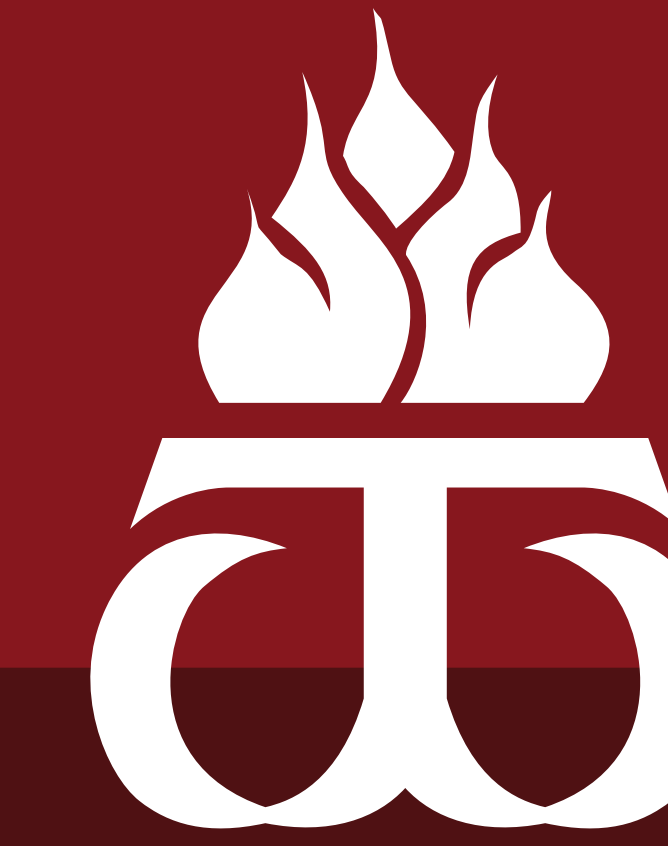


Self-monitoring of blood pressure (SMBP) at home has several significant advantages compared to blood pressure (BP) monitoring by a clinician in a clinical setting. The purpose of this study was to evaluate the accuracy of a SMBP system, the iHealth, and determine the effectiveness of wirelessly transferring the results via the internet to another site, such as a clinician's office. The iHealth accuracy was determined on 91 subjects, age range 18 to 83, with a systolic BP range of 97 to 171 and diastolic range of 46 to 140 mmHg. The BP of each subject was measured 3 times with the iHealth test device alternating with 3 measurements with the reference instrument, the MABIS SmartSpeed Plus. Accuracy was determined by the ANSI/AAMI SP10:2002/A1:2003 standard. The systolic and diastolic mean difference was -1.9 (S.D.=7.6) and -1.0 (S.D.=4.2) mmHg. Therefore, in this study, the iHealth satisfied the ANSI/AAMI BP accuracy standard for systolic and diastolic of +/- 5 mmHg or less and S.D.=8 or less. The iHealth accurately transmitted the BP data via the attached iPad in 100% of the 150 attempts. In conclusion, the iHealth BP monitor with attached iPad appeared to accurately measure BP and reliably transmit the information over the wireless internet connection in this study.

# EVALUATION OF THE iHEALTH BLOOD PRESSURE MONITORING SYSTEM

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## INTRODUCTION

Self-Monitoring Blood Pressure (SMBP) at home has several advantages compared to blood pressure (BP) monitoring in a clinical setting. SMBP can be less expensive, and can reduce the number of visits to a clinic or healthcare provider, while still producing an appropriate number of readings required for the monitoring and diagnosis of hypertension or hypotension. It can also eliminate false readings secondary to white coat syndrome. However, potential disadvantages of SMBP include at home devices unable to save data, which could result in observer transcription error, and also the lack of information transmission in a timely manner.

The iHealth BP monitoring system uses oscillometric means of BP measurement, and records systolic, diastolic, and heart rate with day/date/time decreasing the likelihood of error that can occur in handwritten diaries, and allowing for a chronological arrangement of data. A user can manage personal data using World Health Organization (WHO) classifications, graphs and average calculation. Lastly, this system offers the ability to share individual measurements in real time, or in the form of a list. Results can be emailed to health care professionals, enabling an ongoing relationship concerning BP between provider and patient.

## PURPOSE

The purpose of this study was to evaluate the accuracy of the iHealth BP Monitoring System\*, as well as to determine the effectiveness of transferring subject data to another source, therefore testing the reliability of the device's capability to send patient information to a clinician.

