Performance Review of a Noninvasive Blood Pressure Monitor

FIGURE 1. Vita-Stat model 90550.

Promotion of health awareness and accessibility to accurate, reliable and easy-to-use semi-automatic noninvasive blood pressure (NIBP) measuring devices have assisted in the detection, treatment and monitoring of hypertension. Several such devices have been installed in retail pharmacies, chain drug stores, mass merchandisers, supermarkets, health clinics, and companies in a variety of industries. Vita-Stat Medical Services Inc. (VS) has designed an NIBP measuring device (VS 90550) that addresses the special needs of these environments by providing accurate and reliable blood pressure measurements in an unsupervised setting with high ambient noise and high volume.

ANDREW R. NARA, M.D., Ph.D., F.A.C.C., F.C.C.P.

Monitoring and controlling blood pressure has been shown to reduce disability and death due to cardiovascular disease and stroke.[1] The purpose of this paper is to objectively evaluate the performance of the VS 90550 using the American National Standard *Electronic or automated sphygmomanometers* (ANSI/AAMI SP10-1992)[2] performance criteria.

DEVICE DESCRIPTION

The VS 90550 is an oscillometric based NIBP device (Figure 1). While comfortably seated, the subject places the upper arm into a fully automated cuff assembly which is at heart level. This design promotes adherence to the American Heart Association (AHA) guidelines.[1] After pressing the start key, systolic, diastolic and heart rate measurements appear in less than one minute on easy to read digital displays. Each unit undergoes regularly scheduled calibration by manufacturer-trained service personnel.

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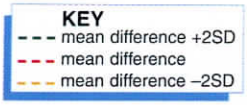


FIGURE 2. Bland-Altman plot for interobserver systolic blood pressure.

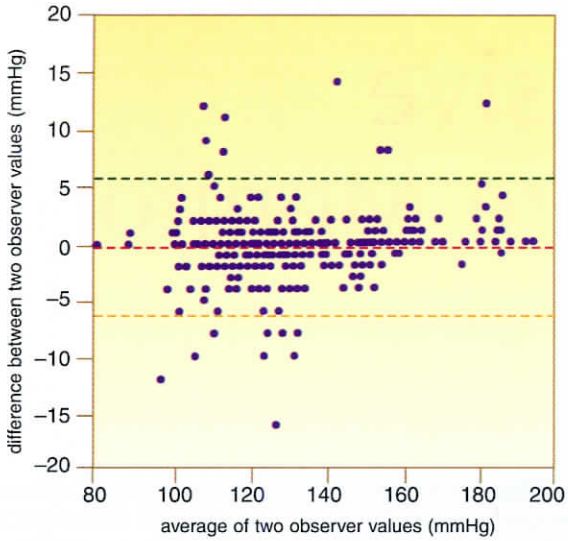
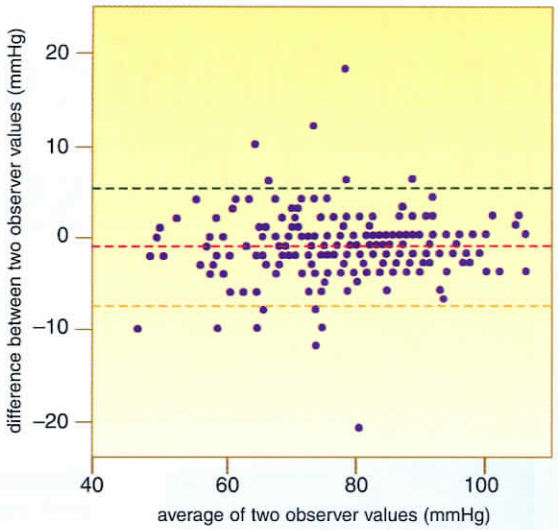


FIGURE 3. Bland-Altman plot for interobserver diastolic blood pressure.



STUDY POPULATION

A total of 88 subjects from normal and hypertension clinic populations participated including elderly, diabetic and renal patients. Volunteers consisted of a representative cross-section of people who would normally use the device. There were 44 women and 44 men, with a mean age of 47 years (range 22 to 85).

TABLE 1 — CLINICAL TRIAL CHARACTERISTICS

PARAMETER	
Study Population	
Subjects	88
Age Range	22-85
Mean Age ±SD	47±15
Male (%)	44 (50%)
Female (%)	44 (50%)
Cuff Location	Brachial
AHA Protocol	Yes†
# Observers*	2
Device Limitations	
Limb Circumference (cm)	21.6–35.6
Systolic BP (mmHg)	≤260
Method	Oscillometry

Abbreviations: BP = blood pressure; SD = standard deviation
† 1993 AHA protocol.
* Simultaneous BP measurements by two blinded observers using a double biauricular stethoscope.

