An Evaluation of the Vita-Stat Automatic Blood Pressure Measuring Device

B. FRANK POLK, M.D., M. Sc., BERNARD ROSNER, PH.D., RUDY FEUDO, M. ED., AND MARTIN VANDENBURGH, B.A.

SUMMARY Four Vita-Stat (VS) automatic, coin-operated, blood pressure measuring devices were evaluated for accuracy and precision. Under field conditions, 342 adults had two blood pressure measurements with both the VS device and with the Random-Zero (RZ) device. Two of the VS machines gave significantly higher systolic (SBP) and diastolic blood pressure (DBP) values, compared to the RZ values. The mean difference between these two units and the RZ device were clinically important (14.0 and 6.9 mm Hg SBP; 7.5 and 6.8 mm Hg DBP), and resulted in the misclassification of 23% of normotensives as hypertensives. We observed a significant order effect on SBP with the VS device, with a mean decrement of 4.9 mm Hg between the first and second SBP values, compared to 0.6 mm Hg with the RZ device. Even after adjusting for this bias, all four VS devices gave significantly more variable SBP readings than the RZ unit; two of the four also gave more variable DBP values. These data suggest that the VS device is neither accurate nor precise enough at the present time to be recommended for widespread use. These findings also raise questions concerning the monitoring of performance of this and similar devices in the field. (Hypertension 2: 221-227, 1980)

KEY WORDS • blood pressure measuring device • Vita-Stat device • Random-Zero device

RELIABLE automatic blood pressure measuring devices may have an important role in the detection of elevated blood pressure and perhaps in improving compliance with therapy among individuals with known hypertension. Recently, a coin-operated device called the Vita-Stat Computer (Vita-Stat Medical Services, Tierra Verde, Florida) has been distributed to many pharmacies, department stores, banks, shopping centers, and hotels across the United States. This device is fully automatic and uses the standard auscultation (Korotkoff sound) principle of measurement. Despite the claim of the company that "Independent research studies by leading medical authorities have proven the accuracy of the Vita-Stat computer," only one such study has been published, to our knowledge.1 We have evaluated four of these machines, under field conditions, for accuracy and precision.

Patients and Methods

During December, 1978, adult customers (ages 20 and over) in one pharmacy, one department store, and two shopping centers were invited to have their blood pressures measured. A list of 61 locations in northern New England was provided by the company, which was not aware of the evaluation program. These four locations were chosen from the list because they were in the greater Boston area, and because it was estimated that their customers would be reasonably representative of the general adult population of New England, and would be sufficiently numerous so that approximately 100 persons could be screened at each site in a short period of time.

The Vita-Stat device (VS) measures systolic and diastolic blood pressures and is based on the auscultation principle. The customer places his left arm in a
looped cuff so that when the cuff closes automatically it will be placed starting at the elbow. A microphone is mounted in the cuff such that it is near the brachial artery when the arm is inserted. When the start button is pressed, the cuff tightens snugly by use of a slip clutch and inflates to 160 mm Hg. If Korotkoff sounds are sensed at that pressure, inflation continues in 20 mm Hg increments until Korotkoff sounds are no longer sensed or a maximum pressure of 220 mm Hg is reached. The cuff then deflates in 4–6 mm Hg decrements with a brief pause after each decrement to determine the presence or absence of Korotkoff sounds. Systolic blood pressure (SBP) is registered at the appearance of Korotkoff sounds and diastolic sounds. Systolic blood pressure (DBP) at their disappearance. There is an artifact rejection system built into the machine so that extraneous noise and false sounds are filtered out or rejected.

The blood pressure values recorded by VS were compared to those obtained by a trained observer using the modified Random-Zero device (RZ) (Hawksley, Sussex, England). This device is similar in principle to the standard mercury sphygmomanometer. A mechanical device interposed between the mercury reservoir and manometer column, however, draws variable amounts of mercury into an expandable chamber. This modification has the effect of obscuring the true zero level of mercury until the end of the reading, thus minimizing observer bias. Labarthe et al. have shown good agreement between overall mean SBP and DBP as determined by the RZ device compared to a standard mercury sphygmomanometer (Baumanometer 300), although RZ values tended to be slightly lower.

