National Standard for Measurement of Resting and Ambulatory Blood Pressures With Automated Sphygmomanometers

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The Association for the Advancement of Medical Instrumentation develops voluntary standards for medical devices so that manufacturers might provide information on their product and basic safety and performance criteria that should be considered in qualifying the instrument for clinical use. American national standards are generated through a consensus process by committees consisting of experts in research, development, and design from user, industry, and government communities. Draft standards are made available for public review and may become American national standards after review by the American National Standards Institute. The first American national standard for electronic and automated sphygmomanometers was published in monograph form in 1987. The objective of the revised 1992 standard for electronic and automated sphygmomanometers is to provide updated labeling, safety, and performance requirements that help ensure that consumers and health care professionals are supplied with safe, accurate devices for the indirect measurement of blood pressure, including ambulatory blood pressure recorders. This standard permits validation of the automatic or electronic device by comparison with either direct, intra-arterial blood pressure measurements or the noninvasive cuff/stethoscope technique, based on Korotkoff sounds identified by individuals trained in auscultation. This summary report of the 1992 American national standard for automatic sphygmomanometers provides recommendations for the methods of comparison, statistical analysis of the data, presentation of the results, and criteria for acceptability. Users, researchers, and instrument designers should refer to the American national standard monograph for detailed requirements. (Hypertension 1993;21:504–509)

KEY WORDS • blood pressure determination • blood pressure monitors

Hypertension, or high blood pressure, is one of the leading causes of cardiovascular morbidity and mortality.1 An elevated blood pressure has become a surrogate for hypertensive vascular disease, and the measurement of blood pressure is a regular occurrence in hypertension detection and follow-up programs. Blood pressure measurement is performed regularly with automated or electronic devices by physicians, nurses, and technicians in hospitals and clinics, patient wards, critical care units, operating rooms, recovery rooms, and emergency departments. Automated and electronic sphygmomanometers are also widely available to patients for self-monitoring of blood pressure.

As automated and electronic instrumentation for recording blood pressure proliferated, a monograph was published by the American Association for the Advancement of Medical Instrumentation (AAMI) in 1987 that became a national standard2 for generating the requirements for evaluation of automated sphygmomanometers before marketing in the United States. The 1987 standard for assessing sphygmomanometers has only been available as a monograph obtainable from the AAMI office. During the mandatory 5-year review and revision of the American national standard for electronic and automated sphygmomanometers, the AAMI Sphygmomanometer Committee recommended that a summary report of the standard be published in the scientific literature to improve its visibility and availability of the recommendations to manufacturers, users, and academicians interested in blood pressure devices. The National High Blood Pressure Education Program recommended to AAMI that the revised standard ad-

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Participation by federal agency representatives (A.S.B. and E.R.) in the development of this standard does not constitute endorsement by the federal government or any of its agencies. The opinions in this summary report are those of the authors of the article and do not constitute endorsement by the Association for Advancement of Medical Instrumentation.

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dress ambulatory blood pressure recording because of the increasing clinical and epidemiological applications of this procedure. The 1992 revised standard contains a section on evaluation of ambulatory blood pressure recorders. This report provides a summary of these new guidelines.

Scope of the American National Standard for Electronic or Automated Sphygmomanometers

The standard establishes safety and performance requirements for electronic measurement devices that are used with an occluding cuff for indirect blood pressure determination. These devices may or may not have an automatic cuff-inflation system. The standard also now encompasses ambulatory blood pressure monitors, which are portable, automatic devices worn by the patient to obtain repeated determinations of blood pressure and heart rate during activities of ordinary daily living. Excluded from the scope of this standard are nonautomated sphygmomanometers (a separate national standard exists for these devices), systems lacking an occluding cuff, and invasive devices such as those used for direct, intra-arterial blood pressure measurement.

Labeling Requirements and Information Manual

The device itself shall display sufficient information for traceability and identification. In addition, in devices intended for public or home use, the following information should be provided on the device or in the device manual: precautions for use, adequate operating instructions, and a statement describing the ranges of blood pressures over which the device has been validated as well as the arm size distribution of the subjects used in validation testing.

