Welch Allyn® FlexiPort™ Functional Equivalence Clinical Studies

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Advancing Frontline Care ™

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Test Report Summary of FlexiPort™ Functional Equivalence Clinical Studies

The following table summarizes the clinical studies conducted by Welch Allyn to establish functional equivalence to blood pressure cuffs that ship as original equipment with Welch Allyn and competitors' NIBP devices. These tests were independently audited by Dr. Bruce Alpert, Co-chair of the AAMI committee. Dr. Alpert approved the study protocols, observed the clinicians during the study, and approved the statistical significance of the results.

Test	*Design of Study*	*Tested Monitors*	*Statistical Significance*	*Result*
Welch Allyn FlexiPort™ Blood Pressure Cuff Functional Equivalence Test with Welch Allyn Electronic NIBP Devices	A complete randomization design was employed in this clinical study. Seven Welch Allyn monitors were tested with both FlexiPort™ cuffs and OEM cuffs. For each type of FlexiPort™ cuff (reusable, soft and vinyl), thirty subjects were tested.	1. Spot 2. Spot LXi 3. Atlas 620 4. PIC50 5. Propaq LT 802 6. Propaq CS 246 7. VSM300	The randomization guarantees the statistical significance. With 30 subjects, the test demonstrated at least 90% power of statistical equivalence	For all Welch Allyn monitors tested in the study, in average, the FlexiPort™ cuff provides statistically equivalent blood pressure readings as the OEM cuffs.
Welch Allyn FlexiPort™ Blood Pressure Cuff Functional Equivalence Test with Competitive NIBP Monitors	A complete randomization design was employed in this clinical study. Nine monitors were tested with both FlexiPort™ cuffs and OEM cuffs. For each type of FlexiPort™ cuff (reusable, soft and vinyl), thirty subjects were tested.	1. Criticare 507N3 2. Dinamap GE PRO 3. Datascope Duo 4. Datascope Passport2 5. Datascope Trio 6. Agilent A1 7. GE Dash 4000 8. Bp TRU 300 9. CAS 740-3NL	The randomization guarantees the statistical significance. With 30 subjects, the test demonstrated at least 90% power of statistical equivalence	For all competitive monitors tested in the study, in average, the FlexiPort™ cuff provides statistically equivalent blood pressure readings as the OEM cuffs.

FlexiPort Blood Pressure Cuff
Accuracy Testing Summary

Clinical Accuracy Testing

Welch Allyn has developed a test protocol specifically to evaluate cuff performance and compatibility. Contributing to the development of the protocol were R&D engineers, Biostatisticians, Clinical personnel, and an independent expert, Dr. Bruce Alpert M.D, the physician chair of the Association for the Advancement of Medical Instrumentation (AAMI) sphygmomanometer committee. Dr. Alpert served as the principle investigator chair for the study.

The test was developed to evaluate the performance and compatibility of Welch Allyn FlexiPort™ blood pressure cuffs in use with currently-marketed Welch Allyn and competitive blood pressure monitors to assure equivalence to the (OEM) cuffs that ship with these devices as original equipment. The test is constructed as a Randomized Block design. The block design allows Welch Allyn to control for the variability of the device. By randomizing the study, differences between the subjects and the devices were eliminated allowing for focused analysis on the differences caused by the cuffs. These tests are the most sensitive way to augment the device's AAMI SP10 validation and ensure cuff performance and compatibility.

To date, Welch Allyn has tested FlexiPort cuffs on the following Welch Allyn devices:
Atlas 6200, PIC 50, Propaq LT, Propaq CS, VSM 300 series, Spot Vital Signs, and Spot Vital Signs LXi.

In addition, Welch Allyn has tested the following competitive devices:
Criticare 506N3, Dinamap GE Pro Series 410, Datascope Duo, Datascope Passport 2, and Datascope Trio, Agilent A1, GE Dash 4000, BPTRU 300, CAS 740-3NL.

Welch Allyn has tested 452 subjects and obtained 3248 readings. As the hypothesis predicted, the FlexiPort cuffs gave statiscitcally equivalent values to the OEM cuffs on all tested devices.

Bench Testing

In addition to clinical testing, Welch Allyn also developed bench testing protocols to verify the functional compatibility of the FlexiPort cuff line with competitors' automated NIBP devices. Devices were selected for this testing that have Oscillometric Blood Pressure measurement capability. The functional compatibility of the Welch Allyn FlexiPort cuff line was evaluated.

The test protocol is segmented into 3 sections:

1. **General BP determination mechanism and cuff attribute comparison** - evaluated the method of blood pressure determination and critical cuff attributes of the devices in the test.

2. **Extended range reading comparison on an NIBP simulator** - utilized an NIBP simulator (BioTek BP Pump) to evaluate the readings from competitors' devices using the OEM cuff on the simulator to the readings from the same devices using the FlexiPort cuff. A range of blood pressure simulations was selected to exceed the broad range of blood pressures outlined in the AAMI SP10 Sphygmomanometer standard. This wide range represents the blood pressure ranges expected during clinical use.

3. **FlexiPort cuff family functional compatibility test** - This section evaluated the competitive devices' ability to inflate and deflate the entire range of FlexiPort cuffs. Cycles were performed with all size FlexiPort cuffs using the NIBP simulator and the competitive devices.

To date, Welch Allyn has bench tested FlexiPort cuffs on the following Competitor devices: Philips VS3, Criticare 506N3, Agilent A1, DataScope Duo, GE Dash 4000.