All data were collected by one screener who had extensive training and experience in blood pressure screening programs. Training and standardization included orientation to physiologic aspects of systemic arterial blood pressure, to the techniques of its indirect measurement, and to familiarization with the modified RZ. This screener was trained and tested by performing multiple readings with a double stethoscope on several subjects, and was standardized by a technique based on audio cassette tapes described by Rose.

A brief questionnaire was administered before the blood pressures were obtained. Data collected included age, sex, race, history of hypertension, and antihypertensive treatment.

When the participant was sitting, four blood pressure measurements on the left arm were taken: two with the VS and two with the RZ. For the RZ measurements, the appropriate cuff size was chosen on the basis of arm circumference. The devices were used in an alternating sequence, and the order of the sequence (VS- VS-RZ- RZ vs RZ-RZ- VS- VS) was determined by using a table of random numbers. The 50 cents required for each VS measurement was supplied by the investigators. The RZ device was calibrated between sites.

A paired t test was used to compare mean blood pressures obtained with the VS and RZ machines. This method also was used to compare the order effect (first reading minus second reading) for the two devices. The measure of variability chosen was the mean absolute difference between replicates after correcting for the above order effect = δx (δy) = |X11 - X21 - Δx| (|Y11 - Y21 - Δy|), where X11, X21 and Y11, Y21 are the first and second readings for the VS and RZ devices respectively, and Δx (Δy) = X11 - X21 (Y11 - Y21). For each location, Δx and Δy were computed separately. A paired t test was then used to compare δx and δy based on the statistic δx-δy = |X11 - X21 - Δx| - |Y11 - Y21 - Δy|.

### Results

**Patient Characteristics**

A total of 412 individuals were interviewed: 106, 101, 105, and 100 from locations A–D respectively. Individuals were excluded from analysis if they were missing one or more systolic or diastolic readings on either machine. There were no missing RZ readings, but 70 persons (17.0%) were excluded from analysis because of missing VS readings (8, 17, 7, and 38 respectively). In each instance of missing values, the VS read out blank readings and returned the coins. A third measurement was not attempted in these cases.

Characteristics of the 342 persons for whom blood pressure data were complete are presented in table 1. The study population was predominantly white (92.4%), had a median age of 57 years, and was approximately half men and half women. Of interest, nearly half (47.4%) had been told in the past by a physician that their blood pressures were elevated, over one-third (36.4%) had at one time been treated for hypertension, and 29.0% were taking antihypertensive medication(s) at the time of screening.

### Accuracy

The mean systolic and diastolic blood pressures are presented by location in table 2. At two locations there were negligible, nonsignificant differences between VS and RZ blood pressure readings. Two of the VS machines, however, gave notably higher mean SBP (14.0 and 6.9 mm Hg) and DBP (7.6 and 6.8 mm Hg) measurements compared to those obtained with the RZ. For these two units, the differences were significant, with p values < 0.001. The frequency distributions of these differences are given in table 3. At locations C and D, the mean of two systolic readings with the VS was > 20 mm Hg higher than the RZ in 28.6% and 9.7% of participants respectively; the mean of two diastolic readings with the VS was > 10 mm Hg higher than the RZ in 40.8% and 37.1% of participants respectively.

The potential effects on sensitivity and specificity if the VS readings were used to diagnose high blood pressure are shown in table 4. We assumed that the "correct" diagnosis is given by the RZ and that high blood pressure is defined (arbitrarily) as SBP 160 mm Hg and/or DBP 95 mm Hg, because these are the
**Table 1. Characteristics of 342 Participants: Age, Sex, Race, and Hypertension Status**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age distribution (n = 342)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>39</td>
<td>11.4</td>
<td>11.4 ± 53.0</td>
</tr>
<tr>
<td>30-39</td>
<td>39</td>
<td>11.4</td>
<td>11.4 ± 61.1</td>
</tr>
<tr>
<td>40-49</td>
<td>54</td>
<td>15.5</td>
<td>15.5 ± 107.3</td>
</tr>
<tr>
<td>50-59</td>
<td>66</td>
<td>19.3</td>
<td>19.3 median = 57</td>
</tr>
<tr>
<td>60-69</td>
<td>100</td>
<td>29.2</td>
<td>range = 20-89</td>
</tr>
<tr>
<td>70-79</td>
<td>38</td>
<td>11.1</td>
<td></td>
</tr>
<tr>
<td>80-89</td>
<td>6</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>Sex distribution (n = 342)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>164</td>
<td>48.0</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>178</td>
<td>52.0</td>
<td></td>
</tr>
<tr>
<td>Race distribution (n = 342)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>316</td>
<td>92.4</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>23</td>
<td>6.7</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>0.9</td>
<td></td>
</tr>
<tr>
<td>History of hypertension (n = 340)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>161</td>
<td>47.4</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>179</td>
<td>52.6</td>
<td></td>
</tr>
<tr>
<td>Previously taken antihypertensive medication (n = 338)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>123</td>
<td>36.4</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>215</td>
<td>63.6</td>
<td></td>
</tr>
<tr>
<td>Currently taking antihypertensive medication (n = 338)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>98</td>
<td>29.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>240</td>
<td>71.0</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. Mean Blood Pressures and Differences Between Vita-Stat and Random-Zero Device Readings at Four Different Locations**

