

Blood Pressure Monitoring



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Validation of the Pharma-Smart PS-2000 public use blood pressure monitor

Bruce S. Alpert

Objective To test the Pharma-Smart Model PS-2000 public use blood pressure monitor for compliance with the Association for the Advancement of Medical Instrumentation's Standard (AAMI) and to a modified British Hypertension Society (BHS) Protocol.

Methods Subjects tested ranged in age from 18–74, with the average age of 40. Arm circumference ranged from 22–38 cm. Resting systolic blood pressure (BP) ranged from 91–252 mmHg, and resting diastolic pressure ranged from 57–160 mmHg. There were 44 males, and 41 females. For each subject the readings obtained by the PS-2000 were compared with auscultatory readings obtained by two clinicians, blinded to the results of each other and the device. The manual reference measurements were alternated with the readings obtained by the device.

Results The average differences between the reference readings (average of the two clinicians) using the AAMI analysis and the automated readings were 0.07 ± 7.0 mmHg (Mean \pm SD) for systolic BP, and -0.3 ± 6.6 mmHg for diastolic BP.

Conclusions The device met the accuracy requirements of the AAMI standard. In addition, when the data were analyzed to assess the compliance with the current British Hypertension Society Protocol (BHS), the device earned the highest rating of 'A' for both systolic and diastolic pressure. We believe that the Pharma-Smart PS-2000 will provide valid readings when placed in non-medical public use sites. *Blood Press Monit* 9:19–23 © 2004 Lippincott Williams & Wilkins.

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Introduction

Despite increasing awareness and more aggressive treatment of hypertension in the USA, the condition continues to be a leading contributing factor to stroke, myocardial infarction, heart failure, and kidney failure. While a great deal has been documented about the dangers of hypertension, and advances have been made in the management of the condition, statistics continue to reveal that it is largely uncontrolled.

The most recent statistics indicate that hypertension prevalence is increasing in the USA [1]. Year 2000 figures from the National Health and Nutritional Examination Survey (NHANES) indicate that 29% of the adult USA population, (58.4 million individuals), has hypertension. Nearly 30% of all hypertensive individuals (17.5 million) are unaware of their illness. Of the 41 million who are aware they have hypertension, 42% are not being treated, and 69% do not have their hypertension controlled. In addition, nearly 75% of all patients with diabetes and hypertension did not have their hypertension optimally controlled. The goal of the US Department of Health and Human Services that 50% of Americans with hypertension have their blood pressure (BP) controlled by the year

2000 was not met, and this goal has been re-established to be achieved by 2010. Programs improving awareness and treatment of hypertension will be essential in reaching this goal, and are of utmost importance for the health of the USA [1].

Compounding the difficulty of hypertension discovery and management are: poor access to adequate healthcare and screening services; 'white-coat hypertension' which often leads to misdiagnosis in a clinical setting; failure to provide adequate and continuous BP screening data to the physician; and poor levels of education, and as a result, poor compliance to prescriptions.

Currently in the USA, there are approximately 30 000 public use blood pressure devices located in pharmacies and worksites. It is estimated within the industry that these units perform over 500 million measurements each year. While measurement technique employed by existing equipment varies, much of this equipment utilizes forearm BP testing technology, and in some cases measures blood pressure in the standing position. Many of these devices have not been assessed for accuracy using the AAMI standard.

The Pharma-Smart equipment is designed to measure blood pressure in accordance to the American Heart Association (AHA) guidelines [2] for general screening—seated, brachial artery measurement at the level of the heart.

Methods

Subjects

The protocol was approved by the University of Tennessee Institutional Review Board. Subjects tested ranged in age from 18–74 years, with the average age of 40. The majority of subjects worked at the University of Tennessee. Written informed consent was obtained from each subject. Arm size ranged from 22–38 cm in circumference. The device is designed for a range of arm circumference from 18–38 cm. Systolic blood pressure ranged from 91–252 mmHg, and diastolic pressure ranged from 57–160 mmHg. There were 44 males, and 41 females. These subjects were representative of the population expected to use the device.

