allyn Braun 4000 Pro Scan Ear Thermometer that is in widespread use in hospital practice both in the US and EU.

## References

<sup>1</sup>Gerst, Steve, MD *et al.* Comparison of Core Temperature Measurement from Bladder Temperature and ARC Devices InstaTemp MD. 2015.