Midmark White Paper

Validation of the Midmark IQvitals™ Ambulatory Vital Signs Device According to ANSI/AAMI SP10 2002/A2:2006/(R)2008 American National Standard

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Validation of the Midmark IQvitals™ Ambulatory Vital Signs Device According to ANSI/AAMI SP10 2002/A2:2006/(R)2008 American National Standard

Bruce S. Alpert, M.D.

OBJECTIVE

To evaluate the performance of the automated, non-invasive blood pressure algorithm of Midmark's IQvitals™ device compared to manual blood pressure measurements. The test protocol utilized for this validation is the ANSI/AAMI SP10 2002/A2:2006/(R)2008 American National Standard (Standard). An independent evaluation was performed of the Midmark IQvitals oscillometric blood pressure device by West Coast Clinical Trials, Cypress, CA.

METHODS

A total of 97 subjects were included in the study. The Standard calls for no fewer than 85 subjects, including a minimum of 12 subjects 3 to 12 years of age, if the manufacturer wants to claim accuracy in this population. The Standard has specific requirements for arm size, blood pressure distribution, and age. The protocol utilized sequential same-arm testing, alternating device readings with manual auscultatory blood pressure (BP) values. Two independent, blinded, trained clinicians (observers), utilized a dual head, binaural stethoscope, as required by the Standard, and a third clinician (recorder) operated the IQvitals device. The two observers' BP values were averaged to arrive at each manual BP value. Midmark chose to use a more stringent acceptable difference between the two observers of ≤ 4 mm Hg. The Standard requires 100% ≤ 10 mmHg and 95% ≤ 5 mmHg. This tightened value has been adopted as part of the International Standards Organization Standard, which has been accepted by the FDA.

RESULTS

The blood pressure algorithm in the IQvitals family of devices complies with the ANSI/AAMI SP10 2002/A2:2006/(R)2008 American National Standard for blood pressure measurement accuracy and can be recommended for clinical use for adult and pediatric (age 3-12 years) patient populations.

CONCLUSION

The Midmark IQvitals device passed the Standard at an independent clinical research facility. The study was overseen by Bruce S. Alpert M.D., Co-Chair of AAMI Sphygmomanometer Committee, which wrote the Standard. The IQvitals device will give acceptable BP measurements in both children (age 3-12 years) and adults who vary greatly in their BP values and body size composition.

INTRODUCTION

As the medical industry moves toward electronic health records (EHR) the need for accurate, digital medical diagnostic equipment will increase. The use of manual techniques for obtaining vital signs, like blood pressure, is at risk of being entered into a computer system incorrectly via transcription errors. Midmark IQvitals devices eliminate the chance of transcription errors and can be used by medical facilities before and after the adoption of their EHR.

In the U.S. the FDA recognizes the Standard to judge the performance of electronic and automated sphygmomanometers. The Midmark IQvitals has had sufficient internal testing; having passed the Standard criteria and Midmark opted to have an external independent validation study performed as well. Midmark contracted with West Coast Clinical Trials Corporation (WCCT), Cypress, California to perform the independent testing. Bruce S. Alpert, M.D., Co-Chair of the AAMI Sphygmomanometer Committee which wrote the Standard was contracted and supervised the set-up and training of all WCCT clinical personnel. Dr. Alpert had supervisory input throughout the study and during data analyses. Midmark chose to include children ≤ 12 years of age so that physicians will have assurance of the performance of the IQvitals™ device for children 3 - 12 years of age. (Table 2)

METHODS

Subjects

Subjects for this study were recruited by WCCT from a general population. The inclusion criteria followed by WCCT was for males and females three years of age and up. (Tables 1 & 2) The subject population for this study included 46 males and 51 female. (Table 3) The following subjects were excluded from participating in the study: (1) subjects with significantly irregular heart rhythm, such as bigeminy, trigeminy, or atrial fibrillation; (2) subjects not willing to refrain from smoking, eating, or drinking caffeinated or alcoholic beverages 30 minutes prior to BP determinations being performed; (3) pregnant subjects. All study procedures were administered by the WCCT staff and subjects observed for compliance. All Standard criteria for blood pressure, arm circumference, and age were met.

