Validation of the FORA P30 Plus Upper Arm Blood Pressure Monitor, for Clinic Use and Self/Home Measurement, According to the European Society of Hypertension International Protocol Revision 2010

Keywords: Validation, blood pressure, device, automatic, measurement

Device Detail

Brand: FORA Model P30 Plus
Manufacturer: ForaCare Suisse AG
Location: Upper arm
Method: Oscillometry
Purpose: Clinical and self/home measurement
Operation: Automatic
Arm cuffs: Wide Ranged cuff from 24 cm to 43 cm
Other features: P30 Plus is particularly suitable for clinical and home measurement for the purpose of automatic applications. Moreover, the P30 Plus offers an automated simple average one button operation (AVG technology). Furthermore, it offers the function of detection Irregular Rapid Beat with our IRB technology. A built in Auscultatory function allows for use with elderly and obese patients and those with arrhythmia or diabetes.

Methodology

Familiarization

Several pre-test were performed in house before clinical test started. No problems were encountered.

Recruitment

Subjects were recruited from those attending to medical services in local clinics. Some subjects participated immediately after clinic, and others made appointments for blood pressure measuring specially. Subjects with BP in the normal and low range were easy to collect. Some difficulty was occurred during recruiting of subjects with DBP in the high range. To overcome this problem, clinic staffs assisted in screening patients from regular measurement in clinic and recruiting subjects with blood pressure in high range. Patients on antihypertensive treatment or any other medication would not be disturbed by this test.

Screen and recruitment			Recruitment ranges			
Total screened	63			mmHg	All	On Rx
Total excluded	30			<90	0	
Range completed	0		Low	90-129	11	1
Range adjustment	15	SBP	Medium	130-160	11	6
Arrhythmias	5		High	161-180	8	5
Device failure	0			>180	3	
Poor quality sounds	9					
Cuff size unavailable	1			<40	0	
Observer disagreement	0		Low	40-79	11	2
Distribution	0	DBP	Medium	80-100	11	6
Other reasons	0		High	101-130	11	6
Total recruited	33			>130	0	

Procedure

The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely. Overseen by an independent supervisor, measurements were recorded by two observers blinded from both each other's readings and from the device readings [1].

The sequential same arm measurements were performed. Two observers took blood pressure measurement with a mercury sphygmomanometer. Only a discrepancy between the two observers smaller than 4 mmHg was accepted [1].

Data are mean differences plots and they should be exactly as shown in the validation report. According to the European Society of Hypertension International Protocol Revision 2010 recommendation, the x-axes of these plots represents blood pressures in the systolic range 80mmHg – 190mmHg (see result: Figure 1) and the diastolic range 30mmHg – 140mmHg (see result: Figure 2). The y-axes represent errors from –30mmHg to +30mmHg. Horizontal reference lines are drawn at 5mmHg intervals from +15mmHg to –5mmHg. The mean of each device pressure and its corresponding observer pressure is plotted against their difference with a point. Differences greater than 30mmHg are plotted at 30mmHg. Differences less than –30mmHg are plotted at – 30 mmHg. The same scales should be used for both SBP and DBP plots.

The x-axes of those plots needed to be increased in order to include all measurements (see result: Figure 3).

Where points are superimposed, these should be indicated either by proportionately larger points or by different symbols.

Result

Subject details		
Sex		
Male : Female	16 : 17	
Age (years)		
Range (Low : High)	25 : 81	
Mean (SD)	51.6 (17.6)	
Arm circumference (cm)		
Range (Low : High)	24 : 38	
Mean (SD)	28.2 (3.7)	
Cuff for test device		
Wide Ranged	33	(24-43cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	91:206	43 : 121
Mean (SD)	144.6 (30.1)	84.5 (20.6)

Observer measurements in each recruitment range

SBP (mmHg)		DBP (mmHg)	
Overall range (Low : High)	84 : 204	Overall range (Low : High)	45 : 121
Low (<130)	31	Low (<80)	35
Medium (130–160)	41	Medium (80–100)	37
High (>160)	27	High (>100)	27
Maximum difference	14	Maximum difference	10

Observer differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	0.4 (1.9)	0.0 (1.8)	0

Validation results

Part 1	≦5mmHg	≦10mmHg	≦15mmHg	Grade1	Mean (mmHg)	SD (mmHg)
Pass Requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	83	99	99	Pass	-1.1	3.3
DBP	80	99	99	Pass	-0.4	3.7

Part 2	2/3 ≦5mmHg	0/3 ≦5mmHg	Grade 2	Grade 3
Pass Requirements	≧24	≦3		
Achieved				
SBP	28	0	Pass	Pass
DBP	28	2	Pass	Pass