\*Exclusive USA distributor:  
Veridian Healthcare  
1175 Lakeside Dr.  
Gurnee, IL  
60031

Manufacturer:  
iHealth Lab  
719 N. Shoreline Blvd.  
Mountain View, CA  
94043

## METHODS

In this study, the iHealth BP Monitoring System measurements were compared with an accurate reference standard BP instrument compliant with accuracy requirement standards of ANSI/AAMI SP10-2003. (ANSI/AAMI/ISO 81060-2)

- Each subject's BP was taken three times with the iHealth System and with the reference standard instrument in alternating order.
- iHealth BP measurements emailed via iPad when internet connections were available.



Figure 1. iHealth Blood Pressure Monitoring System with iPad option.

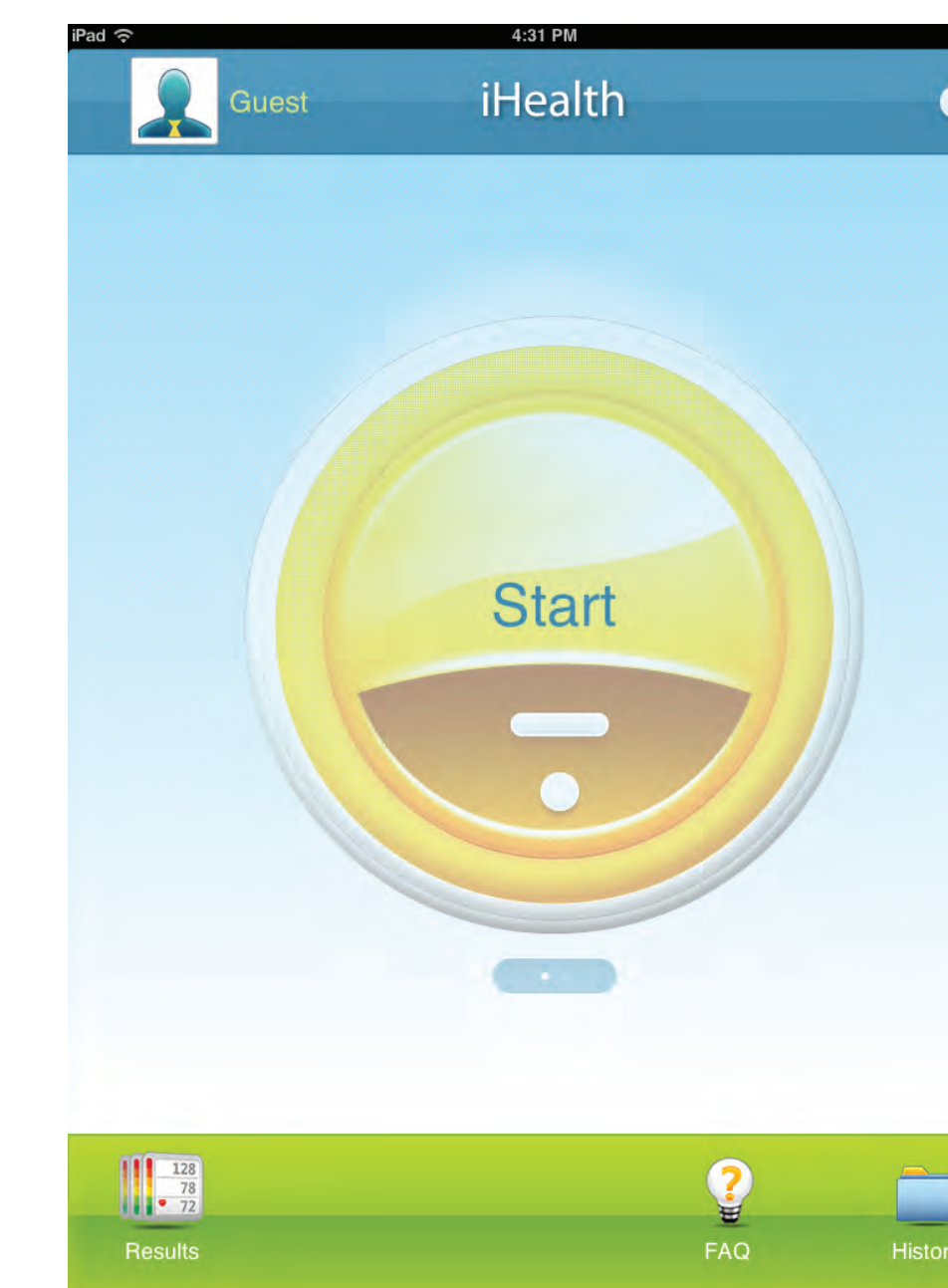


Figure 2. iPad screen for initiation of BP measurement.

