VALIDATION REPORT

of the Spacelabs 90227 OnTrak device according to the ANSI/AAMI/ISO 81060-2:2009 protocol

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Objective

To assess the accuracy of the Spacelabs 90227 OnTrak device compared to mercury sphygmomanometry in 85 subjects (including 35 children) with a wide range of blood pressures according to the ANSI/AAMI/ISO 81060-2:2009 protocol.

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 over a period of 6 months (11/06/2013 to 12/12/2013).

Study sites

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

Study population

Subjects were recruited to fulfill the protocol requirements and included both adults and children (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.

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Table 1. Protocol Requirements

Subject Recruitment Criteria	Subjects (required)	Subjects (recruited)	Protocol Ref
Total number of subjects	>=85	85	5.1.1
Total number of measurements	>=255	255	
Male Subjects	>25[1]	27	5.1.2
Female Subjects	>25[1]	58	
Children (between ages 3-12years)	35	35	5.1.3
Blood Pressure Distribution	**Measurements (required)**	**Measurements (recruited)**	**Protocol Ref**
Systolic BP <=100mmHg	>=13[2]	24	5.1.5
Systolic BP >=140mmHg	>=51[2]	64	
Systolic BP >=160mmHg	>=13[2]	35	
Diastolic BP <=60mmHg	>=13[2]	38	
Diastolic BP >=85mmHg	>=51[2]	75	
Diastolic BP >=100mmHg	>=13[2]	32	
Limb Size Distribution	**Subjects (required)**	**Subjects (recruited)**	**Protocol Ref**
Child Cuff	>=9[3]	21	5.1.4
Small Adult Cuff	>=9[3]	25	
Medium Adult Cuff	>=9[3]	20	
Large Cuff	>=9[3]	10	
Extra Large Cuff	>=9[3]	9	

[1] The protocol requires a minimum of 30% male and 30% female subjects. As this study included 85 subjects, 30% is at least 26 subjects.
[2] At least 5% of readings are required to be in the range <=100/60mmHg; 5% >=160/100mmHg; 20% >=140/85mmHg. In a subject set of 85 subject, this translates to the number of measurements shown in the table.
[3] The 90227 OnTrak device has a set of 5 different cuff sizes available for use. The protocol requires a minimum of 1/(2*5) or (1/10) of subjects in each cuff size i.e. (1/10) x 85 = 9 subjects.

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Table 2. Demographics of study population

	Mean ± SD [range]
Age (years)	29 ± 19 [4-71]
Arm circumference (cm)	25 ± 8 [13-43]
Systolic Blood Pressure	127 ± 26 [81-219]
Diastolic Blood Pressure	78 ± 17 [36-126]

Study design

All subjects were required to give written informed consent as specified by the local research ethics committee. Children older than 7 years signed an assent form as stipulated by the LREC and written consent was also obtained from their parent or guardian. 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 subject's approximate heart level. The subject was advised not to talk or move during measurements, but to notify the observers if any discomfort was experienced. Korotkoff 5 was used to determine diastole in adults and K4 in children (according to 5.2.2 of the ANSI/AAMI/ISO 81060-2:2009). Three trained observers, experienced in the performance of validation studies, took all blood pressure measurements. Blood pressure values obtained by the observers were documented on separate sheets. Observers obtaining auscultatory readings used a double-headed teaching stethoscope and calibrated mercury sphygmomanometers and were blinded to each other's readings and to the device readings during the procedure. The following exclusion criteria applied: any cardiac arrhythmia; unclear Korotkoff sounds; reference systolic blood pressure determinations that varied by more than 12mmHg and reference diastolic blood pressure determinations that varied by more than 8mmHg for the complete dataset (standard validation).

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Subjects were seated and allowed to rest for at least 5-10 minutes before commencing the measurements. Nine sequential same arm blood pressure measurements (according to 5.2.4.2 of the protocol) were taken from each subject, alternating between mercury sphygmomanometry and the device.