Part 3	Result
	Pass

Plots

Figure 1 Plot of the systolic observer – device blood pressure differences in the systolic range 80mmHg – 190mmHg

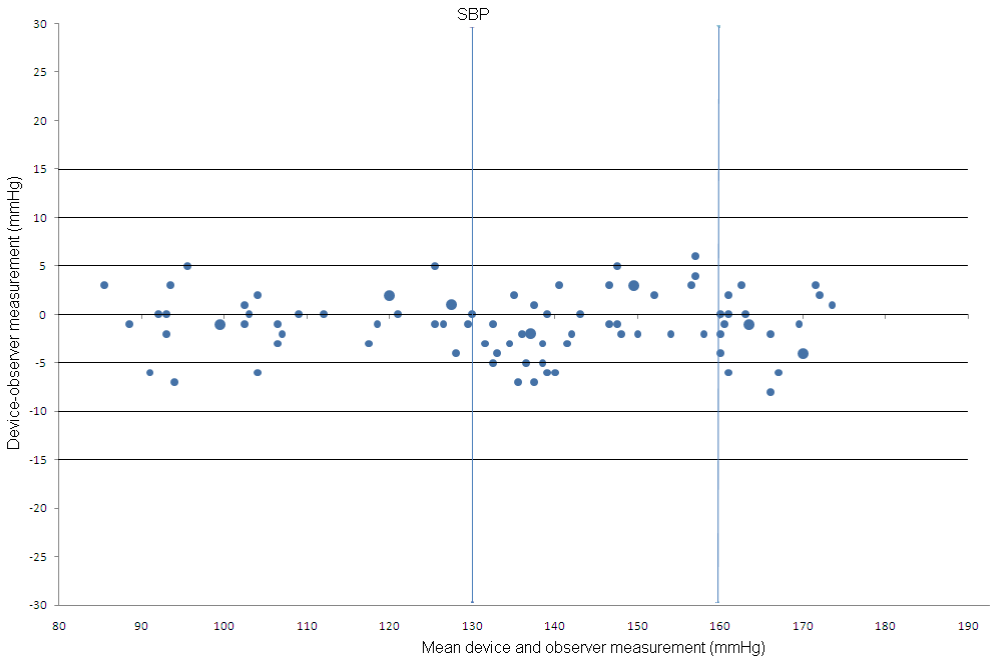


Figure 2 Plot of the diastolic observer – device blood pressure differences in the diastolic range 30mmHg – 140mmHg

