Validation of the Kinetik Blood Pressure Monitor – Series 1 for use in adults at home and in clinical settings, according to the 2002 European Society of Hypertension International Protocol on the validation of blood pressure devices

Schwartz CL[1], Edwards K[2], Gamble W[2], Kirkham A[2], Lacy P[3], Lewis P[4], McDonagh STJ[5], Peers C[2], Sheppard JP[1], Swales P[2], Howarth J,[6] Williams B[3]

[1] *Nuffield Department of Primary Care Health Sciences, NIHR School for Primary Care Research, University of Oxford, Radclife Observatory Quarter, Oxford OX2 6GG, UK;*

[2] *University Hospitals of Leicester, Glenfield Hospital, Leicester LE3 9QP*

[3] *Institute of Cardiovascular Sciences, NIHR UCL Hospitals Biomedical Research Centre, University College London, 170 Tottenham Court Road, London, W1T 7HA, UK*

[4] *Stockport NHS Foundation Trust, Stepping Hill Hospital, Stockport, SK2 7JE*

[5] *Primary Care Research Group, University of Exeter Medical School, College of Medicine and Health, Smeall Building, St Luke's Campus, Exeter, UK*

[6] *British and Irish Hypertension Society, UK*

Correspondence to:

Dr James Sheppard email: james.sheppard@phc.ox.ac.uk

Abstract

The aim of this study was to assess the blood pressure (BP) measurement accuracy of the Kinetik Blood Pressure Monitor – Series 1 (BPM-1) for use in home or clinical settings according to the 2002 European Society of Hypertension International Protocol (ESH-IP). Forty-two participants were recruited to fulfil the required number of systolic and diastolic BP measurements according to the ESH-IP. Nine sequential same-arm BP readings were measured and analysed for each participant using the test device and observer mercury standard readings according to the 2002 ESH-IP. The 41 participants were used to obtain 33 sets of systolic and diastolic BP readings and were included in the analysis. Mean difference between the device measurements and the observer (mercury standard) measurements was 1.1±7.2/1.1±6.8 mmHg (mean ± standard deviation; systolic/diastolic). The number of systolic BP differences between the test and observer measurements that fell within 5, 10 and 15 mmHg was 65, 86 and 92. For diastolic readings, the number of test - observer measurement differences within 5, 10 and 15 mmHg was 77, 91 and 94. The number of participants with at least two out of three differences within 5 mmHg was 28 for systolic and 40 for diastolic BP readings. Three participants had no differences between the test and observer measurements within 5 mmHg in both the systolic and diastolic measurement categories. The Kinetik BPM series 1 device fulfilled the requirements of the ESH-IP validation procedure and can be recommended for clinical use and self-measurement within the home.

Abstract word count: 247

What is known about this topic

- Clinical validation of blood pressure monitors is important to ensure they are accurate for use at home and in routine clinical practice.
- The consistency of the validation process is ensured by the use of standardised protocols such as that developed by the European Society of Hypertension in 2002.

What this study adds

- The present study examined the accuracy of the Kinetik BPM series 1 electronic monitor using the European Society of Hypertension International protocol.
- In 41 subjects, the mean blood pressure difference between the device measurements and the observer (mercury standard) measurements was 1.1±7.2/1.1±6.8 mmHg (mean ± standard deviation; systolic/diastolic). In a total of 99 measurements, the number of systolic differences that fell within 5, 10 and 15 mmHg was 65, 86 and 92.

  The Kinetik BPM series 1 device fulfilled all of the requirements of the ESH-IP validation procedure and can be recommended for clinical use and self-measurement within the home.

