

AAMI Blood Pressure Device Standard Targets Home Use Issues

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In this article, leaders of the AAMI Sphygmomanometer Committee report on their efforts to address home use issues in standards for blood pressure devices, and the importance of standards to ensuring safety and effectiveness of home use devices.

The effectiveness of home use blood pressure (BP) devices for the early detection and treatment of hypertension depends on the accuracy and reproducibility of the measured blood pressure and requires that the user has sufficient information to operate the device correctly and safely. Prior to the development of standards for noninvasive blood pressure (NIBP) monitors, the majority of home BP monitors were found

to be inaccurate^{1,2} and lacked adequate instructions for use,³ which limited their value as a tool to diagnose and treat hypertension.

The publication of the first AAMI sphygmomanometer committee (SP10) standard in 1987, followed by protocols from the British Hypertension Society and the European Society of Hypertension, resulted in an increase in the number of home use BP devices with validated accuracy.⁴ In addition, the AAMI standards developed by the SP10 committee specify safety, labeling, and performance requirements designed to protect the home user of the device. While they are not required to do so, manufacturers that have designed and tested their devices to meet AAMI and/or ISO/IEC standards usually label their packages to indicate compliance. When selecting BP monitors for home use, it is important for both consumers and healthcare professionals to recognize that those devices should meet the same standards as devices used in hospitals.



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Importance of Home Monitoring

Based on data from the latest National Health and Nutrition Examination Survey (NHANES) study, at least 65 million adult Americans have hypertension.⁵ The lifetime risk of hypertension, as reported by investigators in the Framingham Heart Study, is approximately 90%, even for individuals who were normotensive at 55–65 years and lived to age 80–85.⁶

The accurate measurement of blood pressure (BP) is essential to determine BP-related risk and to guide treatment. There is increasing evidence that self-measured BP readings taken at home can often predict future cardiovascular events and are useful for monitoring the effects of hypertension treatment.⁷

It has been demonstrated that a patient's BP can be transiently high when measured in a physician's office, a phenomenon known as white-coat hypertension. Self-monitoring of BP at home using automated devices can be used to assess BP for clinical use.⁸ Conversely, there are patients with "masked hypertension" who have nor-

mal office BP and hypertension everywhere else. Bobrie has shown that home BP measurement is the most cost-effective method to detect and treat this form of hypertension.⁹

Patients initially used auscultation-based non-automated devices to measure their BP at home. First developed in the early 1900's, auscultation requires the inflation of a cuff on the upper arm to a pressure above systolic. The cuff is gradually deflated, and the patient listens with a stethoscope placed over the brachial artery below the cuff. The audible Korotkoff sounds are used to estimate systolic and diastolic pressures. While widely used in physician's offices and hospitals, its use for self-measurement was limited because the proper application of auscultation requires significant training and practice.

Automated oscillometric BP monitors for home use were introduced in the early 1980s and greatly simplified BP self-measurement. With oscillometric measurement, changes in measured pressure pulses (or oscillations) during cuff deflation are related to systolic, mean, and diastolic pressures. As the cuff is inflated on the limb, the pressure is transmitted to the underlying artery causing it to collapse. As the cuff pressure is released, the compliance of the artery changes producing a characteristic pattern of pressure pulses. The devices use proprietary software algorithms to estimate systolic, diastolic, and mean arterial pressure from the pattern of pressure pulses. This method can also be used to measure pressure during inflation of the cuff.

The first automated devices for home use employed a cuff placed on the patient's upper arm and required the user to inflate the cuff manually by squeezing a bulb. The cuff was deflated either by a leak through a fixed orifice or by an electrically controlled valve. Newer models included a pump to inflate the cuff (Figure 1). In the late 1990s manufacturers also introduced devices for use on the wrist (Figure 2).

The current worldwide sales of automated devices for self-measurement has grown to over 18 million units annually.¹⁰ The cost of automated home BP monitors can be as low as \$20 for a device with manual inflation and more than \$150 for automatic inflation units with additional features such as printers and USB ports. With the increasing use of home BP monitors, it is important to recognize these devices are covered by the same performance standards as BP monitors used in the hospital environment.



Figure 1. Upper arm sphygmomanometers

Standards Development Efforts

The AAMI Sphygmomanometer Committee was established in 1978 to develop a standard to “ensure that consumers and health care professionals are supplied with safe, accurate devices for the indirect measurement of BP.” The committee includes representatives from clinical practice, the medical device industry, academia, and government agencies. The first SP10 standard was released in 1987,¹¹ with revisions in 1992¹² and 2002.¹³ These standards contain requirements that ensure the safety and accuracy of both manual and automated BP monitors.

