Failure of the Community-Based Vita-Stat Automated Blood Pressure Device to Accurately Measure Blood Pressure

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Objective: To evaluate the Vita-Stat automated blood pressure computer (a patient-operated blood pressure measuring device available in the community) to determine its value as an instrument to monitor blood pressure in the ambulatory patient.

Design: Comparative study using the Vita-Stat vs a gold standard, the mercury sphygmomanometer.

Setting: Three local grocery stores.

Participants: Sixty-three passersby who agreed to answer questions and to sit for several measurements of blood pressure.

Interventions: Simultaneous measurement of blood pressure with each subject wearing a Vita-Stat cuff on the left arm and a mercury sphygmomanometer cuff on the right arm. Two pressures were measured sequentially in the same manner.

Main Outcome Measures: The reproducibility, accuracy, sensitivity, and specificity of the Vita-Stat computer compared with the gold standard.

Results: In sequential measurements, the Vita-Stat readings of both systolic and diastolic blood pressure correlated less well with each other than did the mercury readings (intramachine differences). The Vita-Stat readings also correlated poorly with the mercury readings of systolic and diastolic blood pressure (intermachine differences). The variability in readings recorded by the Vita-Stat were striking, with differences of up to 60 mm Hg from the mercury readings. More than half (63.2%) of the subjects had Vita-Stat readings that were more than 5 mm Hg different from the mercury readings. Vita-Stat systolic readings were usually lower than mercury readings and also varied by as much as 60 mm Hg below in one patient to 58 mm Hg above the mercury reading in another. The sensitivity of the Vita-Stat in correctly diagnosing hypertension was 0.26; the negative predictive value was 0.45.

Conclusions: Our data suggest that the Vita-Stat is not only inconsistent but inaccurate in measuring blood pressure in the ambulatory patient and is, therefore, not appropriate to use as a monitoring device.

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THE MAJORITY of hypertensive people in the United States have inadequate control of blood pressure[1] and need regular, sometimes frequent, follow-up to ensure adequate blood pressure control, to adjust medications, and to monitor for complications of disease or side effects of medications.

Approximately 10% of people with hypertension have blood pressure refractory to treatment[2] and return frequently for modifications of their drug regimen. Even patients with easily controllable hypertension may experience increased blood pressure secondary to weight gain, noncompliance, changes in behavioral patterns, coexisting disease, the addition of new medications, or for other unknown reasons. Both physicians and hypertensive patients could benefit from an accurate, accessible, out-of-office ambulatory blood pressure monitoring method.

Frequent blood pressure measurement, done accurately, could improve control. Although some patients have quality equipment and are able to accurately check home blood pressures, many do not. An informal survey of the hypertensive patients in our clinics indicated that many use the automated blood pressure devices located in local

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MATERIALS AND METHODS

THE VITA-STAT

The Vita-Stat (Space Labs Inc, Redmond, Wash), a fixed-unit blood pressure computer, is one of the most commonly used automated blood pressure devices in the United States (Space Labs Inc, oral communications, 1991 to 1994). The Vita-Stat device was introduced in 1976 to screen for hypertension. At the time of this study, approximately 8000 such devices were in use in the United States, providing more than 10 million measurements per year. There are approximately 198 Vita-Stat computers in Colorado alone, with approximately 50% in the Denver metropolitan area. Placement sites include grocery stores, pharmacies, private physicians' offices, medical clinics, and work sites. Each machine measures 300 to 3000 pressures per month. We tested three Model 8000 machines. The 8000 measures pressures by an auscultatory method. All three machines had been calibrated by a Vita-Stat technician within the 3 months preceding our study.

STUDY POPULATION

We visited three different study sites for 3 sequential weeks. The study sites were chosen randomly from all local supermarkets that displayed a Vita-Stat device. In each of the three sites, the Vita-Stat was conveniently located near the pharmacy and away from the mainstream of traffic and noise. A study nurse (from Shared Care Research and Education Consulting Inc, Torrance, Calif, which certifies individuals who have successfully completed their course, "Standardization of Blood Pressure Measurement According to the Techniques and Guidelines Recommended by the American Heart Association") recruited 63 passersby, 62 of whom completed the study, and asked if they would answer some (n=16) short questions and sit for three measurements of blood pressure using both the Vita-Stat device and a standard mercury sphygmomanometer. The questionnaire requested information about previous diagnosis of hypertension, knowledge of "usual blood pressure," and prior use of the Vita-Stat device.

