Validation of the Omron automated oscillometric blood pressure monitoring devices
(HEM 7130 / HEM 7120/HEM 7322)

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Background

Self-measurement and home monitoring of blood pressure is now recommended by most guidelines to determine the adequacy of control in hypertensive patients. The newer automated oscillometric BP monitoring devices have also been shown to provide an easier and more convenient way for patients to do their self-measurement compared to the standard mercury sphygmomanometer. Safety issues with the mercury sphygmomanometer have also made digital BP monitoring devices more practical and safer to use. However, the concern for the accuracy of these automated monitoring devices has been a valid source of concern, and there is increasing pressure for manufacturers to provide evidence of independent testing.

Methods

Adults, 18 years old and older, were recruited from general medical and specialist clinics. Ethical approval will be obtained from the local ethics committee, and all the subjects will be asked to sign a written consent form.

Participants were excluded if they had:

1. Atrial fibrillation and frequent extrasystoles; and
2. Weak Korotkoff sounds, which compromises accuracy of auscultation.

The devices, which were all standard production models, were provided by the manufacturer. A pre-use and after-use calibration of the devices were performed.

All observers were trained in mercury sphygmomanometry with the Philippine Society of Hypertension (PSH) module on BP certification. After the training, the observers were tested against each other and against an expert observer with 10 patients using the same Mercury sphygmomanometer with a dual

stethoscope. All BP measurements using the sphygmomanometer must be read to the nearest 2 mmHg. For the observers, to be considered qualified their readings must be within 4 mmHg of the readings of the expert observer.

For the actual in-use or field validation, demographic information (age, height, weight and gender) was recorded for each subject.

The participants were seated in a warm quiet room and allowed to rest for at least 10 minutes.

Measurements were done using a correctly sized cuff, with the arm circumference measured at the mid-point of the upper arm. The standard cuff was used if the arm circumference is not more than 31.5 cm, and a large cuff was used for arm circumferences greater than 31.5 up to 42 cm.

BP measurements were taken using the left arm, with the participant in the sitting position with the cuff at heart level. An initial reading was taken for familiarization purposes and to classify the patient according to BP level, but was not used in the analysis.

Subjects were classified to fulfill the recommended numbers (40 each) for the three ranges of both systolic and diastolic BP as follows:

Table 1.

	SBP (mmHg)	**DBP (mmHg)**
Low	90 – 129	40 – 79
Medium	130 – 160	80 – 100
High	161 – 180	101 - 130

The validation team consisted of three persons: two observers (Ob 1 & 2) trained in accurate BP measurement and a supervisor (Sp).

Nine sequential readings, at one-minute intervals, were as follows:

BPms: Entry BP, by Ob 1 and 2 with the mercury sphygmomanometer (MS)
BPod: Omron device (OD) recorded BP, by Sp
BP1: Ob 1 and 2 with MS
BP2: Sp with OD
BP3: Ob 1 and 2 with MS
BP4: Supervisor with OD
BP5: Observers 1 and 2 with MS
BP6: Supervisor with OD
BP7: Observers 1 and 2 with MS

Ob 1 & 2 used a properly calibrated MS using a dual stethoscope. Ob 1 & 2 wrote down their BP readings separately and beyond each other's view. The Sp wrote down the BP recorded by the OD, the LCD panel of which is covered so the other two observers cannot see the BP recorded. This strict blinding of the observers was observed and if there was an unintentional breach, the BP measurement was repeated. Sp made sure that there is agreement in the readings of Ob 1 & 2 such that the difference in each of the readings between the two is no more than 4 mmHg for systolic and diastolic BP values. Otherwise, the measurement was repeated.

Study Results:

Study Participants:

A total of 206 participants were recruited to fill in the specified BP categories for low, medium and high level for systolic and diastolic blood pressure measurements. However, as specified in the study protocol, the desired number for each level category is 40 participants. Random sampling was done for the low and medium level categories to select a total of 40 participants at each level. For the high category, the requirement of 40 participants was not met, hence all participants categorized in the high level were included. Mean age and BMI of the study participants per BP apparatus is shown below:

Table 2.

BP Model	SBP sample	DBP sample
HEM 7130		
Age	42.3 (39.29-45.37)	43.1 (40.16-46.14)
BMI	26.0 (24.90-27.06)	26.0 (24.85-27.25)
HEM 7120		
Age	43.6 (40.19-47.09)	42.6 (39.27-46.02)
BMI	24.8 (23.75-25.80)	25.2 (24.17-26.29)
HEM 7322		
Age	46.2 (43.19-49.25)	41.4 (38.43-44.34)
BMI	25.2 (24.38-26.05)	25.0 (24.08-25.97)

Proportion of male participants for the 3 validation groups ranged from 41.0% to 44.4% while female participants from 55.6% to 58.9%.