Per Standard requirements, the systolic blood pressure (SBP) distribution for subjects included in the study must include ≥10% with BP measurements less than 100mmHg, and ≥10% with BP measurements greater than 160mmHg. The Standard requirements for diastolic blood pressure (DBP) distribution for subjects included in the study call for ≥10% of subjects with blood pressure measurements less than 60mmHg, and ≥10% of subjects with blood pressure measurements greater than 100mmHg. The BP distribution for subjects involved in this study exceeded the Standard requirements and is outlined in Table 4.

Number of Subjects & Measurements	
AAMI SP10 2008 (Required)	**Study Results**
≥85 subjects	97 subjects
≥255 measurements	291 measurements

Table 1

Age	
AAMI SP10 2008 (Required)	**Study Results**
12 subjects age 3-12 yr	12 subjects age 3-12 yr

Table 2

Gender	
AAMI SP10 2008	**Study Results**
No requirement	46 male / 51 female

Table 3

Blood Pressure Distribution	
Systolic	
AAMI SP10 2008 (Required)	**Study Results**
≥10% <100 mmHg	13%
≥10% >160 mmHg	12%
34% subjects measured were within 130-160 mmHg range.	
Diastolic	
AAMI SP10 2008 (Required)	**Study Results**
≥10% <60 mmHg	17%
≥10% >100 mmHg	12%

Table 4

Observer training

Two skilled clinicians (observers), were trained in using a reference auscultatory sphygmomanometer for performing a resting BP determination, and performed all measurements for the study. Observers possessed sufficient practice in performing BP determinations. A third clinician (recorder) was trained to use Midmark's IQvitals device to measure the subject's blood pressure.

The observers were trained in the proper determination of Korotkoff sounds for all adult and pediatric subjects as well as how to determine the appropriate size cuff for each subject. 100% of interobserver differences in BP readings were ≤ 4mmHg, which is more stringent than the Standard requires. The Standard requires 100% ≤ 10 mmHg and 95% ≤ 5 mmHg.

Observer and recorder measurement
Each of the simultaneous observer's recordings was blinded from each other as well as those of the recorder. Each observer conducted three simultaneous, same-arm, BP determinations on each subject using a dual head, binaural stethoscope and a calibrated aneroid sphygmomanometer. The observer's individual values for each reading were averaged for reference calculations. Reference measurements and device measurements were performed sequentially.

Procedure
Informed consent was obtained for each participating subject during the screening visit, and prior to any study-related procedure. Subjects were instructed to refrain from smoking, eating, or drinking caffeinated or alcoholic beverages 30 minutes prior to performing BP determinations. Each subject's pulses were palpated manually in both arms and the BP measurement was performed on the arm with the strongest pulse.

The Standard requires that ≥10% of the data come from patients with arm circumference >35cm. The following cuff sizes were used for this study:

- 13-20 cm range, Child
- 18-26 cm range, Small adult
- 26-35 cm range, Adult
- 32-42 cm range, Large adult

Table 5 outlines the distribution of cuff sizes recorded among the subjects measured for this study.

The subject was seated with his or her back supported and both feet flat on the floor or stool, and allowed to relax in a quiet environment for a minimum of five minutes. Each subject's arm was supported during all blood pressure measurements and there was no talking by subject, observers or recorder during the BP measurement process. A series of seven BP measurements were performed in sequence (beginning and ending with a reference measurement). The observers' individual values for each reading were averaged for reference for a total of three average reading results. The recorders' results were documented and accounted for the fourth reading. There was a one minute interval between measurements.

Arm/ Cuff Size Distribution	
AAMI SP10 2008 (Required)	**Study Results**
≥10% <25 cm	24%
≥10% >35 cm	21%
Cuff Sizes used in study	**Study Results**
Child	11%
Small Adult	13%
Adult	55%
Large Adult	21%

Table 5

Analysis
All study data were collected by the WCCT clinical investigators and staff and recorded on source documents. Analysis of the final data was overseen by Dr. Alpert.

RESULTS

A total of 97 subjects met the criteria for participation, provided informed consent, and underwent the above described BP measurements per the Standard. An additional requirement of the Standard is to construct Bland-Altman plots for both SBP and DBP data. Data for SBP and DBP was analyzed using Method 1 specified in the Standard section 4.4.5.1.B. (Table 6). Device and Observer data for SBP and DBP data is plotted using the method of Bland and Altman in Figure 1 and Figure 2.

