Validation Study of the Midmark Serenity BP™ Linear Deflation Algorithm for Non-Invasive Blood Pressure Measurement in an Automated Sphygmomanometer


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**Objective**  
Clinical validation of the Serenity BP™ linear deflation algorithm for non-invasive blood pressure measurement from Midmark Corporation using ANSI / AAMI / ISO 81060-2:2013 standard testing and data analyses, as well as British Hypertension Society grading methods.

**Methods**  
Childhood and adult volunteers were tested at a clinical research facility in California. Assent and / or consent were obtained in writing. The protocol followed the ANSI / AAMI / ISO 81060-2:2013 standard requirements. One hundred and one subjects, 65 adults and 36 children had full data sets for analyses.

**Results**  
Six different cuff sizes were included in the testing. The mean difference from reference to device values was 0.9 mmHg for systolic (S) BP and 1.1 mmHg for diastolic (D) BP. The standard deviation for Criteria 1 and 2 were 6.6 and 5.2 for SBP and 6.3 and 5.4 for DBP. All passed the required tolerance set by the standard. The British Hypertension Society protocol requires that at least 60% of readings from the device are within 5 mmHg of the manual readings, 85% ≤ 10 mmHg, and 95% ≤ 15 mmHg. The device readings fulfilled these requirements for both SBP and DBP. This resulted in an AA grading.

**Conclusions**  
The Serenity BP linear deflation algorithm for non-invasive blood pressure measurement passed both ANSI / AAMI / ISO81060-2:2013 and British Hypertension Society statistical requirements. Novel features for this primary deflation algorithm include the use of BP and heart rate during inflation, limiting inflationary SBP. This reduces patient discomfort and allows faster cycle time, which allows the clinician more frequent BP readings in unstable patients.

**Introduction**  
With the progressive phase-out of mercury sphygmomanometers, clinicians are relying upon automated blood pressure (BP) devices to estimate their patients' BP. A majority of the currently available devices use a deflation-based algorithm with step rather than linear deflation. Almost all devices also use oscillometry vs. Korotkoff sounds. The pump inflates the upper arm cuff to a pre-set mmHg level, often considerably higher than needed. This leads to significant patient discomfort. If the initial inflation pressure does not reach systolic (S) BP...
then the device must re-inflate the cuff, adding to the duration of the BP measurement, and contributing to even more patient discomfort. If a device algorithm could use data from inflation to determine the optimal inflation pressure, then each reading would take less time and produce less patient discomfort.

The current United States national standard for the validation of automated sphygmomanometers is the ANSI / AAMI / ISO 81060-2, 2013. The standard enumerates the testing protocol and statistical analyses which are usually submitted to the U.S. Food and Drug Administration to clear a device for sale / use in the U.S. The standard specifies many requirements, including subject number, gender, age, BP ranges, and reporting formats. This report gives the results of such a study on the Serenity BP linear deflation algorithm which has additional features, such as utilization of data from both of inflation and deflation, which lead to very accurate systolic (S) BP and diastolic (D) BP values, reduced time to obtain readings, and reduced patient discomfort.

Subjects
Volunteers were recruited by a Los Angeles, California clinical research enterprise, West Coast Clinical Trials (WCCT, Inc.). Each adult signed written informed consent of the protocol approved by a national institutional review board. Children over the age of 8 signed written assent and a parent / guardian signed consent for each pediatric subject (≤ 18 years of age).

Methods
The staff at WCCT were trained and tested for auscultatory BP measurement by the author; consistent pairs of testers were utilized after multiple sessions of “practice” BP measurement on other staff members. This practice helped ensure that the 2 observers in each pair assigned almost identical SBP and DBP values when blinded from each other. The testing was done in private rooms, with low ambient noise levels.

The testing protocol required that the subject sit quietly for 5 minutes before any readings were performed. The upper arm was not covered by clothing. The staff member measured the arm at the midpoint between the shoulder and elbow. The cuff to be used had to have a width at or above 40% of the arm circumference. The subject’s feet were flat on the floor, with the arm supported at heart level, and back supported. The observers used a calibrated aneroid gauge and a dual-earpiece stethoscope which allowed simultaneous auscultation. The observers were blinded from each other; a 3rd observer recorded the individual SBP and DBP values and insured that they did not differ by >4 mmHg from each other to be accepted.

