Validation of the Welch Allyn Pro BP 2000, a professional-grade inflation-based automated sphygmomanometer with arrhythmia detection in a combined pediatric and adult population by ANSI/AAMI/ISO standard testing
Bruce S. Alpert

Objective The Welch Allyn Pro BP 2000, an automated sphygmomanometer, was subjected to ANSI/AAMI/ISO testing.

Patients and methods The protocol used was the same-arm sequential procedure described in the ANSI/AAMI/ISO 2013 Standard. Eight-eight (53 adults and 35 children aged 3–12 years old) patients completed testing successfully. Arm circumferences ranged from 15 to 49.5 cm. Seven different cuff sizes were used, including two long cuffs.

Results All requirements for age, sex, blood pressure (BP), and cuff sizes were fulfilled. The mean ± SD was –2.8 ± 6.37 mmHg for systolic BP for criterion 1 and –3.6 ± 6.14 mmHg for diastolic BP. The SD for criterion 2 were 5.29 for systolic BP and 5.75 for diastolic BP. All data passed the Standard’s requirements.

Conclusion The Pro BP 2000 uses an accurate inflationary algorithm. The time for each inflation/deflation cycle is short, thus improving patient comfort. There is also arrhythmia detection to caution the use of BP values obtained during irregular heart rhythms. The algorithm for the professional-grade Pro BP 2000 is also contained in the Home BP 1700, targeted for home use. This encourages out-of-office self-measurement. The healthcare professional can be confident that the values obtained at different sites are comparable.

Introduction
The 2017 US Clinical Guidelines for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults [1] stressed the need for devices to be ‘validated with an internationally accepted protocol’ and that the results be ‘published in a peer-reviewed journal’ (p. 29). This mandate is equally necessary for devices used in hospitals, clinics, and self-measurement sites, such as patients’ homes. Devices that utilize inflation-based algorithms take much less time for each blood pressure (BP) determination, with less discomfort. The Welch Allyn Pro BP 2000 is a professional-grade automated sphygmomanometer that uses inflation-based readings with deflation ‘back-up’ and has the added feature of arrhythmia detection. Blood pressure values measured in the presence of arrhythmia are likely to be inaccurate and, thus, should be reported to a patient’s healthcare provider for clinical acceptance [2].

This study reports the results of independent validation testing in a combined pediatric and adult population.

Patients and methods
Patients
The study was carried out at Clinimark, a clinical research center in Louisville, Colorado. Clinimark investigators and staff have performed many such validation studies using the ANSI/AAMI/ISO protocol. The protocol was approved by the Salus Independent Review Board before clinical testing. All patients provided written consent, or assent, depending on age. Ninety patients who fulfilled the sex (≤30% male) and age requirements were consented, but two were eliminated: one because the systolic BP variation was more than 12 mmHg and one because of poorly audible Korotkoff sounds. Thus, a total of 88 (53 adults/adolescents older than 12 years of age and 35 children 3–12 years old; 44% male, 56% female) participants comprised the final group reported here. Reference blood pressure distribution requirements and the data for each are given in Table 1.

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DOI: 10.1097/MBP.0000000000000350
Protocol
The ANSI/AAMI/ISO protocol utilized was for the same-arm sequential data collection. The initial inflation/deflation cycle used manual auscultatory determination of the BP and the second cycle was performed by the Pro BP 2000 (Welch Allyn, Skaneateles Falls, New York, USA). The data from these two cycles were discarded. Manual auscultation was used for cycles 3, 5, 7, and 9. The device estimated BP on cycles 4, 6, and 8. The auscultatory values from the two blinded observers were averaged for cycles 3 and 5, and this value was compared with the device reading number 4. The same bracketing was used for the next sets of cycles; thus, a total of three comparisons of auscultatory to device BPs were recorded. The statistical analyses prescribed in the Standard [2] were carried out.

The Standard [2] calls for the use of K5 as the surrogate for diastolic BP in adults and K4 in children. These recommendations for children are based on the only known published data comparing direct intra-arterial BP with that obtained by auscultation (references 26 and 27 in the Standard).

Cuffs
Because of the wide range of arm circumferences, seven cuffs were used for the device readings. The characteristics and distribution of the individual cuffs are shown in Table 2. The two long cuffs were produced and tested for cuffs were used for the device readings. The character-
istics and distribution of the individual cuffs are shown in Table 2. The two long cuffs were produced and tested for patients whose upper arms were high in circumference, but short in length. The long cuff was utilized when the next size larger cuff would have extended over the elbow joint.

