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IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices

IEEE Engineering in Medicine and Biology Society

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IEEE Std 1708™-2014

IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices

Sponsor

Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

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Abstract: IEEE Std 1708™ establishes a normative definition of wearable cuffless blood pressure (BP) measuring devices and the objective performance evaluation of this kind of device. The standard is independent of the form of the device or the vehicle to which the device is attached or in which it is embedded. The standard is applicable to all types of wearable BP measurement devices including epidermal and unobtrusive BP devices that have different modes of operation (e.g., to measure short-term, long-term, snapshot, continuous, beat(s)-to-beat(s) BP, or BP variability). This standard is, however, limited to evaluation of devices that do not use a cuff during measurement and do not cover evaluation of all sphygmomanometers that are used with an occluding or inflatable cuff for the indirect determination of BP on the upper arm or wrist. This standard provides guidelines for manufacturers to qualify and validate their products, potential purchasers or users to evaluate and select prospective products, and health care professionals to understand the manufacturing practices on wearable BP devices.

Keywords: blood pressure measuring devices, cuffless, epidermal, hypertension, IEEE 1708™, performance evaluation, unobtrusive, wearable

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Introduction

This introduction is not part of IEEE Std 1708™-2014, IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices.

Hypertension is an important public-health challenge worldwide [B12]. In 2000, the estimated global number of adults with hypertension was 972 million, 26.4% of the adult population [B12]. Hypertension is important not only because of its high frequency but also because it is a major modifiable risk factor for cardiovascular and kidney disease [B12]. It was reported by WHO report 2002 [B2] that about 62% of strokes and 49% of heart attacks are caused by hypertension; 7.1 million die from hypertension, which is about 13% of the global fatality in total [B35].

Despite the risk people with hypertension may face, lack of awareness makes the situation difficult to control. The Joint National Committee 7th report (JNC 7) [B5] stated that the percentage of persons in whom hypertension is properly controlled (BP < 140 mmHG/90 mmHg) is limited; more than 30% of the hypertensive populations are still unaware of their condition and are therefore not receiving treatment.

BP measured in a clinical setting by a trained physician using the auscultative technique with the mercury column has been used as the standard parameter for clinical diagnosis for over 100 years [B25]. It is, however, becoming increasingly clear that this reading is often inadequate or even misleading to represent a patient's true BP status [B25]. On the other hand, ambulatory BP measurement (ABPM) and home (or self) BP measurement (HBPM) are shown to be superior to clinic BP measurement (CBPM) in predicting cardiovascular mortality [B6]. Comparing to CBPM, ABPM, and HBPM have the following advantages [B5], [B10], and [B16]: (1) eliminate the white-coat effect; (2) helpful to the assessment of clinic effects, drug effects, and work influence on BP; (3) better predict cardiovascular events and mortality; and (4) cost effective.

Therefore, in 2008, the American Heart Association (AHA), American Society of Hypertension (ASH), and Preventive Cardiovascular Nurses Association (PCNA) published a joint scientific statement that recommended using HBPM and further stated that HBPM should become a routine component of BP measurement in the majority of patients with known or suspected hypertension [B25].

Current devices employed for ABPM and HBPM are usually developed based on the oscillometric method, which has to be used with an inflatable cuff during measurement. Those systems have several drawbacks which hinder their popularizing in the broad masses. One of the major problems is the employment of an inflatable cuff during the measurement. Patients find the cuff pressure is intolerable, particularly those with very high BP and who need frequently repeated readings; petechiae of the upper arm and bruising under the inflating cuff may occur; sleep disturbance is fairly common.

Moreover, to have an accurate measurement, an appropriate cuff size must be selected according to the upper-arm circumference of users [B7]. Applying a cuff that is inappropriately small or large against the upper-arm circumference will contribute a substantially false elevation or reduction to the BP readings [B7]. Educating practitioners about appropriate sized cuffs for out-of-office BP measurement is necessary [B7] but increases the workload of the nurses.

Last but not least, the readings by conventional devices may be insufficient indicators for hypertension. Since only intermittent measurements of single snapshot readings are provided, current devices are incapable of recording the time varying BP or capturing the dynamic state of the cardiovascular system throughout the day [B15]. In addition, study of pathogenesis of hypertension reveals that the systolic hypertension is dependent on a series of changes in the vasculature, the most important of which is increased central arterial stiffness [B8]. Those signals are diffused by the relative imprecision in the techniques utilized by current devices [B8].

In the past few years, there was an emerging interest in developing non-invasive BP measuring devices without an occluding cuff. Leading investigators in this field suggest that BP can be estimated indirectly from pulse transit time (PTT), which is a time period taken for the pulse wave to travel along the artery and arrive at the periphery, or parameters such as pulse arrival time (PAT), pulse wave velocity (PWV), pre-ejection period (PEP), etc., or their combinations. Models that relate BP, PTT, and other physiological parameters have been developed based on biological and mechanical properties of the cardiovascular system, e.g., elastic modulus, dimensions and stiffness of the intervening vessels. Based on these models, systems that use electrocardiographic, photoplethysmographic, and/or phonocardiographic sensors have been proposed for the cuffless and continuous measurement of BP [B15], [B8], [B4], [B28], [B27], and [B18].

Cuffless BP measuring devices successfully release the users from the cuffs and are therefore more suitable to be implemented into the HBPM or ABPM systems, where frequent measurements are usually needed. When they are designed as wearable devices, e.g., a shirt [B40] or watch [B26] and [B29], or integrated with furniture at home, e.g., a chair [B36] or bed [B9] for unobtrusive BP monitoring, or epidermal BP devices based on flexible-stretchable-printable electronics, the long-term and out-of-office monitoring becomes more comfortable and thus more attractive to the patients.

In addition, those devices have the great advantage of being not only capable of providing a snapshot of BP, but also potentially being usable for continuous BP monitoring. This special feature makes them superior to CBPM for the prompt identification of cardiovascular risk. Also, since signals (e.g., arterial stiffness) are implemented into the estimation model, the cuffless devices are potentially more capable of providing informative indication of the patient's health condition.

Nevertheless, since the physiology coefficients employed for BP estimation are subject-dependent, calibration is crucial to ensure the accuracy of the cuffless devices. A major challenge is to find a simple and accurate way to calibrate the device individually or estimate BP directly without a calibration procedure.

