Validation of the Welch Allyn Home blood pressure monitor with professional SureBP algorithm with a special feature of accuracy during involuntary (tremor) patient movement

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Background Current blood pressure (BP) measurement guidelines recommend certain patient requirements, especially keeping still for 5 min. Some patients cannot comply. My colleagues and I have reported accurate performance of the Welch Allyn SureBP algorithm for BP estimates during voluntary patient motion. No validation studies for involuntary patient movement (tremor) BP readings have been reported. This paper reports the validation of the Welch Allyn Home BP monitor, the 1700 Series, which contains that same SureBP algorithm, and the results of tremor testing as well. This device has multiple clinical advantages.

Patients and methods Eighty-five patients (49 females) were studied using the ANSI/AAMI/ISO 81060-2, 2013 requirements. Three sizes of cuffs were included. The tremor experiments used a simulator programmed to frequency and amplitude of oscillometric impulses typically seen in patients with diseases causing tremors. This is the first protocol developed for this clinical scenario. The device uses an inflation-based algorithm, reducing discomfort and cycle times.

Results The mean $\pm$ SD for the device minus manual readings per ISO Criterion 1 were -2.93 ± 6.64 mmHg for

systolic BP and -2.453 ± 5.48 mmHg for diastolic BP. The tremor testing was performed at low, normal, and high BP simulations. The device recorded a BP value for every cycle tested. The errors (device minus manual BP estimates) were quite low.

Conclusion The Welch Allyn Home BP monitor is accurate in the presence of involuntary patient motion (tremor). Clinicians can have a high level of confidence in the use of a self-measurement device, which operates using the same algorithm as contained in the 'professional grade' family of devices. *Blood Press Monit* 24:89–92 Copyright © 2019 The Author(s). Published by Wolters Kluwer Health, Inc.

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Introduction

Clinical guidelines for blood pressure (BP) estimation by noninvasive procedures [1,2] state that the subject/patient be seated and still for 5 min, with the arm and back supported and feet flat on the floor. In ideal circumstances these requirements can be attained with careful preparation, but many violations commonly occur. Many individuals, such as children and the elderly, cannot voluntarily be still. A protocol for accuracy of BP estimation by the Welch Allyn SureBP during voluntary patient arm movement has been reported [3]. The algorithm contained in the Connex Spot Monitor was able to perform estimations with acceptable error. To date there are no validation studies for devices that demonstrate accuracy during involuntary patient movement (tremors).

The algorithm-development engineers at Welch Allyn, who created the protocol for voluntary arm movement testing, have also developed a protocol for tremor that uses a simulator rather than diseased patients. The precedent for simulator use has been set by the members of the ISO Sphygmomanometer Committee, who have been working on a protocol for transport-induced motion artifact. This will be published as ANSI/AAMI/ISO 81060-4, hopefully in 2019. Actual transport data from road, fixed-wing air, and rotary ambulances will be collected and then reproduced by a specially designed simulator.

As self-measured BP becomes more critical for optimal BP assessment and disease control, the accuracy of self-(home) measurement devices becomes a much more important issue [1]. Healthcare providers currently are 'at the mercy of' the algorithms contained in affordable devices for sale in pharmacies, department stores, etc. If a device for home use contained the same quality/identical algorithm as the professional device the provider uses for diagnosis and treatment, that concern would be eliminated.

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Fig. 1

The artifact signal was generated for 4 s, and then off for 0.5 s. The pattern shows when the 'tremor' signal was either on or off.

Table 1 Bin requirements of systolic and diastolic blood pressure values and cuff sizes

Systolic bin requirements (3 points for all 85 patients)				
	≤ 100 mmHg	≥ 140 mmHg	≥ 160 mmHg	
Bins	5% of data points	20% of data points	5% of data points	Total number of points
Number of points collected	18	54	25	255
Percentage of data points (of 255 points)	7	21	10	
Meets bin requirement	Yes	Yes	Yes	
Diastolic bin requirements (3 points for all 85 patients)				
	≤ 60 mmHg	≥ 85 mmHg	≥ 100 mmHg	
Bins	5% of data points	20% of data points	5% of data points	Total number of points
Number of points collected	13	66	19	255
Percentage of data points (of 255 points)	5	26	7	
Meets bin requirement	Yes	Yes	Yes	
Cuff sizes (total of 85 patients)				
Minimum 14 patients required for each cuff size	Small cuff	Adult cuff	Large cuff	
Number of patients	14	57	14	
Meets bin requirement	Yes	Yes	Yes	

Patients and methods

The ISO validation study was performed at Clinimark Laboratories (Louisville, Colorado, USA). Three Welch Allyn BP cuffs from the same 'family' were tested. The testing protocol in the 2013 version of 81060-2 was followed [4]. Forty-nine of the 85 patients were females. The mean age was 42.9 years, with a range from 18 to 84 years. The arm circumference range was 21–53.3 cm, with a mean of 30.3. In

addition to the standard language and current requirements the inclusion criteria required patient age to be at least 18 years, with an arm circumference of 15–54 cm. The exclusion criteria, as in all validations studies, required that there be no significant heart dysrhythmias.

The device tested was the Welch Allyn (Skaneateles Falls, New York, USA) Home BP monitor, which utilizes

the SureBP algorithm. This algorithm provides reduced patient discomfort and short estimation cycle length because the BP values are recorded during inflation. The rate of inflation is 7.5 mmHg/s. The bladder dimensions

of the three cuffs used were 8×16 cm (small), 12.5×23 cm (adult), and 19×37 cm (large adult).

