Validation of the OMRON® 705 IT blood pressure measuring device according to the International Protocol of the European Society of Hypertension

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The aim of the present study was to validate the OMRON® 705IT device according to the International Protocol (1). This new validation protocol published by the European Society of Hypertension can be applicable to the majority of blood pressure (BP) measuring devices on the market. It is a simplified protocol that does not sacrifice the integrity of the earlier Association for the Advancement of Medical Instrumentation (AAMI) and British Hypertension Society (BHS) protocols.

1. Methods

The OMRON® 705IT device was provided and randomly selected by the manufacturer. It is an automatic device for self-measurement of blood pressure using the oscillometric method. Three sizes of cuffs, small, standard (medium) and large were used for the evaluation. The small cuff is adapted to an arm circumference less than 22 cm, the standard cuff is adapted to an arm circumference of 22-32 cm and the large cuff size is used if the arm circumference is more than 32 cm.

Cuff Size	Small	Medium (standard)	Large
Arm circumference (cm)	17-21	22-32	33-38

The validation team consisted of three persons: two observers trained in accurate BP measurement and a supervisor. The 2 observers have completed a training session according to the training program of the French Society of Hypertension. The agreement between the 2 observers was checked all over the evaluation period by the supervisor to make sure that the difference between the two is no more than 4 mmHg for systolic and diastolic BP values. Otherwise, the measurement should be repeated.

Two standard mercury sphygmomanometers, the components of which have been carefully checked before the study, were used by the 2 observers as a reference standard. Measurements were taken to the nearest 2 mmHg simultaneously by the 2 observers.

All measurements were made on the left arm supported at heart level.
The circumference of the arm was measured to ensure that the bladder being used is adequate for the subject.

At all nine sequential same-arm measurements using the test instrument and the standard mercury sphygmomanometer were recorded as follows:

BPA	Entry BP, observers 1 and 2 each with the mercury standard
BPB	Device detection BP, supervisor
BP1	Observers 1 and 2 with mercury standard
BP2	Supervisor with the test instrument
BP3	Observers 1 and 2 with mercury standard
BP4	Supervisor with the test instrument
BP5	Observers 1 and 2 with mercury standard

BP6	Supervisor with the test instrument
BP7	Observers 1 and 2 with mercury standard

Inclusions were ongoing until 15 subjects, fulfilling the criteria of the international guidelines, have been included. The device was then evaluated (first phase of the international protocol). Then inclusion were carried out until 33 subjects at all, fulfilling the criteria of the international guidelines, have been included. The device was then evaluated (second phase of the international protocol).

Recruitment of subjects was done in order to fulfill the recommended ranges of BP. There is three ranges for SBP and three for DBP:

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

For the primary phase, five of the 15 subjects should have a SBP in each of the ranges. Similarly, five of the 15 subjects should have a DBP in each of the ranges. For the secondary phase, 11 of the 33 subjects (including the first 15 subjects) should have SBP and DBP in each of the ranges.

For each subject, the device measurements BP2, BP4 and BP6 were first compared to observer measurements BP1, BP3 and BP5 respectively and then to observer measurements BP3, BP5 and BP7 respectively. Comparisons more favourable to the device were used. BP1, BP3, BP5 and BP7 are the means of the 2 observer measurements.

2. Results :

For all measurements, the difference between the 2 observers was 0.8 ± 1.5 mmHg and 0.1 ± 1.4 mmHg for systolic and diastolic BP respectively.

Thirty three subjects were selected according to the international protocol recommendations. No patient had atrial fibrillation or other sustained arrhythmia.

Table 1: characteristics of the subjects:

Number of subjects	33
Age (years)	54 ± 13
Arm circumference (cm)	30 ± 4
Gender (M/F)	18/15

Mean ± SD

No subject had an arm circumference below 22 cm. The large cuff was used in 3 subjects with an arm circumference > 32 cm.

Mean BP for the classification of the subjects (BPA) was 141 ± 26 mmHg and 88 ± 16 mmHg for the SBP and the DBP respectively.

Table 2: Number of comparisons falling within the 5, 10 and 15 mmHg error bands, Result of phase 1:

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation
Required	One of	25	35	40	
Achieved	SBP	38	43	44	Continue
	DBP	31	42	45	Continue

Table 3: Number of comparisons falling within the 5, 10 and 15 mmHg error bands, mean difference (mmHg) and standard deviation (mmHg), Result of phase 2.1:

Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	83	96	98	Pass	-1.3	5.6
	DBP	74	94	97	Pass	-0.4	4.8

Table 4: Number of comparisons per subject falling within 5 mmHg, Result of phase 2.2:

Phase 2.2		2/3 ≤5 mmHg	0/3 ≤5 mmHg	Recommendation
Required		≥ 22	≤ 3	
Achieved	SBP	31	0	Pass
	DBP	26	3	Pass

3. Discussion

The objective of the study was to assess the accuracy of the OMRON® 705IT device according to the international validation protocol of the European Society of Hypertension (1).