To date, there is no defined and independent standard for wearable cuffless devices. Existing standards for evaluating sphygmomanometers are intended only for devices that are used with an occluding cuff and, therefore, do not cover all aspects needed for the emerging cuffless devices. As a result, validating approaches of the cuffless techniques or devices vary largely from study to study.

Since cuffless approaches have become important in hypertension research in recent years, a section of this standard is devoted to the assessment process. It is crucial for the clinicians and engineers to join efforts in establishing an evaluation standard. Although existing standards for evaluating sphygmomanometers were developed for devices with an occluding or inflatable cuff, parts of them are still applicable to the evaluation of cuffless devices. The experiences of these current standards need to be carefully appreciated during the development of the new standard.

In typical settings of wearable cuffless devices, biosignals such as biopotentials and body motion signals are acquired by wearable sensors attached to a patient's body (or epidermal sensors on the skin) and sent to a nearby intermediate terminal for processing and/or relaying to a remote terminal. The wearable sensors may be equipped with a sensor of optical transmitter and detector, accelerometer, pulse meter, thermometer, pressure sensor, and galvanic skin reflex (GSR) electrodes to monitor the user's health conditions and/or movements. The signals collected from the sensors may also communicate with the personal server, which in turn connects to a mobile gateway for further signal processing and storage. Cellular communication capability may be added to expand service coverage to outdoors. Wireless body area networks (BSN) have great potential to be implemented into the settings.

For compatibility and convenience, the standard is organized to cover all of the following aspects: 1) device accuracy, 2) wearable sensors, 3) network with communication protocols if used, 4) electrical safety, and 5) stability.

Contents

IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices

1. Overview

1.1 Scope

The intent of this standard is to establish objective performance evaluation of wearable, cuffless blood pressure (BP) measuring devices. The standard is independent of the form of the device or the vehicle to which the device is attached or in which it is embedded. The standard is applicable to all types of wearable BP measurement devices that have different modes of operation (e.g., to measure short-term, long-term, snapshot, continuous, beat(s)-to-beat(s) BP, or BP variability). This standard is, however, limited to evaluation of devices that do not use a cuff during measurement and does not cover evaluation of all sphygmomanometers that are used with an occluding or inflatable cuff for the indirect determination of BP on the upper arm or wrist.

1.2 Purpose

There is currently no defined, independent standard for wearable cuffless BP measurement devices, which have drawn growing interest in recent years. Existing standards for evaluating sphygmomanometers are intended only for devices that are used with an occluding cuff and, therefore, do not cover all aspects needed for the emerging wearable devices. This standard provides guidelines for manufacturers to qualify and validate their products, potential purchasers or users to evaluate and select prospective products, and health care professionals to understand the manufacturing practices on wearable BP devices.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

ANSI/AAMI SP10:2002, American National Standard for Manual, Electronic, or Automated Sphygmomanometers.

ANSI/NFPA 99-1996, Standard for Health Care Facilities, Annex 2, "Flammable Anesthetizing Locations."

IEC 60601-1, Medical Electrical Equipment—Part 1: General Requirements for Safety.

IEEE Std 11073-10407™, IEEE Standard for Health Informatics—Personal health device communication—Device Specialization—Blood Pressure Monitor.[1,2]

IEEE Std 11073-10101™, IEEE Standard for Health Informatics—Point-of-Care Medical Device Communication—Part 10101: Nomenclature.

IEEE Std 11073-10201™, IEEE Standard for Health Informatics—Point-of-Care Medical Device Communication—Domain Information Model.

IEEE Std 11073-20101™, IEEE Standard for Health Informatics—Point-of-Care Medical Device Communication—Application Profile—Base Standard.

The British Hypertension Society Protocol for the Evaluation of Blood Pressure Measuring Device. *J Hypertens*, vol. 11, pp. S43-S63, 1993.

3. Definitions, acronyms, and abbreviations

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause. [3]

3.1 Definitions

blood pressure classification: Blood pressure characteristic range defined by JN7 report [B5].[4]

calibration: Act or process of determining the unknown parameters in estimating blood pressure.

paired measurement: Parallel blood pressure measurement carried out by the reference measurement and the device under test.

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reference measurement: Measurement provided by two trained observers simultaneously with one reference mercury sphygmomanometer (using a "Y" connector). If the two observers' measurements are no more than 4 mmHg apart, the mean value of the two is used as the reference measurement.

3.2 Acronyms and abbreviations

AAMI American Association for the Advancement of Medical Instrumentation

BHS British Hypertension Society

BP blood pressure

CP cumulative percentages

CP_L cumulative percentages of differences falling within limit of L

DBP diastolic blood pressure

ECG electrocardiogram

ESH European Society of Hypertension

JNC 7 Joint National Committee 7^{th} report

KS Kolmogorov-Smirnov

MAD mean absolute difference

MAPD mean absolute percentage difference

MD mean difference

PAT pulse arrival time

PEP pre-ejection period

PPG photoplethysmograph

PTT pulse transit time

PWV pulse wave velocity

RMSD root mean square difference

SBP systolic blood pressure

SD standard deviation

*t*4 generalized *t* distribution with degree of freedom of four

4. Performance evaluation

The performance evaluation clause is divided into six subclauses as follows:

— 4.1 Summary

— 4.2 Observer training and measurement

— 4.3 Subject selection

— 4.4 Validation procedure

— 4.5 Validation criteria

— 4.6 Data reporting

4.1 Summary

The validation team should consist of two properly trained observers and/or one engineer from the manufacturer if necessary. The validation procedure is summarized in Figure 1:

a) Observer training and measurement. Two observers are trained in accurate BP measurement and get familiar with the data collecting procedure and device operation.

b) Subject selection. Twenty subjects are recruited at Phase 1of the assessment, and devices passing the criteria of this phase will proceed to Phase 2, where an additional 25 subjects are recruited. The characteristic of recruited subjects should follow the requirement stated in this standard.

c) Main validation. The procedure is broken down into three levels: static test, test with BP change from the calibration point, and test after a certain period of time from calibration. Practitioners should properly design their validation protocol to cover the validation from each of the three levels. Observer measurements and test device measurements are conducted with stated validation procedures.

d) Data analysis. The collected data are analyzed and compared to the stated accuracy criteria.

e) Data reporting. The results are presented in recommended format.