Data analysis and Results

A total of 3 device-observer differences for each participant were included in the analysis. Selection of paired device-observer is based on the highest number of pairs with at least 5 points difference between the device and observer (as shown below). Analysis were done separately for SBP and DBP.

Table 3.

HEM 7130	**SBP-obs1**	**SBP-obs2**	**DBP-obs1**	**DBP-obs2**
	SBP1-SBP2	SBP3-SBP4	DBP3-DBP4	DBP3-DBP4
	SBP3-SBP4	SBP5-SBP6	DBP4-DBP5	DBP4-DBP5
	SBP6-SBP7	SBP6-SBP7	DBP6=DBP7	DBP6-DBP7

HEM 7120	SBP-obs1	SBP-obs2	DBP-obs1	DBP-obs2
	SBP1-SBP2	SBP3-SBP4	DBP2-DBP3	DBP2-DBP3
	SBP3-SBP4	SBP5-SBP6	DBP4-DBP5	DBP4-DBP5
	SBP4-SBP5	SBP6-SBP7	DBP5-DBP6	DBP5-DBP6

HEM 7322	SBP-obs1	SBP-obs2	DBP-obs1	DBP-obs2
	SBP3-SBP4	SBP3-SBP4	DBP3-DBP4	DBP3-DBP4
	SBP4-SBP5	SBP5-SBP6	DBP4-DBP5	DBP4-DBP5
	SBP6-SBP7	SBP6-SBP7	DBP5-DBP6	DBP6-DBP7

The device-observer differences derived from the 3 pairs from each group were categorized into ≤ 5, ≤ 10 and ≤ 15 difference. The device was graded based on the British Hypertension Society grading criteria - A, B, C, D. The device is validated if it obtains grade A or B both for SBP and DBP readings. To obtain a particular grade all three percentages for SBP and DBP must be equal to or higher than the values required by the BHS. (Table 4)

To achieve the highest grade (A), 80% of the test device's readings must fall within 5 mm Hg of the standard MS readings, 90% must fall within 10 mm Hg, and 95% must fall within 15 mm Hg. Grade B must fall within 5 mm Hg in 50%, within 10 mm Hg in 75%, and within 15 mm Hg in 90%.

Table 4. Grading criteria used by the British Hypertension Society

	Absolute difference between standard and test device (%)		
Grade	**5**	**10**	**15**
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

With all levels of BP combined, HEM 7130 and 7322 models achieved an overall satisfactory A/B while a B/B grading was achieved by HEM 7120.

For the HEM 7130 model, systolic BP readings differed within 5 mmHg in 59.9 %, within 10 mmHg in 81.4%, and within 15 mmHg in 92.1% achieving Grade B criteria. Diastolic BP readings differed within 5 mmHg in 63.6 %, within 10 mmHg in 87.5%, and within 15 mmHg in 94.7% achieving Grade A criteria.

For the HEM 7120 model, systolic BP readings differed within 5 mmHg in 58.4 %, within 10 mmHg in 80.2%, and within 15 mmHg in 91.1% achieving Grade A criteria. Diastolic BP readings differed within 5 mmHg in 61.2%, within 10 mmHg in 84%, and within 15 mmHg in 93% achieving Grade B criteria.

For the HEM 7322 model, systolic BP readings differed within 5 mmHg in 65.4 %, within 10 mmHg in 86%, and within 15 mmHg in 94.3% achieving Grade A criteria. Diastolic BP readings differed within 5 mmHg in 65.2%, within 10 mmHg in 89.2%, and within 15 mmHg in 95.8% achieving Grade A criteria.

Table 5. Overall BHS Grading of HEM 7130, 7120 and HEM 7322 Omron device models

	Absolute difference between MS standard and Omron device (%)			
Grade	**5**	**10**	**15**	**Grade**
HEM 7130 model				
Systolic BP readings	59.9	81.4	92.1	B
Diastolic BP readings	63.6	87.5	94.7	A
HEM 7120 Model				
Systolic BP readings	58.4	80.2	91.1	B
Diastolic BP readings	61.2	84	93	B
HEM 7322 Model				
Systolic BP readings	65.4	86	94.3	B
Diastolic BP readings	65.2	89.2	95.8	A

Each model was also graded based on the level of BP, classified as low, medium and high. It was noted that for the HEM 7130 model, Grade A was given to those with low and medium SBP and DBP readings while Grade A/B was given to those with high SBP and DBP respectively. For the HEM 7120 model, Grade B was given for all BP levels while for HEM 7322 model, Grade A was given to those with low and medium SBP and DBP, high DBP while a Grade B was given to those with a high SBP.