The information manual supplied with the device shall contain sections summarizing precautions for use; how to unpack, set up, and use the device; information on routine care and maintenance; and recommended frequency of recalibration. Furthermore, the manual must describe the device's basic method of measurement (e.g., auscultatory or oscillometric) and a statement that describes the relation of blood pressure measurement obtained by the device and that obtained by one of the independent methods described in the standard (i.e., validation against the indirect cuff/stethoscope, trained observer auscultation, or intra-arterial blood pressure measurement). The device's manual should also specify, where applicable, the ability of the device to function in the presence of cardiac arrhythmias, over a wide range of heart rates, and with patients in different positions.

Environmental Performance and Stability

The device shall maintain the safety and performance characteristics specified in the standard over the following ranges of environmental conditions: 1) temperature, 10–40°C, 2) humidity, 15–90% (noncondensing), and 3) altitude, –170 to 1,700 m referenced to sea level. The device shall maintain the safety and performance characteristics specified in the standard for a minimum of 10,000 full-scale cycles (a pressure change from 20 mm Hg or less to full scale and back to 20 mm Hg or less).

Safety Requirements

Maximum cuff pressure shall never exceed 330 or 30 mm Hg above the upper limit of the instrument's manufacturer-specified operating range, whichever is higher. The cuff pressure will not be maintained above 10 mm Hg for longer than 5 minutes. Electrical safety and conductive components must comply with the requirements of the American National Standard for electromedical apparatus.

Overall Efficacy of the Blood Pressure Device

The overall performance of the device must be as follows: for systolic and diastolic blood pressures, treated separately, the mean difference of the paired measurements of the test system and the comparison system shall be ±5 mm Hg or less, with a standard deviation of 8 mm Hg or less. Device performance must be evaluated against either the commonly used cuff/stethoscope auscultation method or intra-arterial pressures, with strengths and weaknesses of each of these references being recognized. The selection methods for individuals entered into the study must not introduce bias. More than one study site is recommended to enhance the heterogeneity of the study population.

The Auscultatory Method as the Reference Standard

The auscultatory method should use a reference sphygmomanometer with a maximum calibration error of ±1 mm Hg. The reference sphygmomanometer should have a minimum bleed rate of 2 mm Hg/sec and a maximum bleed rate of 6 mm Hg/sec. Simultaneous same-arm measurements should be obtained unless the bleed rates for the automated test system do not conform to the above specifications. If different limbs are used for simultaneous or sequential measurements, additional tests must be performed for each subject to determine important physiological differences in limb blood pressure.

Study population for the auscultatory comparison. The number of subjects for an auscultatory comparison shall be at least 85, and their demographics must be documented. Because instrument accuracy is often affected by limb size and blood pressure level, a heterogeneous group of subjects is specified that includes a wide range of blood pressures and arm sizes. At least 10% of the systolic pressures should be above 180 mm Hg and at least 10% below 100 mm Hg, with the remainder distributed between these values. Ten percent of the diastolic pressures should be above 100 mm Hg and 10% below 60 mm Hg, with the remainder distributed between these values. Furthermore, 10% of the subjects should have an arm size of less than 25 cm in circumference (taken at midpoint between the olecranon process and the shoulder) and 10% greater than 35 cm in circumference, with the remainder between these values. It is noteworthy that the 1992 revised standard does not have a discrete age requirement. However, if the device is specifically intended for use in children, additional subjects in the lower blood pressure ranges and smaller arm size ranges should be incorporated into the study population. It is also suggested that study populations are heterogeneous and include special patient groups such as the elderly, diabetics, and patients with renal disease. Separate studies of 85 subjects in these popu-
Inappropriate cuff/arm relation
Stethoscope or transducer not over the brachial artery
Observer error: Inadequate hearing acuity* or incorrect technique
Rapid cuff deflation†

*Skilled observers participating in clinical validation should have an audiogram before the study.
†Deflation rates should be at 3 mm Hg/sec or per heart beat. For best results in an auscultatory comparison.

The Intra-arterial Method as the Reference Standard

Verification of the efficacy of an automated/electronic sphygmomanometer by comparison with direct (intra-arterial) blood pressure is more complex than by the use of a mercury column sphygmomanometer as a reference standard. In most instances, it is not appropriate to use intra-arterial blood pressure measurements as the reference standard for devices that will be used in clinics, for self-monitoring by patients, or for ambulatory blood pressure recordings. Simultaneous intra-arterial blood pressure and auscultated blood pressure typically yield different values.8-13 However, the direct method may be desirable for instrumentation designated for critical care units, operating rooms, and investigative laboratories.