METHODS

The protocol was explained to each subject who agreed to participate and they were seated at the machine. They were asked to use the Vita-Stat as they normally would or as directed by instructions on the control panel. At this stage no help was offered to the participant. After this first "introductory" measurement by the Vita-Stat (which was not recorded), arm circumference was measured at midpoint between the olecranon and acromion to ensure use of the appropriate mercury cuff and to detect any significant difference in size between the two arms. The American Heart Association guidelines[3] were used to select the correct mercury cuff size.

Of the 62 participants, 42 were evaluated with a regular cuff and 20 with a large cuff. Two subjects had a difference in arm circumference that would have required two different size cuffs to measure pressure accurately in each arm. Although the differences between the arms were minimal (less than 1 cm in both cases), in each instance we used a large cuff to measure blood pressure in the right arm as the right was larger than the left and greater than 32 cm, the cutoff for the use of a regular size cuff.

After being seated for 5 minutes, the participant's left arm was then positioned correctly in the Vita-Stat cuff while an appropriate sized cuff was applied to the right arm. Using the American Heart Association guidelines for measuring blood pressure, a second trained study nurse (Shared Care) who was blinded to all blood pressure measurements determined by the Vita-Stat, measured blood pressure in the subject's right arm while the Vita-Stat was activated to measure blood pressure in the left arm. Given the fact that blood pressure varies with time and situation, we chose to measure pressures simultaneously to obtain a better comparison. The effect of simultaneous measurement on the level of blood pressure seemed less relevant than obtaining a good value for comparison. The study physician (B.L.W.) recorded the blood pressure measurements from the Vita-Stat and then asked for the mercury readings. After a standard 2-minute interval, the measurements were repeated. Any discussion of or questions about the blood pressure was discouraged during the waiting period. Arm position was not changed between measurements and the participants were asked to avoid talking or moving during pressure recording and between measurements. Four measurements were obtained from each subject, two from the Vita-Stat and two from the mercury sphygmomanometer.

The same study nurse performed each set of blood pressure masurements for all 62 patients from the three sites. She used the same mercury sphygmomanometer at each site, having had the device calibrated by our bioengineering department before each site visit.

BLOOD PRESSURE MEASUREMENTS

For the purposes of this study, a subject was categorized as normotensive or hypertensive on the basis of blood pressure measured by the mercury sphygmomanometer rather than by history. Twenty of 31 subjects who claimed they did not have hypertension or did not know if they had hypertension were, in fact, hypertensive during our limited study. In accordance with the latest Joint National Committee definition of hypertension,[4] subjects were considered hypertensive if either the diastolic blood pressure was 90 mm Hg or greater or the systolic blood pressure was 140 mm Hg or greater. Of the 62 participants, 24 were normotensive and 38 were hypertensive.

Mercury sphygmomanometer readings were used as the gold standard; Vita-Stat readings were compared with this standard. Realizing that our gold standard was not perfect, we measured the reproducibility of each method by comparing the two pressures taken by each device with each other. This allowed intramachine comparisons of both systolic and diastolic pressure.

grocery stores and pharmacies. While accurate blood pressure measurements by such devices could be beneficial, inaccurate measurements could mislead the patient and physician.

We decided to assess the accuracy and reproducibility of one such blood pressure apparatus, the Vita-Stat, to determine its suitability for use in monitoring blood pressure in the ambulatory setting.

RESULTS

SUBJECT PROFILE

A total of 63 passersby were recruited to participate in the Vita-Stat study; 21 in each of three stores. The average age was 62 years, with a range of 18 to 87 years. Twenty-nine men (46%) and 34 women (54%) volunteered to complete a questionnaire and to sit for several blood pressure readings. One woman dropped out, leaving a total of 62. Of these 62, the majority were white (92%). There were no exclusion criteria and only a few passersby refused our offer. For simplicity we did not further stratify patients by race, gender, or age.

Half (n=31) of the participants identified themselves as hypertensive. Nineteen of the remaining 31 categorized themselves as normotensive, while 12 were unsure whether their blood pressure was high or low. Those who were unsure of their usual blood pressure answered no to the question, "Has a doctor ever told you that you have hypertension or blood pressure?" Of the 31 self-identified hypertensive subjects, 27 knew their usual blood pressure and 21 had previous experience with the Vita-Stat device. Of interest, seven of those who had used the Vita-Stat in the past used the device incorrectly during the introductory measurement. Eleven of those who had never used the device also failed to use it correctly.