<table>
<thead>
<tr>
<th>Location</th>
<th>Vita-Stat</th>
<th>Random-Zero</th>
<th>Difference*</th>
<th>t statistic</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Systolic blood pressure (mm Hg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>98</td>
<td>142.5</td>
<td>21.0</td>
<td>142.0</td>
<td>18.1</td>
</tr>
<tr>
<td>B</td>
<td>84</td>
<td>134.1</td>
<td>22.5</td>
<td>133.6</td>
<td>23.2</td>
</tr>
<tr>
<td>C</td>
<td>98</td>
<td>147.9</td>
<td>20.3</td>
<td>133.9</td>
<td>18.3</td>
</tr>
<tr>
<td>D</td>
<td>62</td>
<td>135.4</td>
<td>16.7</td>
<td>128.5</td>
<td>19.0</td>
</tr>
<tr>
<td></td>
<td>Diastolic blood pressure (mm Hg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>98</td>
<td>83.9</td>
<td>12.6</td>
<td>85.2</td>
<td>11.3</td>
</tr>
<tr>
<td>B</td>
<td>84</td>
<td>79.7</td>
<td>13.1</td>
<td>79.7</td>
<td>12.0</td>
</tr>
<tr>
<td>C</td>
<td>98</td>
<td>89.0</td>
<td>12.0</td>
<td>81.4</td>
<td>9.9</td>
</tr>
<tr>
<td>D</td>
<td>62</td>
<td>87.3</td>
<td>13.3</td>
<td>80.4</td>
<td>10.9</td>
</tr>
</tbody>
</table>

*A paired means t test was used to analyze differences between the means of two machines.*

cutoff points chosen for the definition of definite hypertension by the U. S. Public Health Service* as well as by the distributors of the VS. Overall, 23.3% of the normotensive participants were incorrectly classified as hypertensive, and 16.4% of the hypertensive participants were incorrectly classified as normotensive.

**Precision**

As shown in table 5, we observed a significant and noteworthy order effect on SBP values with the VS. That is, there was a significant decrement between the first and second VS SBP readings (mean difference = 4.88 mm Hg; p < 0.001) compared to a small and non-significant decrement between the first and second RZ SBP readings (mean difference = 0.58 mm Hg; p not significant). The difference in order effect between the VS and RZ was about twice as great when the VS recordings are first and second (overall mean difference = 5.72 mm Hg) as compared to when the RZ recordings are first and second (overall mean difference = 2.83 mm Hg). The order effect on systolic readings, however, is significantly larger for VS in
**TABLE 3. Frequency Distribution of Differences Between Mean Values of the Vita-Stat Replicates and Random-Zero Replicates**

