Validation of the STEP deflation algorithm of the Midmark IQvitals Zone Vital Signs Monitor: part of a novel clinical ecosystem

Bruce S. Alpert*

Objectives **Assess the accuracy of the Midmark IQvitals Zone Vital Signs Monitor STEP deflation algorithm according to the ANSI/AAMI/ISO 81060-2 Standard.**

Methods **A total of 85 subjects completed the testing protocol. All standard requirements for gender, blood pressure (BP) values, and arm circumferences were met. Manual auscultation was performed by testers blinded to the device; the manual BP values were compared to the device readings.**

Results: **The Standard Criterion 1 data analyses showed mean ± SD device minus manual BP values of 1.22 ± 6.3 mmHg for SBP and −1.67 ± 6.09 mmHg for DBP. The SD values for criterion 2 were 5.06 mmHg (SBP) and 4.98 mmHg (DBP).**

Conclusions **The device passed all Standard requirements. The Midmark IQvitals Zone device has features to improve accuracy and reduce or eliminate transcription errors and inaccuracy from improper patient positioning.** ***Blood Press Monit*** **XXX: 000–000**

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Department of Pediatrics, University of Tennessee Health Science Center, Memphis, Tennessee, USA

Correspondence to Bruce S. Alpert, MD, 1350 Poplar Ridge Dr., Memphis, TN 38120, USA
Tel: +1 901 229 3719; e-mail: bsa2347@gmail.com

*Retired.

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Introduction

As the world phases out the use of mercury, diagnostic oscillometric-based automated sphygmomanometers have become the standard for both in-office and out-of-office blood pressure (BP) determination. A recent publication by Munter *et al.* [1] stresses the need for precision in the evaluation of BP. The critical dividing lines for various diagnostic categories are at 120, 130, and 140 mmHg. Thus, the automated BP device must be able to achieve a high level of accuracy. The current worldwide standard for BP device validation is the ANSI/AAMI/ISO 81060-2 Standard [2]. The protocol for meeting the requirements of the Standard calls for testing of ≥85 subjects, with necessary goals for gender, BP levels, and arm sizes.

The goal of this study was to validate the Midmark IQvitals Zone Vital Signs Monitor (IQvitals Zone) STEP deflation algorithm to meet the Standard protocol requirements. A validated linear deflation algorithm also is available to provide an option for clinician preference. Innovative improvements to that algorithm are being finalized and will be validated in a future study. IQvitals Zone has novel features that ensure precision and provide added efficiency. These features include programmable automated BP determination without an operator present during the readings to help reduce the effects of white coat hypertension, automated transfer of BP data to the electronic medical record (EMR) via a Bluetooth Low Energy connection to eliminate transcription errors, and, when used in conjunction with the Midmark 626 Examination Chair, accomplishing American Heart Association (AHA) and American College of Cardiology (ACC) requirements for patient positioning [1].

Materials and methods

The IQvitals Zone was developed with a STEP deflation algorithm that utilizes advanced signal processing to monitor accurately and analyze the stability and quality of the baseline prior to extracting true pulse waves with enhanced accuracy of measuring the mean arterial pressure point. This algorithm allows for short reductions of pressure by increments of 10 mmHg, with a brief variable hold duration based on the patient's heart rate. The hold duration ranges from 1 s for rapid heart rates to approximately 2.5 s for slow heart rates at each pressure step until DBP is achieved, followed by rapid deflation.

Validation testing for the IQvitals Zone STEP deflation algorithm was performed independent of manufacturer supervision by the staff at Clinimark, LLC in Louisville, Colorado, USA. For this study, 87 subjects were recruited and two were excluded because the

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observers could not hear the K sounds well enough to assign K1 and K5 values. The 85 subjects completing the study included 50 adults and 35 children per the testing requirements [2]. Subjects ranged in age from 3 to 77 years and arm circumferences were 15.5–44 cm. For this study, the same-arm sequential protocol was followed. Written informed consent from adults and assent from children (7–17 years of age) were obtained for all study subjects. The studies were approved by the Salus Institutional Review Board and were performed in late 2019 and into 2020.

Procedure

Subjects were seated in the Midmark 626 examination chair, which provides adjustments to ensure recommended positioning: feet flat on the floor, back supported, and the arm with the cuff applied supported at heart level. The testing room was quiet; no talking was allowed during BP acquisitions. The Standard protocol was strictly followed, with alternating readings performed by testing personnel doing simultaneous auscultation or IQvitals Zone device BP measurements. The personnel performing auscultation were blinded to the results of the device readings. The cuff for the auscultation method was a standard two-piece cloth cuff with a bladder diameter between 0.37 and 0.5 times the subject's arm circumference. IQvitals Zone cuffs of the recommended size were used for the automated readings.

Analyses

Each individual device reading was compared to the average of the two auscultation readings, one prior to and one following the device reading. Means ± SDs were calculated per both Criterion 1 and Criterion 2 of the Standard [2].

Results

Data were analyzed per the Standard requirements [2] and expressed as the mean ± SD of the differences between the device and manual BP readings (Table 1). The mean difference values approached zero, indicating a robust result. The Standard also requires Bland–Altman plots demonstrating the scatter of data points expressed in a different way (Fig. 1a and b) for both SBP and DBP readings.