RELIABILITY OF EQUIPMENT

Blood pressure readings were successfully obtained in 123 of 124 attempts using the standard mercury sphygmomanometer. The only failure occurred when the Velcro fastener on the cuff released prematurely. The Vita-Stat device failed in 10 of 124 measurements registering 0/0 with each failure. In only one instance did the Vita-Stat fail with both attempts. Order made no difference in the incidence of failures nor did level of blood pressure. The Vita-Stat failed equally at the first attempt and the second across all levels of blood pressure measurement.

INTRAMACHINE CORRELATIONS

The mercury sphygmomanometer provided more reproducible readings than the Vita-Stat. The correlation of the first (Vita-Stat 1) and second (Vita-Stat 2) Vita-Stat readings of diastolic blood pressure differed significantly from the correlation of the first (mercury 1) and second (mercury 2) mercury sphygmomanometer readings (hereafter, mercury readings) (.76 vs .91, *P*=.009). The first and second Vita-Stat readings of systolic blood pressure also correlated less well with each other than the mercury readings (.85 vs .92, *P*=.07), but the difference did not reach statistical significance (**Table 1**).

We wondered if the correlations would be the same if readings from normotensive subjects were separated from the readings of hypertensive subjects; in other words, were the Vita-Stat readings more

Table 1. Intramachine Correlations of Vita-Stat Computer and Mercury Sphygmomanometer Measurements*

	V2-S	V2-D	M2-S	M2-D
V1-S	.85			
V1-D		.76		
M1-S			.92	
M1-D				.91

**V indicates Vita-Stat; M, mercury sphygmomanometer; 1, first measurement; 2, second measurement; S, systolic; and D, diastolic. V-D correlation vs M-D correlation, .76 vs .91 (P=.009) and V-S correlation vs M-S correlation, .85 vs .92 (P=.07).*

Table 2. Intermachine Correlations of Vita-Stat Computer and Mercury Sphygmomanometer Measurements*

	M1-S	M1-D	M2-S	M2-D
V1-S	.82			
V1-D		.76		
V2-S			.71	
V2-D				.81

**V indicates Vita-Stat; M, mercury sphygmomanometer; 1, first measurement; 2, second measurement; S, systolic; and D, diastolic.*

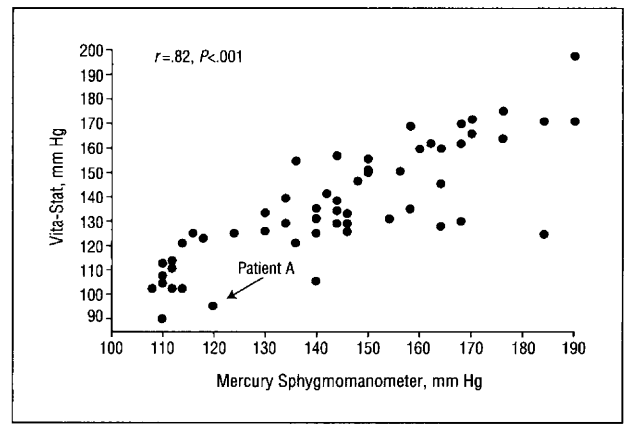

Figure 1. *Variability of systolic blood pressure measurements. Each solid circle represents a patient's initial systolic blood pressure measurement taken by the mercury sphygomanometer vs the measurement taken by the Vita-Stat device.*

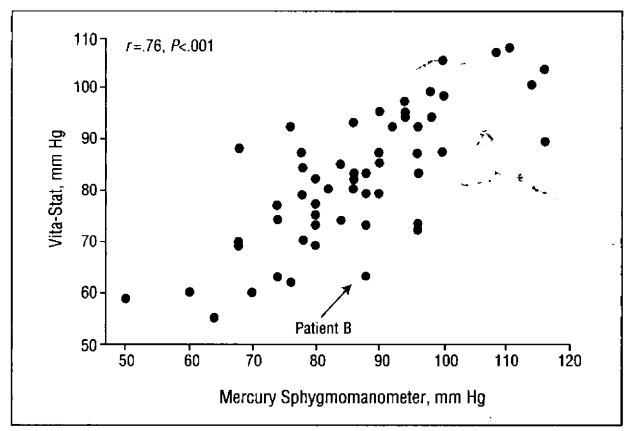

Figure 2. *Variablity of diastolic blood pressure measurements. Each solid circle represents a patient's initial diastolic blood pressure measurement taken by the mercury sphygmomanometer vs the measurement taken by the Vita-Stat device.*

