Validation and Reliability of PerformTek® Earbud Heart Rate Sensor Utilizing 12 Lead ECG

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PURPOSE
This report examines the accuracy and repeatability of Valencell, Inc.’s PerformTek® earbud sensor relative to a 12 lead electrocardiogram for measuring heart rate during exercise.

INTRODUCTION
Healthy living has seen a global resurgence as people place more value on staying active to live more fulfilling, healthier and longer lives. In this environment, fitness applications enjoy a meteoric rise across mobile phones, gaming and consumer fitness products. Workout efforts are optimized when receiving feedback on target heart rate zones and physical activity (Jeukendrup and Van Diemen, 1998). Additionally, heart rate monitoring of training intensity provides more accurate information than self-reports of training intensity (Gilman and Wells, 1993). The American College of Sports Medicine reports that heart rate monitoring has been shown to result in improvements in cardiorespiratory fitness when used for exercise prescription (ACSM, 2011).

New technology has allowed the collection of metabolic data in a variety of ways including an earbud sensor module. The module obtains measures from the ear region using an approach akin to reflective-mode photoplethysmography (PPG). Highly miniaturized, the sensor module is designed to fit inside audio earbuds while still providing sufficient room for an audio cavity, speaker driver, and the other elements of a high-performance sports audio headset. Unlike pulse oximetry ear clips, this sensor module is completely embedded in the audio earbud, with no ear clips or ear supports required in order to function appropriately. The embedded sensors allow for real-time analysis of exercise data such as heart rate, distance traveled, calories burned, and VO2max (aka aerobic fitness). These sensors operate with light emitting diodes (LED) and are harmless to the users.

The use of heart rate monitors is highly popular with individuals who exercise. Currently continuous heart rate monitors utilize a chest strap that transmits data to a specialized watch. These chest strap units are highly accurate as examined by Goodie et. al. (2000) but somewhat invasive and uncomfortable (Schonfelder et. al., 2011) in that the strap must be applied below any clothing at the level that the rib cage comes together. Earbud technology would eliminate the need for the chest strap. And because a growing number of individuals listen to music via headphones while exercising, earbud sensors are seamless and compatible with existing consumer behavior.

A solution for mobile monitoring of heart rate during exercise must not only be seamless but also accurate and repeatable. However, PPG sensing of heart rate is notoriously limited by motion artifacts resulting in unsatisfactory performance (Burke and Whelan, 1987; Gehring et al., 2002; Yamaya et. al, 2002; Webb et. al., 2005; Comtois et. al, 2007). To the best of the author’s knowledge there have been no reports with sufficient cohort data examining accuracy and reliability of heart rate sensors that are truly in the form-factor of audio earbuds that people are already used to wearing.

METHODS
Clinical trials examining validity and reliability of Valencell’s PerformTek® earbud sensing technology was completed using 41 healthy participants (22 males, 19 females, 29.7 ± 10.6 years, 76.5 ± 13.2 kg, 171.8 ± 9.7 meters, 25.9 ± 3.7 BMI). Participants completed one of three 15.5 minute protocols involving sitting, standing, walking, and running while heart rate was monitored via a 12 lead electrocardiogram (ECG) and the Performtek® sensor both devices recorded heart rate at 5-second intervals. Additionally, 36 participants returned to the laboratory and repeated the protocol within two weeks of the first trial to examine reliability.
### RESULTS

Results indicated high correlation between the ECG and PerformTek® (r = 0.99, r² = 0.98, SEE 4.43, 95% confidence intervals = Lower: -9.55 Upper: 8.18, bias = -0.68). It was found that 87% of PerformTek® HR measurements fell within ± 5 BPM of ECG HR measurements. This data indicates that earbud sensors provide an accurate and valid measure of heart rate. Additionally, test-retest reliability was high (r = 0.93) and similar to that of the ECG (r = 0.96).

![Figure 1. PerformTek® placement in participant’s ear.](image)

![Figure 2. Correlation/regression analysis for trial 1 PerformTek® vs. ECG (7626 data points).](image)

![Figure 3. Frequency distribution for trial 1 PerformTeK® vs. ECG. (7626 data points).](image)

![Figure 4. Bland-Altman plot for trial 1 PerformTek® vs. ECG. (7626 data points).](image)

### CONCLUSION

High correlations in combination with low SEE indicate the PerformTek® is a valid instrument for the measurements of HR during various activity levels. Additionally, test-retest reliability correlations similar to the benchmark measure...
demonstrated accuracy with repeated use. Heart rate monitoring using the PerformTek® system may be used effectively as an alternative to ECG or chest strap monitors.

REFERENCES


Goodie JL, Larkin KT, Schauss S. Validation of Polar Heart Rate Monitor for Assessing Heart Rate During Physical and Mental Stress. *J. Psychophysiology* 2001; 14(3): 159-164


APPENDIX A: Summary Statistics and Individual Data Plots of PerformTek® Earbud Heart Rate Sensor Utilizing 12 Lead ECG Heart Rate

SUMMARY STATISTICS

Table A1. Validity summary Trial 1

<table>
<thead>
<tr>
<th>Device</th>
<th>Heart Rate Mean ± SD n=7440</th>
<th>Coefficient of determination (r^2) (vs. ECG)</th>
<th>Standard error of estimate (SEE)</th>
<th>Bias</th>
<th>95% limits of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG (bpm)</td>
<td>116.13±28.70</td>
<td></td>
<td></td>
<td>0.98</td>
<td>4.43</td>
</tr>
<tr>
<td>PerformTek® (bpm)</td>
<td>115.44±28.46</td>
<td>0.98</td>
<td>4.43</td>
<td>-0.68</td>
<td></td>
</tr>
</tbody>
</table>

Table A2. Test-retest reliability Trial 1 vs. Trial 2

<table>
<thead>
<tr>
<th>Device</th>
<th>Correlation (R) between Trial 1 and 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG (bpm)</td>
<td>0.95</td>
</tr>
<tr>
<td>PerformTek® (bpm)</td>
<td>0.93</td>
</tr>
</tbody>
</table>
INDIVIDUAL DATA PLOTS

S1

S2

S3

S4
S7 Poor ECG data participant, hardware issues during T1 Participant unable to attend trial 2
S13 Participant unable to attend trial 2

S14

S15
S16

S17 Participant unable to attend trial 2

S18
S19 - Participant unable to attend trial 2

S20 Participant had small ears and subsequent poor fit of earbud. Trial 2 ended due to inability to keep earbud in ear.

S21
S28 Participant unable to attend trial 2

S29

S30
S40

S41

S42

S43 Participants ear anatomy did not allow for fit of earbud