

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.

SunTech 247	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. 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 SunTech 247 using the 1993 modified BHS protocol, the 2002 International Protocol, and the 2002/03 AAMI standards. The study concluded that the 247 achieved the requirements stated by the 2002 IP and fulfilled the AAMI standards. In addition, the study recommended the 247 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.⁸

References

- ¹ Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jones DW, Materson BJ, Oparil S, Wright JT, Roccella EJ, and the National High Blood Pressure Education Program Coordinating Committee. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The JNC7 Report. *JAMA*, 2003; 289(19):2560-2572.
- 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 Polo Friz H, Facchetti R, Primitz L, Beltrame L, Galbiati V, Ricioppo A, Bombelli M, Sega R. Simultaneous validation of the SunTech 247 diagnostic station blood pressure measurement device according to the British Hypertension Society protocol, the International Protocol and the Association for the Advancement of Medical Instrumentation standards. *Blood Press Monit* 2009;14:222-227.