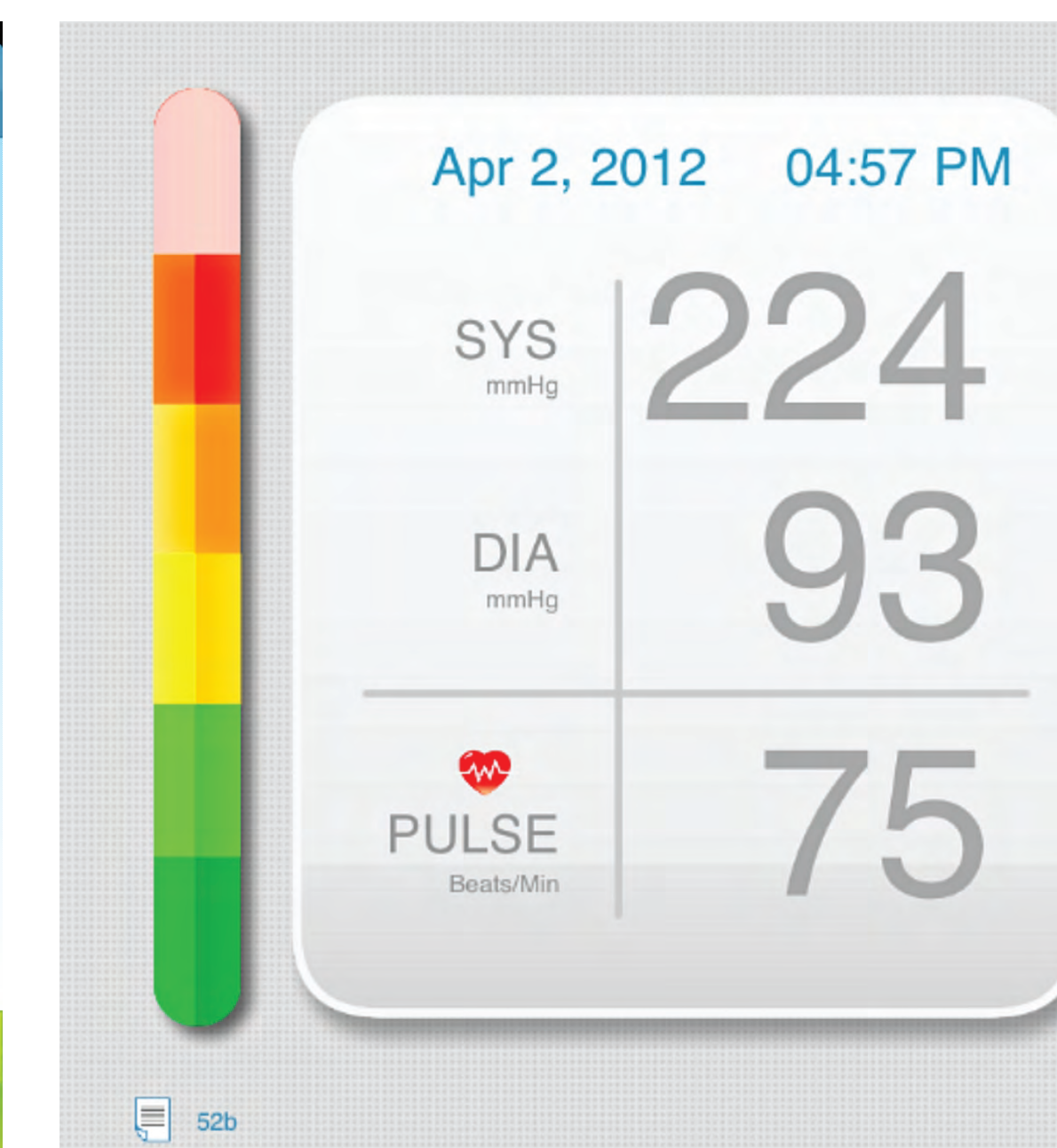


Figure 3. Sample output screen of BP measurement.