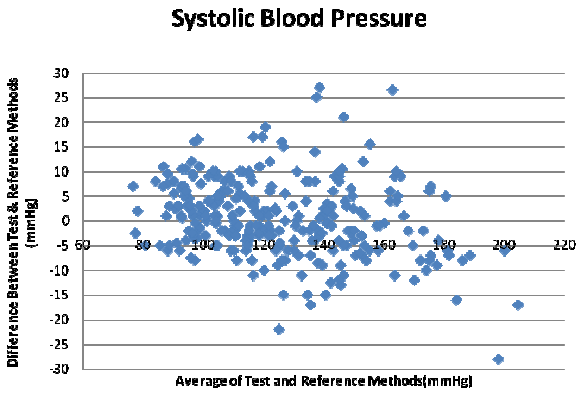

Figure 1

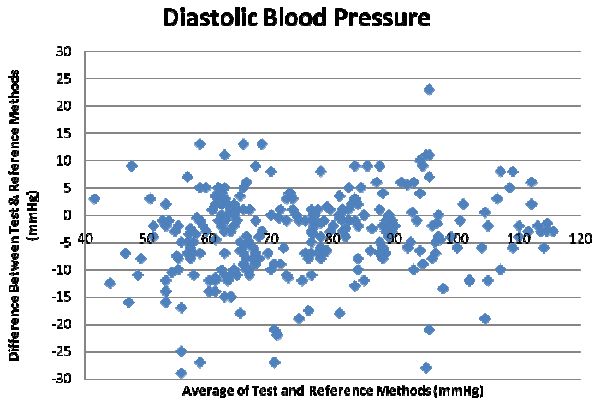

Figure 2

Observer-device agreement

Standard data analyses requirements include the statistical accuracy of both SBP and DBP differences between device and paired observers'. The mean difference shall be ± 5 mmHG or less and the standard deviation shall be ≤ 8 mmHG. (Table 6)

Mean Difference		
	Mean Difference*(mm Hg)	Standard Deviation
SBP	0.84	7.62
DBP	-3.5	7.5

**The mean difference of the device minus reference value.*

Table 6

Summary

The Midmark IQvitals™ device passed the ANSI/AAMI SP10 2002/A2:2006/(R)2008 American National Standard through testing conducted by West Coast Clinical Trials, an independent, off-site, clinical research facility. The study validated the accuracy of the blood pressure technology used in the Midmark IQvitals automated, non-invasive, vital signs device for both SBP and DBP measurements in adult and pediatric (age 3-12 years) patient populations. Midmark chose to include children ≤ 12 years of age so that physicians who care for children will have assurance of the performance of the IQvitals™ device for children over two years of age.

It is often difficult to obtain accurate BP values in patients with large arm circumference. The Standard requires that ≥10% of the data come from patients with arm circumference >35cm. Midmark chose to enrich the data set with 21% of the data coming from patients with arm circumference >35cm. (Table 5) In this way clinicians can have further assurance that the IQvitals™ gives valid BP data in this increasingly more common population.

The Standard criteria for the acceptable difference between the two observers' determinations are relatively wide, requiring 100% ≤ 10 mmHg and 95% ≤ 5 mmHg.. Midmark chose to use a more stringent acceptable difference of ≤ 4 mm Hg. This tightened value has been adopted as part of the International Standards Organization Standard, which has been accepted by the FDA. Midmark sought to have the highest level of rigor to insure the highest level of device accuracy.

The study was overseen by Bruce S. Alpert, M.D., the Co-Chair of the AAMI Sphygmomanometer Committee which wrote the Standard. The Midmark IQvitals device will give acceptable BP measurements in both children (age 3-12 years) and adults who vary greatly in their BP values and body size/composition.

References

1. ANSI/AAMI SP10 2002/A2:2002/(R)2008 Manual, electronic, or automated sphygmomanometers.
2. ISO 81060-2:2009, Non-invasive sphygmomanometers- Part 2: Clinical validation of automated measurement type

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