

Validation of the Tiba Medical Ambulo 2400 ambulatory blood pressure monitor to the ISO Standard and BHS protocol

Bruce S. Alpert

Objective We evaluated the Tiba Medical Ambulo 2400 ambulatory blood pressure monitor accuracy by both the International Standards Organization (ISO) Standard and the British Hypertension Society (BHS) protocol.

Methods We tested children, adolescents, and adults. The requirements for both ISO and BHS were completed for 85 individuals each.

Results The Ambulo 2400 passed both ISO and BHS criteria. For ISO method 1, the mean \pm SD for the difference between device and manual systolic blood pressure (SBP) was -1.8 ± 6.5 mmHg; for diastolic blood pressure (DBP) the values were 0.7 ± 7.3 mmHg. For the method 2 analyses, the differences were -1.8 ± 4.7 and 0.7 ± 6.3 mmHg for SBP and DBP, respectively. The percentage of differences within 5, 10, and 15 mmHg were 60, 86, and 98% for SBP, and 60, 85, and 96% for DBP.

Conclusion The Ambulo 2400 passed all phases of the ISO testing and achieved an A grade for both SBP and DBP

per BHS analyses. There was no decrease in accuracy in either high or low BP ranges. The Ambulo 2400 integrates activity monitoring for assigning actual awake and asleep times. There are software features that are particularly beneficial to monitor children and adolescents. *Blood Press Monit* 00:000–000 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

Blood Pressure Monitoring 2010, 00:000–000

Keywords: ambulatory blood pressure monitor, British Hypertension Society, International Standards Organization, validation

Department of Pediatrics, University of Tennessee Health Science Center, UT Medical Group, and Le Bonheur Children's Medical Center, Memphis, Tennessee, USA

Correspondence to Bruce S. Alpert, MD, Department of Pediatrics, University of Tennessee Health Science Center, UT Medical Group, and Le Bonheur Children's Medical Center, Suite 215, 777 Washington Avenue, Memphis, TN 38105, USA
Tel: +1 901 287 6380; fax: +1 901 287 5107; e-mail: bsalpert@uthsc.edu

Received 21 January 2010 Revised 13 April 2010 Accepted 14 April 2010

Introduction

In 2009, the American National Standard for the validation of new noninvasive blood pressure (BP) measurement devices changed from the American National Standards Institute/Association for the Advancement of Medical Instrumentation SP10 to the International Standards Organization (ISO) Standard [1]. The ISO standard was developed by experts representing many countries, and will soon be accepted as the sole worldwide standard. When it is adopted worldwide, manufacturers will need to validate their new equipment to only one standard to be able to submit documentation to sell the products in any country. The members of the ISO committee from the USA expect that the Food and Drug Administration will soon accept ISO as the preferred testing standard, as it is now the official national standard. The ISO Standard calls for auscultatory validation studies to include 85 individuals. There are new requirements concerning the use of all cuffs tested, and the elimination of arm circumference requirements. The number of readings at the high end and low end of the BP range has been specified more precisely. Sex distribution requirements have been added.

In some markets worldwide, users have demanded that monitors pass various other protocols with which they have more familiarity and experience, such as that of the British Hypertension Society (BHS) [2]. The BHS

protocol uses bracketed readings, rather than paired readings, and different BP classification cutoffs than the ISO Standard.

Tiba Medical, Inc. (Portland, Oregon, USA) has developed a new 24-h ambulatory BP (ABP) monitor with advanced recording and reporting features. We initially sought to perform a validation study of this ABP monitor using the ISO Standard. After beginning the study, the manufacturer also requested that we fulfill the requirements of the BHS protocol within the same study. The monitor has been tested earlier, but not by an independent laboratory. There are no publications to date concerning its accuracy.

Methods

Per ISO Standard requirements for a pediatric and adult study, adults, adolescents, and children were recruited. Thirty-five children were recruited, as required. The protocols were approved by the Institutional Review Board at the University of Tennessee Health Science Center and performed at the UT Medical Group (UTMG) Pediatric Research Facility by UTMG employees. Each child's parent(s) or legally authorized representative signed the informed consent for participation. Adult participants signed their own informed consent; children above 8 years also signed assent forms.