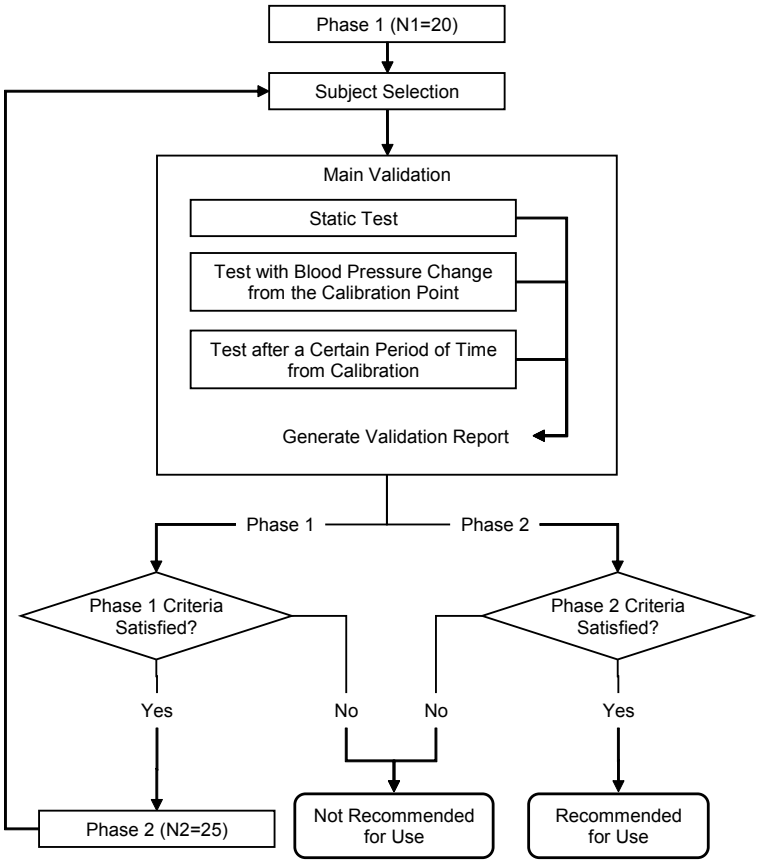


Figure 1—Summarized validation procedure

4.2 Observer training and measurement

4.2.1 Observer training

Two trained observers are required for the evaluation of a device. The training procedure of the observers shall follow the recommendation called out by ESH protocol [B23]. The procedure is reproduced in Annex B.

4.2.2 Observer measurement

Wearable cuffless devices with calibration process may be complex and vary from device to device. It is important for the observer to get familiar with the operation of the device strictly according to the instruction provided by the manufacturer. An engineer from the manufacturer may be needed to assist this process and provide cautions that may influence the validation procedure, e.g., the influence of cuff inflation when using the reference sphygmomanometer.

Reference measurement should be provided by two trained observers and measured simultaneously with one reference mercury sphygmomanometer (using a "Y" connector). The sphygmomanometer used as the reference standard shall meet the requirement called out by ISO 81060-2:2013 or ANSI/AAMI SP10. SBP and DBP measurements with the mercury sphygmomanometer were determined using the Phase 1 and Phase 5 Korotkoff sounds respectively. All measurements should be recorded to the nearest 2 mmHg. If

both of the measurements from the two observers are no more than 4 mmHg apart, the mean value of the two is used as the reference measurement. Otherwise, the measurement should be taken again.

During the validation procedure in 4.4, BP readings from the test device and the observer should be collected either simultaneously or sequentially according to the concrete conditions described in 4.2.2.1 and 4.2.2.2. At least 30 s should be allowed after observer measurement to avoid venous congestion. When reference and test device measurements are conducted sequentially (see 4.2.2.2), no more than 60 s should be allowed after observer measurement or variability may be increased.

Note that for beat-to-beat BP measuring devices, the mean of all beats over a 20 s period should be used as the test device measurement data.

4.2.2.1 Simultaneous measurement

Condition: At least one arm, when used for reference measurement, must not interfere with the test device measurement. That arm shall be used for the observer measurement. If both arms are available, the left arm is preferred.

When deflation of the reference mercury sphygmomanometer begins, the test device should start the measurement to provide simultaneous measurement with the reference. At least 30 s should be allowed after observer measurement to avoid venous congestion. Differences are calculated by subtracting the reference measurements from the paired measurements of the test device.

4.2.2.2 Sequential measurement

Condition: Either arm, when used for reference measurement, will interfere with the test device measurement.

Test device measurement should be conducted after the reference measurement. At least 30 s should be allowed after reference measurement to avoid venous congestion, but not more than 60 s or variability may be increased. Differences are calculated from the test device measurement and the adjacent two reference measurements. The difference which is more favorable to the test device is selected.

4.3 Subject selection

The summarized requirements on subject selection are presented in Table 1. Forty-five subjects, with at least 22 females and 22 males, aged between 18 years and 65 years old shall be recruited if the device is intended for adult use. The study participants are to be introduced to the observers, who will explain to them the eligibility requirements and specific procedures. Initials, sex, date of birth, medical history and current medications are to be recorded on the case report form. Pregnant, pediatric, or elderly people, or those with present arrhythmias, should not be included in the study.

The subjects shall also have a specified range of BP. The endpoint of the BP classification is determined according to the JNC 7 report [B5]. The BP used in the analysis should be the entry BP measured by a trained observer following the recommendation called out by BHS protocol [B21]. Three measurements are required at the sitting position, and the averaged value is used as the entry BP to determine the subject's BP classification.

Table 1—Subject selection requirements

Number of subjects: 45 (20 subjects for Phase 1; 25 subjects for Phase 2)					
Blood pressure ranges:					
Blood pressure classification	**Systolic blood pressure (mmHg)**		**Diastolic blood pressure (mmHg)**	**Subjects in Phase 1**	**Subjects in Phase 2**
Normal	<120	and	<80	5	≥6
Prehypertension	120-139	or	80-89	5	≥6
Stage 1 hypertension	140-160	or	90-100	5	≥6
Stage 2 hypertension	≥160	or	≥100	5	≥6
Gender:					
At least 22 males and 22 females					
Age:					
All subjects should be aged between 18 and 65 years old.					

4.4 Validation procedure

4.4.1 Introduction

As recommended by the ESH protocol [B23], the overall outcome of a device can be apparent from a very early stage. To avoid the unnecessary waste of time and money, and an inconvenience to subjects, the validation process is divided into two phases. In Phase 1, only 20 subjects are recruited, and any device failing this phase should be eliminated from further testing. Those passing devices will proceed to Phase 2 in which another 25 subjects are recruited.