Because this method is invasive, studies must be conducted on clinical patients in whom an intra-arterial line has already been placed for reasons other than sphygmomanometer verification. This could include patients undergoing cerebral arteriography, cardiac catheterization, or invasive hemodynamic studies approved by an Institutional Review Board.

Study population for the intra-arterial comparison. In contrast to the relative ease of recruitment for the auscultatory method, the difficulties associated with intra-arterial measurements make it highly unlikely that 85 subjects can be recruited for this type of study. Thus, the standard specifies a minimum of 15 subjects. As the number of subjects for intra-arterial testing is smaller than the auscultatory method, the range of observed blood pressures may be less evenly distributed. The range of blood pressures and arm sizes should be as close as possible to that specified for auscultatory comparisons.

Data acquisition. Ten device readings should be made in each of the subjects. The same limb should be used for simultaneous comparison of the intra-arterial and indirect blood pressure measurements. The intra-arterial catheter should be proximal to the occluding cuff when same-arm determinations are made. The subclavian, axillary, and brachial arteries are the most desirable sites for static intra-arterial measurements. It is important to visualize the distal aspect of the blood vessel by angiography for safety reasons as well as to assure that an intact arterial lumen has been chosen for measurement. If same-arm intra-arterial blood pressures are unfeasible, then contralateral brachial arm determinations may be used. The analytic and performance requirements are the same for the different methods of determination.

For blood pressure in neonates, the intra-arterial catheter should be placed in the aorta, as is generally the case when an umbilical artery is used.

Data collection. Comparisons between invasive and noninvasive blood pressure measurements must be simultaneous if they are to be valid. The best method is to synchronize data output from the noninvasive device on a separate channel of a strip-chart recording with that of the intra-arterial pressure tracing. This is possible to perform with auscultatory units by displaying Korotkoff sounds. The strip-chart recording also supplies a source document for further review and inspection.

It is also recommended that a comparison of the intra-arterial pressure and mercury column blood pressure determinations be made in each subject to obtain an estimate of error between the clinical measurement of blood pressure and intra-arterial pressure.

Data Analysis and Presentation

Description of the Study Group

A report of the study findings should include the description of the target population and selection procedure, the number of subjects/patients and their demographics (age, height, weight, gender), any special categories of patients studied, the distribution and
range of arm and cuff sizes, and the distribution and range of systolic and diastolic pressures and heart rates.

Analysis of Data Comparing the Test Device and Reference Standard

All data must be reported if a blood pressure is obtainable in a subject. If blood pressure measurements from either the standard method or the automated device are unavailable, data for that individual may be excluded with an accompanying explanation. Additional individuals must be entered into the study to achieve the designated sample size.

When comparisons are made against cuff/stethoscope auscultatory references with a subject population of 85 individuals, there will be at least 255 observations; all individual measurements should be analyzed separately rather than averaging three or more recordings.

Between-Observer Comparisons

Systolic and diastolic pressures should be examined independently. Ninety-five percent or more of recordings made simultaneously by observers using the auscultatory method should agree to within ±10 mm Hg, and 85% or more should agree within ±5 mm Hg. If observer agreement meets these criteria, then the average of each pair of recordings made simultaneously by the observers should be used for comparison against the test device. If observer agreement fails to meet these criteria, the study should be regarded as unacceptable. It is important for observers to test their agreement before the actual recorder evaluation to avoid the inefficient outcome of invalidating a study secondary to observer disagreement.

Test-Reference Method Comparison

The recommended method of assessment is an analysis of the limits of agreement between the test device and the standard. A scatterplot of average blood pressures versus the difference between methods should be drawn for each comparison (Figure 1). The average blood pressure represents the mean value of the test and reference method, which is an estimate of the (unknown) true blood pressure at each point. On each scatterplot, the lines representing the mean difference and plus or minus one and two standard deviations of the mean difference should be superimposed. This methodological approach replaces the methods of least-squares estimation recommended in the 1987 edition of the standard. The parameters that should be assessed by the method of agreement are shown in Table 2.