Introduction

The Kinetik BPM series 1 electronic monitor is a simple, automatic, lightweight, portable monitor that was developed to be an accurate and affordable method of measuring blood pressure (BP). The device is intended for home use by adults and in clinical settings by health professionals. The popularity of patients self-monitoring their BP is increasing,[1] particularly as self-monitoring can lead to more effective BP control.[2] Due to ease of use and portability, electronic BP monitor usage has also increased within general practice.[3] It is important that health professionals and patients have confidence in the accuracy of the BP measurements. A monitor that has been independently validated against a well-established set of criteria is a vital factor when considering, or recommending, a monitor to purchase. The aim of this study was to assess the BP measurement accuracy of the device in adults using the European Society of Hypertension International Protocol (ESH-IP) for the validation of BP measuring devices in adults from 2002.[4]

Participants and Methods

Test Device

The Kinetik BPM series 1 (produced by Kinetik Medical Devices Ltd, Elstree, Herts, UK) is an automated, electronic, digital, upper arm BP monitor. The device operates using the oscillometric[5] method and is designed for use at home and in clinical practice. It is powered by four AAA batteries or an external 6V, 600mA DC adapter (not included as standard). The device has a BP measurement range of 0 to 300 mmHg and a heart rate detection range of 40 to 180 beats per minute. The measuring accuracy is stated to be within ± 3 mmHg for BP and within ± 5 % for heart rate. The device, which has memory capacity for 60 sets of BP readings, comes with three cuff sizes; a standard cuff, supplied with the monitor (22 – 30 cm arm circumference), a large cuff (30 – 42 cm arm circumference) and an extra-large cuff (42 – 48 cm arm circumference). The manufacturer states that periodic re-calibration is not required if the BP monitor is used according to instructions. The manufacturer provided three samples of the monitor and all three sizes of cuff to test.

Recruitment and Participant Selection

At least 33 participants are needed to fulfil the BP monitor validation requirements, 15 for phase 1 and a total of 33 for phase 2. Forty-two participant and staff volunteers were recruited from the outpatient hypertension clinic at Glenfield Hospital, Leicester, UK. As specified by the ESH-IP, all participants were over the age of 30 years and special groups, such as pregnant women, were not included.[4] Written, informed consent was obtained from all study participants. Twenty-one were recruited for phase 1, based on inclusion of five systolic and five diastolic readings for each BP category (low, medium and high), and at least five male and five female subjects across the BP categories. Participants had their arm circumference recorded to ensure that the appropriate cuff (standard, large or extra-large) was used according to the participant's measurement. This was not needed for the selection process as the ESH-IP assumes that there will be a representative spread based on the BP selection criteria.[4] An additional 20 participants were recruited for phase 2 to achieve the required 11 systolic and 11 diastolic BP readings in each BP category (low, medium and high).

Procedure

The study was conducted in one of the consulting rooms in the Glenfield Hospital, Leicester, UK, by an experienced supervisor and member of the British Hypertension Society (BHS) Blood Pressure Measurement Working Party, and three trained observers, overseen by a principal investigator. Observers were fully trained in accurate BP measurement according to the test requirements of the BHS DVD specified in the ESH-IP[4] and were familiarised with the device prior to the study. Participants were instructed not to eat, smoke or drink caffeinated drinks or alcohol for one hour before the first BP measurement. The participant was seated comfortably for 10 minutes prior to BP measurement. The participant's arm was supported and the cuff placed at heart level whilst the BP measurement was taken; talking and moving was avoided.

Reference BP

One cuff was connected to two mercury sphygmomanometers via a Y-tube connector (calibrated before the study initiation) and this was used for simultaneous, reference auscultatory BP measurements by two observers using the manual and then the test BP monitor cuff. The observers were blinded from each other's readings and there had to be agreement between the readings within +/- 4 mmHg. The appropriate cuff was used for each participant to ensure that the bladder covered at least 80 % of their arm circumference but not more than 100 %.

Test BP

Nine sequential same arm measurements were taken at 30-60 s intervals using the test monitor and the standard mercury device, with separate cuffs. The appropriate cuff size was used for each participant following measurement of arm circumference. Two initial BP readings were taken, one with the reference standard to determine the systolic and diastolic BP category for the participant (high, medium or low) and the other taken with the test device. This was followed by seven BP measurements, alternating the mercury standard (BP1, BP3, BP5 and BP7) with the test device (BP2, BP4 and BP6).

