

# Human study of the Biobeat device allowing for non-invasive wireless continuous measurement of blood pressure

Arik Eisenkraft <sup>1,2</sup>, Dean Nachman <sup>1</sup>

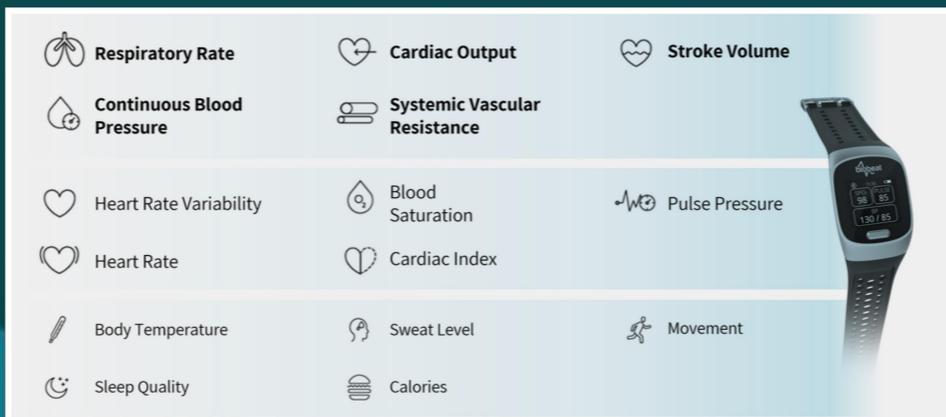
<sup>1</sup> The Institute for Research in Military Medicine (IRMM), <sup>2</sup> BioBeat Technologies LTD.



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## Background

Currently used blood pressure (BP) devices are based on the non-invasive manometry method, which is cumbersome, not accurate, and does not allow for continuous monitoring. An arterial transducer provides an accurate and continuous measurement, yet it is invasive, has several potential severe adverse effects, could be used only in the setting of an ICU or an operating room. The **BB-613** is an advanced disruptive wireless wearable sensor which includes a mobile application. It continuously monitors Heart Rate (HR), SPO2, BP, Stroke Volume (SV), Cardiac Output (CO), Cardiac Index (CI), Systemic Vascular Resistance (SVR), Respiratory rate (RR), and more. The aim of this study was to compare the BB-613 to the common manometry.



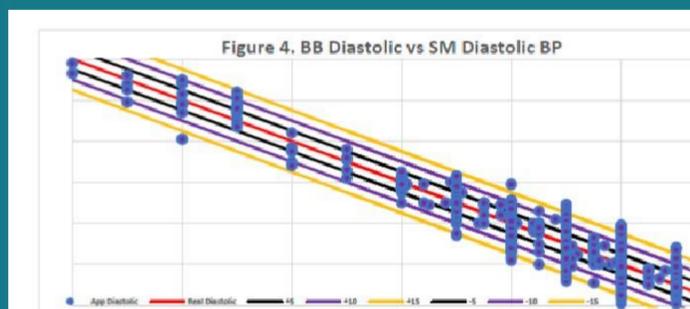
## Methods

This comparative prospective study was approved by an institutional review board (IRB). Male and female volunteers aged 8–98 years were included. Each came for a routine BP checkout as provided by the Israeli EMS. Full recorded BP measurements were provided in 1417 volunteers. BP was measured using a standard manometry device on one hand, and at the same time BP values as measured by the **BB-613** were recorded from the other hand. The collected data for BP measurements were analyzed using mean, maximum, minimum, mode, average deviation (AD), standard deviation (STD), and confidence. Correlation analysis was performed using the Bland-Altman method. The **BB-613** application was compared to the manual sphygmomanometer and the differences between them were analyzed.

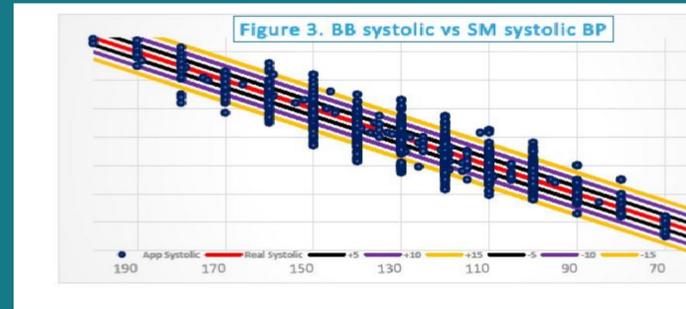
## Results

There were no adverse events during the study, showing BB-613 to be a safe device. The two measurement methods behave almost the same when looking at all parameters and the correlation was found to be significant at 95% for the SBP and close to it for the DBP (R2=0.907 for SBP, and R2=0.862 for DBP).

## Comparing Biobeat measurements to the International Protocol (Revision 2010) requirements:

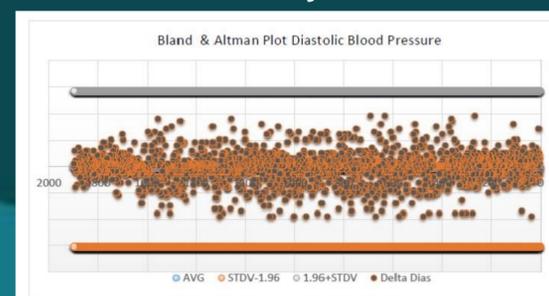


DBP – black lines depict the  $\leq 5$  mmHg difference limit, purple lines depict the  $\leq 10$  mmHg difference limit, yellow lines depict the  $\leq 15$  mmHg difference limit

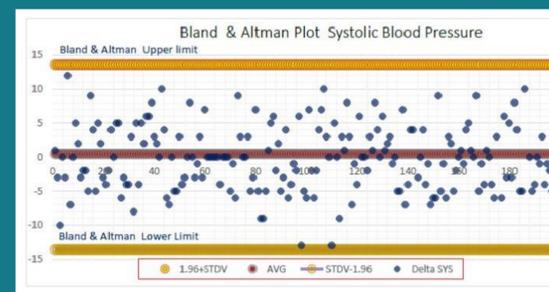


SBP – black lines depict the  $\leq 5$  mmHg difference limit, purple lines depict the  $\leq 10$  mmHg difference limit, yellow lines depict the  $\leq 15$  mmHg difference limit

## Bland-Altman analysis:



100% of all DBP measurements are in range.



92.8% of all SBP measurements are in range.

	Before	After
Manometer SBP	1.0000	1.000
Biobeat SBP	0.90	0.92
Manometer DBP	1.0000	1.000
Biobeat DBP	0.92	1.00

The correlation results before and after Bland-Altman analysis.

## Conclusion

The **BB-613** sensor and application achieved accuracy in the 96-98% level range. These readings were within the required 95% level as defined to be acceptable levels by the European International Protocol for BP devices. This means that the **BB-613** can be formally used as an accurate and reliable BP measurement device.