The Association for the Advancement of Medical Instrumentation (AAMI) SP10 standard

The AAMI standard [3] is intended to be used for a wide variety of devices, and provides for a modification of the ranges if this represents the population mix that is expected to use the device being tested. The PS-2000 is intended to be used to assist in identifying adults that may have hypertension, assist the medical professional in managing the individual's blood pressure, and to encourage compliance. With this in mind, the requirement that 10% of the subjects have diastolic pressure lower than 60 mmHg was not representative of the intended population. The lower blood pressure range was raised to ≤ 70 mmHg (Table 1).

Protocol

The comparison standard was auscultatory blood pressure, Korotkoff phase I and phase V. The clinical team consisted of three members, two clinicians who were blinded to one another and the clinical supervisor who had visibility of all of the readings. The device display was covered such that results were not visible to the subjects or to the clinicians. Device readings were printed on 'tickets' processed by the Pharma-Smart unit. The

clinicians both viewed the same mercury manometer and used a dual-headed binaural stethoscope. If agreement between clinicians was not achieved, i.e., the difference between paired values was ≥ 10 mmHg, the supervisor instructed the clinicians to repeat the measurement without any further discussion relating to the reason for the disagreement. The clinicians were very experienced, and agreement with each other and the clinical supervisor was demonstrated before the start of the validation protocol.

The PS-2000 is a sit down kiosk, and has a single size cuff that is designed to measure BP accurately using arm sizes from 18–38 cm in circumference. In use, the cuff surrounds the brachial artery, and is at heart level. Because a major portion of the validation is to determine that the cuff does not introduce significant errors, it was necessary to employ sequential same arm readings rather than simultaneous same arm readings. All measurements were performed on the left arm.

Cuff size

Most device validations, using auscultation as the reference measurement, use the same cuff for both the device and the reference measurements. If the cuff is inappropriately sized, it introduces a similar error into both the clinicians' readings and the device's measurement. For this study the cuff size was of extreme importance, as the device results, with its integral cuff, were compared to readings performed with different cuffs. Any errors would not be shared by the clinicians and the device being tested.

The cuffs used for auscultation were the Baumanometer V-Lok® Child/Small Adult, and Large Arm sizes. The larger-sized cuff was employed when the arm size fitted between two cuff sizes. These cuffs were selected because of their frequent use in clinical environments and rather close compliance with AAMI recommendation that the width of the bladder be 40% of the arm circumference.

Measurement order

The device performed the first blood pressure determination. This was to familiarize the subject with the device in order to reduce the subject's blood pressure variation during the testing series. This reading was not utilized in the data set. The appropriate-sized cuff was then applied to the arm, and the clinicians performed the next blood pressure determination. This reading was used as the classification reading, and to familiarize the clinicians with the auscultatory characteristics of the subject. Then a second device reading was taken which was not utilized in the data set. Next the team performed their second manual measurement. This was the first measurement used to compare to the device being

Table 1 The AAMI requirements and the study population measurements

	Min. AAMI requirement	Actual study population
Systolic BP > 160 mmHg	10%	15.3%
Systolic BP < 10 mmHg	10%	10.6%
Diastolic BP > 100 mmHg	10%	18.8%
Diastolic BP < 70 mmHg (increased from 60, see above explanation)	10%	17.6%
Arm circumference > 35 cm	10%	15.3%
Arm circumference < 25 cm	10%	14.1%

BP, blood pressure.

tested. This alternating series was continued until there were a total of five device readings and five manual readings. The last four clinician readings and the last three device readings were used to determine device validity. The measurements were spaced about 1 min apart, which was as close as practical when applying and removing the manually applied cuff before and after each of the clinical reference measurements.

