VALIDATION REPORT

of the Spacelabs 90227 OnTrak device according to
the British Hypertension Society Protocol

- 30 AUGUST 2013 -

Report by: Annemarie de Greeff • **email:** annemarie.de_greeff@kcl.ac.uk
Principal Investigator: Prof Andrew Shennan • **email:** andrew.shennan@kcl.ac.uk

+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com

Objective

To assess the accuracy of the Spacelabs 90227 OnTrak device compared to mercury sphygmomanometry in 85 adult subjects with a wide range of blood pressures.

Study Procedure

Test device

Spacelabs 90227 OnTrak: An automated, oscillometric, ambulatory upper arm device. The device is suitable for clinical use and has five cuff sizes available: Child (12-20cm); Small Adult (17-26cm); Standard Adult (24-32cm); Large (32-42cm) and Extra Large (38-50cm). The manufacturer supplied 2 test devices.

Reference devices

Two calibrated mercury sphygmomanometers.

Test dates

The study was completed in 10 weeks (11/06/2013 to 16/08/2013).

Study sites

Patients were recruited at Kimberley Hospital Complex (South Africa).

Study population

Subjects were recruited to fulfill the protocol requirements (Table 1). All subjects in the study had an upper arm circumference within the permitted range of the cuffs. Demographic information of the study population is shown in Table 2. Any subject with a cardiac arrhythmia or unclear Korotkoff sounds was excluded.

+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com
www.validateglobal.com

Table 1. Protocol Requirements for Blood Pressure * Minimum protocol requirements

Systolic BP	n*	recruited	Diastolic BP	n*	recruited
<100 mmHg	8	8	<60 mmHg	8	8
100-129 mmHg	20	23	60-79 mmHg	20	22
130-160 mmHg	20	20	80-100 mmHg	20	25
161-180 mmHg	20	20	101-110 mmHg	20	20
>180 mmHg	8	14	>110 mmHg	8	10

Table 2. Demographics of study population

	Mean ± SD [range]
Age (years)	42 ± 16 [20-83]
Arm circumference (cm)	28 ± 5 [18-38]
Systolic Blood Pressure	148 ± 35 [84-244]
Diastolic Blood Pressure	89 ± 22 [44-144]
Small : Standard : Large : Extra Large Cuff use	25 : 44 : 16 : 0

+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com
www.validateglobal.com

Study design

All subjects were required to give written informed consent as specified by the local research ethics committee. Subjects were seated and allowed to rest for at least 5-10 minutes before commencing the measurements. Arm circumference was measured at the approximate midpoint of the upper arm to determine the correct size cuff to be used. The arm was supported on the desk or armrest of the chair to ensure that it was in line with the patient's approximate heart level. The patient was advised not to talk or move during measurements, but to notify the observers if any discomfort was experienced.

Three trained observers took nine sequential same arm blood pressure measurements from each subject, alternating between mercury sphygmomanometry and the device. Blood pressure values obtained by the observers were documented on separate sheets. Observers obtaining auscultatory readings were blinded to each other's readings and to the device readings during the procedure. A gap of 30s to 1min was allowed between readings to reduce venous congestion and to limit variability in blood pressure.

Analysis

Data was entered on Excel (Microsoft Office) and analysed according to the guidelines of the British Hypertension Society protocol. The first reading of observer 1 was used to classify the subject according to the systolic (SBP) and diastolic (DBP) pressure range requirements and not used in the analysis. The first device reading was not used in analysis either.

The subsequent three device readings where then alternately compared to each observer's manual/mercury sphygmomanometer reading 'before' and 'after' that device reading. This resulted in two sets of differences (one 'before' and one 'after') for each observer and for SBP and DBP respectively. The best set of differences for each observer was selected for final analysis and defined as the set with the lowest individual absolute values.

+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com
www.validateglobal.com

To determine whether the device passed the protocol, the percentage of differences in each of three categories specified by the BHS protocol (≤5, ≤10 and ≤15 mmHg) was calculated and compared to the protocol requirements. The device had to achieve a minimum of a B grade for both SBP and DBP to be recommended for clinical use (Table 3).

In addition the device was required to conform to the criteria of the Association for the Advancement of Medical Instrumentation (AAMI) by having a mean difference (standard deviation) of ≤5 (8) mmHg. Mean-against-difference plots[2] were used to graphically illustrate the device accuracy by plotting the mean pressure of the better observer and the test device against their difference.

Table 3. Grading criteria of the British Hypertension Society Protocol

Grade	≤ 5mmHg (%)	≤ 10mmHg (%)	≤ 15mmHg (%)
Cumulative percentage of readings (%)			
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com
www.validateglobal.com

Results

The first 85 subjects recruited to fulfill the BHS protocol criteria were selected for analysis. Demographic data of the study group is shown in Table 2.

The Spacelabs 90227 OnTrak device achieved an overall A grade for both systolic and diastolic pressures (Table 4). The device maintained an A/A grading for the low and medium pressure ranges and achieved a B/A grading in the high pressure range (Table 5). The mean difference ± standard deviation fulfilled the AAMI standard for both systolic 1.7 ± 7.7 mmHg and diastolic 1.6 ± 7.8 mmHg pressure. Figures 1 and 2 show the mean-against-difference plots of the data.

Observer accuracy was excellent with 100% of systolic differences being within 5 mmHg. For diastolic pressures, 99.7% of observer readings were within 5mmHg and 100% within 10mmHg.

Conclusion

The Spacelabs 90227 OnTrak device fulfills the requirements of the British Hypertension Society protocol. It achieves an overall A grade for both systolic and diastolic pressures. The Spacelabs 90227 OnTrak device can be recommended for clinical use in an adult population.