<table>
<thead>
<tr>
<th>Mean of 2 VS readings minus mean of 2 RZ readings*</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ -20</td>
<td>3</td>
<td>3.1</td>
<td>4</td>
<td>4.8</td>
</tr>
<tr>
<td>&gt; -20, ≤ -10</td>
<td>14</td>
<td>14.3</td>
<td>15</td>
<td>17.9</td>
</tr>
<tr>
<td>&gt; -10, ≤ 0</td>
<td>28</td>
<td>28.6</td>
<td>21</td>
<td>25.0</td>
</tr>
<tr>
<td>&gt; 0, ≤ 10</td>
<td>36</td>
<td>36.7</td>
<td>30</td>
<td>35.7</td>
</tr>
<tr>
<td>&gt; 10, ≤ 20</td>
<td>15</td>
<td>15.3</td>
<td>10</td>
<td>11.9</td>
</tr>
<tr>
<td>&gt; 20</td>
<td>2</td>
<td>2.0</td>
<td>4</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>98</td>
<td>98</td>
<td>84</td>
<td>84</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ -15</td>
<td>2</td>
<td>2.0</td>
<td>3</td>
<td>3.6</td>
</tr>
<tr>
<td>&gt; -15, ≤ -10</td>
<td>6</td>
<td>6.1</td>
<td>7</td>
<td>8.3</td>
</tr>
<tr>
<td>&gt; -10, ≤ -5</td>
<td>19</td>
<td>19.4</td>
<td>13</td>
<td>15.5</td>
</tr>
<tr>
<td>&gt; -5, ≤ 0</td>
<td>31</td>
<td>31.6</td>
<td>14</td>
<td>16.7</td>
</tr>
<tr>
<td>&gt; 0, ≤ 5</td>
<td>24</td>
<td>24.5</td>
<td>24</td>
<td>28.8</td>
</tr>
<tr>
<td>&gt; 5, ≤ 10</td>
<td>10</td>
<td>10.2</td>
<td>13</td>
<td>15.5</td>
</tr>
<tr>
<td>&gt; 10, ≤ 15</td>
<td>5</td>
<td>6.1</td>
<td>8</td>
<td>9.5</td>
</tr>
<tr>
<td>&gt; 15</td>
<td>0</td>
<td>0.0</td>
<td>2</td>
<td>2.4</td>
</tr>
<tr>
<td></td>
<td>98</td>
<td>98</td>
<td>84</td>
<td>84</td>
</tr>
</tbody>
</table>

*VS = Vita-Stat device; RZ = Random-Zero device.

**TABLE 4. Sensitivity and Specificity of Diagnosis of Hypertension Made by the Vita-Stat Device, Using Criteria of Mean SBP ≥ 160 mm Hg and/or DBP ≥ 95 mm Hg**

<table>
<thead>
<tr>
<th>Mean RZ &lt;160 ≤ 95 (RZ normotensive)</th>
<th>Mean RZ 160+ and/or (RZ hypertensive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Mean VS &lt;160 ≤ 95</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>A</td>
<td>60</td>
</tr>
<tr>
<td>B</td>
<td>62</td>
</tr>
<tr>
<td>C</td>
<td>50</td>
</tr>
<tr>
<td>D</td>
<td>39</td>
</tr>
<tr>
<td>All</td>
<td>211</td>
</tr>
</tbody>
</table>

*Abbreviations: SBP = systolic blood pressure; DBP = diastolic blood pressure; RZ = Random-Zero device; VS = Vita-Stat device.*

Both instances. The sequence of recordings began with the VS in 52% of participants. There was not an important order effect on DBP measurements with either device.

Finally, the variability of each VS machine is compared to the RZ in table 6. At all 4 locations, SBP measurements on the VS were significantly more variable than the RZ counterparts. Two of the VS machines also gave significantly more variable DBP measurements compared to the RZ.

**Discussion**

**Accuracy**

As one very important performance characteristic of automatic blood pressure measuring devices,
TABLE 5. Comparison of Difference Between First and Second Blood Pressure Readings with Vita-Stat and Random-Zero Devices

