

Welch Allyn® Durable One-Piece Cuff Functional Equivalence Report Electronic NIBP Monitors

The Welch Allyn Monitor Style Durable One-Piece Blood Pressure Cuffs

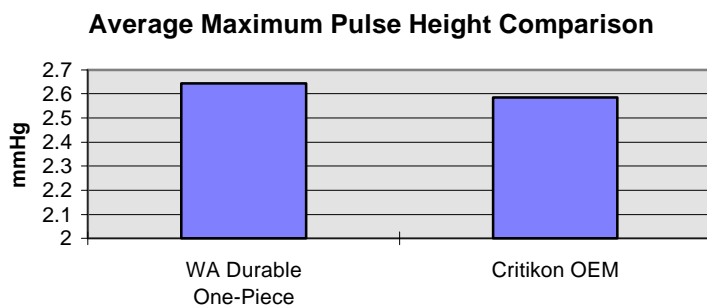
The Welch Allyn Durable One-Piece cuffs provide NIBP monitors with an oscillometric signal that is similar to the signal from the Critikon OEM cuffs in the areas of pulse amplitude, pulse shape accuracy, ring damping time, and intra-step pressure drift. The Welch Allyn Durable One-Piece cuffs are designed to work with Critikon, Hewlett Packard, Siemens, Marquette, and Spacelabs NIBP monitors. Welch Allyn makes adapters available for each brand of monitor.

In clinical testing conducted with a Critikon Dinamap+ monitor by Citech, an independent testing lab, using the Welch Allyn Durable One-Piece cuff was shown to yield similar blood pressure readings to those obtained using the Critikon OEM cuff.

In testing conducted with a Welch Allyn Vital Signs Monitor by Welch Allyn, the cuffs were found to be functionally equivalent in regard to the parameters that were tested.

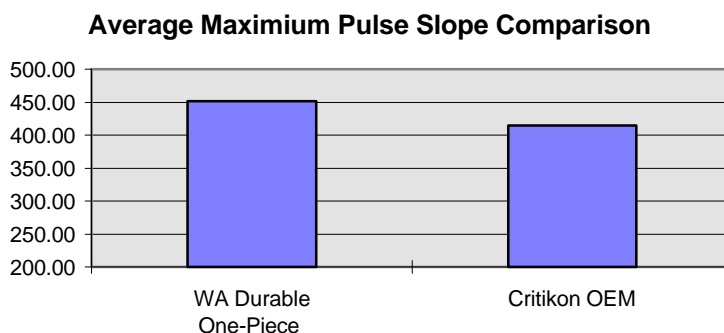
- **Evaluation of pulse height sensitivity**

The cuff serves as both the blood flow occluding device and the signal pickup transducer for an oscillometric blood pressure monitor. Because it is the cuff that picks up the oscillometric signal, it is important that a replacement cuff detects the oscillometric signal in a way that is similar to the OEM cuff. Using the pressure waveforms collected by the Welch Allyn Vital Signs Monitor, a comparison was made between the 2 types of cuffs to determine the relative height of the oscillometric signal. The average difference in pulse height was +2.53% for the Welch Allyn Durable One-Piece cuffs demonstrating that the cuffs deliver a stronger pressure signal to the blood pressure monitor.



- **Pulse Shape accuracy**

A second critical aspect of the oscillometric signal was evaluated. It is important that the cuff is able to accurately represent the shape of the oscillometric pulses. One aspect of the pulse shape that can be accurately measured is the slope of the systolic side of the pulse. The waveforms collected were compared on the basis of the average maximum pulse slope detected for each cycle. The average difference in maximum pulse slope was +8.75 % for the Welch Allyn Durable One-Piece cuffs demonstrating that these cuffs were able to detect higher fidelity oscillometric information than the Critikon OEM cuffs.



Disclaimers

1. When using the Welch Allyn Durable One-Piece cuffs with a NIBP monitor it is the user's responsibility to check the instructions of the manufacturer of that device to ensure that the cuff is compatible with that device. It is also the responsibility of the user to ensure final efficacy of the system.
2. Some monitors may rely on parameters of a cuff that were not evaluated in the testing summarized above.

Welch Allyn[®] One-Piece Cuff Evaluation

Durable and Disposable (SPU) Styles

Electronic NIBP Monitors*

Criticare 506DXNT

Test Protocol

36 healthy adult test subjects (12 male, 24 female) were recruited. Four blood pressure readings were taken with the Criticare 506DXNT: The first and the last readings were both with the Criticare cuff; these would serve as the controls. The second and third readings were with the Welch Allyn Durable and Disposable One Piece Cuffs (their order was alternated among the test subjects). If the two control readings of systolic or diastolic blood pressure differed by more than 15 mm Hg, that series of four readings was rejected and taken over.

Analysis

The data was analyzed by comparing the readings from each Welch Allyn cuff with the average of the two control readings from the Criticare cuff. The mean differences and standard deviations of the 36 systolic readings and 36 diastolic readings, compared against the average control readings, were calculated. Cuffs passed the test if the mean difference of the 36 readings was not greater than 3 mm Hg and the standard deviation was not greater than 8 mm Hg.

Results and Conclusions

The results showed that the Welch Allyn Durable and Disposable One Piece Cuffs met the preset criteria for passage.

The conclusions from this study are that both Welch Allyn Durable and Disposable One Piece Cuffs provided blood pressure readings equivalent to those of the Criticare cuffs.

* Complete independent testing data on file, Welch Allyn, Inc.