Analysis

The analysis was carried out as specified in the 2002 ESH-IP[4]. Each test BP measurement (BP2, BP4, and BP6) was paired with the mercury reference reading (BP1, BP3, BP5 and BP7) taken immediately before and immediately after. The measurements with the smaller absolute difference (device - mercury BP) were used for analysis (or, if the difference was equal, the first of the mercury reference values was used). The BP differences were then categorised as within 5 mmHg, 10 mmHg or 15 mmHg. This was performed separately for systolic and diastolic BP values. The criteria for the device passing the validation was based on two phases: Phase 2.1 representing the absolute number of

comparisons falling between 5, 10 and 15 mmHg for the 33 participants (99 comparisons) and Phase 2.2 representing the number of comparisons per participant which fell within 5 mmHg.

Results

Participants

Forty-two participants were recruited of whom 41 were needed to fulfil the required number of systolic and diastolic BP readings for analysis. One recruited participant's data was in excess of requirements and therefore not included in the analysis. Participants' characteristics are presented in Table 1. Requirements in the protocol for gender, age and BP ranges were fulfilled.

Validation

As per the ESH-IP, phase 1 validation was carried out on 15 participants, 5 in each BP category.[4] The Kinetik BPM series 1 device successfully passed the requirements for this phase for both systolic and diastolic BP (Table 2) and, therefore, validation continued to the second phase. Standardised Bland-Altman plots are presented in Figures 1 and 2 and display the differences in BP between the device and the observer (mercury standard) for phase 2 measurements. Paired comparisons for mean device BP readings and mean observer BP readings in each BP category are shown in Table 3. Overall, the device-observer difference was 1.1 ± 7.2/1.1 ± 6.8 mmHg in the phase 2 participants (n = 33). The validation analysis, based on classifying the differences between the BP measurements from the tested device and the measurements from the mercury standard, fulfilled the requirements to pass parts 2.1 and 2.2 of the phase 2 analysis (Table 4).

Discussion

The Kinetik BPM series 1 electronic monitor has been tested using the 2002 ESH-IP validation protocol. The device tends to overestimate low systolic BP and underestimate high systolic BP relative to measurements obtained using a mercury standard. On two occasions, the monitor failed

to give a measurement, both of which involved different subjects with systolic pressures in the "high" BP category. The monitor is more accurate at determining diastolic BP.

The device was able to meet the minimum criteria required for passing the validation test for systolic and diastolic BP (phase 2.1 and 2.2). Therefore, the device can be recommended for home and clinical use.

The "standard" cuff size (22-30 cm) used with this monitor is smaller than specified for many automated BP devices (22-32 cm) and may account for reports from some study subjects that repeated measurements were uncomfortable due to the tightness of the cuff, particularly at high BP levels. The discrepancy in cuff size may result in an inappropriate cuff being used for some subjects by operators not fully familiar with the cuff size range specified for this device.

Acknowledgements

The British and Irish Hypertension Society, Blood Pressure Measurement Working Party

Conflicts of Interest

Funding

Future Legends

*Table 1 – Characteristics of the included participants, BP – blood pressure, * In order to get the required number of systolic and diastolic BP readings for the low, medium and high categories 21 participants were included overall.*

Table 2 – Validation results for phase 1. Device passed therefore phase 2 validation recommended. SBP – systolic blood pressure, DBP – diastolic blood pressure.

Table 3 – Paired comparisons between the device and mercury/observer systolic and diastolic blood pressure for each blood pressure diagnostic group, BP – blood pressure.

Table 4 – Validation results for Phase 2. Completion of analysis produces differences between test and observer measurements for all 33 participants in phase 2 (99 in total). Part 1 requires the number of these comparisons that fall within 5, 10 and 15 mmHg to be determined. The comparisons are then analysed per subject to determine the number that fall within 5 mmHg. The Kinetik BPM1 device passed both parts 1 and 2. SBP – Systolic blood pressure and DBP – Diastolic blood pressure.