The validation may proceed to Phase 2 only if the test device passes accuracy criteria in Phase 1 (see 4.5.2); if not, the device should be eliminated from further testing.

Two test devices should be randomly chosen from the device pool. Those two devices should be used through the whole validation procedure with each device completing validation on at least 22 subjects.

Concerning the special feature of the cuffless BP measuring devices, where the calibration efficacy would greatly influence the device accuracy, the validation procedures are considerably different from that of the cuff-based devices. For each subject, the procedure is broken down into three levels: static test, test with BP change from the calibration point, and test after a certain period of time from calibration. Practitioners should properly design their validation protocol to cover the validation from each of the three levels.

4.4.2 Static test

Device validation should be performed at room temperature without disturbing influences. The subjects are asked to relax for 10 minutes. Calibrate the test device according to the instructions provided by the manufacturer. Recalibration is allowed if a fail-calibration alarm occurs. The BP at calibration point should be carefully recorded for later use when calculating the BP change (see 4.4.3).

After the calibration, three pairs of measurements for each subject, from the test device and observers, are carried out. Either simultaneous or sequential is allowable, depending on whether the inflation and deflation of the cuff used by the reference mercury sphygmomanometer would interfere with the test device measurement (see 4.2.2).

4.4.3 Test with blood pressure change

To evaluate whether a device has been properly calibrated, the validation protocol should require a test that contains BP data distributed widely around the BP measured at calibration. For each subject, three pairs of measurements from the test device and observers are to be carried out. The methods and procedures of inducing the BP change are not restricted in the protocol, while the range and proportion of the induced change should be in accordance with the requirements in Table 2.

Table 2—Requirements on the induced blood pressure changes[a]

	Changes of blood pressure from the point of calibration (mmHg)			
Systolic blood pressure	-30 – -15	-15 – 0	0 – 15	15 – 30
Diastolic blood pressure	-20 – -10	-10 – 0	0 – 10	10 – 20
Required percentage of samples (at least)	13.6%	34.1%	34.1%	13.6%

[a]Blood pressure change refers to the reference reading measured by the observers minus the value of at the calibration point.

4.4.4 Test after a certain period of time

To test whether the calibration of the device ages as well as what is claimed by the manufacturers, the protocol shall cover a sufficient period of time. This procedure is different from the in-use (field) validation in the BHS protocol [B21], which aims to subject the device to a period of fairly strenuous use. Instead, the purpose is to test if the device has been efficiently calibrated and is working at a tolerable accuracy level during the period between the two pints of calibration. Similar to the previous tests, three pairs of measurements for each subject from the test device and observers are carried out.

4.5 Validation criteria

4.5.1 Introduction

The manufacturer should determine the accuracy of the test device according to the requirements in this subclause by analyzing the data collected from 4.4. All datasets shall be included for the analysis. If a problem is encountered when collecting the data, explanation shall be provided in the report.

To analyze the data, mean absolute difference (MAD) and mean absolute percentage difference (MAPD) are introduced in addition to those parameters employed by the current standards. For the detailed information and considerations on the statistical aspect of the criteria, see Annex A. The MAD and MAPD are calculated as,

$$\mathrm{MAD} = \left(\sum_{i=1}^{n} \left| p_i - y_i \right| \right) / n , \tag{1}$$

$$\mathrm{MAPD} = \left(\sum_{i=1}^{n} \left| 100(p_i - y_i) / y_i \right| \right) / n , \tag{2}$$

where p_i is the test device measurement, y_i is the average of the adjacent two reference measurements taken before and after device measurement as defined in ISO 81060-22, and n is the data size. Equation (1) and Equation (2) above give the differences that are calculated from the test device measurement and the average of the adjacent two reference measurements.

Realizing that the device performance may also depend on the subject's BP level, the accuracy is also calculated within different BP classifications defined in Table 1. Since larger BP variability presents at the higher BP level and will introduce undesired error when sequential measurement is used, a comparatively larger measurement difference as compared to lower BP level is allowable to a certain extent.

It should be noted that at this time, the accuracy limits are only set temporarily. Modification may be needed after a significant number of devices have been validated according to this standard and sufficient data has been provided. To provide a general idea about the accuracy of the test devices, Table 3 describes the accuracy level that is equivalent to the result using ISO 81060-2:2013 or ANSI/AAMI SP10 and the BHS protocol that are recommended for cuff-based devices.

Table 3—MAD accuracy level with comparison to the ANSI/AAMI SP10 and BHS evaluation systems

MAD (mmHg)	ANSI/AAMI SP10	BHS	Recommended grading
≤4	pass	Grade A	A
4-5	pass	mostly in Grade A, less in Grade B	A
5-6	pass or fail	mostly in Grade B, less in Grade A, extremely less in Grade C and Grade D	B
6-7	mostly fail, less pass	mostly in Grade C, less in Grade B and Grade D	C
≥7	fail	worse than Grade C	D

4.5.2 Phase 1

After completing the validation on 20 subjects according to 4.4.2, the MAD for all the differences between test device and reference measurement and for data collected from different tests (e.g., static test, test with BP change from the calibration point, test after a certain period of time from calibration) analyzed separately should be within 7 mmHg for both SBP and DBP measurement.

If satisfied, the validation may proceed to the next phase; if not, the device shall be eliminated from further testing. A fail decision may be made in this phase.

4.5.3 Phase 2

After completing the validation on the additional 25 subjects, data from all 45 subjects is analyzed altogether. The measurement data is assessed according to the following criteria in 4.5.3.1, 4.5.3.2, 4.5.3.3, and 4.5.3.4.

4.5.3.1 Overall accuracy

MAD for all the measured differences between test device and reference measurement for both SBP and DBP measurements are calculated. The grading is determined according to Table 3, where Grade A for MAD ≤5 mmHg, Grade B for MAD = 5-6 mmHg, Grade C for MAD = 6-7 mmHg, and Grade D for MAD ≥7 mmHg.

4.5.3.2 Accuracy at different BP change levels

MAD at different BP change levels (see Table 3) using the readings collected after the BP change inducement should be within 7 mmHg for SBP and DBP analyzed separately.

4.5.3.3 Accuracy after a certain period of time from calibration

The accuracy should be consistent with the pass/fail criteria specified in 4.5.3.1 after a period time no longer than the calibration frequency claimed by the manufacturers. If that is not the case, it means that the calibration of the device does not age as well as what is claimed, and the manufacturer should properly increase the calibration frequency for better tracking of the BP variation.