As part of the process to develop globally harmonized standards, the AAMI SP10 committee members actively participated in the development of three new ISO/IEC standards, which have now been adopted by AAMI/ANSI. Of these, ANSI/AAMI/IEC 80601-2-30:2009 *Medical electrical equipment—Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers* describes the requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, including those used in the home healthcare environment.

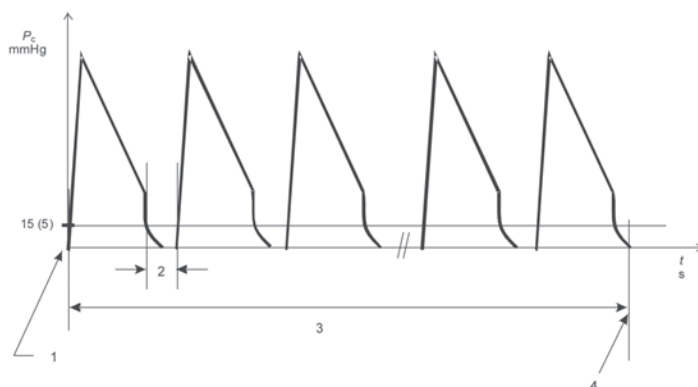


Figure 2. Wrist sphygmomanometers

Considerations for the Home Environment

Minimum requirements are included in the standard for the operating instructions and the labeling of the device. If the device is intended for home use, the packaging is required to provide: the identification of the appropriate range of arm circumferences on which the cuff enclosed with the device can be used; the operating and storage temperature and humidity ranges for the device; and any special requirements for a battery-powered device. These requirements are intended to provide important information to the consumer prior to purchasing the device. Additional requirements for equipment in the home healthcare environment are found in IEC 60601-1-11:2010.¹⁴

The major non-electrical safety issues addressed in the 80601-2-30 deal with potential faults in the pneumatic system of automated sphygmomanometers. In the inflation cycle, these include: too high a target inflation pressure for the intended population; too long an inflated period; or too rapid a repetition rate for a prolonged period. There is also a risk that an inflated cuff could fail to deflate during a determination, when the device is turned off, or unexpectedly loses power. Any of these situations could result in injury to the patient, which might go undetected when the devices are used outside of healthcare facilities. The requirements of the standard specify how the device must operate under single fault conditions to mitigate the risk to the patient.



Key

- 1 OPERATOR starts SELF-MEASUREMENT MODE
- 2 Deflated time ≥ 5 s after each DETERMINATION
- 3 SELF-MEASUREMENT MODE limited to 6 DETERMINATIONS
- 4 SELF-MEASUREMENT MODE ends

CUFF pressure, P_c , as a function of time

Figure 3. Self-measurement automatic mode

The current standard adds a description of a specific automatic mode useful for measurement of BP both in the home and in physicians' offices (Figure 3). Current recommendations for the diagnosis of hypertension recommend that at least two determinations should be taken at intervals of at least one minute, and the average of those determinations should be taken as the patient's BP.¹⁵ The increased use of home BPs resulted in the addition of this measurement mode to the current standard. The time between measurements, which is specified by the manufacturer, may be from several seconds to several minutes.

As with all medical devices, automated sphygmomanometers are required to meet the requirements for electromagnetic compatibility. While the details of the testing are contained in a collateral standard,¹⁶ the standard contains requirements for the allowable error of the device during the testing.

A BP monitor in normal use will be subjected to mechanical stresses. Therefore, it needs to be robust enough to withstand the vibration, shock, bumps, and drops that it will encounter in normal use. The requirements in the standard were chosen recognizing that these devices are used in various environments including the home, healthcare institutions, and professional transport. Testing requirements also vary based on whether the device is hand-held, portable, or fixed. Most devices used in the home fall into the hand-held category. After the testing is completed, the device must maintain all basic safety and performance requirements of the standard.

Validation methods and accuracy criteria for home use devices are also spelled out in the standard. Sphygmomanometers designed for home healthcare will typically use the second of three methods of clinical validation testing specified in the standard, which is to use manual auscultatory BP measurements as the reference. The standard also specifies two accuracy criteria that BP monitors must meet.

Conclusion

Standards have played and will continue to play an important role in ensuring the accuracy, safety, and effectiveness of home use blood pressure devices. The inclusion of issues encountered in the home use environment in these standards offers a model for other standards development groups whose products may also be used in the home environment. ■

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