The International Protocol has been published by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension aiming to simplify the 2 main available guidelines, BHS and AAMI, without loosing their merits.

The main advantages of the International protocol is that it requires less subjects, 33 instead of 85, simplifying the procedure, without affecting the accuracy of the validation.

Our experience has shown that recruiting subjects at the extremes of high and low BP, is difficult to obtain, mainly for high diastolic (DBP 101-130) and low systolic (SBP 90-129) groups. The International Protocol recommends for facilitating this issue, that recruitment should begin by targeting subjects likely to have pressures in the low-systolic and high-diastolic ranges, then

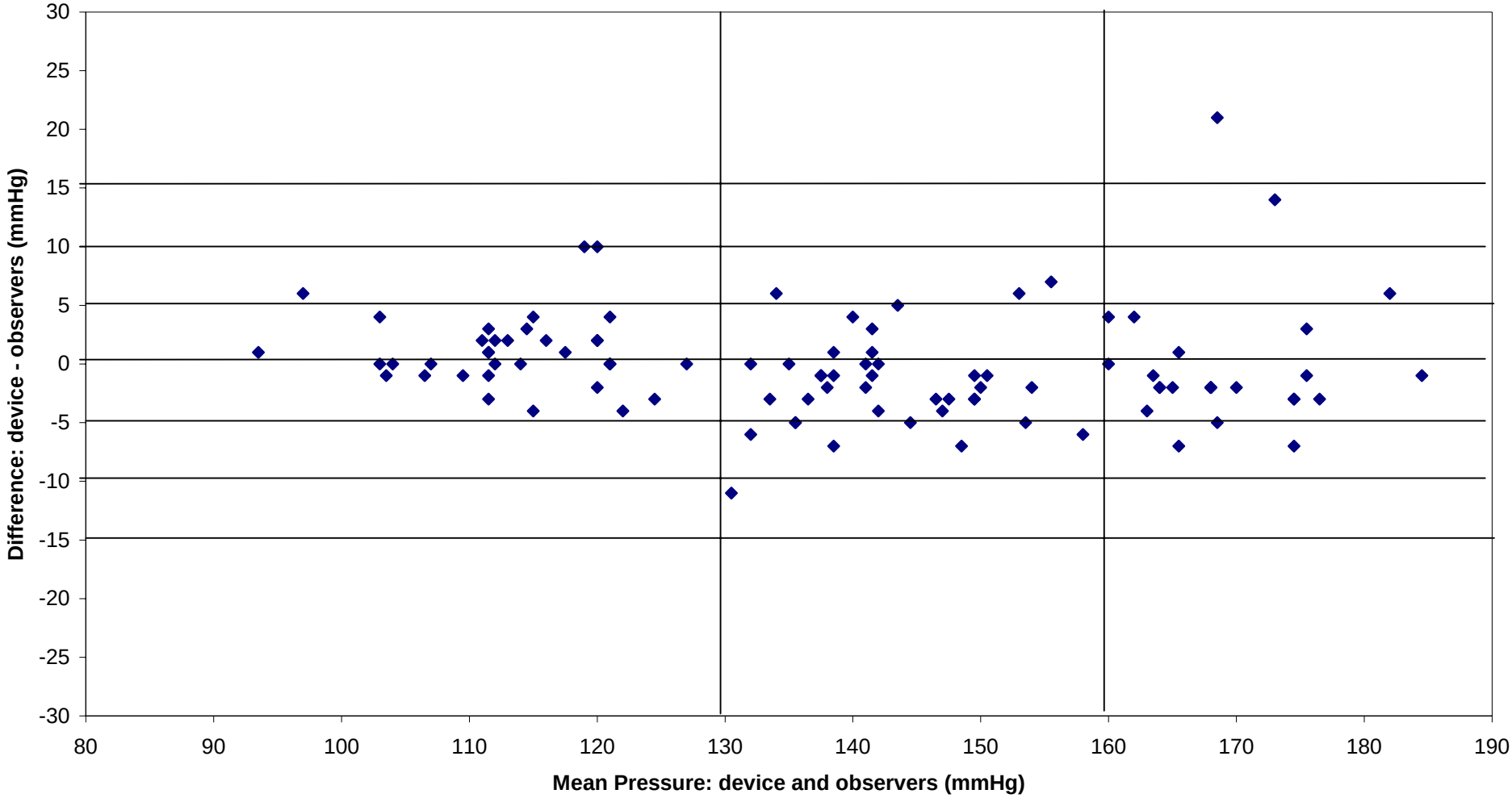
progressing to complete the high systolic and low-diastolic ranges so that it will be easy to complete recruitment with the remaining medium ranges.

4. Conclusion

The OMRON® 705IT device fulfils the recommendations of the international validation protocol.

(1) O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, Mengden T, Imai Y, Waeber B, Palatini P. 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**:3-17.

Plot of SBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)



Plot of DBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)