Validation of the Spacelabs 90227 OnTrak blood pressure measurement device for clinical use according to the European Society of Hypertension International Protocol revision 2010

De Greeff A, Shennan AH.

Women's Health Academic Centre, King's Health Partners, King's College London, 10th Floor, North Wing, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH, UNITED KINGDOM

Device details

Model: 90227 OnTrak

Brand	Spacelabs
Manufacturer	Spacelabs Healthcare
Location	Upper arm
Method	Oscillometric
Purpose	Clinic use
Operation	Automatic
Arm Cuffs	Child cuff (12-20cm) Small Adult Cuff (17-26cm) Standard Adult Cuff (24-32cm) Large Cuff (32-42cm) Extra Large Cuff (38-50cm) (Arm circumference indicated in brackets)
Other features	Ambulatory blood pressure measurement device.

Methodology

Familiarization

Trained study staff performed test measurements before recruiting any subjects. No difficulties were experienced.

Recruitment

Adults above 25 years of age were recruited from outpatient clinics at Kimberley Hospital Complex (Kimberley, South Africa). All patients had a doctor's appointment and none attended for validation purposes specifically/only.

Screening and recruitment details

Screening and recruitment					Recruitment Ranges		
Total Screened		35			mmHg	All	On Rx
Total excluded		2			<90	0	0
Ranges Complete	0			Low	90-129	12	1
Range Adjustment	1		SBP	Medium	130-160	10	5
Arrhythmias	0			High	161-180	7	6
Device failure	0				>180	4	4
Poor quality sound	0						
Cuff size unavailable	0				<40	0	0
Observer disagreement	0			Low	40-79	11	0
Distribution	1		DBP	Medium	80-100	12	8
Other reasons	0			High	101-130	9	7
Total recruited		33			>130	1	1

Procedure

Observers followed the European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults precisely. An independent supervisor oversaw the study and two observers, who were blinded from both each other's readings and from the device readings, recorded blood pressure measurements. No problems were experienced with the device.

Results

Subject details

Sex		
Male : Female	10 : 23	
Age (years)		
Range (Low : High)	25 : 74	
Mean (SD)	39.4 (13.8)	
Arm circumference (cm)		
Range (Low : High)	19 : 38	
Mean (SD)	28.3 (5.0)	
Cuff for test device		
Small Adult	9	(17-26cm)
Standard	17	(24-32cm)
Large	7	(32-42cm)
	SBP	**DBP**
Recruitment BP (mmHg)		
Range (Low : High)	102 : 206	45 : 139
Mean (SD)	146.7 (29.3)	88.7 (21.3)

Observer measurements in each recruitment range

SBP (mmHg)		**DBP (mmHg)**	
Overall range (Low : High)	94 : 208	Overall range (Low : High)	46 : 135
Low (<130)	39	Low (<80)	38
Medium (130-160)	34	Medium (80-100)	39
High (>160)	25	High (>100)	22
Maximum difference	14	Maximum difference	17

Observer differences

	SBP (mmHg)	**DBP (mmHg)**	**Repeated measurements**
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	-0.2 (1.9)	-0.5 (2.1)	33

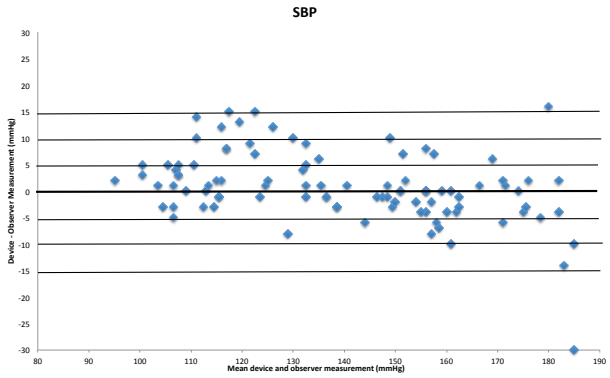
Validation results

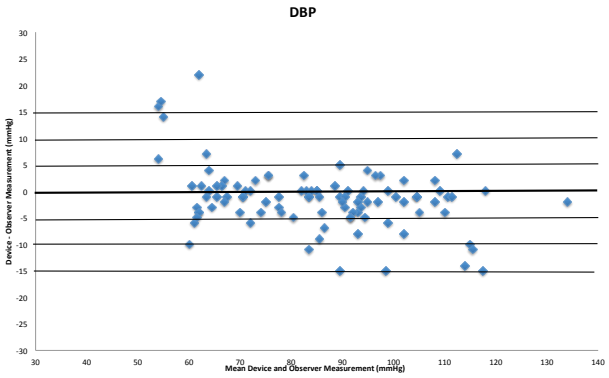
Part 1	**≤5mmHg**	**≤10mmHg**	**≤15mmHg**	**Grade 1**	**Mean (mmHg)**	**SD (mmHg)**
Pass requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	69	90	97	Pass	0.9	6.8
DBP	77	89	96	Pass	-1.4	5.9

Part 2	**2/3 ≤5mmHg**	**0/3 ≤5mmHg**	**Grade 2**	**Grade 3**
Pass requirements	≥24	≤3		
Achieved				
SBP	24	3	Pass	Pass
DBP	26	3	Pass	Pass

Part 3	Result
	PASS

Plots





Discussion

No specific problems were encountered during validation and distribution conditions were fulfilled. Recruitment of subjects in high pressure ranges were more difficult and time consuming than those in medium or low categories, which is commonly reported in validation studies.

Conclusion The Spacelabs 90227 OnTrak device can be recommended for clinical use in an adult population.

Acknowledgement and Conflict of Interest

Spacelabs Healthcare funded the study and provided two test devices for evaluation in the study. None of the authors have any association with Spacelabs Healthcare. The study was performed as part of a validation service that is universally offered and administered via Accuracy Assessed Medical Devices CC, but with academic independence.

Reference

O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R et al.; on behalf of the Working Group on Blood Pressure Monitoring of the European Socieyty 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**:23-28.

A de Greeff	22 July 2013
Signature & Initials	**Date**