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

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

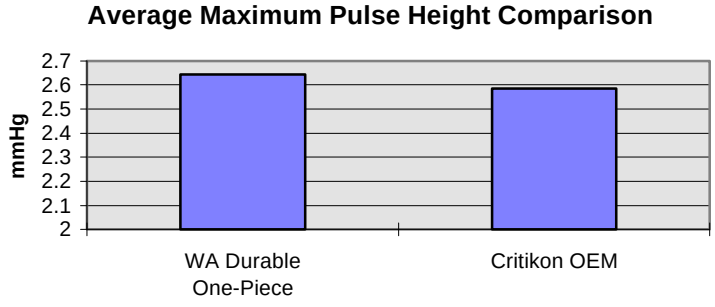
The Welch Allyn Durable One-Piece cuffs provide NIBP monitors with an oscillometric signal that is similar to the signal from the Critikon OEM cuffs in the areas of pulse amplitude, pulse shape accuracy, ring damping time, and intra-step pressure drift. The Welch Allyn Durable One-Piece cuffs are designed 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.

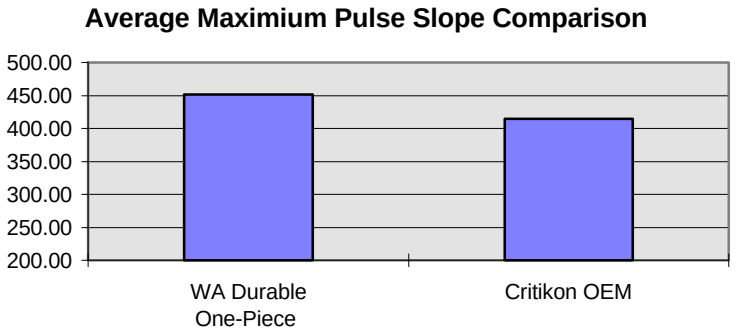
- **Evaluation of pulse height sensitivity**

  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.