

Innovation is Hot: Use of a Skin Patch Device to Obtain Temperature Measurements

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Background

Determination of body temperature is an important vital sign providing a quick indication of a person’s general physical condition (McCallum & Higgins, 2012). Numerous devices applied to varying body sites are available for measuring body temperature (Carr et al., 2011; Sund-Levander & Grodzinsky, 2013).

An innovative temperature skin patch (TSP) device that provides continuous skin temperature measurements is now available (TEMP®TRAQ® Continuous Temperature Monitoring). The TempTraq is thin, disposable, flexible and battery-powered allowing wireless transmission to a personal device (i.e. smart phone, etc.).

This study was conducted in an adult population per IRB request and the results were submitted for review prior to studying the device in a pediatric patient population. Results of this testing were used to determine the risk of the device in a future study of pediatric patients.

Study Purpose and Aims

Purpose: To conduct preliminary testing of the device on adult volunteer participants to determine the accuracy and feasibility of the TempTraq.

Aims

1. Compare body temperature measurements when obtained using a TempTraq vs. a standard temperature measurement (i.e. oral, axillary)
2. Evaluate the feasibility of wireless continual TempTraq temperature measurements transmission

Methods

Design and Sample

- Descriptive, quantitative, comparative
- Convenience sampling of adult volunteer participants employed at study institution (n=31)
- Participants recruited prior to dayshift (0630-0800) and nightshift (1830-2000) via announcements through hospital communications
- Criteria:
 - Inclusion:
 - Healthy adult hospital employees
 - Exclusion:
 - Use of thick body lotions
 - Expansive use of deodorants



Device

The TempTraq continually measures temperature, records every two minutes

Procedures

- TempTraq device tested to verify no interference with operation of other medical equipment prior to participant enrollment
- Obtained informed consent from all volunteers
- Provided participants verbal instructions along with TempTraq user manual
- Participants downloaded TempTraq application to personal devices (Android or iOS operating systems)
 - Encouraged to keep devices on person or nearby (within 40 feet)
- Device applied by participant
 - Temperature measurements recorded prior to application of TempTraq
 - Oral and/or axillary method(s)
 - TempTraq placed below axilla on lateral aspect of upper thorax under arm
 - Continuous skin temperature measurements initiated upon application
- Participants wore TempTraq for 12-24 hours
 - Temperature measurements recorded prior to removal of TempTraq
 - Oral and/or axillary method(s)
- Data collected
 - Location of device placement
 - Standard temperature measurements, time obtained and method
 - Prior to application
 - Prior to removal
 - TempTraq temperature measurements and time obtained
 - Participants emailed TempTraq readings to the investigator at removal
 - TempTraq continual measurements recorded every two minutes
 - Descriptive user experience feedback regarding TempTraq and data recordings

Analytical Plan

- Data examination and calculation of summary measures for TempTraq data
- Repeated Measures Factorial (RMF) ANOVA utilizing summary measures
- Agreement analysis utilizing a Bland-Altman plot
- Shukla’s Method for determination of precision equality between devices
 - Analysis of agreement focuses on summary measures

Results

Sample

- 30 participants met criteria for inclusion
- Placement:
 - Left axilla (n=23, 76.7%)
 - Right axilla (n=5, 16.7%)
 - Both left and right* (n=1, 3.3%)
 - Location not recorded (n=1, 3.3%)

*Participant changed location of TempTraq midway through application

Aim 1

- Comparison of TempTraq to oral and axillary temperature measurements at application, 4 hours, 8 hours and removal
 - No significant difference over time between TempTraq and oral ($p=0.25$) or TempTraq and axillary ($p=0.33$)
- RMF-ANOVA: no significant effect of time or method ($p=0.36$ & 0.99 respectively)
 - No within subject differences or interactions noted

Agreement & Precision

Figure 1. Bland-Altman plot μ TRAQ vs. μ Oral (Table 1)

