

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

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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.

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

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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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.

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.

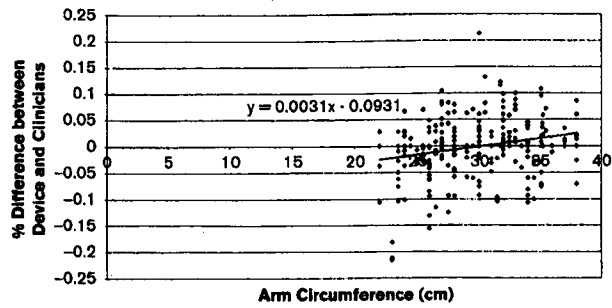
Arm size effects on accuracy

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)

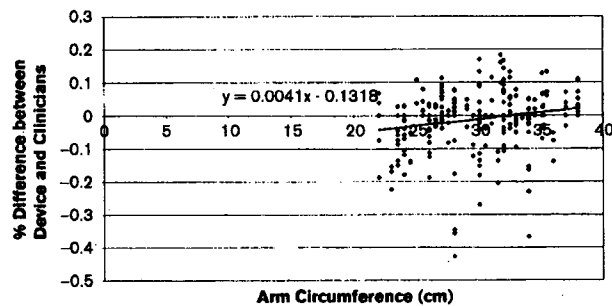
AAMI Method 1	Requirement	PS-2000 Systolic	PS-2000 Diastolic
Mean error	≤ 5 mmHg	0.0 mmHg	-0.3 mmHg
Standard deviation	≤ 8 mmHg	7.0	6.6

Fig. 1



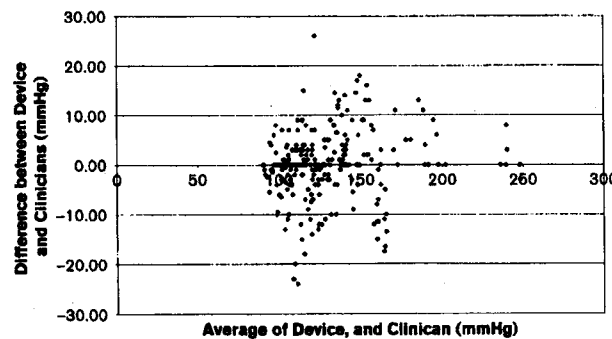
Systolic Pressure Difference vs Arm Circumference.

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

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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