Validation of a new algorithm for the BPM-100 electronic oscillometric office blood pressure monitor
James M. Wrightab, Gurdial S. Mattua, Thomas L. Perry Jrab, Mark E. Gelferc, Kevin D. Strange c, Anton Zorn c and Yunquan Chen c

Background To test the accuracy of a new algorithm for the BPM-100, an automated oscillometric blood pressure (BP) monitor, using stored data from an independently conducted validation trial comparing the BPM-100Beta with a mercury sphygmomanometer.

Design Raw pulse wave and cuff pressure data were stored electronically using embedded software in the BPM-100Beta during the validation trial. The 391 sets of measurements were separated objectively into two subsets. A subset of 136 measurements was used to develop a new algorithm to enhance the accuracy of the device when reading higher systolic pressures. The larger subset of 255 measurements (three readings for 85 subjects) was used as test data to validate the accuracy of the new algorithm.

Methods Differences between the new algorithm BPM-100 and the reference (mean of two observers) were determined and expressed as the mean difference ± SD, plus the percentage of measurements within 5, 10, and 15 mmHg.

Results The mean difference between the BPM-100 and reference systolic BP was \(-0.16 \pm 5.13\) mmHg, with 73.7% ≤ 5 mmHg, 94.9% ≤ 10 mmHg and 98.8% ≤ 15 mmHg. The mean difference between the BPM-100 and reference diastolic BP was \(-1.41 \pm 4.67\) mmHg, with 78.4% ≤ 5 mmHg, 92.5% ≤ 10 mmHg, and 99.2% ≤ 15 mmHg. These data improve upon that of the BPM-100Beta and pass the AAMI standard, and ‘A’ grade BHS protocol.

Conclusion This study illustrates a new method for developing and testing a change in an algorithm for an oscillometric BP monitor utilizing collected and stored electronic data and demonstrates that the new algorithm meets the AAMI standard and BHS protocol. Blood Press Monit 6:161–165 © 2001 Lippincott Williams & Wilkins.

Blood Pressure Monitoring 2001, 6:161–165

Keywords: blood pressure, measurement, monitor, algorithm, oscillometric

Introduction The use of electronic blood pressure measuring instruments in diagnosing hypertension and monitoring blood pressure (BP) has increased dramatically over the past several years. There have been many articles written supporting the use of such devices, especially in the home setting (self) [1] and for ambulatory use (24 h) [2]. Most of these devices use the oscillometric technique, which measures the mean arterial BP directly from cuff pressure, then calculates the systolic and diastolic BP’s according to an algorithm that is unique to each device or manufacturer. These instruments can be validated by testing them against auscultatory measurement using a mercury sphygmomanometer, according to established protocols set by either the Association for the Advancement of Medical Instrumentation (AAMI) [3] or the British Hypertension Society (BHS) [4]. It is known that most oscillometric monitors, though accurate, tend to underestimate and give a higher standard of deviation for higher systolic pressures when compared with standard auscultatory methods [5].

The BPM-100 is an oscillometric blood pressure measuring instrument that has been developed and manufactured by VSM MedTech Ltd. of Vancouver, Canada. This device was designed specifically for the primary care setting, to aid the clinician in diagnosing hypertension and in monitoring the patient’s course. It was tested in an independently conducted validation study according to the AAMI standard; the details of this study are reported separately in a companion article [6]. The device performed well, passing both the AAMI standard and BHS protocol, but tended to underestimate the higher systolic blood pressures as detected with the Bland–Altman plot. In this article, we report a method for the development and testing of a modification to the algorithm for estimating systolic BP using stored electronic data.
Methods

Subjects were recruited and tested at the Blood Pressure Clinic of the University of British Columbia according to the method reported in the companion paper and included ethical approval, explicit inclusion and exclusion criteria, target population objectives, study design, data analysis and results [6].

