# Validity of BioHarness™ Heart Rate vs 3-lead ECG

## Introduction

This report concerns an evaluation of the heart rate monitoring performance of Zephyr Technology's BioHarness™ product. The evaluation aimed to assess the heart rate validity of the BioHarness™ system in comparison to a standard measurement system.

The BioHarness™ is a bio-monitoring system used to measure physiological conditions including heart rate, respiration rate, temperature, activity and posture.

The system comprises an electronics module and a Smart Fabric garment that is worn on the torso. Data may be transmitted to a PC and viewed in real-time or logged on the device and later uploaded for review and analysis.

## Methods

Four participants completed a test protocol involving three 5 minute duration exercises, static, walking & running on a treadmill. The participants were male and aged between 28 and 52 with moderate to good fitness levels.

**Table 1 – Test Participant Data**

| Subject | Sex | Age | Hgt (cm) | Wgt (kg) |
|---|---|---|---|---|
| 1 | M | 28 | 170 | 70 |
| 2 | M | 38 | 169 | 95 |
| 3 | M | 52 | 191 | 100 |
| 4 | M | 28 | 185 | 70 |

During the exercises, the participants wore a BioHarness™ and a Cortex BioPhysik MetaMax CPX system with 3-lead ECG. Heart rate data from each system was then sampled and compared to assess validity[1].

Research studies[2,3] have given validity criteria for heart rate as: 1) an SE less than 5 beats, 2) a correlation between the recorded heart rate and the corresponding ECG measurement of >0.9. To compensate for effects on correlation due to the range of heart rates, an alternative is to use mean bias and SE to assess validity, along with a correlation r>0.98[4]. For athletes, validity criteria based on changes in performance have been shown to be on the order of 3 beats. Therefore, the validity criteria used for this evaluation were based on a mean bias and SE of less than 3 beats.

## Results

Overall, the BioHarness™ was valid in terms of heart rate when compared against the MetaMax, with r=0.99, bias = 1.3 and SE = 0.29 (n=144). The table and figures below provide a summary of results.

**Table 2 – Summary of Heart Rate Comparison Data**

| Parameter | | Value | Confidence Limits (95%) | |
|---|---|---|---|---|
| | | | Upper | Lower |
| r | | 0.99 | 0.98 | 0.99 |
| Bias | | 1.3 | 0.7 | 1.9 |
| SE | | 0.29 | | |
| 95% Limits of Agreement | Lower | -5.5 | -6.5 | -4.5 |
| | Upper | 8.1 | 7.1 | 9.1 |

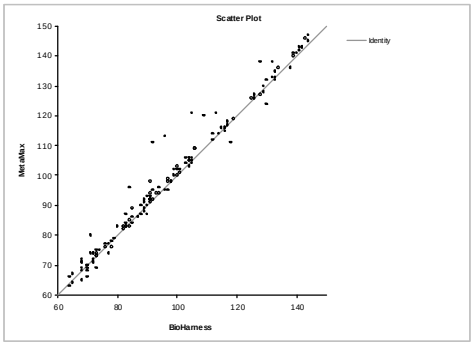


**Fig 3.1 Scatter Plot MetaMax vs. BioHarness™ Heart Rate**

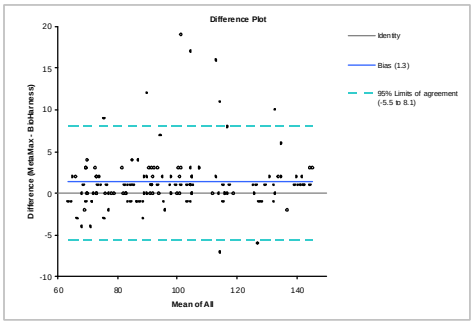


**Fig 3.2 Bland-Altman Plot, MetaMax and BioHarness™ Heart Rate**

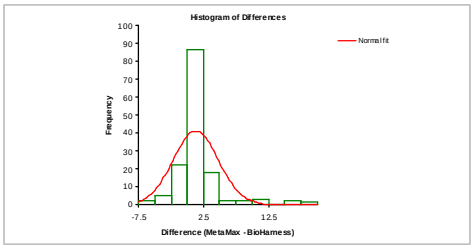


**Fig 3.3 Histogram of Differences (MetaMax - BioHarness™)**

Outliers in the plots were related to movement artefacts at higher activity

levels. If the data are grouped by activity (static, walk, run), the bias and SE can be seen to mildly increase with activity level as shown in the plot below.

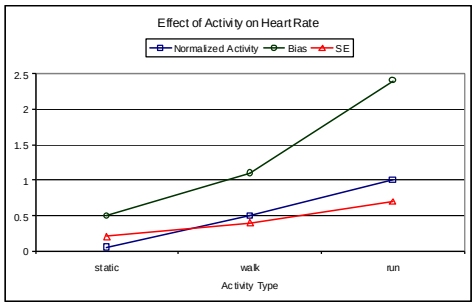


**Fig 3.4 Effect of Activity on Heart Rate**

The normalized activity measure was taken from the average of the cumulative VMU data for each exercise as measured by a StayHealthy RT3 activity monitor.

An example of BioHarness™ heart rate plotted against MetaMax heart rate for a running exercise case is shown below.

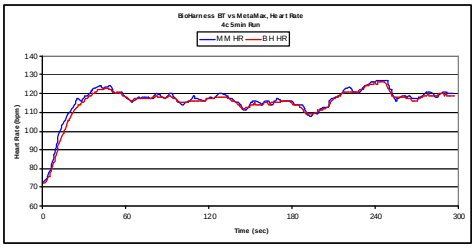


**Fig 3.5 Example of BioHarness™ vs. MetaMax, subject 4, run**

## Conclusions

Using a bias and SE of less than 3 beats, the BioHarness™ is a valid practical measure of the criterion ECG measure of heart rate under common exercise conditions. The high degree of correlation (>0.98) and low bias and SE makes the BioHarness™ suitable for a wide range of physiological monitoring applications.

## References

1. Altman DG, Bland JM. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet*, 1986; i: 307-310.

2. Leger L, Thiveirge M. Heart rate monitors: validity, stability, and functionality. *Physician and sportsmedicine*, 1988; 16(5): 143-151.

3. Terbizan DJ, Dolezal BA, Albano C. Validity of seven commercially available heart rate monitors. *Measurement in Physical Education and Exercise Science*, 2002; 6(4): 243-247.

4. Hopkins WG. How to interpret changes in an athletic performance test. *Sportscience*, 2004;8:1-7