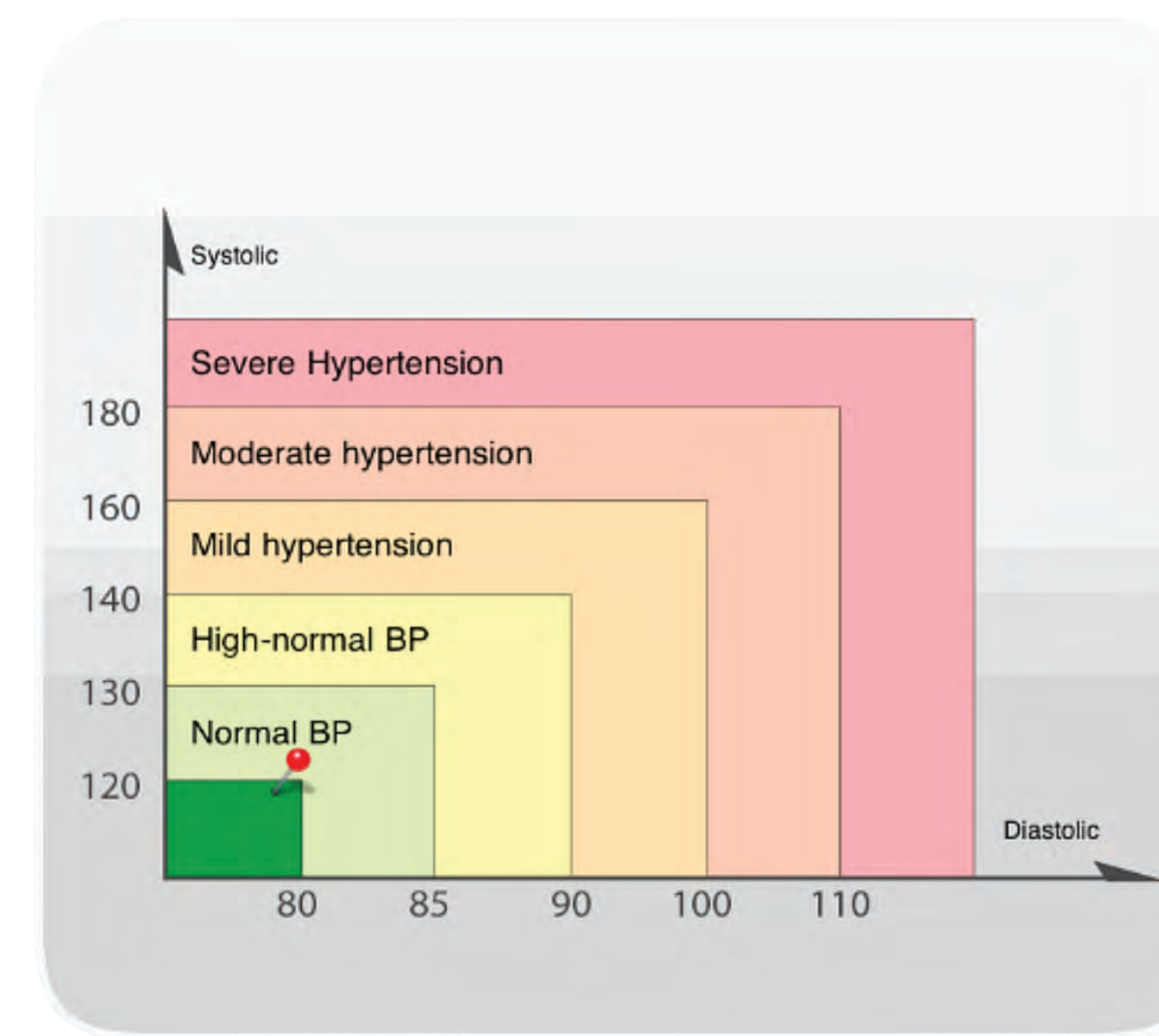


Figure 4. Sample output screen of WHO classification of BP.