Figure 1 – Bland-Altman plot showing the difference between the observer (mercury) systolic BP and the device systolic BP against the mean value

Figure 2 - Bland-Altman plot showing the difference between the observer (mercury) diastolic BP and the device diastolic BP against the mean value.

References

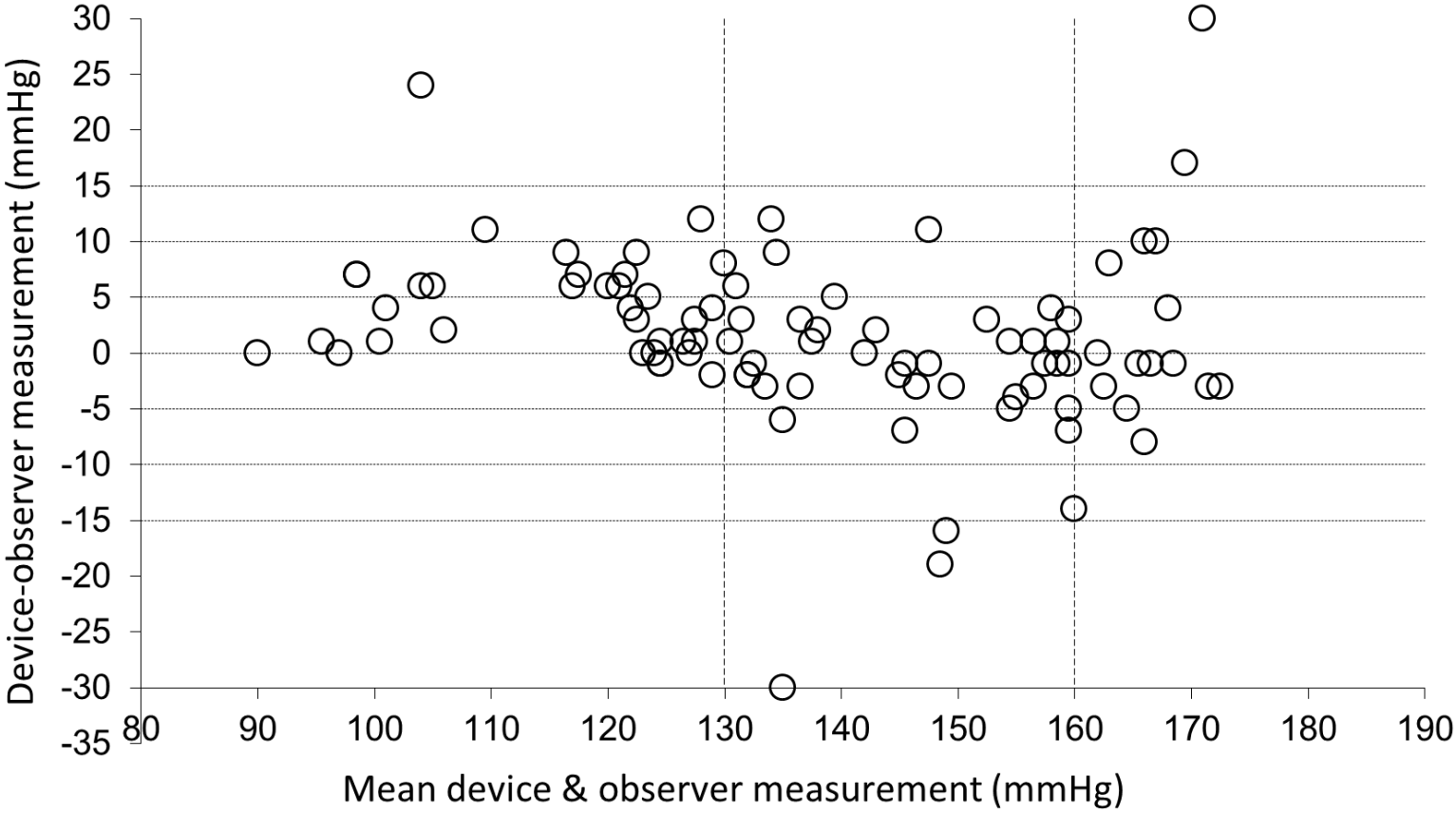
1. McManus RJ, Wood S, Bray EP, Glasziou P, Hayen A, Heneghan C *et al*. Self-monitoring in hypertension: a web-based survey of primary care physicians. Journal of human hypertension. 2014;28(2):123-7.