Analysis

Data was entered on Microsoft Excel (Microsoft Office) and analysed according to the guidelines of the ANSI/AAMI/ISO 81060-2:2009 protocol.

Part of the data gathered was used in a preceding analysis according to the British Hypertension Society (BHS) protocol and the Revised 2010 International Protocol of the European Society of Hypertension (ESH-IP2) and therefore contained one additional auscultatory measurement (i.e. 9 in stead of 8 blood pressure measurements per subject).

Therefore, in order to fulfill the ANSI/AAMI/ISO protocol requirement of randomizing the order of test and reference measurements, the following methodology was followed: For all odd-numbered subjects, the first three observer measurements were used and for all even numbered subjects, the last three observer measurements were used to compare to the test device measurements obtained.

A total of one hundred and forty subjects were recruited to fulfill the BHS, ESH-IP2 and ANSI/AAMI/ISO protocol requirements for standard validation. The first eighty-five subjects to fulfill the protocol recruitment criteria (Table 1) were selected for analysis. Initial analysis of the data (50 adults; 35 children) showed that the device accuracy in children was not optimal. The manufacturer updated the software, which was uploaded onto the test device and a new dataset of 35 children were recruited using the updated software and following the procedure for standard validation as described in the sections above. The manufacturer confirmed that

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the original software would be used for any adult measurement. For measurements in children, child mode is selectable from the initialization screen. When child mode is selected an icon is displayed at the top right corner of the screen. This icon is visible on every screen for the duration (e.g.24hrs) of the test.

Criterion 1: Three observer measurements (averaged for observer 1 and 2) were compared individually to the three test device measurements obtained per subject (n=255). To pass the device has to achieve a mean difference ± standard deviation of ≤5 ± 8 mmHg.

Criterion 2: The average of all the observer measurements per subject were compared to the average of all the test device measurements obtained for that subject (n=255). To pass the device has to achieve a mean difference ± standard deviation according to specific protocol requirements (Table 1 of the ANSI/AAMI/ISO 81060-2:2009)

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.

Results

Demographic data is shown in Table 2. All observer measurements agreed within 4mmHg. Mean difference ± standard deviation for observer agreement was 0.02±2.0mmHg and 0.11±2.2mmHg for systolic and diastolic pressures respectively.

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Criterion 1 The device achieved a mean difference ± standard deviation of 0.4±7.3mmHg for systolic pressures and -1.5±7.3mmHg for diastolic pressures. It therefore achieves the protocol criteria of having a mean difference ± standard deviation of ≤5 ± 8 mmHg. Figures 1 and 2 show the mean-against-difference plots of the data.

Criterion 2 The device achieved a mean difference ± standard deviation of 0.4±6.2mmHg for systolic pressures. Table 1 of the ANSI/AAMI/ISO 81060-2:2009 protocol sets the maximum acceptable standard deviation for a mean difference of 0.4mmHg at 6.93mmHg. The device therefore achieves the requirements of criterion 2 for systolic pressure.

The device achieved a mean difference ± standard deviation of -1.5±6.1mmHg for diastolic pressures. According to Table 1 of the ANSI/AAMI/ISO 81060-2:2009 protocol the maximum acceptable standard deviation for a mean difference of -1.5mmHg is 6.78mmHg. The device therefore achieves the requirements of criterion 2 for diastolic pressure.

Conclusion

The Spacelabs 90227 OnTrak device fulfills the requirements of both criterion 1 and 2 of the ANSI/AAMI/ISO 81060-2:2009 protocol for standard validation in adults and children.