Table 3. Mean Blood Pressure Difference (Systolic/Diastolic) in Normotensive and Hypertensive Subjects

	Blood Pressure Measurements, mm Hg				
	Mercury Sphygmomanometer	Vita-Stat Computer	Mean Difference	SD	*P*
Normotensive	120.3/75.9	113.6/72.6	−6.65/−3.0	10.85/7.1	.013/.055
Hypertensive	157.4/91.7	147.6/87.4	−9.78/−4.0	14.8/10.0	.000/.013

reproducible when the blood pressure was in the normal range or in the hypertensive range.

In normotensive subjects, there was a trend suggesting that the Vita-Stat systolic correlation was lower than the mercury sphygmomanometer correlation (.60 vs .86, $P<.075$). The Vita-Stat diastolic correlation was also lower than the mercury sphygmomanometer correlation (.75 vs .87, $P<.298$), but again, not significantly so. Among hypertensive subjects, the Vita-Stat systolic and diastolic correlations were both lower than the mercury sphygmomanometer correlations (.84 vs .86 and .63 vs .87, respectively), but only the diastolic correlation was significantly different ($P=.002$).

INTERMACHINE CORRELATIONS

To compare the two devices, direct comparisons of simultaneous Vita-Stat to mercury measurements were made for each of four pairs of pressures: Vita-Stat 1 diastolic vs mercury 1 diastolic and Vita-Stat 2 diastolic vs mercury 2 diastolic (intermachine comparison of diastolic readings); Vita-Stat 1 systolic vs mercury 1 systolic and Vita-Stat 2 systolic vs mercury 2 systolic (intermachine comparison of systolic readings). The best correlation, .82, was between the first measurements of systolic blood pressure (Vita-Stat 1 vs mercury 1), while the worst correlation, .71, was between the second simultaneous measurements of systolic blood pressure (Vita-Stat 2 vs mercury 2 (**Table 2**). The fact that the best and worst correlations were between two consecutive measurements of systolic pressure suggests greater variability of measurements from the Vita-Stat. The other two correlations fell between the extremes (Table 2).

VARIABILITY OF THE VITA-STAT

To better define the differences between the Vita-Stat and the standard mercury sphygmomanometer, we determined the percentage of subjects whose Vita-Stat readings were greater than 5 mm Hg different from the mercury readings. The data showed that more than half (63.2%) of the subjects had Vita-Stat readings that were more than 5 mm Hg different, higher or lower, from the mercury readings. There was no difference between hypertensive and normotensive subjects in the proportion having Vita-Stat readings greater than a 5–mm Hg difference for either systolic or diastolic pressure.

Vita-Stat systolic readings were usually lower than mercury readings; 54% of the subjects had systolic readings on the Vita-Stat of more than 5 mm Hg lower than the mercury readings. Thirty-nine percent of the subjects had Vita-Stat diastolic readings of more than 5 mm Hg lower than the mercury readings. There was no significant difference between hypertensive and normotensive subjects and no significant differences when comparing pressures obtained at time 1 and time 2 for either systolic or diastolic pressure.

Figure 1 and **Figure 2** illustrate the variability of the Vita-Stat readings vs the mercury readings. For example, patient A on Figure 1 has a mercury systolic blood pressure of approximately 120 mm Hg and a Vita-Stat reading of 95 mm Hg. Similarly, patient B on Figure 2 has a mercury diastolic blood pressure of less than 90 mm Hg and a Vita-Stat pressure of around 65 mm Hg. For both normotensive and hypertensive subjects, the Vita-Stat readings were significantly lower than the mercury readings of systolic and diastolic pressures when assessed separately or combined. On average, the Vita-Stat systolic readings were 6.6 mm Hg lower for normotensive subjects (SD, 10.85), 9.8 mm Hg lower for hypertensive subjects (SD, 14.82), and 8.7 mm Hg lower for both groups combined (SD, 13.54). The Vita-Stat diastolic readings were 3.2 mm Hg lower for normotensive subjects (SD, 7.10), 4.3 mm Hg lower for hypertensive subjects (SD, 9.96), and 3.9 mm Hg lower for both groups combined (SD, 9.01) (**Table 3**).

