

Home Blood Pressure Monitor Motion Tolerance Clinical Study—Research Summary

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INTRODUCTION

The American Heart Association recommends home blood pressure monitoring for all people with hypertension to monitor for worsening disease and to help the healthcare provider determine whether treatments are working. They recommend using an automatic, cuff-style, bicep (upper-arm) monitor.¹ Although this type of monitor may be accurate in a controlled, clinical setting, home monitors can suffer from inaccuracies due to patient movement or talking during measurement. This study was funded and conducted by Welch Allyn to determine the impact of slight forearm motion on the accuracy of readings and cycle time for a number of home blood pressure devices.

DESIGN

This study measured the performance of several home blood pressure devices under no-motion conditions and while the patient was pronating and supinating their forearm every 5 seconds. Each device reading under no-motion conditions served as the comparison for its own motion reading. Statistics of mean difference and standard deviation between no-motion and motion readings, coverage, and cycle time were calculated.

Data was collected using the following 5 upper-arm, automated home blood pressure devices:

- Omron® BP786 10 Series Upper Arm Blood Pressure Monitor (Omron)
- CVS® Professional Blood Pressure Monitor Arm Model #BP3MV1 (CVS)
- iHealth® BP5 Upper Arm Blood Pressure Monitor (iHealth)
- A&D UA-767 BT-Ci Upper Arm Blood Pressure Monitor (A&D)
- Welch Allyn Home™ Blood Pressure Monitor H-BP100SBP (WA Home)
- Foracare FORA P20B Blood Pressure Monitor (Foracare)

Data was additionally collected with the Welch Allyn Connex® Spot Monitor, which is a clinical-grade device not intended for use in the home. This data was collected for internal purposes and is not included in this report.

RESULTS

Data was collected and analyzed on accuracy of readings, number of readings completed without error, and the time it took to complete a reading under conditions of motion and no-motion. A total of 93 individuals participated, with 513 no-motion readings and 308 motion readings included in the study.

Accuracy of the readings was assessed by calculating the mean of the absolute difference between the motion readings and the no-motion readings for each device. Additionally, error rates were calculated as the percentage of readings that were incomplete, either due to device error or an aborted reading as a result of extreme patient discomfort.

The Welch Allyn Home Blood Pressure Monitor captured accurate readings in about 20 seconds, making it the fastest device in the study. WA Home captured readings twice as fast as Omron, which is the current market leader for home blood pressure devices.²

Welch Allyn Home Blood Pressure Monitor also captured the most readings without error under conditions of motion. Welch Allyn Home had a 97% success rate compared to A&D, CVS, Foracare, and Omron, which failed

more than 50% of the time. Foracare failed to generate a reading under motion conditions nearly 90% of the time. Finally, Welch Allyn Home was also the most accurate device under motion conditions. WA Home had an average error under motion of about 4mmHg, while iHealth had an error of about 7mmHg and all other devices had errors of 12 mmHg or more.

More detailed data can be found in **Exhibit 1**.

Exhibit 1 – Study Data

Home Blood Pressure Motion Study—Results

Data was collected in two different rounds, with Round 1 including WA Home, A&D, and Omron and Round 2 including WA Home, CVS, Foracare, and iHealth. The absolute values of the differences between the no-motion readings and the motion readings were calculated for each device.

Round 1

Systolic BP Delta of..	N	Min	25th Pctl	Median	75th Pctl	Max		Mean	Std Dev
A&D	14	0.5	1.5	8	22	61.5		13.29	16.54
Omron	14	0	2.5	3.5	5.5	47		6.57	11.82
WA Home	37	0	1.5	4	5.5	18		4.22	3.32

It can be observed that except for A&D, 75% of the absolute values of the differences are less than 6 mmHg with the median of about 4 mmHg. The mean absolute value of the differences for WA Home is about 4 mmHg while Omron has a slightly higher mean.

Diastolic BP Delta of..	N	Min	25th Pctl	Median	75th Pctl	Max		Mean	Std Dev
A&D	14	2	2.5	8.5	18	37.5		12.43	12.16
Omron	14	0.5	2.5	6.5	21.5	35.5		12.25	12.46
WA Home	37	0	1.5	3	5	19		4.15	4.31

The average absolute values of the differences for WA Home is 4.2 mmHg. 75% of the absolute values of the differences for WA Home are less than 5 mmHg with the median of 3 mmHg. The absolute value of the differences for Omron and A&D are about 12 mmHg. 75% of the absolute values for Omron and A&D are 21.5 mmHg and 18 mmHg, respectively, with medians of 6.5 mmHg and 8.5 mmHg.

Because of the very small sample sizes of A&D and Omron, we cannot obtain statistical conclusions regarding the performance of those devices. The error rates for the devices were as follows:

	Attempts	Counts of N/A	Error %	95% CI
A&D (M)	38	24	63.2%	(47.8%, 78.5%)
Omron (M)	38	24	63.2%	(47.8%, 78.5%)
WA Home (M)	38	1	2.6%	(0%, 7.7%)*

Additionally, the average time it took to complete each blood pressure reading was calculated for each device. Only successfully completed readings are included in the cycle time calculation.