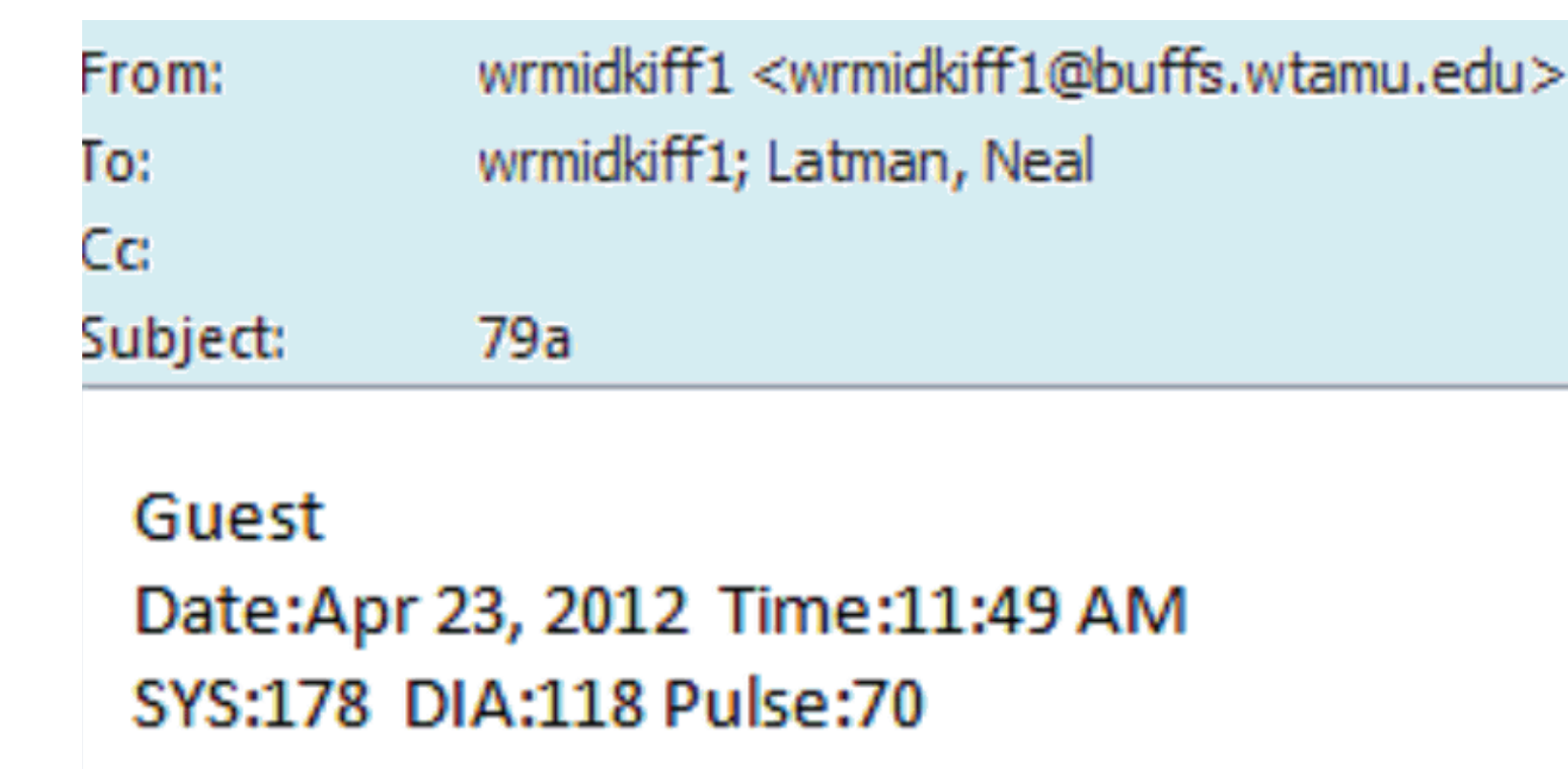


Figure 5. Sample of E-Mailed results for Subject 79a.