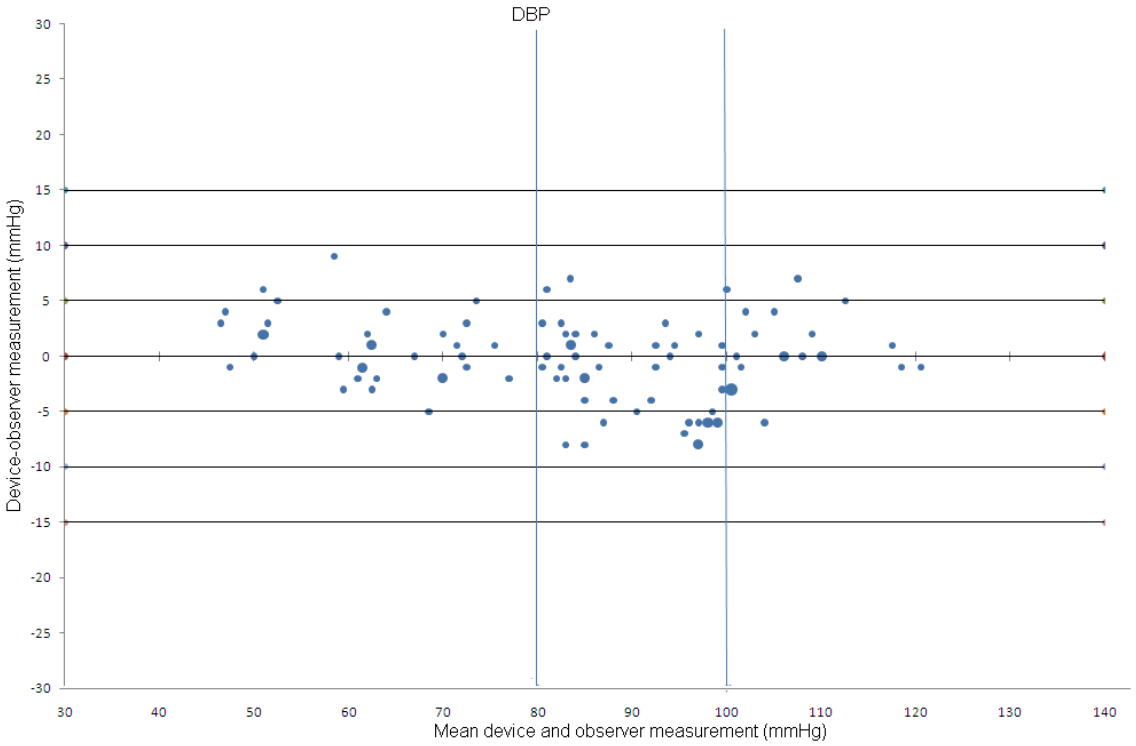
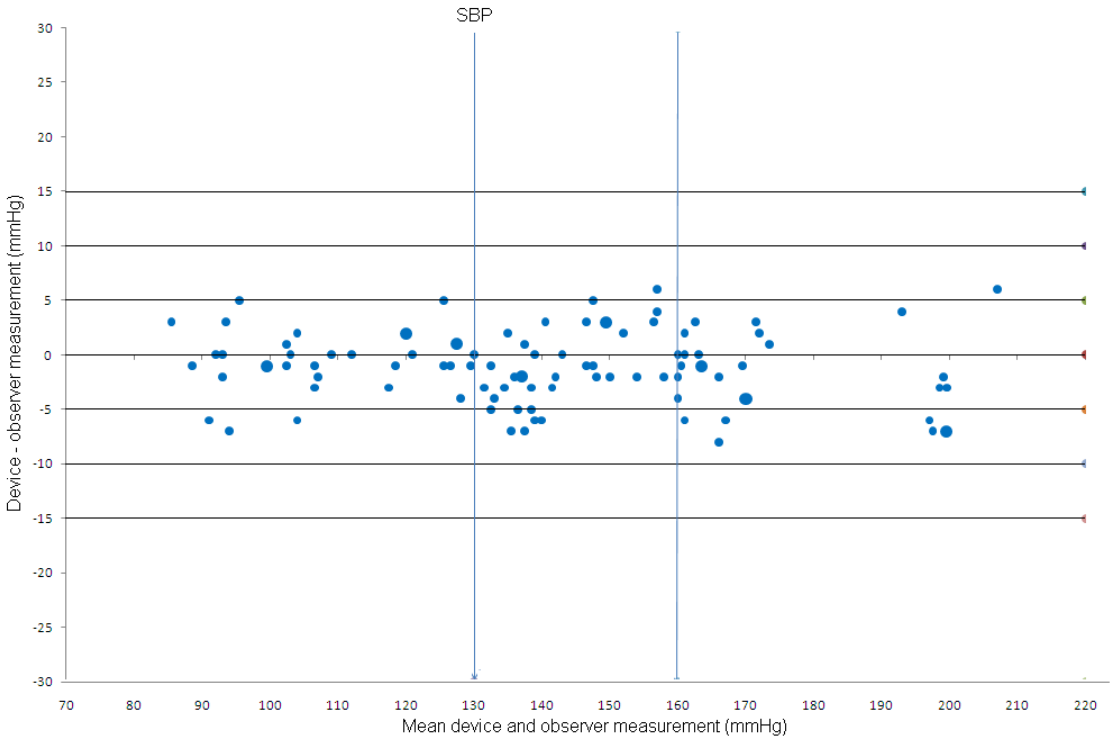


Figure 3 Plot of the systolic observer – device blood pressure differences in the systolic range 70mmHg – 210mmHg



Discussion

Recruitment of subjects with high DBP range was difficult and accounted more screened subjects. The overall distribution shown in the DBP plot reflected most measurements were below 115 mmHg. However, the distribution conditions from 45mmHg to 121 mmHg were fulfilled the requirement of EHS protocol.

The plot of systolic blood pressure shows 90 points including 76 single points and 7 double superimposed points in the range 80 to 190 mmHg according to the European Society of Hypertension International Protocol Revision 2010 recommendation (see Figure 1), with 7 single points and a double superimposed point in the range 190 to 210 mmHg.

At the beginning, the x-axes of the plots needed to be increased in order to include all measurements. Therefore, the SBP axis will need to be extended to 210mmHg. The plot of systolic blood pressure shows 99 points including 83 single points and 8 double superimposed points in the range 70 to 210 mmHg (see Figure 3). This can be followed by the European Society of Hypertension International Protocol Revision 2010 recommendation “It is imperative that all data are completed so that the report contains all of the information required.

The plot of diastolic blood pressure shows 99 points including 74 single points, 22 double points superimposed and 3 points superimposed in the range 30 to 140 mmHg according to the European Society of Hypertension International Protocol Revision 2010 recommendation (see Figure 2).

Conclusion

The device has passed the protocol criteria of the European Society of Hypertension International Protocol Revision 2010, and is recommended for clinical and home use.

References

1. O’Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the Validation of Blood Pressure Measuring Devices In Adults. *Blood Press Monit* 2010;15:23–38.