The participants were tested after 5 min of rest, following the guidelines for arm support, cuff size, posture, etc., all outlined in the ISO Standard [1]. They were seated with their arm(s) supported at heart level. They had their backs straight and feet flat on the floor. No talking was permitted. The device and manual reading were alternated. There were up to 10 inflations, depending upon ISO or BHS requirements. Independent observers were trained by the author in the auscultatory measurement of BP. Any reference reading for which the observers' readings differed by greater than 4 mmHg were excluded. As per both protocols, an independent research assistant recorded the data both from the observers performing the auscultation and from the device. In this way, complete blinding of the observers was assured.

Results

A total of 125 participants underwent the consent process. One hundred and seven participants were enrolled; the remainder were 'screening failures' who had their BPs measured and the BP values were not needed to fulfill BP 'bins' to complete both the data sets. BP values and participants were further excluded when observer BP values differed by more than 4 mmHg from each other, reference (auscultatory) systolic blood pressure (SBP) changed by more than 12 mmHg during the study, or reference (auscultatory) diastolic blood pressure (DBP) changed by more than 8 mmHg during the study.

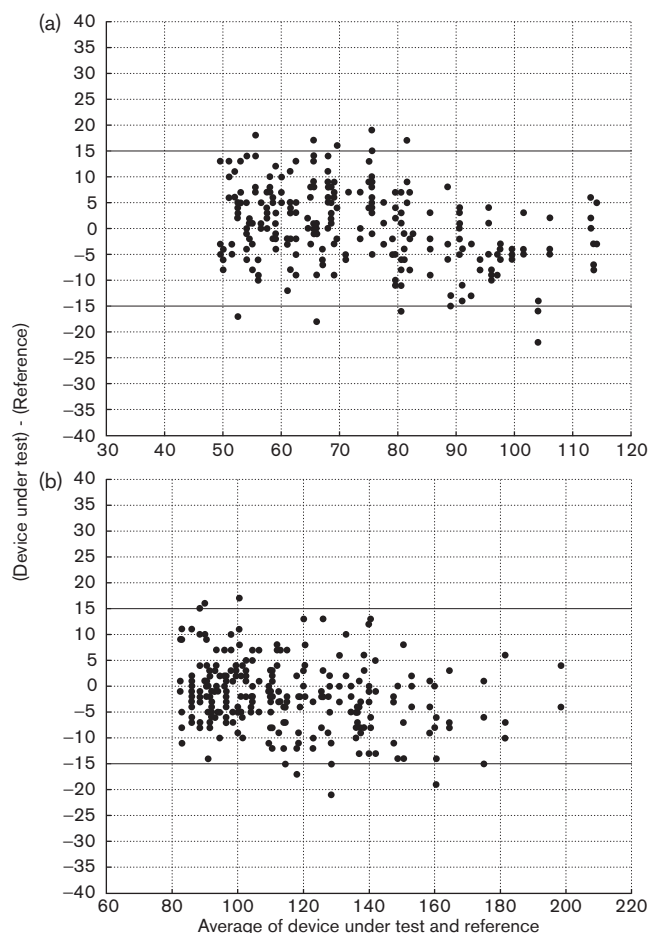
The study was stopped when sufficient BP values had been obtained from at least 85 participants, for a total of at least 255 paired measurements. For the ISO analysis there were 85 participants, whose mean ± standard deviation (SD) age was 29.6 ± 18.1 years. There were 36 males. The mean ± SD values for height, weight, and arm circumference were 140.1 ± 21.3 cm, 73.4 ± 32.8 kg, and 27.9 ± 7.4 cm.