There was a “practice” device measurement and an auscultatory BP performed prior to data collection, to give the subject experience with both techniques. This is helpful to reduce apprehension and to allow the observers to listen to the Korotkoff sounds. Per the current ANSI / AAMI / ISO 81060-2:2013 standard the observers initially measured the BP by auscultation. This measurement was followed by a device reading and another manual auscultatory BP. The manual BP values were averaged to compare to the device BP reading. There were at least 3 such “bracketed” sets of values per subject. If an individual subject was slightly unstable during the test, two valid “bracketed” sets of values may be used. No more than 10% of the subjects may have fewer than three valid “bracketed” sets of values. At least 1 minute separated the individual BP assessments. This protocol is termed the sequential same-arm procedure.

The observers assigned SBP as the first Korotkoff sound (K1). In adults K5 was used to measure DBP. In children ≤12 years of age K4 was utilized if it could be heard, per the current standard recommendation.

Results
One hundred one subjects had complete sets of data and were included in the analyses. There were 65 adults and 36 children (≤12 years of age).
There were 39 females and 62 males. There were 6 different cuff sizes utilized: small adult, adult, large adult, adult long, large adult long, and thigh. Exact dimensions for each are available from Midmark.

The mean ±SD of the differences between the reference and the device readings are shown in Table 1.

<table>
<thead>
<tr>
<th></th>
<th>SBP (mmHg)</th>
<th>DBP (mmHg)</th>
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<tbody>
<tr>
<td>Mean</td>
<td>0.92</td>
<td>1.15</td>
</tr>
<tr>
<td>SD Criterion 1</td>
<td>6.61</td>
<td>6.31</td>
</tr>
<tr>
<td>SD Criterion 2</td>
<td>5.18</td>
<td>5.38</td>
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</table>

The ANSI / AAMI / ISO 81060-2:2013 standard Criterion 1 requires a mean ±SD difference of ≤ 5 ±8 mmHg. The Serenity BP algorithm passed that criterion “easily”. Criterion 2 requires a smaller SD value, using a sliding scale depending on the mean differences. For the mean of 0.92 mmHg (SBP) the upper limit of SD is 6.88 and for DBP, 6.86, compared to the observed values of 5.18 and 5.38. The Serenity BP algorithm also passed Criterion 2.

The required Bland Altman plots are show in Figure 1 and 2.

Another way to express the data distribution is the percent of readings within 5, 10, and 15 mmHg in comparison to the reference BP values. These data are shown in Table 2. These are the criteria of the British Hypertension Society.

<table>
<thead>
<tr>
<th>Difference</th>
<th>≤5 mmHg</th>
<th>≤10 mmHg</th>
<th>≤15 mmHg</th>
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<tbody>
<tr>
<td>SBP</td>
<td>61.9</td>
<td>87.2</td>
<td>96.7</td>
</tr>
<tr>
<td>DBP</td>
<td>62.3</td>
<td>88.6</td>
<td>97.3</td>
</tr>
</tbody>
</table>

Discussion

The data demonstrated that the Midmark Serenity BP linear deflation algorithm for non-invasive blood pressure measurement passed all ANSI / AAMI / ISO 81060-2:2013 standard requirements. The testing included both children and adults, so this automated sphygmomanometer can be recommended for anyone ≥ 3 years of age with a cuff size of small adult or larger. The U.S. standard requires intra-arterial reference testing for children <3 years of age; this was not performed.
The novel features of the Serenity BP algorithm are that it utilizes data from both inflation and deflation. The estimation of both SBP and heart rate (HR) during inflation allows the device to inflate to BP levels only slightly higher than the “expected” SBP, rather than the arbitrary values programmed into most other devices for children and adults. This has several desirable effects for clinical use. First, the device is able to estimate BP faster than almost all deflation-based algorithm devices. That gives the clinician the opportunity to measure BP more frequently in unstable patients. Second, it reduces maximal inflation pressure, giving additional patient comfort from the height and duration of inflation at high pressures. The third novel property of the algorithm is the ability to regulate the deflation rate from the data on SBP and HR obtained during inflation. This feature also allows faster readings at less discomfort.

Summary
The Serenity BP linear deflation algorithm for non-invasive blood pressure measurement from Midmark gave excellent results when tested per the ANSI / AAMI / ISO 81060-2:2013 standard requirements. This standard is recognized world-wide as the most statistically valid assessment of device accuracy. There are other protocols in use in certain parts of the world, but these lack critical statistical power and are not recommended. This linear deflation algorithm has multiple desirable clinical features to reduce patient discomfort and allows more rapid BP assessment, especially critical in unstable patients. The algorithm achieved an AA grading per the British Hypertension Society analyses. The Midmark Serenity BP linear deflation algorithm is highly recommended.

Reference