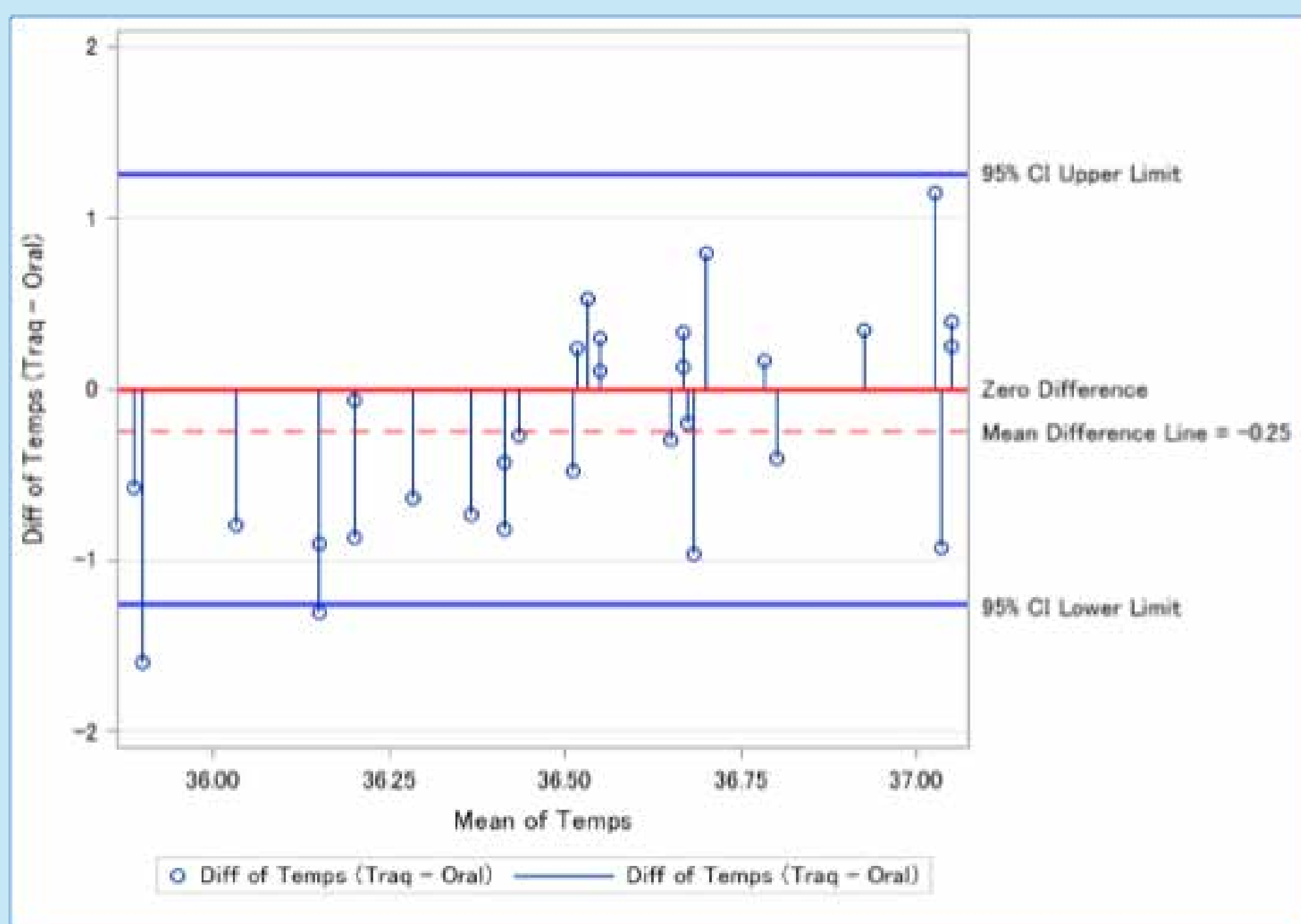


Figure 2. Bland-Altman plot μ TRAQ vs. μ Axillary (Table 1)