<table>
<thead>
<tr>
<th>Location</th>
<th>Systolic blood pressure</th>
<th>Diastolic blood pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(\bar{x})</td>
<td>(s_{d})</td>
</tr>
<tr>
<td>A</td>
<td>4.50</td>
<td>10.38</td>
</tr>
<tr>
<td>B</td>
<td>4.49</td>
<td>12.07</td>
</tr>
<tr>
<td>C</td>
<td>5.97</td>
<td>12.34</td>
</tr>
<tr>
<td>D</td>
<td>4.27</td>
<td>11.09</td>
</tr>
<tr>
<td>All</td>
<td>4.88</td>
<td>11.53</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Location</th>
<th>Systolic blood pressure</th>
<th>Diastolic blood pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(\bar{x})</td>
<td>(s_{d})</td>
</tr>
<tr>
<td>A</td>
<td>1.20</td>
<td>8.04</td>
</tr>
<tr>
<td>B</td>
<td>0.00</td>
<td>7.33</td>
</tr>
<tr>
<td>C</td>
<td>0.37</td>
<td>8.02</td>
</tr>
<tr>
<td>D</td>
<td>0.39</td>
<td>7.05</td>
</tr>
<tr>
<td>All</td>
<td>0.58</td>
<td>7.70</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Location</th>
<th>Systolic blood pressure (mm Hg)</th>
<th>Diastolic blood pressure (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>2.33</td>
<td>7.97</td>
</tr>
<tr>
<td>B</td>
<td>2.51</td>
<td>10.06</td>
</tr>
<tr>
<td>C</td>
<td>2.55</td>
<td>9.44</td>
</tr>
<tr>
<td>D</td>
<td>2.65</td>
<td>8.19</td>
</tr>
</tbody>
</table>

measurements of SBP and DBP should closely approximate readings obtained by adequately trained observers using mercury sphygmomanometers. Evaluation of accuracy should be performed under field conditions and on multiple units of the device. Two of the four automatic units evaluated in this study produced mean SBP and DBP readings that were significantly and importantly higher than paired measurements obtained with the RZ. These mean differences did not result from a few extreme discrepancies; these two devices yielded a mean SBP or DBP that was > 10 mm Hg higher in approximately 60% and 40% respectively of the paired comparisons. It is unlikely that the discrepancies resulted from systematically lower measurements determined by the trained observer, since the RZ minimizes observer...
One's arm into an entrapping machine than that ex-
tained on the VS device. In contrast, there were small
average person engages the machine alone. The im-
screener was present; it is at least possible that blood
remembered that this order effect occurred while a
participants have used the device previously. It should be
experienced with the cuff of a sphygmomanometer that
have adverse psychological and behavioral conse-
implications: who is responsible for monitoring the
data are sparse and conflicting, there have been
physician's offices for confirmation or, more likely,
refutation of the diagnosis of hypertension. Although
consequences presumably are not dependent on accurate
diagnosis but simply on the
label itself.
If measurements are made for the evaluation of
blood pressure status in persons known to be
hypertensive, then the result is misassessment of blood
pressure control. Despite instructions that accompany
the machine, some individuals may decide to change
their antihypertensive medications on their own ini-
tiative, with the possibility of adverse consequences.
At best, spuriously high readings are likely to cause
undue anxiety and unnecessary visits to the physician.
Ironically, this automatic blood pressure measuring
device may be cost-ineffective by increasing the
number of physician visits.
There is, perhaps, a more important question raised
by these data: who is responsible for monitoring the
performance of these commercial machines with
respect to validity and repeatability? How and how
often is performance to be monitored? The data
presented here suggest that the maintenance and/or
calibration provided by the distributor are inadequate.

Implications
The consequences of spuriously elevated blood
pressure measurements depend on the actions taken
by the individuals in question. If measurements are
made for screening purposes, i.e., evaluation of per-
sons with unknown blood pressure status, then mis-
classification as hypertensive may result in un-
warranted anxiety in individuals without sustained
elevations in blood pressure, and misclassification as
normotensive may cause a false sense of security and
delay accurate diagnosis and proper treatment. While
a false positive misclassification of hypertension may
be preferable to a false negative misclassification, it
clearly is better to minimize all classification errors.
Over-diagnosis is not only likely to cause apprehen-
sion, but is likely to result in unnecessary visits to
physician's offices for confirmation or, more likely,
refutation of the diagnosis of hypertension. Although
the data are sparse and conflicting, there have been
suggestions that labelling persons as hypertensive may
have adverse psychological and behavioral conse-
quences. These consequences presumably are not
dependent on accurate diagnosis but simply on the
label itself.