The data from the correlation of the Vita-Stat 1 to Vita Stat 2 pressure readings, mercury pressure to Vita-Stat pressure readings, and these variability data provide evidence that the Vita-Stat readings are more inaccurate and less reproducible in sequential testing than are the mercury readings and that the Vita-Stat is likely to underestimate both diastolic and systolic blood pressure.

More impressive than the correlations and average differences between the groups of pressure readings was the wide variability between individual measurements. Although the Vita-Stat pressure matched the mercury pressure in a few instances (seven matches of systolic blood pressure and 10 matches of diastolic blood pressures, with no matches of both diastolic and systolic pressure), the majority of the Vita-Stat readings were higher or lower than the mercury readings. The greatest variation found was in the measurement of systolic pressures, where the Vita-Stat–registered pressures varied by as much as 60 mm Hg below in one patient and 58 mm Hg above the mercury reading in another.

The variability in diastolic pressures measured by the Vita-Stat was significant but not as striking (from 29 mm Hg below to 20 mm Hg above the mercury pressures). The wide swings in pressure readings were not consistently high or low. Many of the blood pressure measurements varied in opposite directions between the two

Table 4. 2×2 Table for Calculation of Sensitivity, Specificity, and Positive and Negative Predictive Values of Vita-Stat Computer

		Hypertension +	Hypertension −	Total
Test	+	9	29	35
	−	0	21	21
	Total	9	47	56

sets of readings. For example, the first Vita-Stat reading might underestimate the systolic blood pressure by 10 mm Hg and the second Vita-Stat reading might overestimate the pressure by 15 mm Hg. These wide swings in blood pressure measurements were seen in both normotensive and hypertensive subjects and occurred unpredictably.

ARM CIRCUMFERENCE

To determine whether some of the inaccuracy of the Vita-Stat was secondary to arm circumference and therefore cuff size, we examined the data from the subgroups requiring regular vs large mercury cuffs.

The Vita-Stat was more accurate in measuring blood pressure in those subjects whose arms were large than in those whose arms were of normal size. This was true for diastolic and systolic pressures and for all levels of blood pressure. The improvement was not significant. The Vita-Stat device failed more often when the arm circumference was small or normal (seven of 10 failures).

SENSITIVITY, SPECIFICITY, POSITIVE AND NEGATIVE PREDICTIVE VALUES

As our final analysis, we looked at the sensitivity, specificity, and positive and negative predictive values of the Vita-Stat computer (**Table 4**). In this study, the sensitivity of the Vita-Stat in correctly diagnosing hypertension (≥140/90 mm Hg, or mild hypertension as per the Joint National Commission) was 0.26 (95% confidence interval [CI], 0.12 to 0.43) while the specificity was 1.00 (95% CI, 0.40 to 1.00). In other words, of those who truly have hypertension, the Vita-Stat will identify only 26%. Conversely, none of the normotensive subjects will be falsely identified as hypertensive by the Vita-Stat. Given the data above, this makes sense. If the Vita-Stat consistently reads low, as our study suggests, an elevated pressure from the Vita-Stat will likely represent a true hypertensive subject.

The positive and negative predictive values support the same concept. The positive predictive value of the Vita-Stat is 1.00 (95% CI, 0.66 to 1.00) while the negative predictive value is 0.45 (95% CI, 0.45 to 0.60). Again, everyone labeled as hypertensive by the Vita-Stat is highly likely to be hypertensive, while only 45% of patients with normal pressures as measured by the Vita-Stat are truly normotensive. The Vita-Stat device misses the hypertensive subjects more than half the time.

COMMENT

The Vita-Stat automatic blood pressure recorder was introduced in 1976 as a screening device to detect hypertension in those not previously identified as hypertensive. Its performance has been suboptimal. A number of studies[5-9] have identified problems with the Vita-Stat device. Questions of accuracy and reproducibility within and between machines have been raised. Salaita et al[5] studied 10 different Vita-Stat machines and found that they compared poorly against the random-zero mercury sphygmomanometer in terms of reproducibility, accuracy, sensitivity, specificity, and positive predictive value. Because of these limitations, the Vita-Stat automated blood pressure computer is considered inadequate as a screening device. The American Heart Association review of the data resulted in a recommendation against the use of this device for blood pressure screening.[10]