METHODS

Two trained blinded observers (OBS=OB1+OB2), using standard technique[1,2], utilized a double biauricular stethoscope to simultaneously auscultate blood pressure. In addition, the stethoscope bell was carefully positioned over the marked brachial artery and lightly held in place with a specially designed strap to eliminate finger "creak." Korotkoff phases I and V were used as estimates of systolic and diastolic pressure, respectively. A series of 7 regularly spaced sequential blood-pressure measurements were made on the ipsilateral arm (i.e., OBS-device-OBS-device-OBS-device-OBS.) There was a 1 minute deflation time between successive readings. The clinical trial characteristics are detailed in Table 1.

DATA ANALYSIS AND REPORTING

The standard techniques as described by the American National Standard *Electronic or automated sphygmomanometers* (ANSI/AAMI SP10-1992) were used. These included:

- Between-Observer Comparisons
- Test-Reference Method Comparisons
- Bland-Altman Analysis of Agreement
- Mean Difference and Standard Deviation Analysis
- Appropriate Sample Size (minimize α and β errors)

KEY
- - - mean difference +2SD
- - - mean difference
- - - mean difference –2SD

FIGURE 4. Bland-Altman plot for the VS 90550 versus observers (single set) systolic blood pressure.

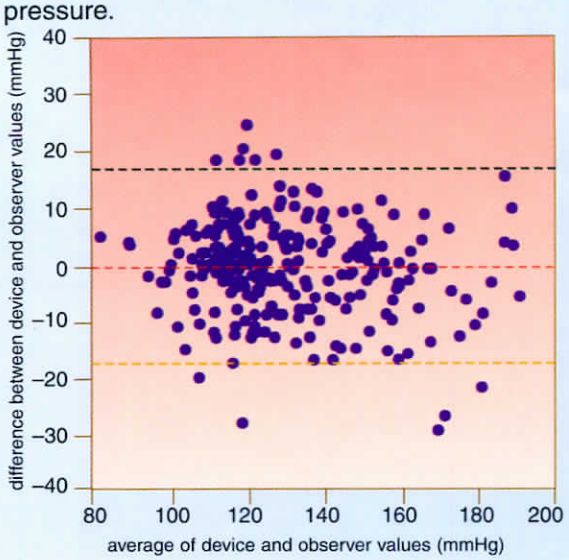
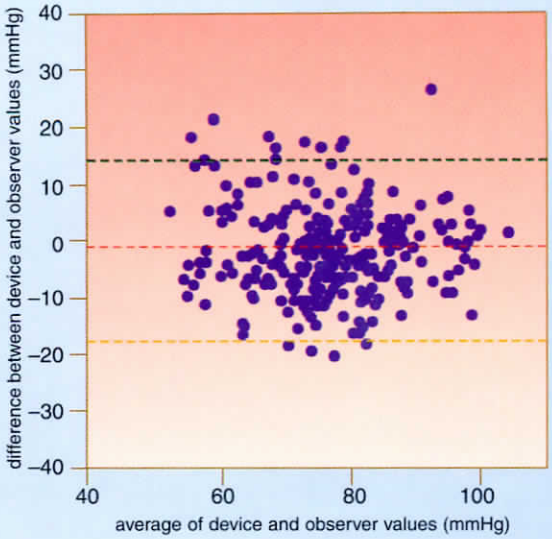


FIGURE 5. Bland-Altman plot for the VS 90550 versus observers (single set) diastolic blood pressure.



Simple linear regression analysis was avoided since such an approach is far less robust in interpreting device performance. Bland-Altman analysis[3,4] plots the difference between methods (A-B) as a function of the average of two methods (A+B)/2. The mean difference (d) and 95% range calculated from the standard deviation (s) are determined. The lack of agreement between the two methods is described by the bias (d) and estimate of error (d ± 1.96s). This plot allows for rapid assimilation of disagreement between device and observer with respect to bias, error, outliers and trends.

Two methods of averaging simultaneous observers readings were employed:

Single Set: Represents the average of a single set of simultaneous blood pressure measurements by two blinded observers (OBS) immediately preceding a device reading. Each subject had three sets of paired human and device (OBS-device) blood pressure readings.

Paired Set: Represents the average of a paired set (i.e., OBS immediately before and after a device reading) of simultaneous blood pressure measurements by two blinded observers. Each subject had four paired human and three device BP readings. This approach adjusts for temporal effects.