Table 1 ANSI/AAMI/ISO 81606-2 Standard criteria testing results

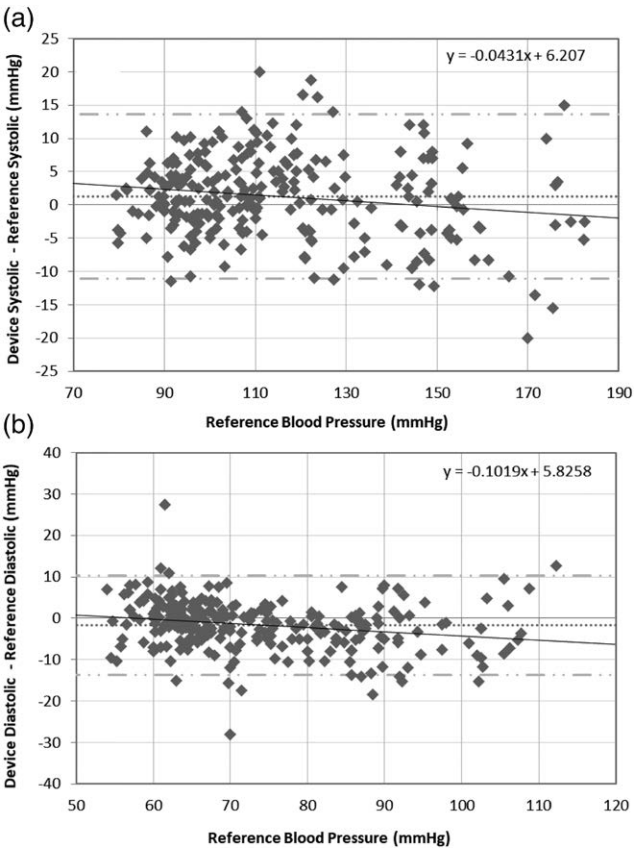
Device under test: Midmark IQvitals Zone Blood Pressure Monitor with STEP algorithm	Criterion 1		Criterion 2	
	Mean error (mmHg)	SD (mmHg)	SD (mmHg)	Pass/fail
Acceptance criteria	≤ ±5.0	≤8.0	Systolic ≤ 6.84 Diastolic ≤ 6.73	
Systolic pressure	1.22	6.30	5.06	Pass
Diastolic pressure	−1.67	6.09	4.98	Pass

Discussion

As clinical guidelines evolve, requiring more precise estimation of BP, automated devices must be developed and validated to perform in compliance with these strict requirements [1]. In addition to the automated device itself, the clinical technique of individual assessments is critical [1]. To satisfy the AHA/ACC guidelines [1], patients must be seated and rested in a quiet room for 5 min, have their feet flat on the floor with their back supported, and have the arm with the cuff applied supported at heart level. Often in current medical care delivery, these guidelines are not followed. If, for instance, the patient is seated on a traditional examination table, none of the three requirements listed can be achieved. Midmark has developed an examination chair (Midmark 626 Barrier-Free Examination Chair) with adjustment capabilities incorporated to ensure that all three of these requirements are met. Use of the IQvitals Zone device in conjunction with the 626 examination chair forms a novel ecosystem that will help achieve the most accurate BP measurements.

Routine manual clinical office BP measurement introduces many factors that can reduce accuracy. A

Fig. 1



Bland–Altman plots of (a) SBP and (b) DBP measurements.

recommendation for Automated Office BP (AOBP) has been incorporated into the AHA/ACC report [1]. AOBP involves multiple readings and various averaging calculations, with the possibility of several protocols (e.g. the SPRINT BP protocol). During many situations in an office visit, when the patient is alone in the examination room, an automated device could perform AOBP readings without operator presence. The IQvitals Zone has six programmable protocol modes: Spot, Interval, Continuous, Averaging, SPRINT, and a Custom protocol allowing users to designate BP protocols with a user-specified number of readings and interval lengths.

With the use of most current automated devices, BP readings are manually transcribed into the EMR, a process prone to human error. The IQvitals Zone utilizes Bluetooth Low Energy technology for confidential electronic transfer of BP readings into nearby computers used for that purpose. The data are stored securely and can be transferred directly into the correct patient's EMR via a protected software link. This feature saves time and eliminates transcription errors.

Conclusion

The Midmark IQvitals Zone automated oscillometric BP device has a STEP deflation algorithm meeting all requirements of both the ANSI/AAMI/ISO 81060-2 Standard and the British Hypertension Society protocol requirements [3], with an AA rating. Because of the rapid deflation rate, the time with the cuff inflated is reduced, thus increasing patient comfort. The IQvitals Zone is part of a connected ecosystem that can increase clinical efficiency, reduce errors made in patient positioning, and eliminate transcription errors. AOBP criteria can be programmed to help reduce the effects of white coat hypertension. Taken together, features of the Midmark IQvital Zone automated vital signs device make it ideal for obtaining more accurate BP readings to improve healthcare for all patients.

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Conflicts of interest

There are no conflicts of interest.

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