Validation of the Nissei DSK-1031 upper arm oscillometric blood pressure monitor intended for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010

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Abstract

The Nissei DSK-1031, an upper arm oscillometric blood pressure monitor intended for clinical use and self measurement, was validated, in a general population, according to the European Society of Hypertension International Protocol revision 2010. The protocol requirements were followed precisely. The device passed all of the requirements and, fulfilling the standards of the protocol, is recommended for clinical use.

Device Details

Brand	Nissei
Model	DSK-1031
Manufacturer	Japan Precision Instruments Inc.
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement, Self/ Home Measurement
Operation	Fully Automatic
Arm Cuff	22.0 cm to 42.0 cm
Other Features	Memory function for two persons; indication of pulse pressure on LCD as well as graphical indication of blood pressure range.

Methodology

Familiarisation

Test measurements were performed by trained study staff before recruiting any subjects. No difficulties were experienced.

Recruitment

Adults above the age of 25 years 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		Low	< 90	0	2
Ranges Complete	0				90 - 129	11	
Ranges Adjustment	0		SBP	Medium	130 - 160	10	7
Arrhythmias	0			High	161 - 180	8	12
Device Failure	0				> 180	4	
Poor Quality Sounds	0						
Cuff Size Unavailable	0			Low	< 40	0	1
Observer Disagreement	0				40 - 79	11	
Distribution	0		DBP	Medium	80 - 100	10	8
Other Reasons	2			High	101 - 130	12	12
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.[1] Overseen by an independent supervisor, measurements were recorded by two observers blinded from both each other's readings and from the device readings.

Results

Subject Details

Sex		
Male : Female	17 : 16	
Age (years)		
Range (Low : High)	26 : 76	
Mean (SD)	50.7 (13.5)	
Arm Circumference (cm)		
Range (Low : High)	22.0 : 38.3	
Mean (SD)	28.3 (3.9)	
Cuff for test device		
Other	33	(22.0 - 42.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	97 : 209	50 : 130
Mean (SD)	149.5 (29.1)	91.4 (20.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	92 : 200	Overall Range (Low : High)	50 : 122
Low (< 130)	33	Low (< 80)	33
Medium (130 – 160)	33	Medium (80 – 100)	33
High (> 160)	33	High (> 100)	33
Maximum Difference	0	Maximum Difference	0

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	0.1 (1.6)	0.1 (1.8)	0

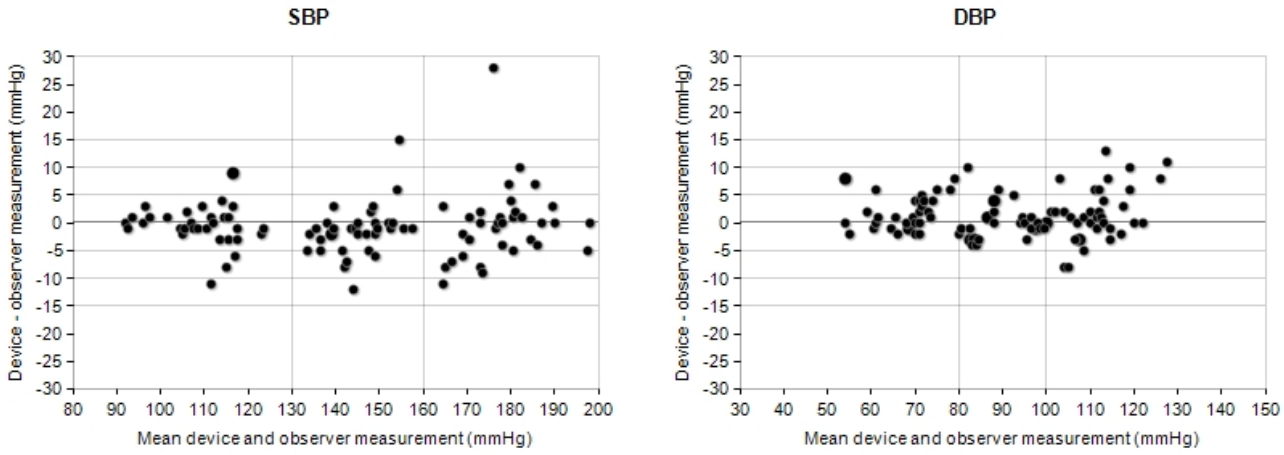
Validation Results

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass Requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	78	94	98	Pass	-0.6	5.3
DBP	80	97	99	Pass	1.3	3.9

Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Grade 2	Grade 3
Pass Requirements	≥ 24	≤ 3		
Achieved				
SBP	28	1	Pass	Pass
DBP	27	2	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. The Nissei DSK-1031 device can be recommended for clinical and home use in an adult population.

This is the first validation of the Nissei DSK-1031 according to a recognised validation protocol.

Conclusion

As the device has reached the required standards, it is recommended for clinical and personal use in a general population.

Acknowledgements and Conflict of Interest

The study was funded by Japan Precision Instruments and three test devices were provided for evaluation in the study. None of the authors has any association with Japan Precision Instruments or has received personal benefit from Japan Precision Instruments.

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.