Results
All of the Standard requirements for sex, age, BP values, and number of each size cuff used were fulfilled. The
Standard requires that two different BP differences (device minus auscultation) be met. Using all 264 comparisons (criterion 1) and 88 comparisons (three comparisons per patient averaged before analysis – criterion 2), the mean ± SD of the device to manual BP differences were calculated and are shown in Table 3.

Bland–Altman plots were drawn to show the distribution of the data points across the BP ranges (Fig. 1a and b). Of the 35 children, K4 was audible and utilized in 34; K5 was used in the other child.

Discussion
The Pro BP 2000 fulfilled all criteria of the current ANSI/AAMI/ISO Standard [2]. The means and SDs were well within the acceptable ranges. The algorithm is inflation based, making the inflation/deflation cycle about 20 s in duration. This also restricts the ‘overshoot’ necessary for inflation-based devices. The comfort level for the patient superior for the Pro BP 2000 compared with deflation-based devices.

The software has arrhythmia detection. If the R–R intervals (impulses) vary more than 20%, a warning alarm is triggered to alert the patient, nurse, physician, etc., that the BP value displayed may not be accurate. The cycle should be repeated in an attempt to obtain a value that can be used for clinical assessment.

The algorithm within the Pro BP 2000 is the same as in many other Welch Allyn professional-grade hospital and office devices. That implies that the healthcare professional can use the Pro BP 2000 BP data similar to those obtained in traditional office settings. The Pro BP 2000 can be used in professional applications at a low cost. For the self-

| Table 1 | Reference blood pressure distribution requirements |
|---------|--------------------------------------------------|
| Systolic reference blood pressure distribution requirements |
| 264 Total points collected |
| ≤ 100 mmHg 5% of data points |
| ≥ 140 mmHg 20% of data points |
| ≥ 160 mmHg 5% of data points |

| Number of points collected | 105 | 55 | 15 |
| Percentage of data patients (%) | 40 | 21 | 6 |
| Fulfills requirement | Yes | Yes | Yes |

Systolic reference blood pressure distribution requirements

| 264 Total points collected |
| ≤ 60 mmHg 5% of data points |
| ≥ 85 mmHg 20% of data points |
| ≥ 100 mmHg 5% of data points |

| Number of points collected | 38 | 63 | 19 |
| Percentage of data patients (%) | 14 | 24 | 7 |
| Fulfills requirement | Yes | Yes | Yes |

| Table 2 | Distribution of test patients’ arm circumference in the specified cuff size range of the test device |
|---------|--------------------------------------------------|
| Flexi Port reusable cuffs | Specified range (cm) | Number of patients |
| Fulfills requirement |
| REUSE – 09 | 15–21 (child) | 26 | Yes |
| REUSE – 10 | 20–26 (small adult) | 14 | Yes |
| REUSE – 11 | 25–34 (adult) | 18 | Yes |
| REUSE – 11L | 25–34 (adult long) | 10 | Yes |
| REUSE – 12 | 32–43 (large adult) | 7 | Yes |
| REUSE – 12L | 32–43 (large adult long) | 7 | Yes |
| REUSE – 13 | 40–55 (thigh) | 6 | Yes |

A minimum of six patients is needed for each cuff.

| Table 3 | Mean ± SD of differences in mmHg (device minus manual blood pressure readings) |
|---------|--------------------------------------------------|
| Systolic blood pressure | − 2.8 ± 6.37 | − 2.8 ± 5.29 |
| Diastolic blood pressure | − 3.6 ± 6.14 | − 3.6 ± 5.75 |

*Passing for systolic blood pressure at this mean difference 6.34 mmHg; passing for diastolic blood pressure at this mean difference 5.89 mmHg.
measurement application, Welch Allyn manufactures the Home BP 1700 (Welch Allyn), which uses the same algorithm as the Pro BP 2000, giving the healthcare professional confidence in the BP values obtained with that device.

The Flexi Port (Welch Allyn) reusable cuff family has been used successfully with numerous automated sphygmomanometers. The availability of a long cuff in two sizes may be commonly needed in our current overweight and obese population.

Acknowledgements
The study of the Pro BP 2000 was carried out with funding from Welch Allyn.

The author thanks Andrea Patters for her editorial expertise.

Conflicts of interest
Bruce S. Alpert serves as a consultant to Welch Allyn.

References
1 Whelton PK, Carey RM, Aronow WS, Casey DE Jr, Collins KJ, Dennison Himmelfarb C, et al. ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension 2018; 71:1269–1324.
2 Association for the advancement of medical instrumentation. Non-invasive sphygmomanometers – part 2: clinical investigation of automated measurement type ANSI/AAMI/ISO 81060-2/ANSI-AAMI, 2nd ed. Arlington, VA: AAMI 2013. Available at: http://my.aami.org/store/detail.aspx?id=8106002.