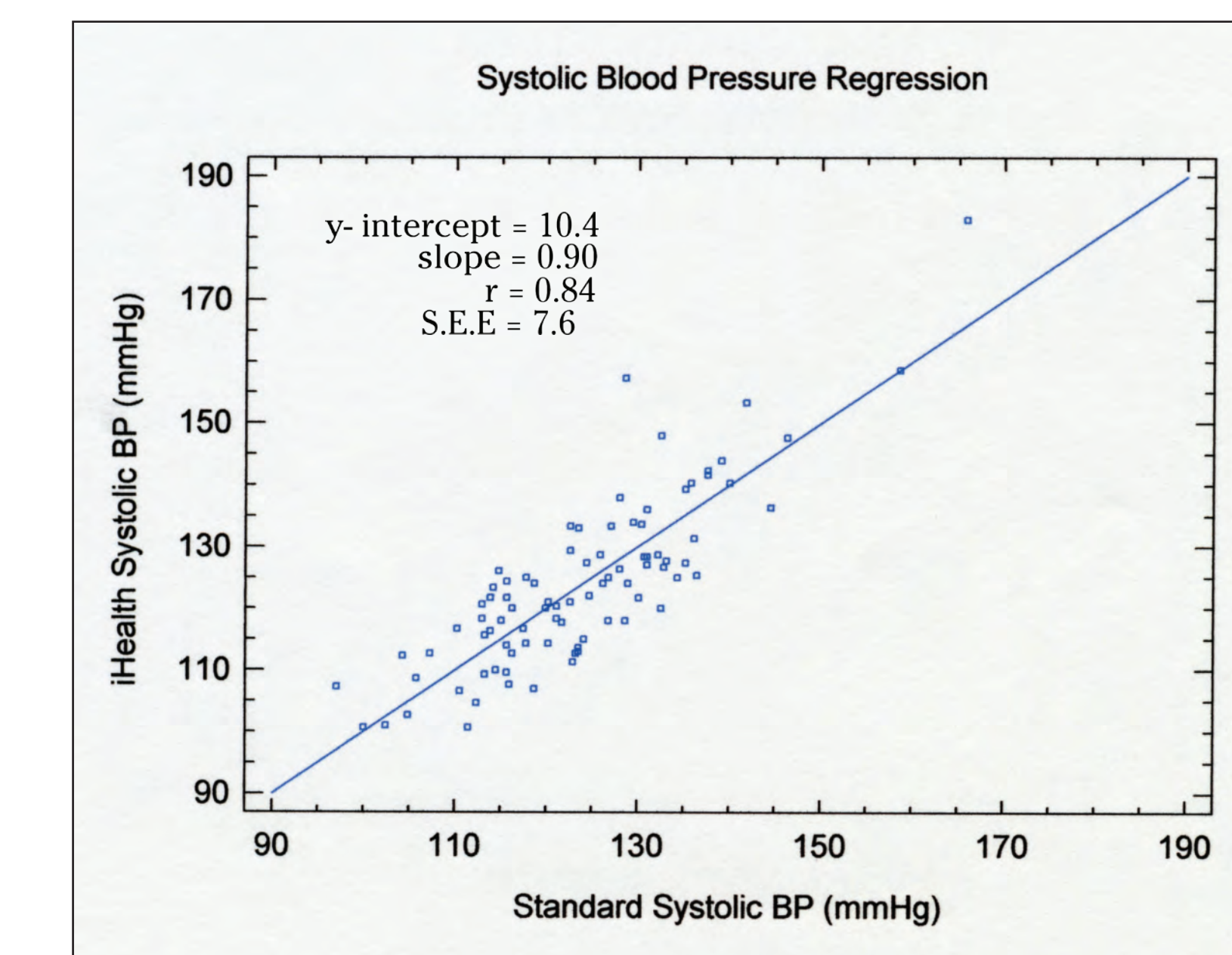


Figure 6. Regression Analysis of Systolic BP Measurements.