A de Greeff — **Initials & Signature**

31 March 2014 — **Date**

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Figure 1. Mean against difference plot for systolic pressures (n=255)

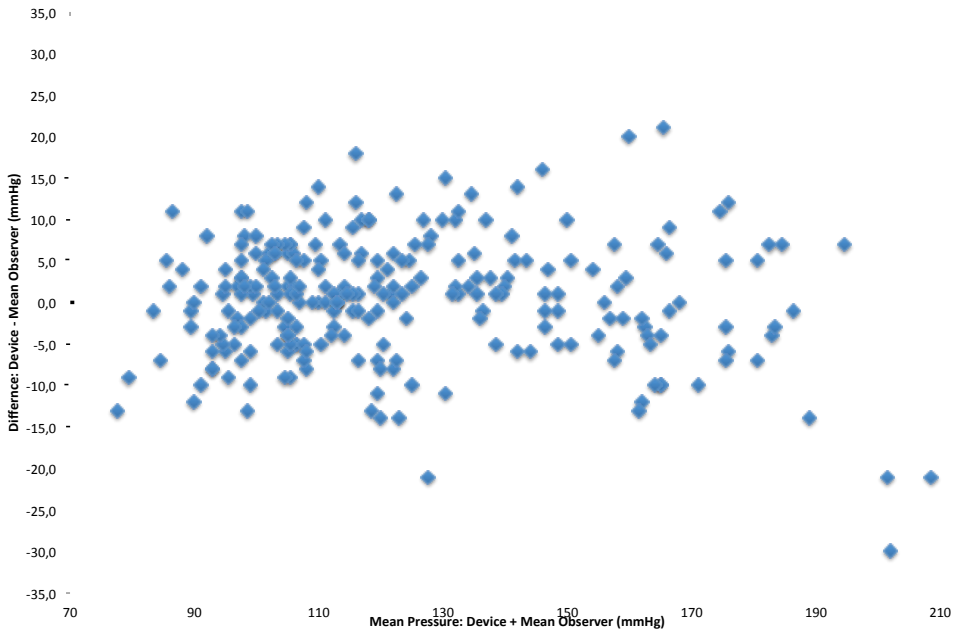
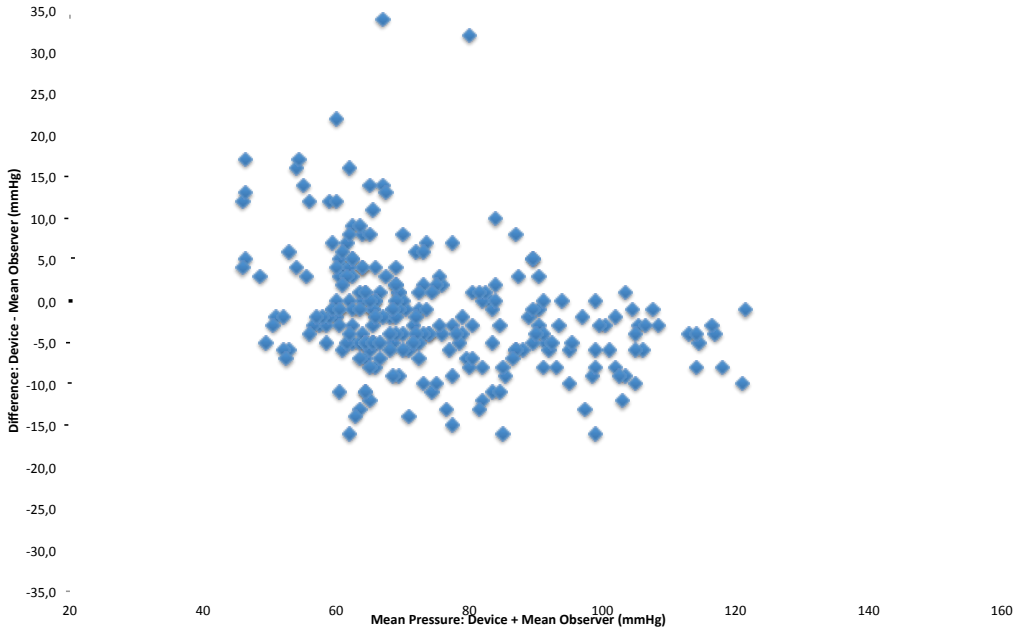


Figure 2. Mean against difference plot for diastolic pressures (n=255)



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