Simulator specifications

The usual maximal oscillometric signal amplitude in the cuff during compression occurs at mean BP; this value is typically about 2.5–4 mmHg. Signals were produced by the simulator to reproduce arm movement during tremor at 5 Hz. This value was obtained from patient testing. The simulator signal amplitude was 1 mmHg. The artifact signal was generated for 4 s, and then off for 0.5 s; this was repeated during laboratory testing of inflation oscillometric signals (Fig. 1). It is clear from the patterns shown when the ‘tremor’ signal was either on or off.

Data analyses

As prescribed in the ISO Standard [4], bracketed (before and after) manual BP values were subtracted from the device values: these were defined as the device errors. Both Criterion 1 (255 individual error value comparisons) and Criterion 2 (85 within-subject average errors) analyses were performed.

Results

The required bins were filled appropriately (Table 1) for systolic blood pressure (SBP), diastolic blood pressure (DBP), and cuff distribution. Requirements related to sex were met. The SBP ranged from 89 to 175 mmHg, and the DBP ranged from 54 to 118 mmHg. As shown in Table 2, the mean and SD of the errors were well within the acceptable limits set by the ISO Standard. Bland–Altman plots (Fig. 2) showed no systematic deviation from the auscultatory values for either low or high BP ranges.

Tremor experiments

The device had the tremor signals introduced as described above at simulated trials of target SBP/DBP of 80/50, 120/80, and 150/100 mmHg. Each trial goal BP was run five times, thus there were 15 total trials. In every case the device was able to report a BP value; no error messages appeared. The differences between the device readings with and without the tremor signals were calculated. Table 3 shows the summaries for the mean and SDs for these differences at the three simulator BP values above. The results were very promising.

Table 3 Mean and SDs of the Welch Allyn Home BP monitor blood pressure value differences with and without tremor signals

Simulated SBP/DBP (mmHg)	SBP (mean ± SD)	DBP (mean ± SD)
80/50	−2.80 ± 2.72	−0.60 ± 0.61
120/80	−1.40 ± 2.39	−0.90 ± 1.87
150/100	−2.00 ± 2.69	−4.00 ± 2.39

DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 2 Mean and SDs (mmHg) of the errors were within the acceptable limits set by the ISO Standard

	Criterion 1 – passed		Criterion 2 – passed	
Systolic				
Mean error	−2.93	SD 6.64	SD 5.34	
Maximum per acceptance criteria	±5	Maximum per acceptance criteria ≤8	Maximum per acceptance criteria ≤6.30	
Diastolic				
Mean error	−2.45	SD 5.48	SD 4.86	
Maximum per acceptance criteria	±5	Maximum per acceptance criteria ≤8	Maximum per acceptance criteria ≤6.47	

Fig. 2

Bland–Altman plots for (a) systolic blood pressure and (b) diastolic blood pressure comparing device versus auscultatory readings.

Discussion

The most innovative clinical aspect of the capabilities of the 1700 Series monitor is the ability to record BP values consistently during simulated patient-induced involuntary motion (tremor). The device reported a reading for every inflation, and the accuracy was good to excellent (Table 3). This novel feature allows clinicians to choose/recommend this device for self-measurement, even for patients with tremors, with a high level of confidence. The same SureBP algorithm has recently been shown to be effective in obtaining accurate BP estimates during voluntary patient motion [3]. Thus, for clinical assessment not during patient transport Welch Allyn devices have added features not available on other automated oscillometric devices. The strict clinical ‘rules’ specified in the current USA guidelines [1] do not necessarily have to be rigidly adhered to.

When the AAMI/ISO Sphygmomanometer Committee completes its work on the Standard ISO 81060-4 in the near future, virtually all ‘nonviolent’ patient motion artifact will be able to be tested to a proven protocol.

Another feature of the 1700 Series is that the device estimates BP during inflation rather than deflation, thus minimizing discomfort. The inflation needs to exceed SBP by only 10–15 mmHg before rapid deflation. The routine deflation-based algorithm initially inflates in adults to about 160 mmHg to capture SBP in most patients. The inflation/deflation cycle is typically about twice as long for deflation-based versus inflation-based algorithms.

Clinicians will be more confident in the self-measured BP values if the home device, at much lower cost than the ‘professional’ grade monitor, uses the same algorithm as the ‘professional’ device. Thus, home BP values can be directly compared with office automated device BP values, with the ‘white coat’ effect eliminated.

Conclusion

The Welch Allyn Home BP monitor 1700 Series and the family of devices that use the SureBP algorithm were shown to be accurate in BP estimation during both voluntary and involuntary patient motion. The protocol for devices claiming transport artifact tolerance should be available soon as ISO 81060-4. The 1700 Series passed the ANSI/AAMI/ISO 81060-2 with respect to all requirements. The 1700 device estimates BP more quickly and with less discomfort compared with deflation-based oscillometric devices. Clinicians will have enhanced confidence in self-measured (home) BP values because the 1700 contains the same SureBP algorithm used in the professional grade family of automated devices (ProBP 2000 and Connex Spot monitors).

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Conflicts of interest

B.S.A. serves as an advisor for Welch Allyn and has received honoraria.

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