INTEROBSERVER PERFORMANCE

The interobserver performance statistics (Between-Observer Comparisons) for 352 systolic and diastolic readings are presented in Table 2. The systolic and diastolic d±s was 0±3 mmHg and –1±3 mmHg, respectively. Ninety-three percent of the systolic and 92% of the diastolic interobserver readings were within ±5 mmHg. Figures 2 and 3 show the Bland-Altman plots for systolic and diastolic readings. The d±1.96s was 0±6 mmHg and –1±6 mmHg, respectively.

TABLE 2 — INTEROBSERVER PERFORMANCE STATISTICS

	Observer 1 — Observer 2 *	
	SYSTOLIC	DIASTOLIC
Subjects	88	88
Readings	352	352
Range**	79–194	42–106
Mean Diff. (mmHg)	0	–1
SD of Mean Diff. (mmHg)	3	3
% Exceeding		
5mmHg	7	8
10mmHg	2	1
15mmHg	0	1

Abbreviation: SD = standard deviation
* Simultaneous BP measurements by two blinded observers using a double biauricular stethoscope.
** Represents the range of BP values for both observers.

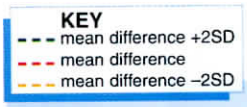


FIGURE 6. Bland-Altman plot for the VS 90550 versus observers (paired set) systolic blood pressure.

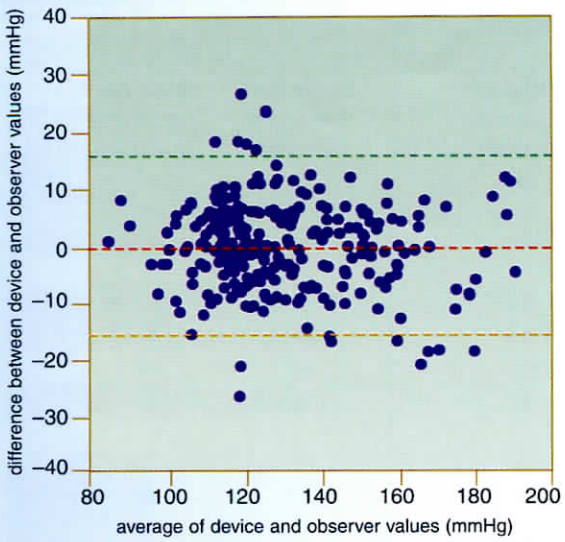
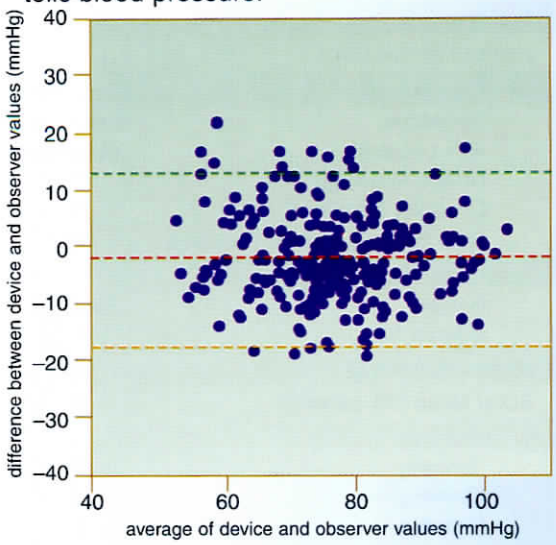


FIGURE 7. Bland-Altman plot for the VS 90550 versus observers (paired set) diastolic blood pressure.



DEVICE-OBSERVERS PERFORMANCE

Table 3 shows the Device-Observer performance statistics (Test-Reference Method Comparisons). A total of 264 single and 352 paired-set readings were obtained. ANSI/AAMI SP10-1992 standards would call for at least 85 subjects and 255 single set readings. No measurement failures were noted.

Single Set: Eighty-one percent of the systolic and 80% of the diastolic readings were within ±10 mmHg, respectively. The systolic and diastolic d±s was 0±8 mmHg and –2±8 mmHg, respectively. Figures 4 and 5 show the Bland-Altman plots for systolic and diastolic readings. The d±1.96s was 0±16 mmHg and –2±16 mmHg, respectively.

Paired Set: Eighty-four percent of the systolic and 80% of the diastolic readings were within ±10 mmHg. The systolic and diastolic d±s was 0±8 mmHg and –2±8 mmHg, respectively. Figures 6 and 7 show the Bland-Altman plots for systolic and diastolic readings. The d±1.96s was 0±16 mmHg and –2±16 mmHg, respectively.