Mean and Standard Deviation

The upper limits of acceptance between the device and reference standard continue to be ±5 and ±8 mm Hg for mean and standard deviation, respectively. Users and instrument designers have accepted these values for both their clinical utility and feasibility of this level of accuracy.

Percentages of Values in Agreement Between Test and Reference Measurements

The mean and standard deviation may be influenced substantially by outlying values. An additional description of agreement between the test device and the reference standard that must be computed and tabu-
Special Considerations for Resting Measurements

As ambulatory blood pressure monitors record pressure in supine, seated, and standing positions, assessment in these three postures is desirable. The validation procedure must include equal numbers of measurements in these three positions, and separate statistical analyses should be performed to define the limits of agreement for all postures. The mean difference of the ambulatory blood pressure monitor and the reference standard for both systolic and diastolic pressures should be ±5 mm Hg, and the standard deviation of the mean should be ±8 mm Hg in each of the three postures.

Because the potential exists for displacement of the cuff sleeve or microphone assembly in patients wearing ambulatory blood pressure monitors, part of the resting assessment to assess an ambulatory blood pressure recorder should include testing before and after a 24-hour study. The disparity between the reference manometer and the device (limits of agreement) at the beginning and end of the study should be compared in 20 subjects and should not exceed 5 mm Hg in 75% of the paired simultaneous test samples.

Measurements During Motion

It is difficult to assess a blood pressure instrument during motion. There are no noninvasive standards for measuring blood pressure during motion, ambulation, or exercise. However, ambulatory blood pressure monitors are worn during a variety of activities that include walking, jogging, or light exercise. Thus, it is important to assess the performance of an ambulatory blood pressure recorder during forms of motion if manufacturers label their device as accurate during various activities.

Precise standard measurements of blood pressure during exercise should be made with intra-arterial recordings of blood pressure in 15 patients.9-11 Assessment of a device during motion requires the use of contralateral arms. Requisite to using contralateral-arms-in-motion testing is assurance by either simultaneous or sequential measurements with a reference sphygmomanometer that the blood pressure in the two arms differs by less than 5 mm Hg.

Two methods of verification of ambulatory blood pressure monitors during motion are useful: 1) comparison with intra-arterial pressures in a laboratory setting during bicycle exercise10 and 2) comparison with intra-arterial blood pressure recordings with an indwelling brachial artery catheter infused continuously with sodium heparin for the period of study.11-13 It is possible to obtain simultaneous analog output from the noninvasive test device and intra-arterial recorder to synchronize the measurements during the study.

Direct measurement of ambulatory blood pressure is the most precise means of assessing a noninvasive monitor during ambulation and other activities of motion. However, its use is restricted to a few centers in the world, and there are a number of potential complications of intra-arterial ambulatory monitoring, including hematomas, arterial dissection, and arterial occlusion.12

Assessment of Clinical Performance

Parameters of clinical performance that should be assessed include reliability with repeated clinical use and data return in ambulatory studies. It is recommended that three different devices be assessed in a minimum of 10 subjects for a total of 30 24-hour studies. A minimum of 75 blood pressure readings in 24 hours should be obtained in each of the subjects. The number of satisfactory readings in 24 hours should exceed 80% of the number programmed for the 24 hours. The types and frequencies of error codes and aborted readings should include a comparison of data return rates at the beginning and end of the 30 studies.

Conclusions

Accurate and precise blood pressure measurement devices are required for appropriate detection of hypertension, especially in the case of unsupervised use. This standard provides for a clinical assessment of overall system efficacy by requiring that blood pressures measured by an automated device achieve a mean difference of ±5 mm Hg and standard deviation of ±8 mm Hg against a reference standard. This performance level was specified in the 1987 sphygmomanometer standard and is reiterated in the 1992 standard. Intra-arterial blood pressure measurements or cuff/stethoscope auscultatory measurements may be used as a reference standard.

For the auscultatory method as the reference standard, trained observers are required, and observer agreement is acceptable if the number of simultaneous readings agrees within 10 mm Hg for 95% or more of the recordings and within 5 mm Hg for 85% or more of simultaneous observations. The AAMI standard recommends that patient/subject selection be heterogeneous and based on level of blood pressure and arm circumference. The requirements in this standard were developed in a consensus process by the AAMI Sphygmomanometer Committee, consisting of university and government researchers, users, and industry instrument designers, and represent minimal acceptable performance.

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References


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