Title: Comparison of Non-invasive and Invasive Blood Pressure Monitors

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Statistical and Data Analysis Plan:

A total of n=30 patients were recruited to optimize the ViTrack technology and compare its performance to radial invasive arterial lines. A total of n=24 patients were used to optimize hardware, device form factor, algorithms, and usability. Then, we used the updated version of the ViTrack device to compare the device performance on 6 patients undergoing vascular surgery in the University of Massachusetts Medical School.

The data was analyzed following the AAMI SP10:2008 standard. Both ViTrack and Invasive arterial pressure data were averaged over a 20-second non-overlapping window, thus providing a paired measurement for comparison every 20 seconds. The average length of the surgery was ~3 hours. After clearing out the segments (both in IAP and ViTrack) affected by motion artifacts, we used the remaining segments for accuracy analysis. Since each dataset might not have a similar number of data points to compare, we weighted the samples to avoid bias to one dataset. A total of 2800 data points across 6 subjects were used for comparison. As per the FDA standard ANSI/AAMI SP10:2008 or the newly adopted ISO 81060-3:2022 standard, the mean error should be <5mmHg or <6mmHg and the standard deviation should be <8mmHg or <10mmHg respectively. We have analyzed ViTrack data on 6 patients and showed the results in **Figure 1** below. ViTrack showed far higher accuracy for both SBP (mean error = 0.19 mmHg [SD = 5.70 mmHg]) and DBP (mean error = 0.90 mmHg [SD = 5.97 mmHg]) measurements when compared to either of the recognized standards **[Fig1].**

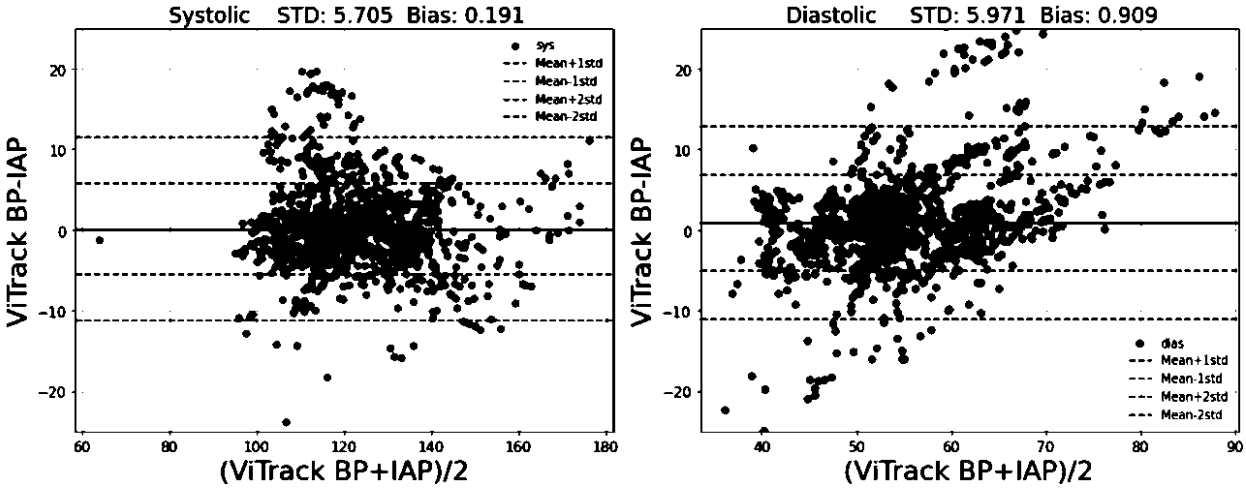

Fig 1: Performance of ViTrack Vs. IAP after motion artifact correction in 6 operating room patients undergoing vascular surgery.