The ISO analyses for SBP and DBP data for both methods 1 and 2 are shown in the Table 1. Methods 1 and 2 are the two distinct statistical methods for determining the mean and SDs. The statistical methodology is given in detail in the ISO Standard. This approach has been in place in the USA National Standard (AAMI) since 2002. In each analysis the Ambulo 2400 passed the ISO Standard accuracy criteria. The BHS analysis requires to achieve an A grade that at least 60, at least 85, and at least 95% of the differences between the device and the reference SBP or

DBP be within 5, 10, or 15 mmHg, respectively. For the SBP differences the Ambulo 2400 achieved values of 60, 86, and 98%. For the DBP values the corresponding data were 60, 85, and 96%. The Ambulo 2400 achieved a grade A rating for both SBP and DBP.

The Fig. 1a and b shows the Bland–Altman plots for both SBP and DBP from the ISO analysis. Visual inspection of these plots shows that there was no significant systematic error that occurred over the entire range of SBP or DBP values, from the lowest to the highest. A Pearson correlation coefficient test was performed to assess whether any statistically significant relationship was present over the range of SBP and DBP. The results of this analysis showed that there were small (not clinically significant) negative correlations: $r = -0.222$ (SBP) and $r = -0.341$ (DBP). These coefficients indicate a tendency for the device to slightly underestimate both SBP and DBP at the upper extremes of BP.

Fig. 1



Bland–Altman plots of (a) diastolic blood pressure and (b) systolic blood pressure (in mmHg).

Table 1 Mean ± SD of differences between device and reference blood pressure (mmHg)

	Method 1	Method 2
Systolic blood pressure	-1.8 ± 6.5	-1.8 ± 4.7
Diastolic blood pressure	0.7 ± 7.3	0.7 ± 6.3

Methods 1 and 2 are described in the text and/or International Standards Organization Standard. SD, standard deviation.

Discussion

The Tiba Medical Ambulo 2400 ABP monitor passed all phases of the ISO Standard testing (at rest) and achieved an A grade for both SBP and DBP when analyzed per the BHS protocol. The Bland–Altman plots show tight clustering of data around the zero error difference, and do not show a decrease in accuracy, in particular, at higher BP values, as is often observed.

A number of clinically valuable features have been programmed into the operation of the Ambulo 2400. These include built-in actigraphy, variable sampling periods, large data storage capacity, and user-friendly application software. The monitor uses a 3-axis accelerometer to assess and store activity data on a minute-to-minute basis for the entire 24 h. These data are used to determine the actual asleep and awake times for use in the data analysis. This eliminates the need for either a diary or a parental observer for children. The analysis related to night-time dipping and morning BP rise are, thus, inherently more accurate.

Within four programmable acquisition periods, readings may be programmed to take place at 5–120 min intervals. If a patient has symptoms at a particular time of day, the Ambulo 2400 can take very frequent measurements for a specified time period to assess the BP frequently during critical clinical observation periods.

The deflation is not a preprogrammed continuous or step deflation, rather a proportional deflation. In this way the

Ambulo 2400 can change its data acquisition rapidly to allow accurate BP measurement in patients with significant dysrhythmia.

The report formats are flexible, allowing customized reports for adults and children. For children the BP upper limits are automatically assigned per guidelines based on height, sex, and age [3].

The Tiba Medical, Inc. Ambulo 2400 24 h ABP monitor provides accurate BP readings in both pediatric and adult populations, with unchanged accuracy in the extremes of BP values. The data acquisition features, such as motion sensor-determined awake and asleep time assignments and flexible software for both pediatric and adult BP load calculations, make the Ambulo 2400 a good choice for both clinical and research applications.

Acknowledgement

Tiba Medical, Inc., provided the equipment, funding of the personnel, and subject incentives.

References

- 1 ISO/OEC 81060-2 International Standard: Non-invasive Sphygmomanometers-Part 2: Clinical validation of automated measurement type. ISO 81060-2: 2009.
- 2 O'Brien E, Petrie J, Littler W, deSwiet M, Padfield P, Altman D, *et al.* The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; **11** (Suppl 2):S43–S62.
- 3 National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. The Fourth Report on the diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. *Pediatrics* 2004; **114**:555–576.