Results

AAMI

The AAMI SP 10, 2002 has two different methods for analyzing the differences between the device and the auscultatory readings. The PS-2000 passed both. The first method utilizes all 255 sets of data for systolic and diastolic pressures treated separately. The PS-2000 had a mean error of 0.07 mmHg for systole with a standard deviation of 7.0, and a mean error of -0.3 mmHg with a standard deviation of 6.6 for diastole (Table 2). Using this method, the results met the first AAMI requirement of a mean error of ± 5 mmHg or less with a standard deviation of 8 mmHg or less.

The second method of the AAMI standard first averages the systolic differences between the device and the average of the clinicians and then the diastolic difference for each subject before evaluating the results against the standard. This results in 85 sets of data for systole, and another 85 sets for diastole. The average allowable difference remains the same as in the previous method, as this averaging step does not affect the mean. However the averaging does reduce the standard deviation. The allowable standard deviation depends on the magnitude of the mean difference, and ranges from 6.95 down to 4.81 depending on the mean difference. Because the average error of the PS-2000 approached zero, the requirement is that the averaged standard deviation be 6.95 or less for systole, and 6.94 for diastole. Using this method, the PS-2000 had a standard deviation of 5.9 for systole and a standard deviation of 6.1 for diastole.

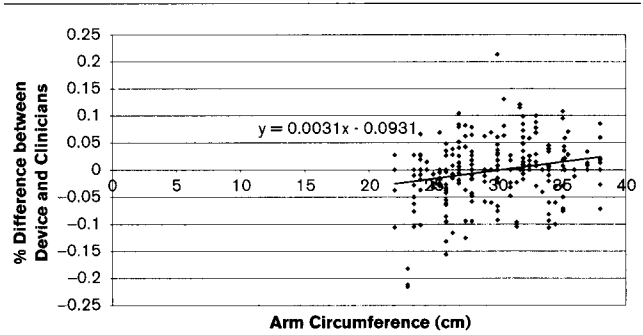
Arm size effects on accuracy

Figures 1 and 2 show the error in systolic and diastolic pressure plotted as a function of arm circumference. The slope and intercept are shown. Both graphs show a tendency to slightly under-estimate blood pressure on a small arm and slightly over-estimate blood pressure on a large arm.

Table 2 Accuracy results for the PS-2000 BP monitor (AAMI method 1)

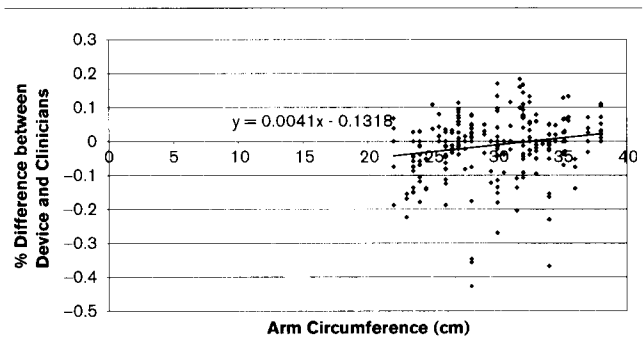
AAMI Method 1	Requirement	PS-2000 Systolic	PS-2000 Diastolic
Mean error	≤ 5 mmHg	0.0 mmHg	-0.3 mmHg
Standard deviation	≤ 8 mmHg	7.0	6.6

Fig. 1



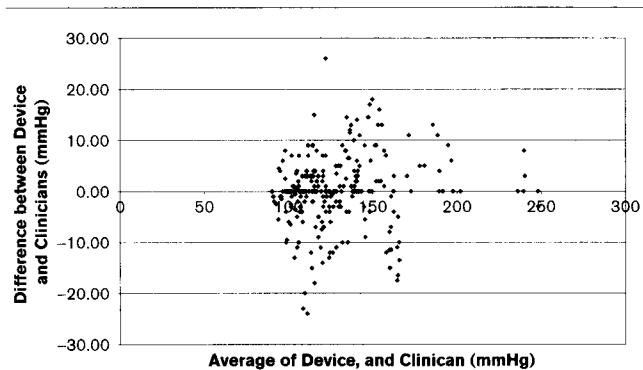
Systolic Pressure Difference vs Arm Circumference.