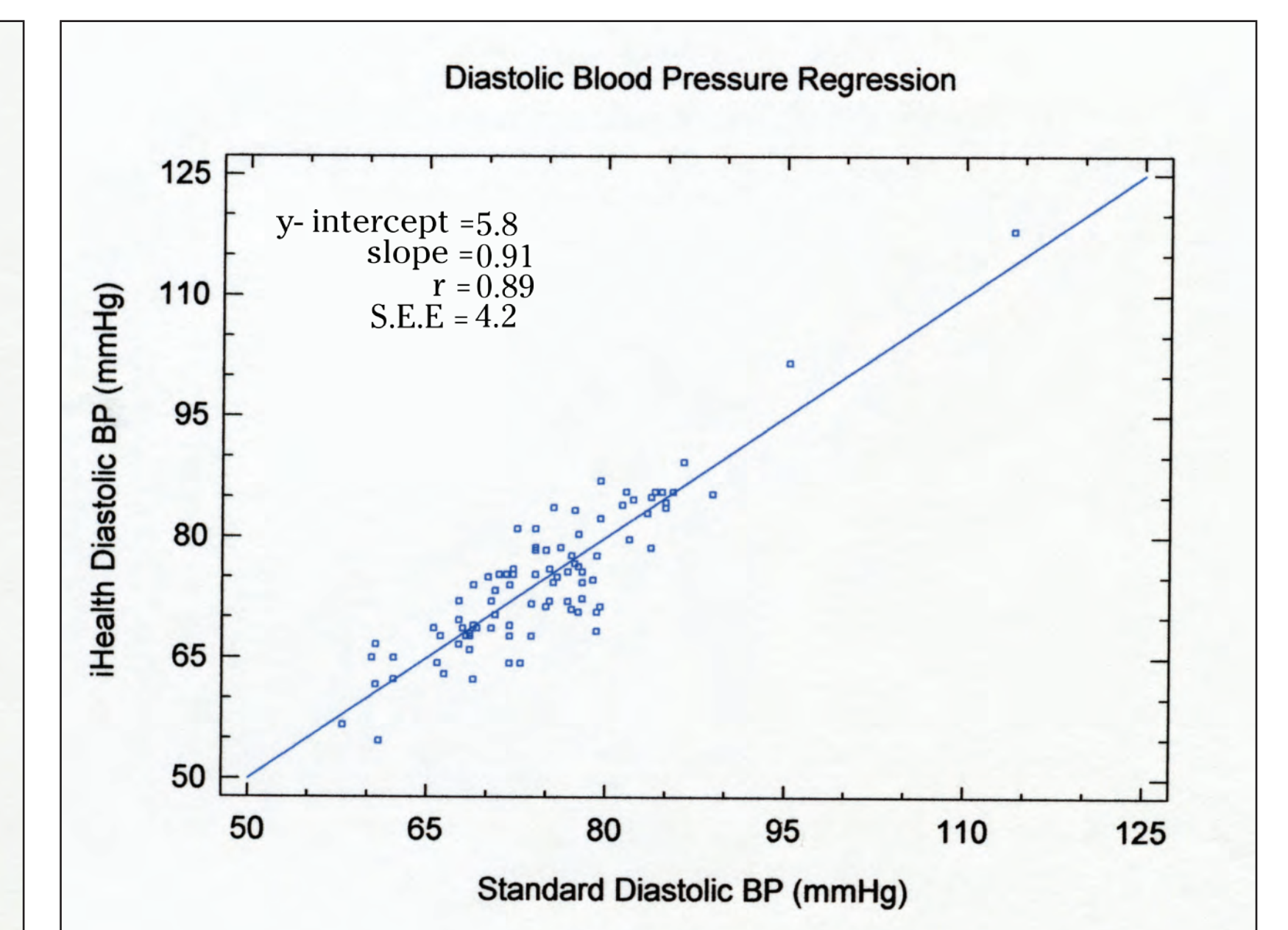


Figure 7. Regression Analysis of Diastolic BP Measurements.

INSTRUMENT	Mean Difference (Systolic)	Standard Deviation of Mean Difference (Systolic)	Mean Difference (Diastolic)	Standard Deviation of Mean Difference (Diastolic)
Accuracy Standard ANSI/AAMI/ISO 81060-2	+/- 5 mmHg or less	8 mmHg or less	+/- 5 mmHg or less	8 mmHg or less
iHealth BP Monitoring System	-1.9 mmHg	7.6 mmHg	-1.0 mmHg	4.2 mmHg

Table 3. Accuracy.

## RESULTS

ARM CIRCUMFERENCE (inches)	ADULT CUFF 8.6 - 11.8 inches	LARGE ADULT CUFF 11.8 - 16.5 inches	X-LARGE ADULT CUFF 16.5 - 18.8 inches
NUMBER OF SUBJECTS	67	22	2

Table 1. Cuff Size Distributions of Subjects.

	AGE (Years)	ARM CIRCUMFERENCE (cm)	SYSTOLIC BP (mmHg)	DIASTOLIC (mmHg)	HEART RATE (beats per minute)
MEAN	32	28	128	77	74
MINIMUM	18	20	97	53	46
MAXIMUM	83	46	171	120	140

Table 2. Subject's Demographics (n = 91 subjects, 273 iHealth BP measurements)

## CONCLUSION

While ease of use for any device can be appealing, it is meaningless if the device is not valid, accurate, and dependable. In this study:

- the iHealth passed the ANSI/AAMI/ISO standard for accuracy, and
- allowed real time transmission of data.
- Therefore this device appears to satisfy the requirements for an accurate and reliable self-monitoring BP instrument for at-home BP monitoring.