4.5.3.4 Accuracy at different BP levels

MAD at different BP classification categories except Stage 2 hypertension (see Table 1) determined by subjects' entry BP should be within 6 mmHg for SBP and DBP measurement analyzed separately.

4.6 Data reporting

A report of validation report, which shall be made available by the manufacturer upon request, shall contain at least the following information.

4.6.1 Subject information

The report should be prefaced with target population and key characteristics information (e.g., BP, sex, age, drug use, diagnosed disease, etc.) of each subject included in the validation procedure. A summarized subject characteristic report shall also be provided which includes at least BP range, sex, and age in the form of Table 4.

Table 4—Subject characteristic report

Selection factor		Phase 1	Phase 2
Total number			
Entry BP range	Normal		
	Prehypertension		
	Stage 1 hypertension		
	Stage 2 hypertension		
Sex	Male		
	Female		
Age	Mean ± standard deviation		
	Range		

4.6.2 Statistical report

The validation result should be presented in the tabular form as Table 5 and Table 6. The column of BP changes is presented as the mean absolute value of the BP change from the calibration point.

Studies [B38] have revealed that the cuffless device presents an apparent relationship between the difference and reference measurement. It is unfair to apply a constant accuracy limit to measurements at both the low and high ends of BP because the variability may increase at high BP and larger errors were inevitability introduced. Therefore, MAPD is used in the protocol. By using the relative difference instead of the absolute difference as the calculation unit, there is great potential to reduce the dependency of the measurement difference with BP level.

In addition, the MD, SD, and CP values are also required to be included in the report due to the consideration of accuracy interpretation among different evaluation systems.

Table 5—Device accuracy report

BP changes (mmHg)	MAD (mmHg)	MAPD (%)	MD (mmHg)	SD (mmHg)	CP_5(%)	CP_{10} (%)	CP_{15} (%)
Static test (N = 135)							
Different time interval							
After calibration (N = 135)							
Before next time of calibration (N = 135)							
Accuracy at different blood pressure change levels							
0-15 mmHg for SBP / 0-10 mmHg for DBP							
15~30 mmHg for SBP / 10-20 mmHg for DBP							
Accuracy at different blood pressure levels							
Normal							
Prehypertension							
Stage 1 hypertension							
Stage 2 hypertension							

Table 6—Induced blood pressure change report

Phase	Systolic blood pressure change interval				Diastolic blood pressure change interval			
	-30 – -15 mmHg	-15 – 0 mmHg	0 – 15 mmHg	15 – 30 mmHg	-20 – -10 mmHg	-10 – 0 mmHg	0 – 10 mmHg	10 – 20 mmHg
Phase 1								
Phase 2								

4.6.3 Graphical representation

For systolic and diastolic values, the following graphical plots should be provided separately for a static test, each subset of data with specified level of BP change, and each subset collected at different time intervals from the last time of calibration.

- Scatter plots of the measuring differences between test device and reference measurement vs. the average of them (i.e., Bland-Altman plot);
- Scatter plots of the measuring differences between test device and reference measurement vs. BP changes from the calibration point (Figure 2);
- The histogram of BP changes for the corresponding subsets of data (Figure 3).

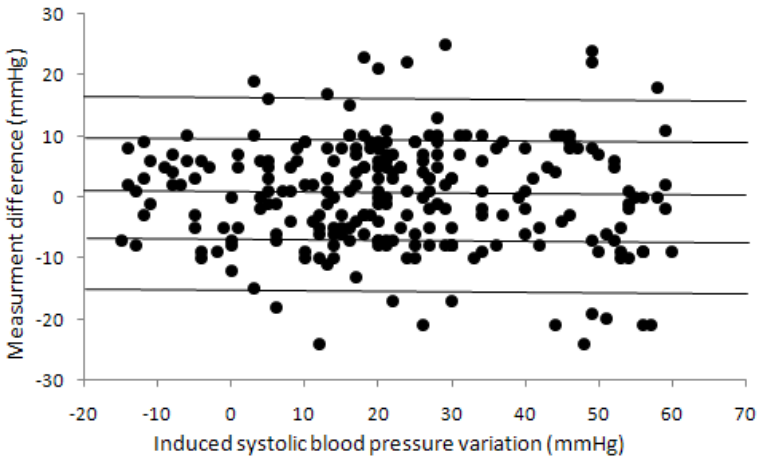


Figure 2—Scatter plot of difference with induced BP change

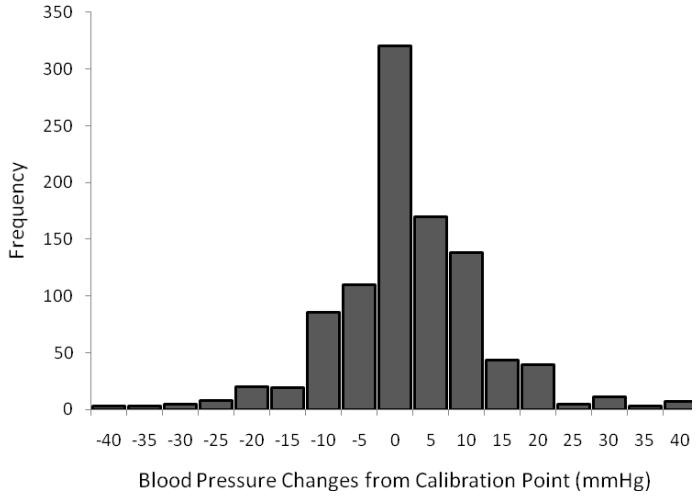


Figure 3—Histogram of blood pressure changes

5. Wearable sensor

Different from the conventional devices which mainly use an inflatable cuff accompanied by a pressure transducer and/or Korotkoff sounds detector, wearable cuffless devices utilize different kinds of sensors for collecting data and/or for achieving the calibration process without using an inflatable cuff. These sensors may include optical transmitter and detector, accelerator, pressure transducer, electrodes, capacitive sensors, organic phototransistors, epidermal sensors based on flexible and printable electronics, etc.

These sensor components shall meet the requirements of the standard for that specific kind of sensor and shall bear the cautionary labeling required by those standards.