Fig. 2



Diastolic Pressure vs Arm Circumference.

Fig. 3



Systolic Pressure Mean Difference 0.0 mmHg Standard Deviation 7.0.

Pressure level effects on accuracy

The device slightly under-estimated low systolic pressure and slightly over-estimated high systolic pressure as shown in Figure 3. The magnitude of this error was less than 2 mmHg between 90 and 160 mmHg systolic pressure. The device also slightly under-estimated low diastolic pressure, and over-estimated high diastolic

pressure as shown in Figure 4. The magnitude of this error was less than 2.5 mmHg from 80 to 100 mmHg. The average error at 140/90 was less than 1 mmHg.

British Hypertension Society (BHS) protocol

The BHS protocol [4] requires more subjects with high systolic pressure than the AAMI standard. The BHS requires a total of 20 subjects that exhibit entry level blood pressures above 160 mmHg, but less than 180 mmHg, and eight subjects with systolic BP above 180 mmHg. AAMI requires nine above 160 mmHg, and none above 180 mmHg. This study population had 13 above 160 mmHg, and five above 180 mmHg, easily meeting the AAMI requirements, but falling short of the BHS goal.

When the results were analyzed as specified in the BHS protocol as revised in 1993, the PS-2000 earned the highest rating—an 'A'—for both systolic and diastolic pressures. See Table 3 for the grading system and Table 4 for the results for the PS-2000.

Discussion

Cuff design

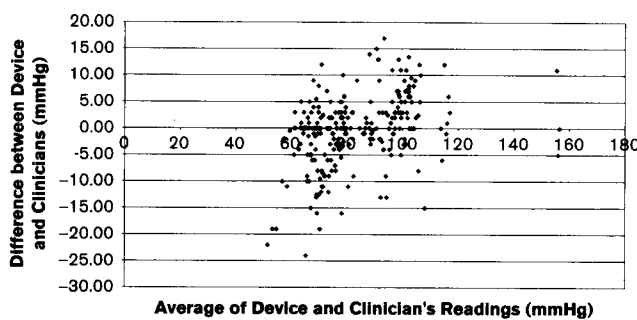
The Pharma-Smart PS-2000 uses a single cuff to accommodate a wide range of arm sizes. The cuff is

provided with a two-axis swivel such that it can align itself with different arm positions. The cuff bladder is 15.2 cm in width, and long enough to encircle almost the entire upper arm. The cuff bladder width is 40% of the circumference of the largest arm that will fit into the cuff, which is 38 cm in circumference. The cuff is designed such that the cuff width contact on the arm is decreased as the arm size is decreased, closely matching the 40% recommendation of AAMI and AHA. The effectiveness of this design is shown in Figures 1 and 2; the cuff slightly over-estimated the blood pressure on the largest size arms and under-estimated the blood pressure on smaller arms. Some of the difference may be attributed to using only the upper portion of the arm circumference range of the small cuff, and the lower portion of the arm circumferences range of the large cuff. The bladder width averaged 38% of arm circumference on small arms, and 43% of arm circumference on large arms. In practice, the errors caused by arm size are small, indicating that the cuff performs well with arm size variations.

Methods used for data analyses

The AAMI SP10 requires that the readings of both clinicians be averaged before comparing with the device being tested. It further recommends sequential same arm testing as preferable to simultaneous dual arm recordings. The AAMI does not directly address the issue of temporal variations in blood pressure, which creates apparent test-reference differences even if none exist. This variation in blood pressure is not a significant source of error in sequential testing. This results in 'penalizing' devices validated using sequential measurements, unless methods are employed to compensate for this issue. While there is not a consensus of how sequential measurements

Fig. 4



Diastolic Pressure Mean Difference -0.3 Standard Deviation 6.6.