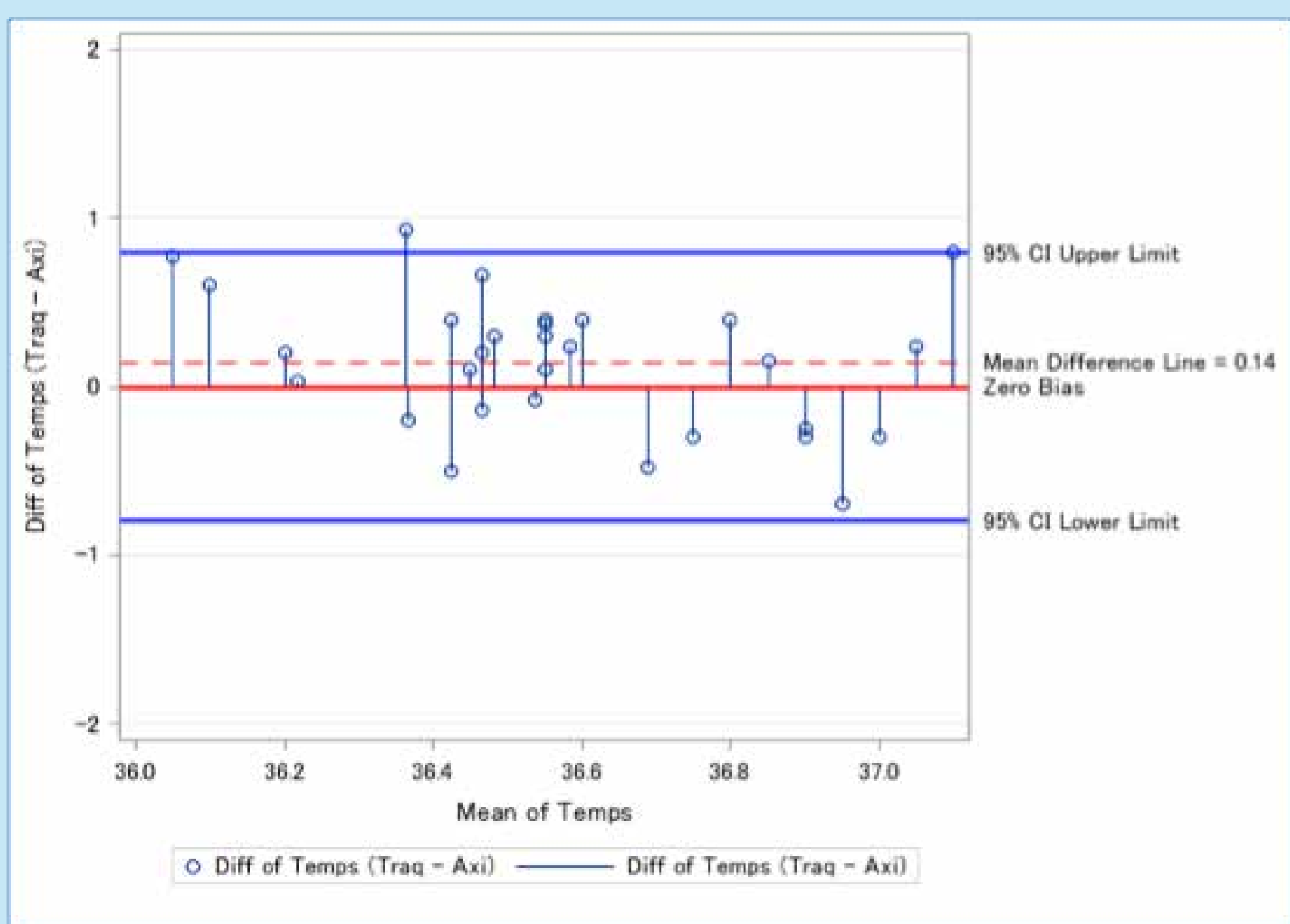


Table 1. Bland-Altman plot and Shukla’s Method Results

Comparison Values	Bland-Altman Limits of Agreement (95% CI)	Shukla’s Method: Correlation Coefficient (sum with difference)	Inference
μ TRAQ vs. μ Oral	(-1.26, 1.26)	$\rho = -0.6$ $p < 0.001$	Poor agreement Potential bias towards higher oral measurements Not equally precise
μ TRAQ vs. μ Axillary	(0.8, 0.8)	$\rho = -0.33$ $p = 0.07$	Modest agreement Potential bias towards higher Temp Traq measurements Equally precise
μ Oral vs. μ Axillary	(-1.1, 1.1)	$\rho = -0.4$ $p = 0.03$	Modest agreement Potential bias towards higher axillary measurements Not equally precise