A de Greeff — **Initials & Signature**

30 August 2013 — **Date**

References

(1) O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J et al. 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(1):3-17.

(2) Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986; 1(8476):307-310.

+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com
www.validateglobal.com

Figure 1. Mean-against-difference plot of the systolic pressures of the better observer and the device plotted against their difference (n=255)

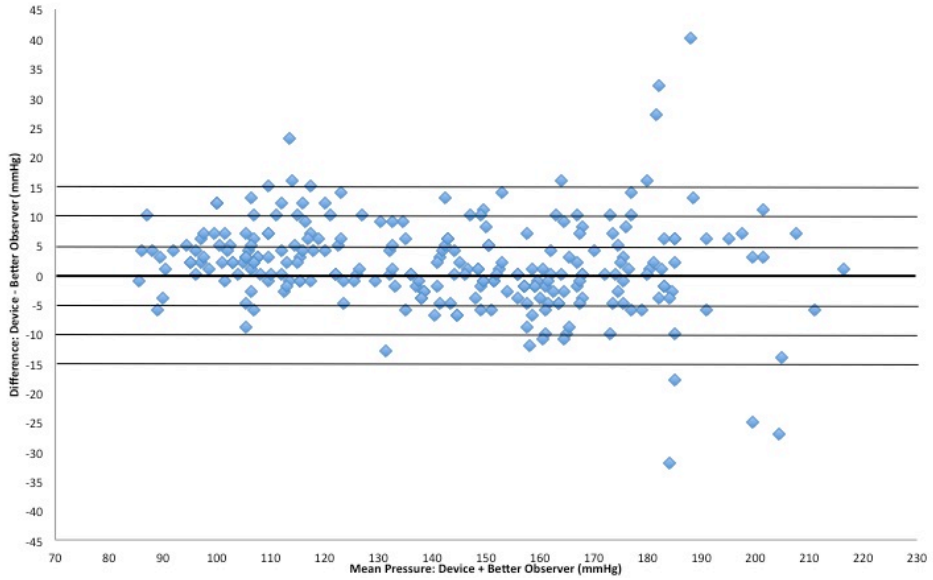
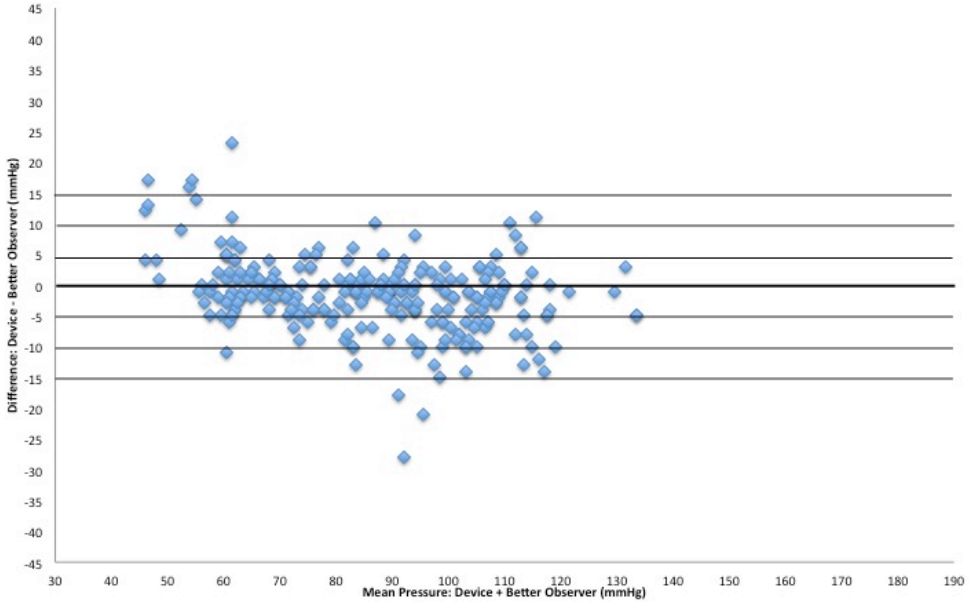


Figure 2. Mean-against-difference plot of the diastolic pressures of the better observer and the device plotted against their difference (n=255)



+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com
www.validateglobal.com

Table 4. Results according to the BHS Protocol

	Grade		≤ 5 mmHg (%)	≤ 10 mmHg (%)	≤ 15 mmHg (%)	Mean Diff ± SD mmHg
Observer 1	**A**	**SBP**	62	88	96	1.7 ± 7.7
	A	**DBP**	73	91	96	-1.7 ± 5.9
Observer 2	**A**	**SBP**	61	86	96	-1.6 ± 7.8
	A	**DBP**	73	92	97	-1.5 ± 6.0
Final Result	**A**	**SBP**	62	88	96	1.7 ± 7.7
	A	**DBP**	73	92	97	-1.5 ± 6.0
Observer Comparison	**A**	**SBP**	100	100	100	0.1 ± 2.0
	A	**DBP**	99.7	100	100	-0.2 ± 2.2

SBP - Systolic Blood Pressure; DBP - Diastolic Blood Pressure; Diff - Difference

Table 5. Analysis for high, medium and low pressure levels for the better observer

	Grade		≤ 5 mmHg (%)	≤ 10 mmHg (%)	≤ 15 mmHg (%)	n
Low Pressure	**A**	**SBP**	66	88	98	93
(<130/80)	**A**	**DBP**	80	90	96	90
Medium Pressure	**A**	**SBP**	68	93	100	60
(130-160/80-100)	**A**	**DBP**	79	95	97	75
High Pressure	**B**	**SBP**	55	84	91	102
(>160/100)	**A**	**DBP**	60	91	99	90

+27 (0)73 030 7127
+27 (0)86 260 2298
annemarie@validateglobal.com
www.validateglobal.com