6. Communication

The manufacturer may design communication functionality between personal telehealth wearable cuffless devices and computing engines (e.g., cell phones, personal computers, personal health appliances, set top boxes, body sensor networks, or body area networks) in a manner that enables plug-and-play interoperability. In this case, the wearable cuffless devices shall meet the requirement specified in ISO/IEEE Std 11073-10407. The manufacturer may design communications functionality between cuffless blood pressure devices and other components of an acute care integrated clinical monitoring system in a manner that enables plug-and-play interoperability. In this case, the wearable cuffless blood pressure device, including the epidermal and unobtrusive BP devices, shall meet the requirements specified in ISO/IEEE Std 11073-10101, ISO/IEEE Std 10201, and ISO/IEEE Std 10407.

7. Safety

For the electrical safety, the device shall meet the requirements specified in IEC 60601-1. Wearable devices or products appear simple; yet sophisticated circuits and complex software could be embedded which are invisible to the user. IEC 60601-1 and IEC 60601-2-23 manage this reality in terms of safety and should be complied with at the appropriate phases and the final design in the product-development process. The components of sphygmomanometers and their accessories that are labeled as conductive shall meet the requirements of the specified section of ANSI/NFPA 99 and shall bear the cautionary labeling required by that standard.

8. Stability

The stability shall be tested according to ANSI/AAMI SP10 and meet the specific requirement in that standard.

Annex A

(informative)

Statistical considerations

A.1 Distribution model considerations

A.1.1 Introduction

Distribution modeling is the foundation for device accuracy assessment. Both the ANSI/AAMI SP10 and BHS evaluation systems were developed based on the assumption that measurement errors are normally distributed [B21], [B1]. Under this assumption, Sun and Jones [B33] developed a statistical map to relate the ANSI/AAMI SP10 criteria (i.e., MD and SD) with the BHS grading criteria (i.e., Grade A, Grade B, Grade C, and Grade D). According to the map they presented, a device that has achieved Grade A or B under the BHS system should deem to comply with the ANSI/AAMI SP10. Xiang's study [B37], however, found in the literature [B24] that there were devices that passed the BHS criteria but failed that of ANSI/AAMI SP10.

Sun and Jones [B33] also found a significant discrepancy between the sample CP_5, CP_{10}, and CP_{15} and their theoretical values estimated from the sample MD and SD. Consequently, more than half of the 67 test entries would be downgraded in the BHS system if the BHS evaluation parameters were estimated from the ANSI/AAMI SP10 parameters using a normal distribution model [B33].

The results suggested that a normal model may not be a good approximation of the underlying distribution of the experimental data, leading to translation problems between the BHS and ANSI/AAMI SP10 evaluation systems. Therefore, other distribution models should be introduced to re-examine the relationship of these two standards.

A.1.2 Distribution analysis on published reports

To solve the problem raised by Sun and Jones's study [B33], we proposed the generalized *t* distribution in a previous study [B37]. Its probability density function is given in [B13] as:

$$p(t \mid u, s, v) = \frac{s^{-1}\Gamma(\frac{v+1}{2})}{\Gamma(\frac{v}{2})\sqrt{v\pi}} \times (1 + \frac{(t-u)^2}{s^2 v})^{-\frac{v+1}{2}} \quad \text{(A. 1)}$$

where

u denotes MD,

s denotes the scalar parameter and equals to $\mathrm{SD} \cdot \sqrt{(v-2)/\pi}$ (v>2),

v denotes the degrees of freedom and

$\Gamma(\cdot)$ denotes the Gamma function.

As the value of v grows, the generalized *t* distribution approaches the normal distribution.

Compared to normal distribution, generalized *t* distribution introduced another parameter, degree of freedom, which controls the shape of the probability density function in terms of the heights of peak and the thickness of tail. This property makes the *t* distribution prominent at identifying outliers.

We assumed that the error distributions of the devices follow either a normal distribution or generalized *t* distribution of a certain degree of freedom. CP_5, CP_{10}, and CP_{15} can then be estimated from the reported MD and SD by the following equations:

$$\mathrm{CP}_L^{\,g}(u,d,L)=\frac{1}{d\sqrt{2\pi}}\int_{-L}^{L} e^{\frac{-(x-u)^2}{2d^2}}dx \tag{A. 2}$$

if it is a normal distribution, and

$$\mathrm{CP}_L^{\,t}(u,d,v,L)=\frac{d^{-1}\Gamma(\frac{v+1}{2})}{\Gamma(\frac{v}{2})\sqrt{(v-2)\pi}}\int_{-L}^{L}(1+\frac{(t-u)^2}{d^2(v-2)})^{-\frac{v+1}{2}}dt \tag{A. 3}$$

if it is a generalized *t* distribution, where L = 5, 10, 15 mmHg as required by BHS protocol [B21], *d* denotes SD. We restricted the selection of *v* to be within 3 and 30 since at distribution with $v \geq 30$, it can be approximated by a normal distribution. The BHS grading for each device was then estimated from the calculated CP_5, CP_{10}, and CP_{15}.

The evaluation results of 40 devices [B39] were collected from literature where the MD, SD, CP_5, CP_{10}, and CP_{15} of the error distribution and the BHS grading for each device on the measurement of SBP and DBP were reported.

To determine the degree of freedom that matched best to the real underlying distribution, estimated gradings were compared to the reported gradings. The Stuart-Maxwell chi-square test [B32] and [B14] was used to quantify the agreement, and the chi-square value and p-value were calculated correspondingly. The test results showed that degree of freedom of four can effectively portray the difference distribution.

Based on this result, Table A.1a compares the reported BHS grading with the estimated grading based on the assumption of normal distribution or *t*4 distribution. Ideally, the numbers should either lie on the diagonal of the table or around the diagonal symmetrically. It is apparent from Table A.1b that *t*4 better described the underlying distribution than the normal model. The matched pairs between the estimated and reported gradings increases from about half to 82.9% and 80.5% for SBP and DBP, respectively when *t*4 distribution was applied instead of normal distribution.