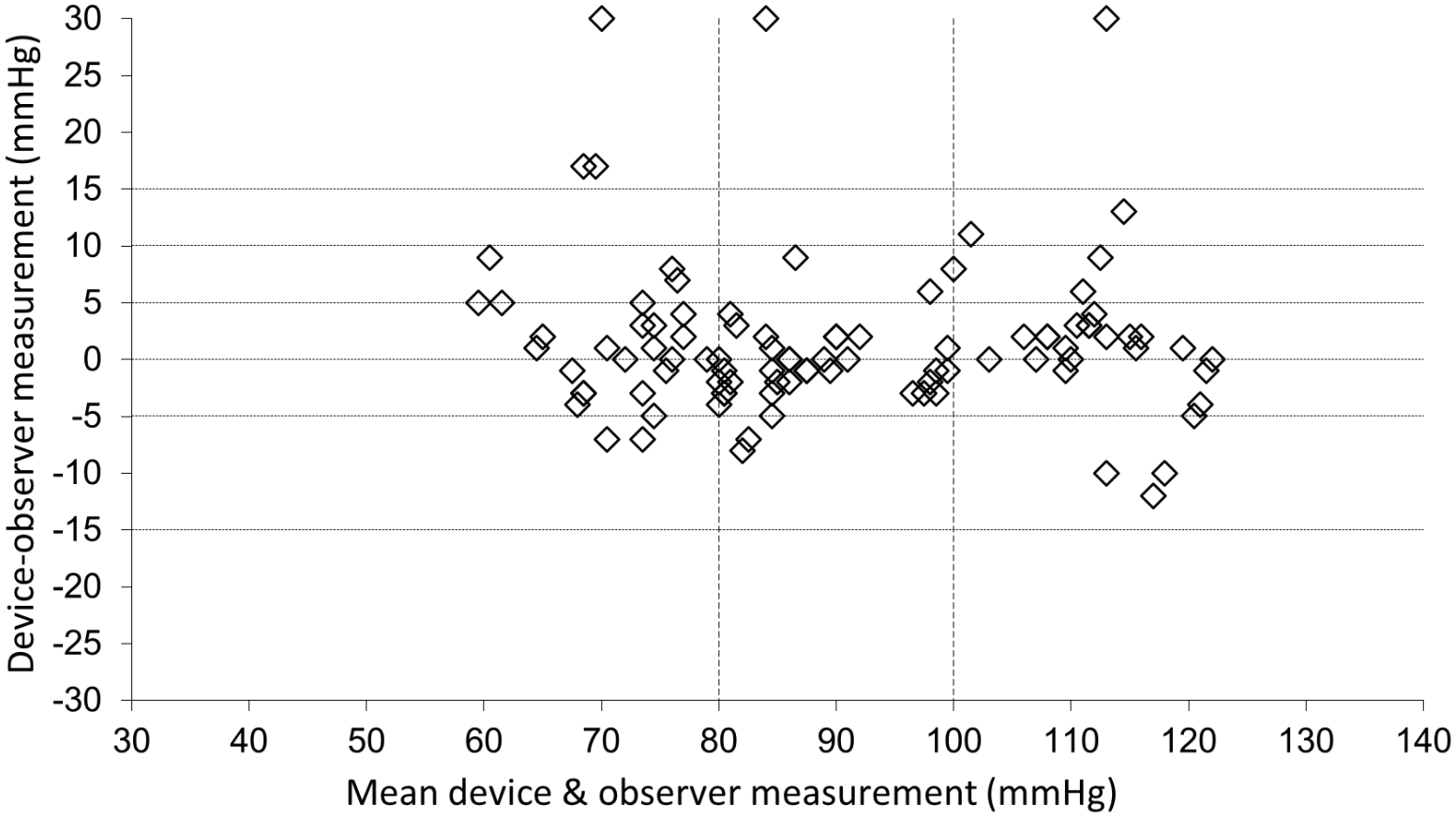
2. Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP *et al*. Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. PLoS medicine. 2017;14(9):e1002389.