	Average Cycle Time	Number of Readings
WA Home (Without Motion)	22.35	76
WA Home (With Motion)	43.39	37
Omron (Without Motion)	39.95	76
Omron (With Motion)	47.50	14
A&D (Without Motion)	39.45	76
A&D (With Motion)	47.57	14

Round 2

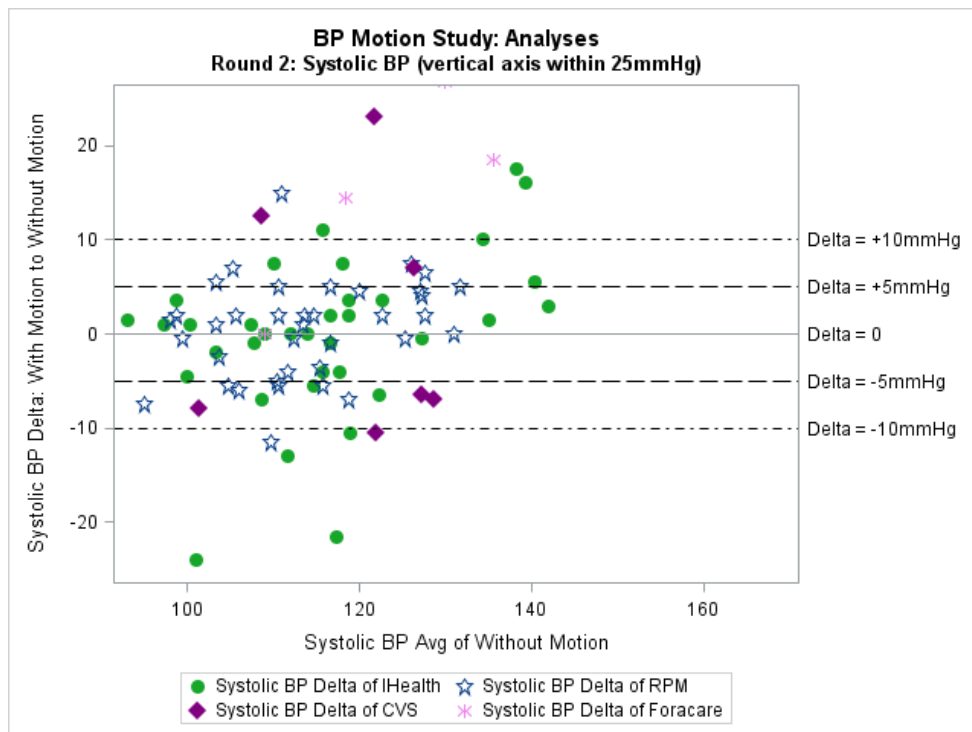
Systolic BP Delta of..	N	Min	25th Pctl	Median	75th Pctl	Max		Mean	Std Dev
CVS	16	6.5	9.25	37	89	129		49.66	44.03
Foracare	4	0	7.25	16.5	22.75	27		15.00	11.28
iHealth	35	0	1	3.5	7.5	24		5.81	6.19
WA Home	38	0	2	4.25	5.5	27.5		4.75	4.91

The average absolute values of the differences for iHealth and WA Home are 5.8 mmHg and 4.8 mmHg respectively. 75% of the absolute values of the differences for iHealth are less than 7.5 mmHg with the median of 3.5 mmHg, while 75% of the absolute values of the differences for WA Home are less than 5.5 mmHg with the median of 4.3 mmHg.