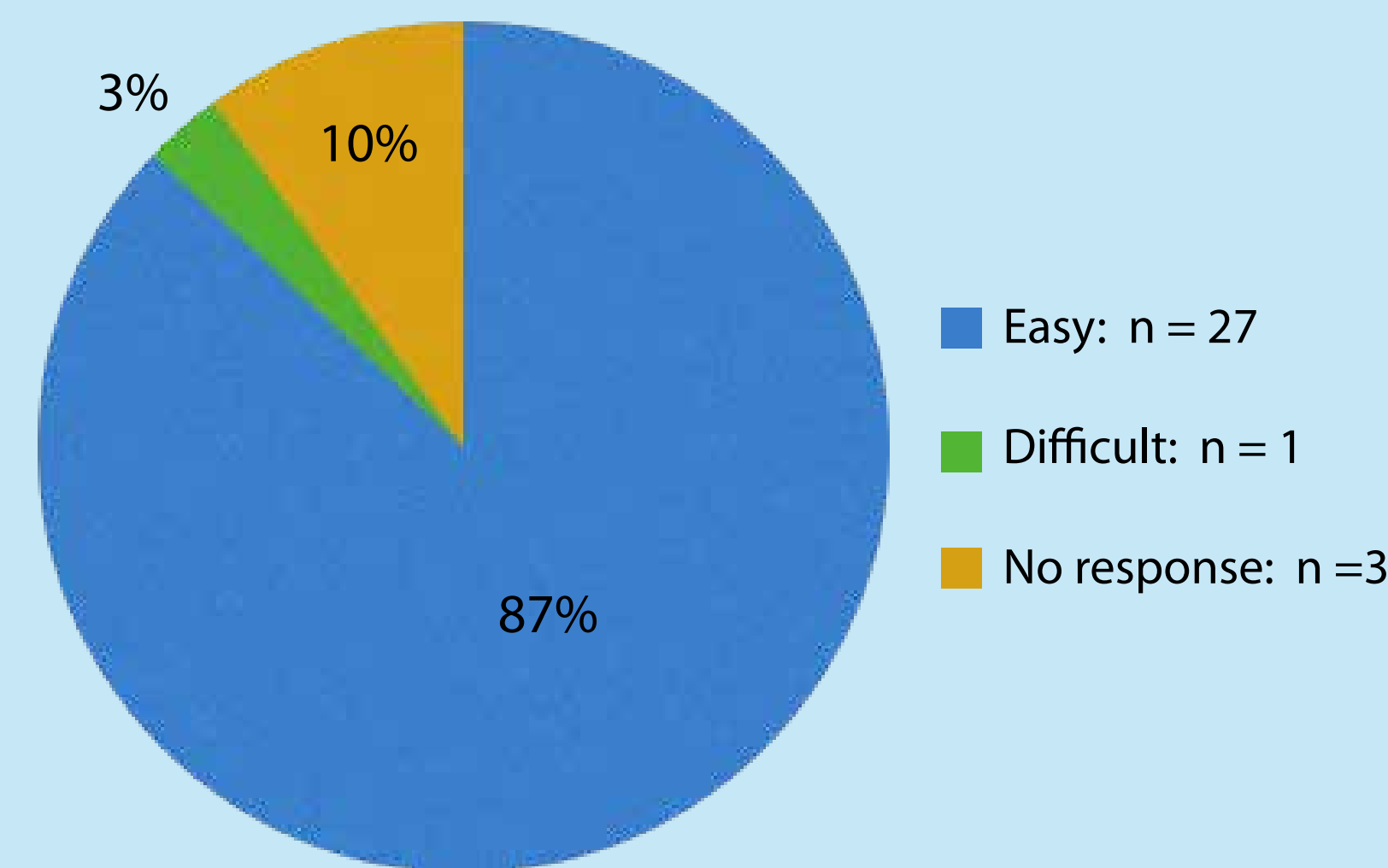
Akron Children’s Hospital



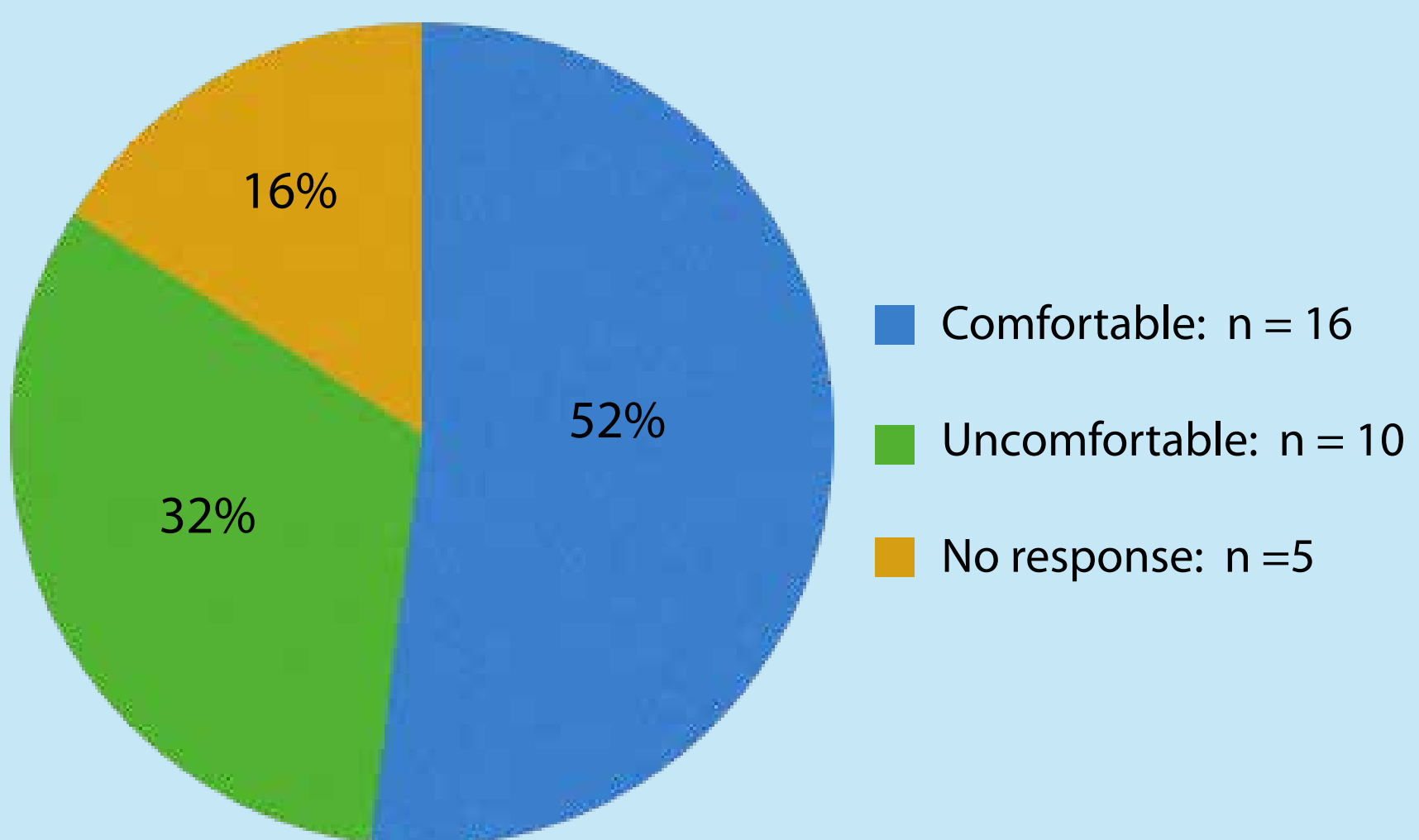
Aim 2: Feasibility

- No participants were excluded from the anagnosis due to lack of data

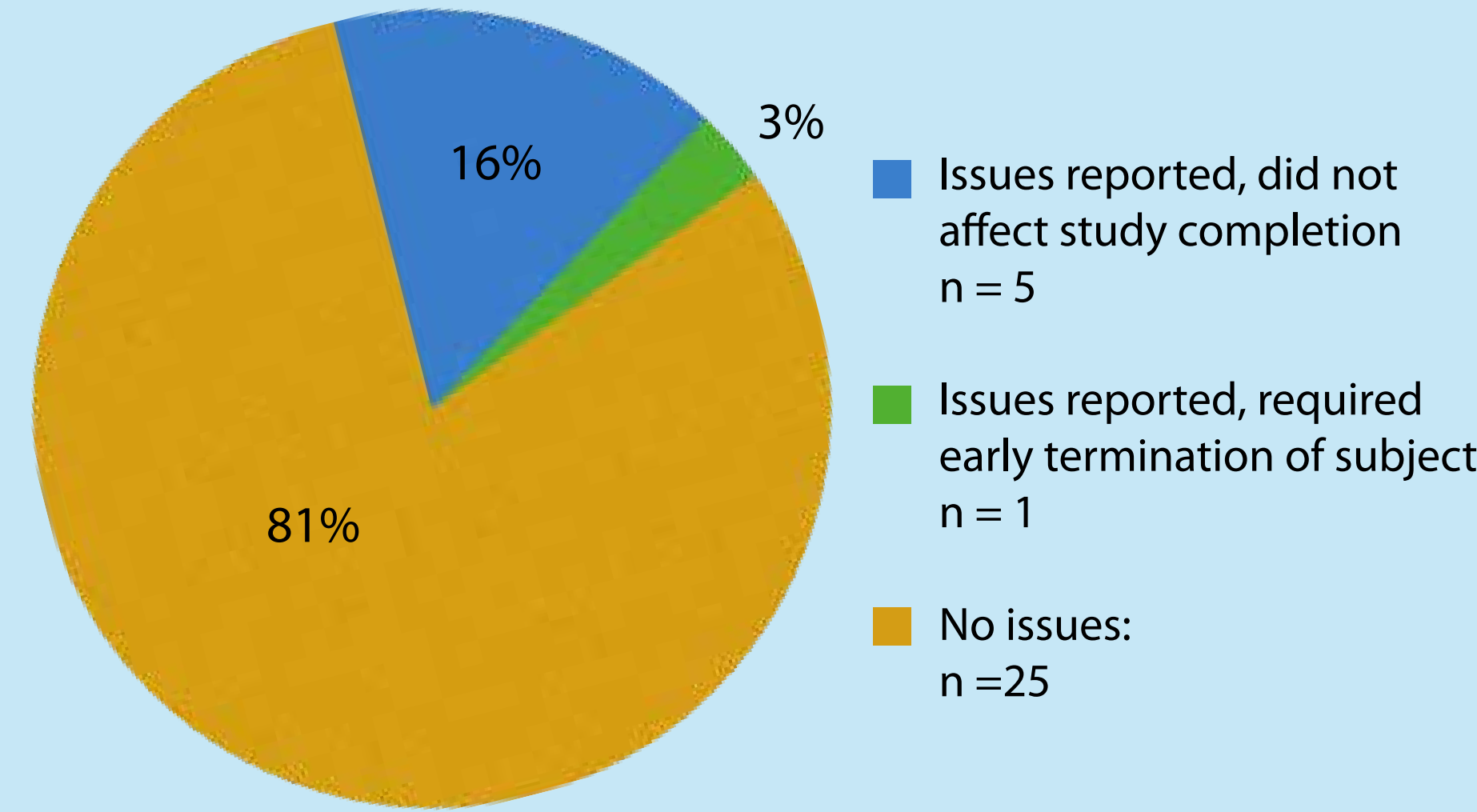
Ease of Application



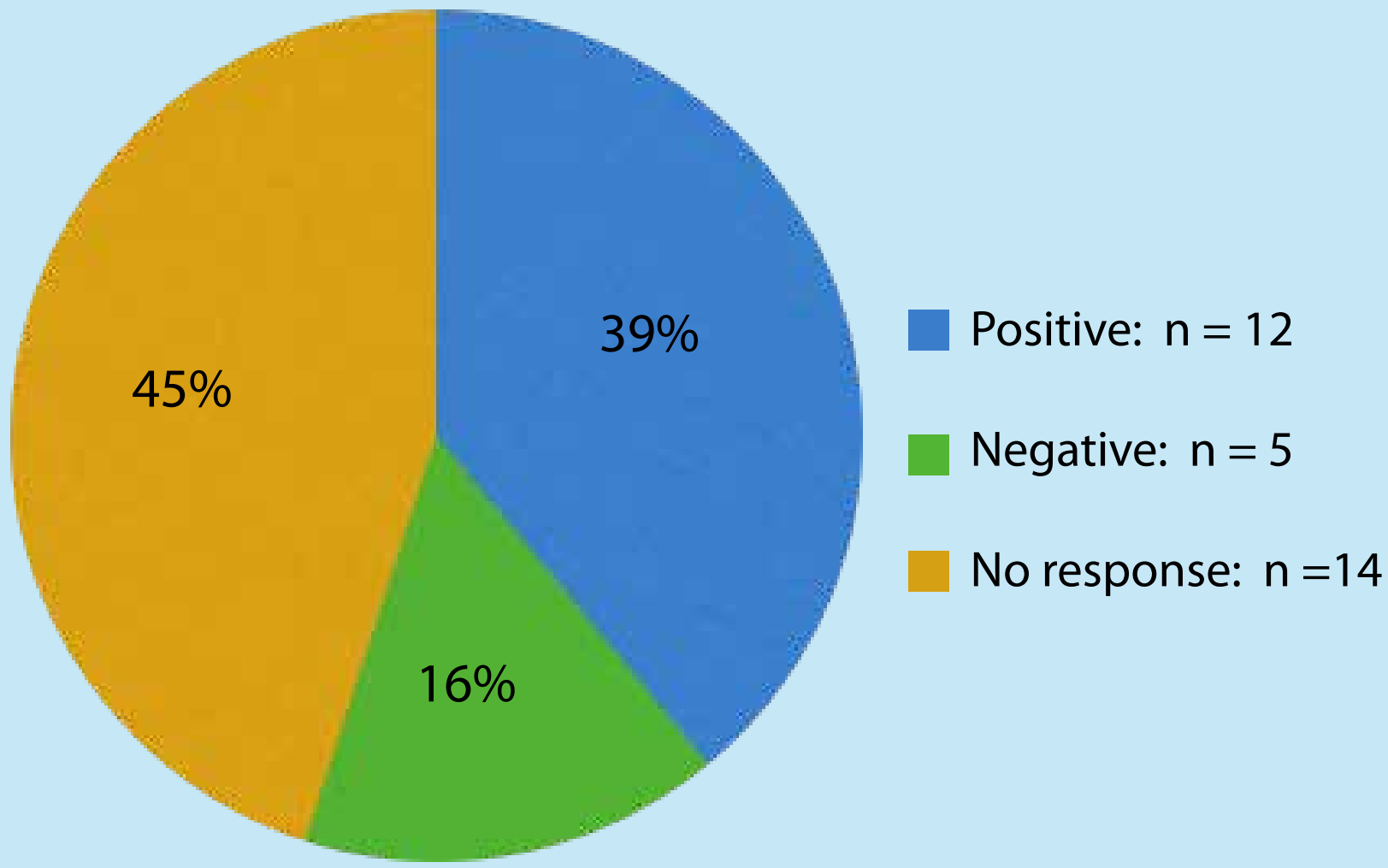
Wear Comfort



Adherence Issues



Transmission/Connectivity Impressions



- Transmission / Connectivity Issues
 - One report of TempTraq not syncing to personal device
 - One report of TempTraq displaying “Out of Range” message

Discussion

Strengths

- No risk identified related to wearing the device
- No risk identified related to transmitting the temperature readings
- No adverse events noted in adult population

Limitations

- Use of summary measures may reduce statistical power
- Use of a convenience sample potentially introduces bias

Conclusions

- No significant effect of time or method (TempTraq, oral or axillary)
- TempTraq is feasible for use in the adult population
- Use of the TempTraq is a viable alternative for temperature measurement

References

Carr, E.A., Wilmoth, M.L., Eliades, A.B., Baker, P.J., Shelestak, D., Helstroth, K.L. & Stoner, K.H. (2011). Comparison of temporal artery to rectal temperature measurements in children up to 24 months. *Journal of Pediatric Nursing*, 26(3), 179-185.
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Disclosures

This study was conducted on behalf of Blue Spark Technologies, Inc. The TempTraq devices were provided by the sponsor.