Table 6. BHS Grading Based on Level of Blood Pressure				
	5	**10**	**15**	**Grade**
HEM 7130 model				
Low SBP (n=120)	73.3	94.2	98.3	A
Low DBP (n=120)	71.7	90	94.2	A
Medium SBP (n=120)	77.3	93.3	96.6	A
Medium DBP (n=120)	66.4	89.9	95.8	A
High SBP (n=111)	63.6	90.9	95.4	A
High DBP (n=101)	56.4	83.2	95	B
HEM 7120 model				
Low SBP (n=120)	60.3	82.5	92.1	B
Low DBP (n=120)	62.2	84.3	93.6	B
Medium SBP (n=120)	56.5	77.8	90.2	B
Medium DBP (n=120)	57.0	80.8	91	B
High SBP (n=75)	58.4	80.2	91.1	B
High DBP (n=75)	61.2	84	93	B
HEM 7322 model				
Low SBP (n=120)	67.5	91.7	97.5	A
Low DBP (n=120)	67.5	88.3	95	A
Medium SBP (n=120)	72.5	89.2	95.1	A
Medium SBP (n=120)	64.5	86	96.7	A
High SBP (n=102)	60.8	86.3	92.2	B
High DBP (n=81)	67.1	94.9	97.5	A

Bland-Altman plots were constructed to describe the agreement between two blood pressure measurements taken using the test device (Omron BP apparatus) and the conventional mercurial sphygmomanometer. Limits of agreement (LOA) were constructed with its 95% confidence interval, to quantify the agreement between the 2 quantitative measurements. Bland & Altman recommended that 95% of the data points should lie within the 95% confidence interval of the limits of agreement. Based on the proportion of paired measurements outside the limits of agreement, HEM 7130 had the lowest at 4.9% for SBP and 5.0% for DBP. HEM 7322 had 5.8% for SBP and 5.0% for DBP while HEM 7120 attained the highest proportion of paired measurements outside the limits of agreement at 7.0% for SBP and 6.7% for DBP.