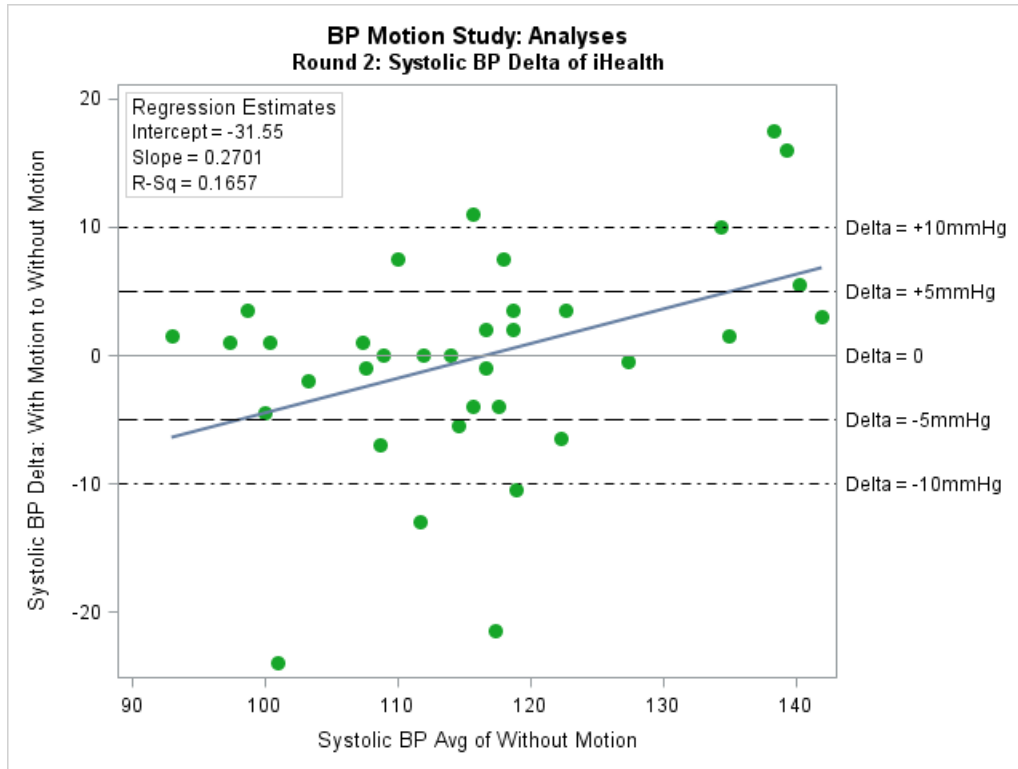
Diastolic BP Delta of..	N	Min	25th Pctl	Median	75th Pctl	Max		Mean	Std Dev
CVS	16	1	4.75	23.5	62.75	116		36.56	36.22
Foracare	4	1.5	4.25	9.25	31.5	51.5		17.88	22.79
iHealth	35	0	2	4	10.5	27.5		6.84	7.24
WA Home	38	0	1	2.25	4	9		2.96	2.28

The average absolute values of the differences for iHealth and WA Home are 6.8 mmHg and 3 mmHg respectively. 75% of the absolute values of the differences for iHealth are less than 10.5 mmHg with the median of 4 mmHg, while 75% of the absolute values of the differences for WA Home are less than 4 mmHg with the median of 2.3 mmHg.

Given that iHealth and WA Home successfully generated readings in a high percentage of cases under motion conditions, further analysis was performed. The following Bland-Altman plot shows the average deltas for the devices included in Round 2:



Based on the observation that for iHealth there is a left-to-right directional trend, a regression analysis was done to further analyze the trend. The output is shown below:



The regression does indicate a mild positive trend (slope = 0.27, R-Sq = 17%) in the scatter plot, which suggests that for iHealth over-estimation of systolic BP readings taken with motion tend to increase (get worse) as the “actual” BP (control BP of the average of the no-motion readings) is higher. In this case, iHealth is likely to over-estimate BP readings with motion when the true BP is elevated. As the highest systolic BPs included in this study were less than 145 mmHg, performance of this device on hypertensive patients cannot be determined.

Because of the very small sample sizes of CVS and Foracare, we cannot obtain statistical conclusions regarding the performance of those devices. The error rates for the devices were as follows:

	Attempts	Counts of N/A	Error %	95% CI
CVS (M)	39	21	53.8%	(38.2%, 69.5%)
Foracare (M)	39	35	89.7%	(80.2%, 99.3%)
iHealth (M)	39	4	10.3%	(0.7%, 19.8%)
WA Home (M)	39	1	2.6%	(0%, 7.5%)*

Average cycle times to complete a blood pressure reading were also calculated.

	Average Cycle Time	Number of Readings
WA Home (Without Motion)	19.25	77
WA Home (With Motion)	42.89	38
iHealth (Without Motion)	27.11	74
iHealth (With Motion)	34.23	35
CVS (Without Motion)	38.41	54
CVS (With Motion)	49.94	18
Foracare (Without Motion)	34.37	43
Foracare (With Motion)	41.5	4

Summary of Results

Average blood pressures, including both systolic and diastolic across the range of blood pressures measured, were calculated for each device. Additionally, average error rates were calculated when the devices failed to generate a reading. The average cycle times were also calculated under conditions with and without motion. This information is included in table below.

Device	Mean Difference	Error Rate	Average Cycle Time	Average Cycle Time with Motion
A&D	12.43 mmHg	63.2%	39.45	47.57
CVS	36.56 mmHg	53.8%	38.41	44.94
Foracare	17.88 mmHg	89.7%	34.37	41.50
iHealth	7.24 mmHg	10.3%	27.11	34.32
Omron	12.25 mmHg	63.2%	39.95	47.50
WA Home	4.15 mmHg	2.6%	20.77	43.14

In this study, WA Home performed the best under conditions of motion, compared to other devices on the market. WA Home had the lowest error rate (2.6%) while measuring the most accurate blood pressure (mean 4.15mmHg difference) and completing readings in the shortest time (20.77 s).

References

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1. American Heart Association, Understanding and Managing High Blood Pressure guide. http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/High-Blood-Pressure_UCM_002020_SubHomePage.jsp May 5, 2016
2. Omron. Toward the Global Share No. 1. <http://www.healthcare.omron.co.jp/bpm/english/history/05.html> August 19, 2016.