In the original BPM-100 β3 clinical trial [6], 85 patients were tested and accepted for statistical analysis. Each patient was measured a total of six times. The first reading was used for subject screening purposes, and not used further in the analysis. The remaining five readings were further screened for exclusion according to pre-determined criteria, resulting in a minimum of three and maximum of five readings for each subject. The total number of readings included for statistical analysis was 391, 136 readings more than the minimum AAMI requirement of 255 readings (85 subjects with three readings for each subject).

During the original study, the oscillometric algorithm of the BPM-100 β3 collected the cuff pressure and pulse information from the blood pressure cuff during deflation and calculated the systolic and diastolic blood pressures as well as the pulse rate. The embedded software in the BPM-100 β3 performed the data collection and BP calculations. After each measurement, the cuff pressure and pulse information was exported to another computer to archive the raw data and allow for analysis of the algorithm.

The original BPM-100 β3 clinical trial data set of 391 measurements was objectively separated into two data subsets as described below. The first subset included a total of 255 measurements, which included three measurements from each of the 85 subjects, and represented the minimum requirements for AAMI criteria. The second subset of 136 measurements was available to assist in the development of a modification to the BPM-100 β3 algorithm. Once the new algorithm was developed the first subset of 255 measurements was used to objectively evaluate the performance of the algorithm on ‘new’ data.

To avoid bias towards early, middle or late data points in the sequence of up to five measurements collected from each subject in the original clinical data [6], the first subset was selected using a rotating selection pointer. The procedure involved selecting the first three available measurements from the first subject and then the second, third, and fourth measurement from the second subject and so on. Some subjects had only three or four measurements, as some were excluded in the original clinical trial data collection, but the pointer skipped to the next available measurement until each subject had exactly three measurements. When the end of the measurements was reached for any subject without selecting three measurements, the selection pointer rotated back to the start of the measurements for that subject.

The smaller subset was used to develop a new algorithm that gave a better estimate for higher systolic measurements. This did not require changing the algorithm for the diastolic BP. After the algorithm modification was successfully developed using the smaller data subset, it was then ready for validation. The external algorithm was formally tested on the first subset of 255 measurements from the original clinical trial population (85 subjects with three measurements per subject). The performance results of the new algorithm were analyzed according to the AAMI standard for all population, observer, and accuracy requirements. The new algorithm was then incorporated into the embedded software to create the BPM-100.

A non-invasive blood pressure (NIBP) simulator (BP Pump, Bio-Tek Instruments, Inc., Winooski, Vermont) was used to provide oscillometric input data to the BPM-100 device. The BPM-100 displayed the results and exported the cuff pressure and oscillometric data to the PC. The new algorithm developed and tested in the PC now used the new data from the simulator via the BPM-100, and calculated and displayed the results. A regression test compared the two sets of data over a wide range of parameters (BP 80 – 220/50 – 130 mmHg and heart rate 50 – 130 beats per minute); acceptance criteria were that the difference between each reading must be within ± 1 mmHg. This test ensured that the algorithms implemented in the two different software platforms operated identically and validated the implementation of the algorithm in the embedded software.

Results

Enrolled subjects

See companion publication for details of enrolled, included and excluded subjects [6]. All target population objectives and requirements of the AAMI protocol were met; as they included the same 85 subjects included in the companion study [6].

Included blood pressure measurements

The total number of included measurements amounted to 255. Twenty-seven blood pressure measurements (10.6%) had a systolic BP of greater than 180 mmHg, and 37 measurements (14.5%) had a systolic BP of less than 100 mmHg. The remaining 191 systolic measurements (74.9%) were between these extremes. Twenty-
five blood pressure measurements (9.8%) had a diastolic BP of greater than 100 mmHg, and 39 measurements (15.3%) had a diastolic BP of less than 60 mmHg. The remaining 191 diastolic measurements (74.9%) were between these extremes.

Excluded blood pressure measurements
For details of the 34 excluded blood pressure measurements see companion study [6]. In addition, a second subset of 136 measurements used to develop the new algorithm was excluded as described in the methods section.