Precision
There was a striking order effect in SBP measure-
ments with all four VS devices; that is, the first VS
SBP reading was significantly and notably higher than
the second (approximately 5 mm Hg higher, on aver-
age) on all four machines. This was especially true if
the first measurement in the sequence of four was ob-
tained on the VS device. In contrast, there were small
and generally nonsignificant order effects with the RZ
SBP readings, and with either device with regard to
DBP readings. Order effects in this direction have
been reported previously and are assumed to be due
to adaptation. The notably greater order effect on SBP
here observed with the VS device may be related to
greater apprehension experienced while placing
one's arm into an entrapping machine than that ex-
perienced with the cuff of a sphygmomanometer that
allows mobility. While it was not done in this study,
future evaluations should record whether or not par-
ticipants have used the device previously. It should be
remembered that this order effect occurred while a
screener was present; it is at least possible that blood
pressures might be even more elevated when the
average person engages the machine alone. The im-
portance of this phenomenon increases when one
realizes that most individuals are not likely to buy two
consecutive measurements within a short time and, in-
deed, are not advised to do so by the literature found
on the machine. The major consequence of this order
effect is on false positive misclassification. Our esti-
mate of 23.3% of normotensives misclassified as
hypertensive was based on the mean of two VS
measurements, and thus are conservative.
Even after accounting for this order effect, the
variability of SBP values in the VS readings was con-
sistently and significantly greater than the variability
in the RZ measurements. As shown in table 6, the ab-
solute differences in mean replicate BP readings and
subtracting the bias (order effect) from the VS and RZ
values are significantly greater for all four VS
machines than their RZ counterparts with respect to
SBP and for two machines with respect to DBP.

Implications
The consequences of spuriously elevated blood
pressure measurements depend on the actions taken
by the individuals in question. If measurements are
made for screening purposes, i.e., evaluation of per-
sons with unknown blood pressure status, then mis-
classification as hypertensive may result in un-
warranted anxiety in individuals without sustained
elevations in blood pressure, and misclassification as
normotensive may cause a false sense of security and
delay accurate diagnosis and proper treatment. While
a false positive misclassification of hypertension may
be preferable to a false negative misclassification, it
clearly is better to minimize all classification errors.
Over-diagnosis is not only likely to cause apprehen-
sion, but is likely to result in unnecessary visits to
physician's offices for confirmation or, more likely,
refutation of the diagnosis of hypertension. Although
the data are sparse and conflicting, there have been
suggestions that labelling persons as hypertensive may
have adverse psychological and behavioral conse-
quences. These consequences presumably are not
dependent on accurate diagnosis but simply on the
label itself.

Precision
There was a striking order effect in SBP measure-
ments with all four VS devices; that is, the first VS
SBP reading was significantly and notably higher than
the second (approximately 5 mm Hg higher, on aver-
age) on all four machines. This was especially true if
the first measurement in the sequence of four was ob-
tained on the VS device. In contrast, there were small
and generally nonsignificant order effects with the RZ
SBP readings, and with either device with regard to
DBP readings. Order effects in this direction have
been reported previously and are assumed to be due
to adaptation. The notably greater order effect on SBP
here observed with the VS device may be related to
greater apprehension experienced while placing
one's arm into an entrapping machine than that ex-
perienced with the cuff of a sphygmomanometer that
allows mobility. While it was not done in this study,
future evaluations should record whether or not par-
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If performance has to be monitored closely by regulatory governmental agencies, the devices may not be cost-effective, even if accurate. Our observation that two of four machines tested in the field were inaccurate implies that all machines would have to be monitored carefully and continuously. A possible alternative would be to restrict distribution of devices to a few locations where they could be carefully and efficiently monitored.

The economics of visits to the physician for blood pressure determinations make a fully automatic blood pressure measuring machine highly attractive. Such a device could have an important role in the detection and management of high blood pressure, and might improve compliance with therapy among some individuals just as self-recording of blood pressures has been shown to do. In evaluating the effect of self-recording of blood pressure, Johnson et al. demonstrated a reduction in blood pressure among hypertensive patients who admitted to difficulty remembering to take their pills.

We agree with a recent editorial in *Lancet* that these devices are to be encouraged "... provided that the measurement is reasonably accurate, that the instructions given are sensible, and that doctors cooperate by checking the blood pressure themselves ..." The data presented here, however, suggest that the Vita-Stat device currently is not "reasonably" accurate, and its use is not to be encouraged at this time. There is a need for further evaluation of more specimens of this device.

References

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