Criticare 506DXNT

(Test Cuff Reading) - (Average Control Reading), mm Hg

Subject	DURABLE TEST CUFF		SPU TEST CUFF	
	Systolic	Diastolic	Systolic	Diastolic
1	-17.5	3.0	5.5	5.0
2	-2.0	7.0	-8.0	0.0
3	-4.5	1.0	1.5	-5.0
4	-1.5	1.0	5.5	-2.0
5	4.0	4.0	1.0	1.0
6	-12.0	1.0	-9.0	-6.0
7	5.0	-1.0	-5.0	1.0
8	-7.0	14.5	-9.0	0.5
9	12.5	4.0	5.5	-1.0
10	-7.5	7.0	-9.5	2.0
11	2.0	0.5	2.0	4.5
12	2.5	6.0	-4.5	-4.0
13	-16.5	-10.0	3.5	5.0
14	2.0	-8.0	-3.0	10.0
15	-5.0	-2.0	8.0	9.0
16	-1.0	0.5	-5.0	-4.5
17	-3.5	8.5	-8.5	-2.5
18	1.5	3.5	-7.5	-2.5
19	13.5	16.0	2.5	-2.0
20	-9.0	1.5	-8.0	-3.5
21	-2.5	-1.5	3.5	-2.5
22	-4.5	4.0	-8.5	-2.0
23	-3.0	-1.0	-11.0	-4.0
24	-12.0	12.0	1.0	-6.0
25	5.5	1.5	-2.5	0.5
26	4.0	7.5	12.0	1.5
27	3.5	9.0	-1.5	-6.0
28	-2.0	0.0	-1.0	0.0
29	10.0	1.5	-4.0	-4.5
30	11.0	2.0	16.0	2.0
31	-10.5	-5.0	-10.5	-7.0
32	-17.0	2.5	-11.0	-5.5
33	8.5	3.0	-2.5	2.0
34	-1.0	-1.5	2.0	0.5
35	-5.5	-2.0	-1.5	3.0
36	-8.0	4.0	-6.0	-4.0
Mean:	-1.88	2.61	-1.88	-0.75
Std Dev:	7.95	5.34	6.57	4.09

Welch Allyn One-Piece Cuff Evaluation

Durable and Disposable (SPU) Styles

Electronic NIBP Monitors*

Critikon DINAMAP® Plus

Test Protocol

36 healthy adult test subjects (12 male, 24 female) were recruited. Four blood pressure readings were taken using the Critikon DINAMAP Plus: The first and the last readings were both with the Critikon cuff; these would serve as the controls. The second and third readings were with the Welch Allyn Durable and Disposable One Piece Cuffs (their order was alternated among the test subjects). If the two control readings of systolic or diastolic blood pressure differed by more than 15 mm Hg, that series of four readings was rejected and taken over.

Analysis

The data was analyzed by comparing the readings from each Welch Allyn cuff with the average of the two control readings from the Critikon cuff. The mean differences and standard deviations of the 36 systolic readings and 36 diastolic readings, compared against the average control readings, were calculated. Cuffs passed the test if the mean difference of the 36 readings was not greater than 3 mm Hg and the standard deviation was not greater than 8 mm Hg.

Results and Conclusions

The results showed that the Welch Allyn Durable and Disposable One Piece Cuffs met the preset criteria for passage.

The conclusions from this study are that both Welch Allyn Durable and Disposable One Piece Cuffs provided blood pressure readings equivalent to those of the Critikon cuffs.

* Complete independent testing data on file, Welch Allyn, Inc.

Critikon DINAMAP® Plus

(Test Cuff Reading) - (Average Control Reading), mm Hg

Subject	DURABLE TEST CUFF		SPU TEST CUFF	
	<u>Systolic</u>	<u>Diastolic</u>	<u>Systolic</u>	<u>Diastolic</u>
1	-1.0	0.0	3.0	-1.0
2	-4.0	-0.5	-11.0	-0.5
3	8.0	3.5	-4.0	1.5
4	-0.5	-1.5	-1.5	-1.5
5	-8.0	7.0	-8.0	-4.0
6	-2.5	-4.5	-11.5	-9.5
7	11.0	5.0	11.0	0.0
8	-4.5	0.0	5.5	-3.0
9	-4.5	2.0	-4.5	-1.0
10	-7.0	-1.5	5.0	-1.5
11	0.5	2.0	-6.5	0.0
12	-1.0	0.5	3.0	-1.5
13	-3.0	4.5	3.0	6.5
14	-3.0	2.5	-4.0	1.5
15	-13.0	2.5	-15.0	-1.5
16	-2.5	-2.5	-4.5	-3.5
17	8.5	4.5	-0.5	3.5
18	-2.0	0.0	-2.0	-2.0
19	8.0	-4.5	0.0	-4.5
20	19.0	5.5	9.0	7.5
21	-15.5	-1.5	-13.5	-2.5
22	-3.0	0.5	-3.0	1.5
23	-3.5	-2.5	-0.5	3.5
24	0.0	0.5	0.0	1.5
25	7.5	5.5	6.5	-1.5
26	0.5	5.0	0.5	2.0
27	1.5	0.5	-2.5	0.5
28	4.5	4.0	0.5	0.0
29	0.0	0.5	-4.0	-1.5
30	-1.0	-4.5	0.0	0.5
31	-2.0	7.5	-1.0	-1.5
32	0.5	1.0	-2.5	-5.0
33	-4.5	-7.0	-1.5	-4.0
34	-1.5	8.5	-4.5	-4.5
35	2.5	7.0	12.5	3.0
36	0.0	0.0	-3.0	-1.0
Mean:	-0.43	1.38	-1.38	-0.65
Std Dev:	6.29	3.69	6.08	3.20