

The accuracy and clinical validation of the SunTech 247™

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 non-invasive 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 | 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 *SunTech 247* 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.

| <i>SunTech 247</i> | Mean difference \pm Standard deviation, mmHg | $\leq 5^*$ mmHg | $\leq 10^{**}$ mmHg | $\leq 15^{***}$ mmHg |
|--------------------|--|-----------------|---------------------|----------------------|
| BHS 'A' req | 5 \pm 8 | 60% | 85% | 95% |
| Sys BP | -0.45 \pm 5.98 | 65% | 91% | 99% |
| Dia BP | 1.50 \pm 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, SunTech rigorously validates the clinical performance of its monitors and has encouraged independent validation of its monitors. Like the *SunTech 247*, the Oscar 2™ ambulatory blood pressure monitor was tested and passed the AAMI SP10⁸ before it was introduced to the market. Since then, three well-regarded published validations have shown the *Oscar 2* to be a highly accurate device by AAMI⁹, BHS¹⁰, and ESH International Protocol¹¹ standards. Because independent evaluations are performed on products that are currently on the market, there is always some time, typically one to two years, between when new devices come to market and when they are independently validated. Currently, the *SunTech 247* is being evaluated by two independent laboratories. As with the Oscar 2, SunTech is confident that these evaluations of the *SunTech 247* will be favorable.

References

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- ² Association for the Advancement of Medical Instrumentation. American National Standard. Manual, electronic or automated sphygmomanometers ANSI/AAMI SP10-2002. 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598, USA: AAMI; 2003.
- ³ O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield PL, Altman D, Bland M, Coats A, Atkins N. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993;11(suppl 2):S43-S63.
- ⁴ British-Adopted European Standard. Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers BS EN 1060-4:2004. rue de Stassart, 36 B-1050 Brussels, Belgium: 06-Oct-2004.
- ⁵ O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, Mengden T, Imai Y, Waeber B, Palatini P with the statistical assistance of Atkins N and Gerin W on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. International protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002;7:3-17.
- ⁶ SunTech part number 99-0053-00-CV-SP10-AP-Rev B.
- ⁷ SunTech part number 99-0053-00-CV-1060-AP-Rev B.
- ⁸ SunTech part number 97-0012-XX-CV Rev A.
- ⁹ Goodwin J, Finn P, Bilous M, Winship S, Jones S. Validation of the OSCAR 2 ambulatory blood pressure monitor according to the association for the advancement of medical instrumentation (AAMI) protocol. *Am J Hypertens* 2005; 18(5):A31-A31.
- ¹⁰ Goodwin J, Bilous M, Winship S, Finn P, Jones SC. Validation of the Oscar 2 oscillometric 24-h ambulatory blood pressure monitor according to the British Hypertension Society protocol. *Blood Press Monit*. 2007 Apr;12(2):113-7.
- ¹¹ Jones SC, Bilous M, Winship S, Finn P, Goodwin J. Validation of the OSCAR 2 oscillometric 24-hour ambulatory blood pressure monitor according to the International Protocol for the validation of blood pressure measuring devices. *Blood Press Monit*. 2004 Aug;9(4):219-23.