ADView 2 Modular Diagnostic Station

WHITE PAPER

# The accuracy and clinical validation of the Adview 9000

The accuracy of a blood pressure (BP) device or monitor is often determined by comparing its measurement relative to the measurement of an observer using a mercury sphygmomanometer and stethoscope on the same patient. The human observer with this setup in a controlled environment, with a meticulously prepared patient, and the practice of careful measurement is considered to be the gold standard of noninvasive blood pressure measurement. Measurements taken in this manner are the basis for the levels that are the current definitions of high BP or hypertension, 140/90, and normal BP, 120/801. Currently, there are four protocols (see following table) that evaluate the accuracy of a BP device against the gold standard human observer.

| Protocol | Protocol Description of use |
|---|---|
| AAMI SP10[2] | Required by the FDA before product can be sold in the US market |
| BHS[3] | Requested by some customers but not formally required by any body or market |
| EN 1060-4[4] | Required for CE mark before product can be sold in the EU market |
| ESH Int'l Protocol[5] | Requested by some customers but not formally required by any body or market |

Although these protocols are not equivalent or interchangeable, they are each built on common methods. They generally agree that the acceptable limits of accuracy are a mean difference between observers and the device of less than or equal to 5 mmHg and a standard deviation of less than or equal to 8 mmHg. In addition, the percentages of measurements within 5 (≤5 mmHg*), 10 (≤10 mmHg**), and 15 mmHg (≤15 mmHg***) are used by two of the protocols as another way to evaluate accuracy. Before the product was introduced to the market, the Adview 9000 was tested and passed the requirements for both the legally required AAMI SP106 (see following table) and EN 1060-47. The following table compares the results of this AAMI SP10 evaluation with the BHS requirements for grade 'A' accuracy.

| Adview 9000 | Mean difference ± Standard deviation, mmHg | ≤5* mmHg | ≤10** mmHg | ≤15*** mmHg |
|---|---|---|---|---|
| BHS 'A' req | 5 ± 8 | 60% | 85% | 95% |
| Sys BP | -0.45 ± 5.98 | 65% | 91% | 99% |
| Dia BP | 1.50 ± 5.46 | 71% | 91% | 99% |

While these results are favorable, today's market for BP devices and monitors places a strong emphasis on these evaluations being conducted by an independent laboratory. Having developed clinical grade BP devices and technology for over 20 years, ADC rigorously validates the clinical performance of its monitors and has encouraged independent validation of its monitors. In 2009, a team of researchers at the University of Milan, led by Dr. Hernan Polo Friz, published a peer-reviewed study that determined the accuracy of the Adview 9000 using the 1993 modified BHS protocol, the 2002 International Protocol, and the 2002/03 AAMI standards. The study concluded that the 9000 achieved the requirements stated by the 2002 IP and fulfilled the AAMI standards. In addition, the study recommended the 9000 for clinical use since it was determined that it could be classified as 'A' grade for both systolic and diastolic blood pressure based on the 1993 modified BHS protocol.

## References

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