Our methods and gold standard differ from those reported by other investigators but were selected as rational and appropriate to the design of the study. We selected as our gold standard a standard mercury sphygmomanometer. We reasoned that the majority of clinicians use the mercury sphygmomanometer to monitor blood pressure in the office setting and is, therefore, their gold standard. Measurements taken with the mercury cuff are the measurements used to make clinical decisions. Although the random-zero device has been touted as the appropriate choice for clinical and epidemiologic research, it is argued that the closest we can get to a gold standard for measuring blood pressure is a trained observer using a standard mercury sphygmomanometer and stethoscope.[11]

Arm circumference is a minor issue in determining the accuracy of the Vita-Stat. We did not have any patients with an arm circumference so large as to require a thigh cuff so we cannot speak about the issue of measuring blood pressure in the morbidly obese.

Simultaneous blood pressure measurement and interarm differences in blood pressure were considered in designing this study. Given data from two prior studies and our own data on arm circumferences, we did not believe we were introducing significant bias with our methods.[12,13]

The Vita-Stat performs poorly when compared with itself (reproducibility) and when compared with the mercury sphygmomanometer (accuracy), and it shows a dramatic variability in blood pressure measurement.

Recognizing the fact that human blood pressure varies beat to beat and minute to minute, the clinician's goal is to have a device that can, with some consistency, detect elevations in blood pressure. In identifying and predicting high blood pressures, the Vita-Stat performs poorly as the sensitivity of 0.26 indicates. As the positive predictive value of 1.0 suggests, if the pressures taken by the Vita-Stat are elevated, the patient most assuredly has elevated blood pressure, but more than 50% of these patients will walk away from the Vita-Stat machine believing that their blood pressure is normal.

Our study population was small and homogeneous but representative of patients who might use the Vita-Stat device. Sixty-seven percent of the self-reported "hypertensives" had used the Vita-Stat automated blood pressure device in the past and more than half of them believed the Vita-Stat readings correlated well with the blood pressure measured by their physician. The instructions of the control panel of the Vita-Stat device clearly state "only a physician is qualified to interpret the significance of blood pressure measurements. Self-diagnosis or self-adjustment of medication is dangerous." A large portion of our hypertensive population use the Vita-Stat computer regularly to monitor their blood pressure between office visits. None of our study subjects had changed their antihypertensive medications on the basis of a Vita-Stat reading but reported the readings to their physicians. We have no information regarding physician use of the data obtained from the Vita-Stat.

Of greatest concern to us was the variation in pressures measured by the Vita-Stat. The automated device underestimated diastolic and systolic blood pressure by more than 5 mm Hg in a significant number of normotensive and hypertensive subjects. In 1992, the American Association for the Advancement of Medical Instrumentation released the revised "Standard for Electronic or Automated Blood Pressure Recorders," which specifically states

> for systolic and diastolic blood pressures treated separately, the mean difference of the paired differences of the test system and the comparison system shall be 5 mmHg or less with a standard deviation of 8 mmHg or less.[14]

The mean difference between the Vita-Stat and mercury systolic pressure readings fails to meet these criteria. The observed variations in blood pressure of 20 to 60 mm Hg are unacceptable and potentially dangerous if considered accurate.

CONCLUSION

The Vita-Stat automated blood pressure computer, originally designed to be a screening device, is widely available, accessible, easy to use, and free of charge. If found to be accurate and reproducible, the potential as a tool to measure blood pressure in the ambulatory patient could be enormous. As a screening device, the Vita-Stat fails. It also fails as a monitoring device as it produces inaccurate, poorly reproducible results. The unpredictable, sometimes wide swings in blood pressure measurements are unacceptable. A monitoring device should not only be accurate and consistent, it should provide the same accuracy in all subjects regardless of arm size and level of blood pressure.

Our data suggest that the Vita-Stat device is not only inconsistent but inaccurate in measuring blood pressure in the ambulatory patient and is, therefore, not appropriate to use as a monitoring device. Patients should be warned not to rely on the measurements taken by the Vita-Stat device to access their blood pressure. At this time we have no data on other automated blood pressure measuring devices so we cannot speak to the issue of availability, cost, or accuracy. Space Labs Inc has placed more than 1400 of the Vita-Stat 9000 model in sites around the country and is in the process of distributing another 3000 of the newest 90550 model. Many of the older 8000 models have been sold to dealers and private offices and businesses and are not accounted for by Space Labs (Mark Schwartz, Vita-Stat representative, personal communication, September 7, 1994).

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