Table 3 Absolute differences between standard and device under test (mmHg) (BHS)

Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
A	60%	85%	95%
B	50%	75%	90%
C	40%	65%	85%
D	Worse than C	Worse than C	Worse than C

Table 4 Accuracy results for the PS-2000 BP monitor (BHS)

	Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Mean ± SD (mmHg)	Mean ± SD of differences (mmHg)
Observer 1						
SBP	B	64%	84%	96%	130.6 ± 29.4	0.3 ± 7.2
DSP	A	65%	87%	97%	82.9 ± 15.7	-0.1 ± 6.7
Observer 2						
SBP	A	65%	87%	96%	131.3 ± 29.5	-0.2 ± 7.0
DSP	A	66%	85%	96%	83.3 ± 16.0	-0.6 ± 6.7
Final Grading						
SBP	A	65%	87%	96%	131.3 ± 29.5	0.2 ± 7.0
DSP	A	66%	87%	97%	82.9 ± 15.7	-0.1 ± 6.7
Obs/Obs						
SBP	A	97%	100%	100%	130.9 ± 29.6	0.7 ± 1.8
DSP	A	96%	100%	100%	83.1 ± 16.0	0.4 ± 2.1

should be analyzed in order to restore parity, various methods have been used. One suggestion is the AAMI SP10, Annex D, which is to discard individual measurements or even an entire measurement series if blood pressure variation exceeds 8 mmHg for diastolic pressure and 12 mmHg for systolic pressure. While this method eliminates the worst of the comparisons, it does not eliminate the bias, just lowers it. Eliminating individuals that have a large variation in blood pressure also exacerbates the issue of finding high blood pressure subjects, as their blood pressure tends to vary more. In the AAMI SP10 there is an additional recommendation that addresses this issue in Annex C. Although this annex is intended to be informative for using intra-arterial pressure as the reference, it addresses this issue. It suggests that the range in intra-arterial blood pressure should be recorded during the time it takes to perform the measurement, and that this be compared for agreement with the device being validated. The equivalent, when utilizing auscultation as the reference, would be the range in the pressure measured preceding and following the device reading, as was done in this validation.

The British Hypertension Standard (BHS) [4,5] has addressed the issue of blood pressure variation between sequential measurements first by using the method employed in this validation and then by choosing the result obtained by the individual clinician that was more favorable to the device being tested. There is not a significant difference in the results obtained in this validation using either method (average systolic and average diastolic pressure changed by 0.2 mmHg and standard deviation stayed the same for systolic, and changed by 0.1 for diastolic pressure). However the AAMI is quite specific that the averaged clinician readings should be used, eliminating the use of the more recent BHS method for analysis.

A list of devices that have been evaluated by the AAMI SP10 or BHS is available [6]. Most (70 of 79) were evaluated using both. Of this total, 11 passed the AAMI protocol but not the BHS protocol, and one passed the BHS protocol but not the AAMI protocol suggesting that the BHS protocol is more difficult to pass. For current information concerning the BHS protocol, see <http://www.bhsoc.org>.

Other studies have used the same method employed by the BHS and in this validation in order to restore parity between sequential and simultaneous readings in order to satisfy the AAMI SP10 [7,8].

In this study, for the AAMI analysis, the simultaneous readings of the two clinicians were first averaged separately for systolic and diastolic BP. The error for sequential measurements was calculated as follows: for device readings that fell between the average of the clinicians' readings before and after the device's readings, a difference of zero was assigned, whereas for device readings that were outside the range of comparison readings, the difference was determined by using the closer average (before or after) to the device reading.

The Pharma-Smart PS-2000 met the AAMI requirements for accuracy. Most notably, the mean difference between well-trained clinicians and the device readings were very small (0.07 systolic and -0.3 diastolic). Further, when analyzed in accordance to the BHS evaluation protocol, the PS-2000 achieved the highest grade—an 'A'. It is well suited for its role as a high volume, self-administered BP screening device.

Acknowledgements

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