Table A.1—Comparison of the estimated and the reported BHS grading [B39]

(a) Normal distribution

SBP					DBP				
Reported BHS grading	Estimated BHS grading				Reported BHS grading	Estimated BHS grading			
	A	B	C	D		A	B	C	D
A	18	13	2	0	A	17	12	3	0
B	0	1	2	2	B	1	0	3	0
C	0	0	0	1	C	0	0	0	3

D	0	0	0	1	D	0	0	0	1
chi-square = 18.9 (p = 0.0003) Matches % = 50.0 %					chi-square = 17.3 (p = 0.0006) Matches % = 45.0 %				

(b) Generalized *t* distribution (degree of freedom = 4)

SBP					**DBP**				
Reported BHS grading	**Estimated BHS grading**				**Reported BHS grading**	**Estimated BHS grading**			
	A	**B**	**C**	**D**		**A**	**B**	**C**	**D**
A	29	4	0	0	A	27	5	0	0
B	0	3	2	0	B	1	2	1	0
C	0	0	0	1	C	0	0	2	1
D	0	0	0	1	D	0	0	0	1
chi-square = 7.0 (p = 0.07) Matches % = 82.5 %					chi-square = 4.7 (p = 0.2) Matches % = 80.0 %				

A.1.3 Distribution analysis on wearable cuffless device

Testing of a wearable and cuffless BP device on at least 85 subjects by a similar protocol described by the ANSI/AAMI SP10 or BHS was not found in literature except the one we reported [B27]. In that study, the 85 volunteers were aged 57 ± 29 yrs. and included 36 males. Among them, 39 subjects (46%) were diagnosed with hypertension. All measurements were taken when the subjects were sitting down.

The accuracy was assessed according to the ANSI/AAMI SP10 passing criteria and BHS grading systems. With the assumption of *t*4 distribution, BHS grading was estimated from the accuracy measures of MD and SD to test its accordance with the reported grading. The estimation method was the same as the former literature study.

The probability distribution of the differences between the estimated readings and the reference was fitted to the normal distribution and *t* distribution. Fitting results were illustrated by cumulative distribution plot with predicted fitting lines. A quantitative statistical method, the Kolmogorov-Smirnov (KS) test, was used to assess the goodness-of-fit of the hypothesized distribution.

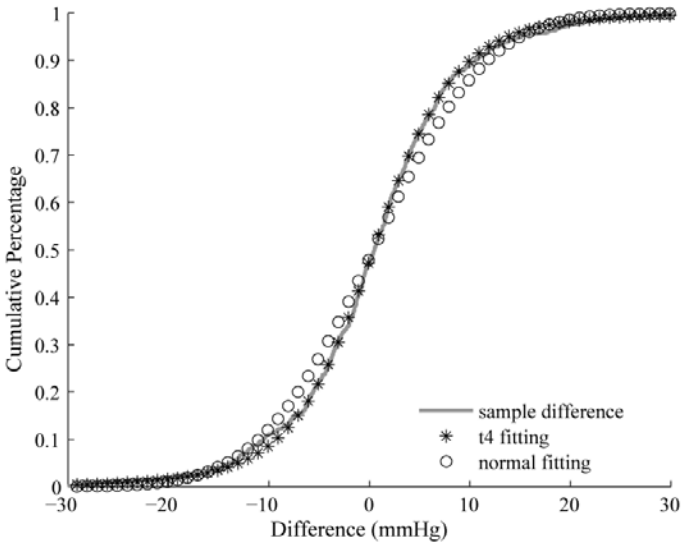
The agreement between the wearable and cuffless device and the reference was 0.36 ± 8.89 mmHg and 1.13 ± 5.88 mmHg for SBP and DBP, respectively. It achieved a BHS Grade B for SBP and Grade A for DBP. When converting the MD ± SD to BHS grading under the assumption of normal distribution, the estimated grading results were C/B; but when *t*4 distribution was applied instead, the estimated grading was the same with the reported ones, which was B/A for SBP/DBP. This result was accordant with the former distribution study on the published reports.

Figure A.1 shows the fitting results of the cumulative percentage of estimation difference of the wearable and cuffless device to the normal distribution and *t*4 distribution. For SBP, *t*4 fitted the experimental data very well, while normal distribution had a deviation in the central part. For DBP, both distributions got a deviation with respect to the experimental data and the deviations were in different directions.

When a new mapping chart, Figure A.2, relating ANSI/AAMI SP10 and BHS protocol was plotted for a *t*4 distribution, the passing criteria of ESH was found to be adopted from the Grade A of BHS, which fall entirely within the requirement of ANSI/AAMI SP10. Figure A.2 also explains why there were devices that received Grade B under the BHS system but failed the ANSI/AAMI SP10 standard [B1].

In conclusion, the results of our study on the validation reports of various cuff-based devices and an experimental study on a cuffless device found that the *t*4 distribution is better than the normal distribution in portraying the underlying error distribution of BP measuring devices. Using the *t*4 model partly resolves the problem of being unable to translate results between the ANSI/AAMI SP10 and BHS evaluation systems when applying the normal distribution.

a) SBP



b) DBP

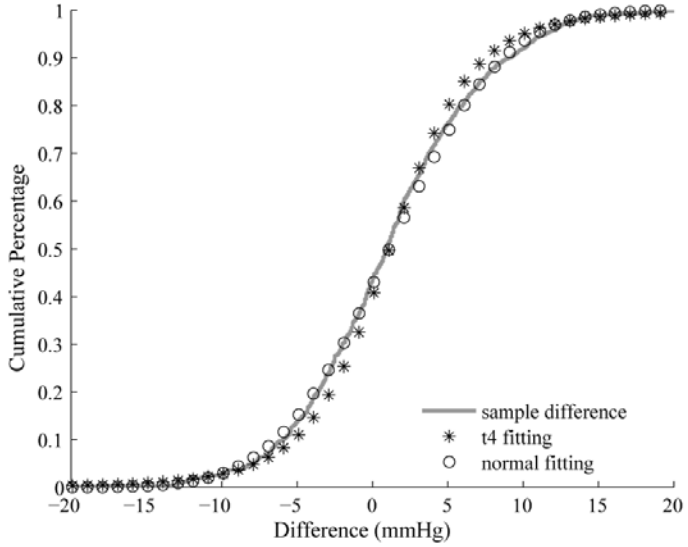


Figure A.1—Cumulative percentage difference with corresponding hypothesized cumulative distribution function values

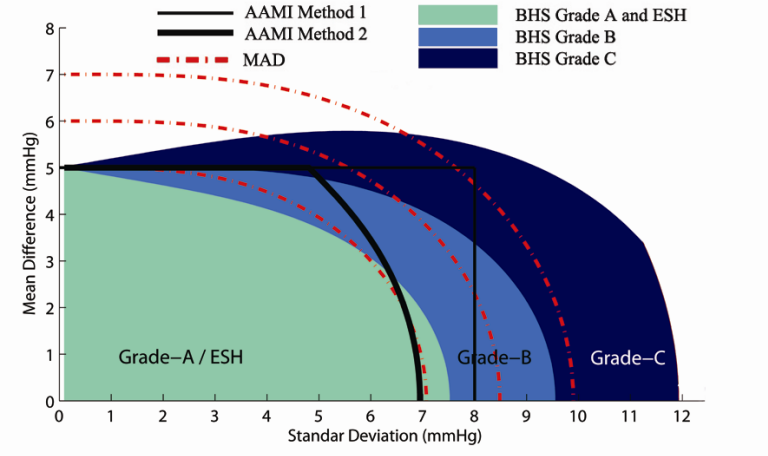


Figure A.2—Mean absolute difference as a function of mean difference and standard deviation under *t*4 distribution. The dashed lines are MAD with values equal to 5, 6, and 7 mmHg from inner to outer. Passing criteria for AAMI and ESH protocols and grading criteria for BHS protocol are also plotted.