DISCUSSION

Blood pressure is an extremely important physiologic parameter. The diagnosis of hypertension is associated with significant prognostic, diagnostic and therapeutic implications. Researchers responsible for the evaluation of blood pressure measurement devices must employ stringent, objective, fact finding methods for the protection of patients and the public. The American National Standard *Electronic or automated sphygmomanometers* (ANSI/AAMI SP10-1992) has been developed to meet this requirement.

The VS 90550 interobserver performance results are well within the ANSI/AAMI SP10-1992 standards which call for "95% or more of recordings made simultaneously by observers should agree to within ±10 mmHg and 85% or more should agree to within ±5 mmHg. If observer agreement fails to meet these criteria, the study should be regarded as flawed."

In addition, ANSI/AAMI SP10-1992 standards also require a mean difference (d) and standard deviation of the difference (s) for systolic and diastolic to be ≤±5 mmHg and ≤±8 mmHg, respectively. The VS 90550 single and paired-set systolic and diastolic pressure data are within this standard.

Self-measurement of blood pressure has become very common. The AHA states, "Self-measurement facilitates patient participation in the health care process and can simplify titration of antihypertensive drug treatment without the need for frequent visits to a health care facility."[1] The VS 90550 was designed to be easy to use

TABLE 3 — DEVICE – OBSERVERS PERFORMANCE STATISTICS

	Device–Observers*			
	SYSTOLIC		DIASTOLIC	
Subjects	88		88	
Device Failures (%)	0		0	
BP Measurements	Single Set†	Paired Set††	Single Set†	Paired Set††
Sequence	Sequential	Sequential	Sequential	Sequential
Arm Location	Ipsilateral	Ipsilateral	Ipsilateral	Ipsilateral
Device Readings	3	3	3	3
Observer Readings	3	4	3	4
Total Paired Observer Readings	264	352	264	352
Reference BP (mmHg)				
Range	80–194‡	84–193‡	47–106‡	48–106‡
Mean ± SD	131±22	130±21	78±11	78±11
Mean Diff. (mmHg)	0	0	–2	–2
SD of Mean Diff. (mmHg)	8	8	8	8
% Exceeding				
5mmHg	47	50	52	52
10mmHg	19	16	20	20
15mmHg	7	6	8	7

Abbreviations: BP = blood pressure; SD = standard deviation

* Simultaneous BP measurements by two blinded observers using a double biauricular stethoscope.

† Represents the average of a single set of simultaneous BP measurements by two blinded observers.

†† Represents the average of a paired set (i.e., before and after a device reading) of simultaneous measurements by two blinded observers.

‡ Represents the range of BP values for both observers.

and provide accurate and reliable blood pressure measurements in order to facilitate professional health care.

CONCLUSION

The VS 90550 clinical trial was properly designed and executed via ANSI/AAMI SP10-1992 standards. Both systolic and diastolic blood pressure performance of the machine met the current requirements of a mean difference ≤±5 mmHg and standard deviation ≤±8 mmHg. □

REFERENCES

1. Perloff, D., Grimm, C., Flack, J., et al, Human Blood Pressure Determination by Sphygmomanometry, American Heart Association Medical/Scientific Statement, Special Report, *Circulation,* 88 (No. 5, Part 1): 2460-2470, 1993.
2. Association for the Advancement of Medical Instrumentation, *Electronic or automated sphygmomanometers,* ANSI/AAMI SP10-92, Arlington (Vir.): AAMI, 1992, American National Standard.
3. Altman, D.G., Bland, J.M., Measurement in Medicine: The Analysis of Method Comparison Studies, *Statistician,* 32:307-317, 1983.
4. Bland, J.M., Altman, D.G., Statistical Methods for Assessing Agreement Between Two Methods of Clinical Measurement, *Lancet,* 1:307-310, 1986.

THE AUTHOR

ANDREW R. NARA, M.D., Ph.D. is an Associate Professor of Medicine at Case Western Reserve University, School of Medicine and practicing cardiologist at University Hospitals of Cleveland, Cleveland, Ohio. He received his training at Case Western Reserve University with an M.D. from the School of Medicine and Ph.D. from Case Institute of Technology, Department of Biomedical Engineering in 1976. He is a Fellow of the American College of Cardiology, American College of Chest Physicians and American Heart Association. His research interests include automated blood pressure measurement and development of arrhythmia and ischemia detection algorithms. Dr. Nara can be contacted at the Division of Cardiology, University Hospitals of Cleveland, 11100 Euclid Ave., Cleveland, OH 44106-5038, 216/844-3713, FAX 216/844-8273, e-mail: arn@po.cwru.edu.