3. Medicines, Healthcare Products Regulatory A. Blood Pressure Measurement Devices London: Medicines and Healthcare Products Regulatory Agency 2013 [Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/403448/Blood_pressure_measurement_devices.pdf.

4. O'Brien E, Pickering T, Asmar C, Myers M, Parati G, Staessen J *et al*. Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. Blood Press Monit. 2002;7(1):3-17.

5. Lewis PS, Chapman N, Chowienczyk P, Clark C, Denver E, Lacy P *et al*. on behalf of the British and Irish Hypertension Society's Blood Pressure Measurement Working Party Oscillometric measurement of blood pressure: a simplified explanation. A technical note on behalf of the British and Irish Hypertension Society. Journal of Human Hypertension **volume 33**, pages 349–351(2019)


Device-observer measurement (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
-25
-30
-35
80
90
100
110
120
130
140
150
160
170
180
190
Mean device & observer measurement (mmHg)


Device-observer measurement (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
-25
-30
30
40
50
60
70
80
90
100
110
120
130
140
Mean device & observer measurement (mmHg)

	Phase 1 participants (n=21)*	**Phase 2 participants (n=41)**
Age, Mean (SD), years	53.6 (13.1)	54.0 (11.6)
Range, years	30 - 80	30 -80
Men, No. (%)	11 (52.4)	21 (51.2)
Arm Circumference, Mean (SD), cm (N=40)	28.2 (3.8)	30.6 (5.8)
Range, cm	23 - 36	23 - 54
Recruitment Systolic BP, Mean (SD), mmHg	143.6 (29.2)	147.7 (28.4)
Range, mmHg	99 - 199	99 - 199
Recruitment Diastolic BP, Mean (SD), mmHg	90.0 (17.4)	89.8 (16.3)
Range, mmHg	58 - 122	58 - 122
Participants in each recruitment range		
Systolic BP Low (<130)	5	11
Medium (130–160)	5	11
High (>160)	5	11
Diastolic BP Low (<80)	5	11
Medium (80–100)	5	11
High (>100)	5	11

	Within 5 mmHg	Within 10 mmHg	Within 15 mmHg
SBP	28	38	41
DBP	40	44	44
Required to pass Validation	25	5	40

Systolic BP				
Group	**Mercury**	**Kinetik**	**Difference**	**Number**
Low	113	118	5	33
Medium	140.9	141.7	0.76	33
High	161.1	158.6	-2.5	32
Diastolic BP				
Group	**Mercury**	**Kinetik**	**Difference**	**Number**
Low	71	74.1	3.1	32
Medium	87.5	87.5	0	33
High	110.6	110.7	0.1	32
			Difference - Device - Mercury mean (SD) mmHg	**Number**
		Systolic	1.1 (7.12)	33
		Diastolic	1.1 (6.77)	33

Part 1				
	Within 5 mmHg	**Within 10 mmHg**	**Within 15 mmHg**	**Validation Result**
Two required	65	80	95	
All required	60	75	90	
Achieved				
SBP	65	86	92	Pass
DBP	77	91	94	Pass
Part 2				
Diff' within 5mmHg	"at least 2/3"	"none"		
Required	≥22	≤3		
Achieved				
SBP	22	3		Pass
DBP	27	3		Pass