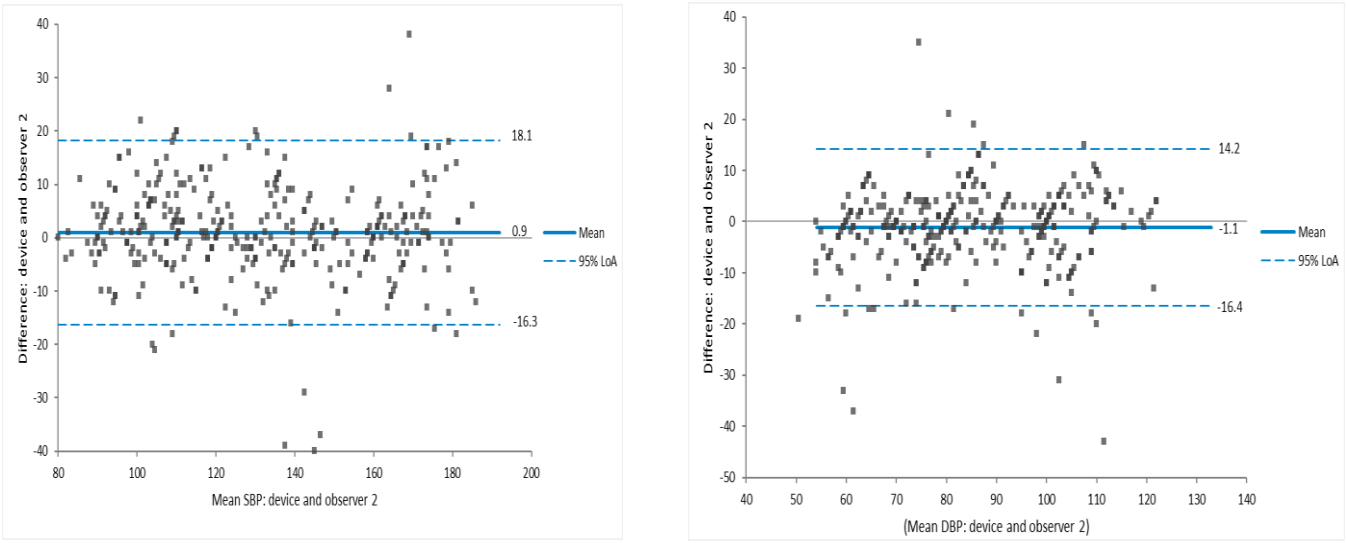

Figure 1. Bland-Altman plots for SBP and DBP using HEM 7130

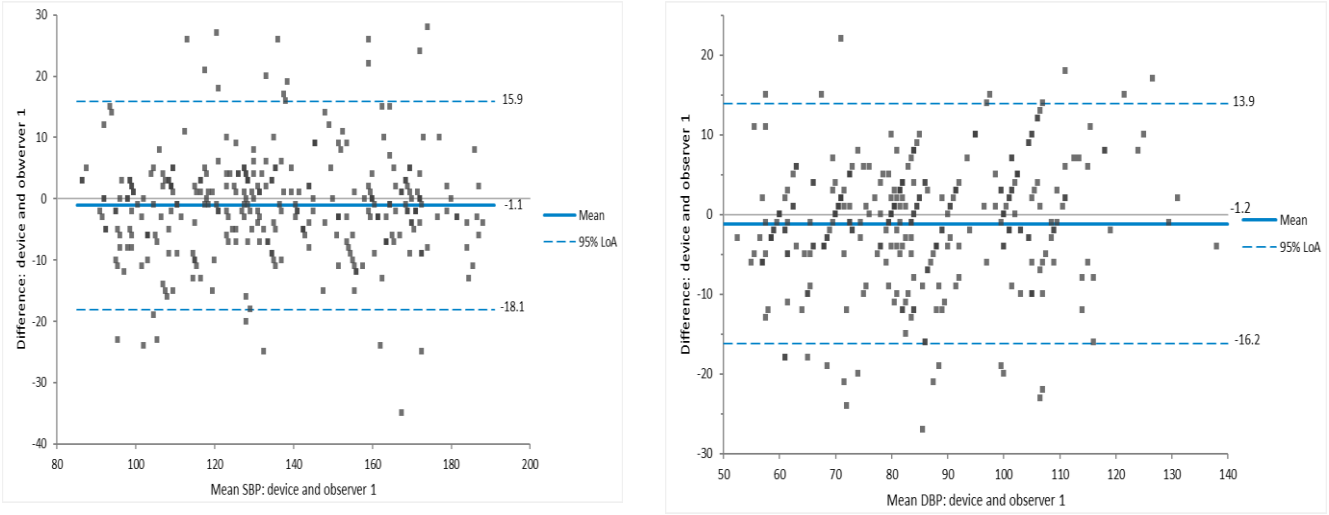

Figure 2. Bland-Altman plots for SBP and DBP using HEM 7120

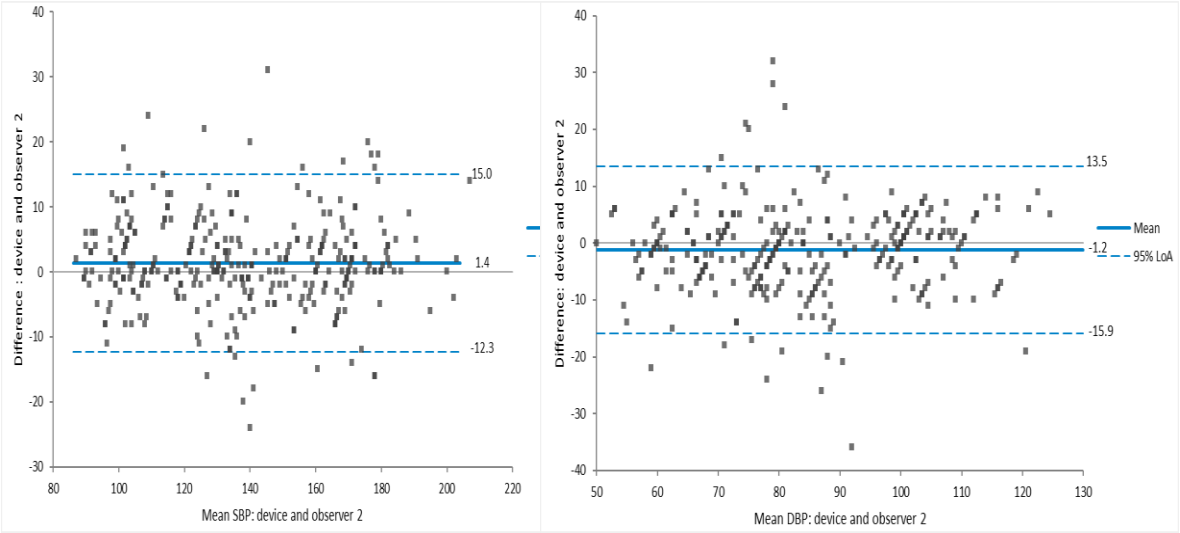

Figure 3. Bland-Altman plots for SBP and DBP using HEM 7322

Conclusion

In the adult population included in this validation trial, the HEM 7130 and HEM 7322 Omron device attained the British Hypertension Society Grade A/B; while the HEM 7120 model attained a BHS Grade B/B. Separate evaluation of the accuracy of the three Omron models based on low, medium and high BP levels also showed satisfactory results. Furthermore HEM 7130 and HEM 7322, attained the highest recommended percentage of paired measurements within the limits of agreement.

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