Reference standard measurements (inter-observer)
Overall mean difference between the observers (observer 1 – observer 2) for the 255 systolic blood pressure measurements was −0.65 ± 1.99 mmHg, (range −10 to +9 mmHg). Most of the systolic measurement differences (98.0%) were within 5 mmHg. All were within 10 mmHg as any outside this range were excluded as one of the exclusion criteria. The overall mean difference between the two observers for diastolic blood pressure was −1.05 ± 2.46 mmHg, (range, −8 mmHg to +7 mmHg). Most (95.3%) were within 5 mmHg and all were within 10 mmHg as described above.

Range and distribution of reference measurements
The overall mean systolic blood pressure for the 255 systolic blood pressure measurements recorded (average of the two observers) was 128.5 ± 30.9 mmHg (range 81.5–223.5 mmHg). The overall mean diastolic blood pressure was 77.3 ± 16.6 mmHg (range 48–119.5 mmHg). The mean heart rate using the Nonin finger pulse oximeter (Onyx, Nonin Medical Inc., Plymouth, Minnesota, USA) was 70.1 ± 12.4 beats per minute (range 42–104 beats per minute).

Accuracy of BPM-100 as compared to the reference standard measurements
The overall mean difference between the reference standard systolic and diastolic blood pressure and the BPM-100 (reference − BPM-100) is well within the AAMI standard and is shown in Table 1 [3]. Table 2 shows the proportion of systolic and diastolic differences within 5, 10, and 15 mmHg and how this conforms to the BHS protocol [4].

In Figure 1, the Bland–Altman display [7] of individual measurements for systolic blood pressure (n = 255) shows that the differences of the reference standard and BPM-100 blood pressures are clustered around 0 over the whole range of systolic readings. In Figure 2, the Bland–Altman display of individual measurements for diastolic blood pressure (n = 255) shows that the differences of the reference standard and BPM-100 blood pressures are clustered around 0 over the whole range of diastolic readings.
pressures gives the same picture as for the 391 measurements in the companion paper. [6]

The mean difference between the reference and measured heart rate (measured minus reference) was 0.16 ± 2.02 beats per minute, with a range of −16 to +6 beats per minute.

Discussion
The BPM-100 electronic office blood pressure instrument with the new algorithm meets the protocol and standard of the Association for the Advancement of Medical Instrumentation for accuracy when compared to traditional mercury BP measurement performed by trained nurses using a research-grade precision mercury sphygmomanometer. It also earned an ‘A’ grade for both systolic and diastolic readings, according to the British Hypertension Society protocol and improves on the accuracy of estimation of higher systolic blood pressures as compared to the previous version (BPM-100 Beta) [6]. The BPM-100 is the only version that is available for sale in North America.

The methods used in this study demonstrate the unique characteristics of using the oscillometric method for detecting blood pressure. The readings were obtained and recorded using standard validation methods. However, because the oscillometric technique utilizes electronic analysis of the pulse waves of each blood pressure measurement, we were able to utilize the previously recorded test readings to develop a new algorithm to improve upon the estimate of systolic blood pressure and subsequently to validate the new algorithm using recognized protocols and standards.

The use of oscillometric devices for measuring blood pressure is rapidly increasing, and O’Brien and others have written about the need for better methods to test and validate these devices [8,9]. They are aware that many manufacturers change the algorithm in their devices and do not always report or re-validate the devices because the cost of re-testing is prohibitive. Presumably, as in the case of the BPM-100, the changes in the algorithm are to improve the accuracy of the device. The method we describe is one way in which companies can validate and report these changes, while saving the time and money associated with repeating the entire validation process. The original clinical data is collected in the prescribed manner, and is recorded and stored both manually and electronically. This data is then available to ‘re-test’ any changes in the algorithms used to estimate the systolic and diastolic blood pressures.

We believe that the method presented could represent a precedent for improving the efficiency of validation of changes to the embedded software of oscillometric blood pressure measuring devices. In this particular case the method created an algorithm that improved the accuracy of the BPM-100 oscillometric device for higher systolic measurements. When this algorithm was tested, it readily satisfied the AAMI standard and BHS ‘A’ protocol.

References
BPM-100 algorithm validation
Wright et al.