A.2 Parameter selection considerations

A.2.1 Introduction

Both ANSI/AAMI SP10 and BHS protocol use more than one evaluation parameter: ANSI/AAMI SP10 uses two and BHS uses three. The use of two or more parameters inevitably makes the comparison between devices difficult in some situations, e.g., when a device performs better in one parameter but worse in another. Therefore, from the user's point of view, comparing devices on an evaluation scale by a single parameter is often preferred.

The benefit of using MD or SD is that each measurement result has to contribute to the final accuracy decision. These parameters are, however, unduly influenced by occasional outlying values [B1]. On the contrary, for a protocol that judges by cumulative percentages, it will be less influenced by these outliers but can be misleading when there are large systematic differences [B1]. It must be noted that the consequences of a systematic bias should never be underestimated for it has been shown that a systematic overestimation of DBP by 5 mmHg would increase the number of hypertensives by as much as 132% or more [B34].

Therefore, we intend to use MAD that take into account the above issues for the development of an evaluation scale.

A.2.2 Mean absolute difference

Mean absolute difference (MAD) is defined as follows:

$$\mathrm{MAD} = \left(\sum_{i=1}^{n} \left| p_i - y_i \right| \right) / n \qquad \text{(A. 4)}$$

where

p_i is the measured value,

y_i is the reference value, and

n is the data size.

For a generalized t distribution, MAD is related to MD, SD, and v as [B29]:

$$\mathrm{MAD} = 2s\sqrt{\frac{v}{\pi}}\frac{\Gamma(\frac{v+1}{2})}{\Gamma(\frac{v}{2})(v-1)}(1+\frac{u^2}{s^2 v})^{\frac{-v-1}{2}} + |u| \cdot (1 - I(\frac{v}{v+(\frac{u}{s})^2}; \frac{v}{2}, \frac{1}{2}) \quad \text{(A. 5)}$$

Based on our study on the error distribution of various BP measuring devices, we created a mapping chart to relate MAD with the ANSI/AAMI SP10 and BHS protocol. ESH criteria were also plotted. See Figure A.2.

For Grade A and Grade B in BHS grading, satisfying the requirement of CP_5 guaranteed that of CP_{10} and CP_{15}. Therefore, only CP_5 were plotted. While for grade C, CP_5 and CP_{15} together determined the grading results.

The idea of developing an evaluation scale is not only to facilitate the direct comparison between devices, but also to present a continuous scale to encourage developers to continue to strive for more accurate products. Besides, it is hoped that the parameter selected for this evaluation scale can appropriately include each measurement difference in the assessment. With regard to this issue, MAD is preferred as it weighs all the differences equally. Also, MAD is easier to relate with the evaluation parameters of ANSI/AAMI SP10, BHS, and ESH protocols and can be shown to be flexible to various error distributions.

Annex B

(informative)

Observer training

This part is reproduced from Appendix B of the ESH protocol.

The first prerequisite for this validation test is to ensure that the observers have adequate auditory and visual acuity, and that they have achieved the required accuracy as laid out below. It is, however, possible that observers who fulfill these criteria at the outset of the study will not do so at the end, and if this happens the observers must be re-assessed for accuracy. To avoid this, analysis should be performed as the study proceeds to detect any drift in agreement between the observers.

Observers may be trained in the following ways:

1. By fulfilling the test requirements of the CD-ROMs produced by the BHS or the Societe Francaise d'Hypertension Arterielle.

   The observers, usually nurses who understand blood pressure measurement, are retrained in blood pressure measurement using a CD-ROM such as that produced by the BHS or the Societe Francaise d'Hypertension Arterielle [B3], [B31]. These demonstrate the technique of blood pressure measurement and permit an assessment period during which trainees can test themselves against a standard mercury sphygmomanometer in which the mercury column falls against a background of recorded Korotkoff sounds. Observers should not move on to the next stage until they have satisfied the test requirements of the CD-ROM. It is helpful for an expert in blood pressure measurement to take trainee observers through the different stages of blood pressure measurement [B22].

   Difficult aspects of interpretation, such as the auscultatory gap and observer bias, should be discussed and illustrated by example. It is recommended that observers have audiograms to detect any hearing deficit.

2. By formal training and assessment.

   As an alternative to self-assessment, observers can be tested formally as in the BHS protocol. Trainee observers are seated at a bench fitted with temporary partitions so that each observer is isolated in a booth in which the only objects are a mercury column, a stethoscope, a pencil and 50 numbered cards on which to write down assessments. The rationale for this procedure is that when more than one observer is being trained and assessed, it becomes difficult to prevent an observer who is unsure of a reading gaining sight of a neighboring observer's reading. It is therefore necessary to separate observers by a series of partitions.

   a. The expert observer occupies a similar adjoining booth, the only difference being the presence of a hand bulb to inflate and deflate the cuff on the arm of the subject.

   b. Five subjects with a range of blood pressure from about 110/60 to 170/100 mmHg are seated behind a partition. The 'supervisor' places the cuffs in random order on the arms without the expert or trainee observers being aware of the order. When the stethoscope head and cuff are in place, the supervisor gives a verbal cue to the observers and the expert observer operates the cuff and deflates it at a rate of 2 mmHg/s.

c. As the inflatable bladder is connected to each of the columns of mercury in the observer booths, all the columns of mercury fall simultaneously for each of the blinded observers and for the expert, all of whom write down their measurements. Using a series of manometers, time must be allowed for each manometer to deflate fully and the mercury meniscus to return to zero.

d. Ten measurements are made by each observer on each of five subjects, giving a total of 50 measurements for each observer.

The accuracy criteria for the test procedure are the following.

a. Forty-five systolic and diastolic differences between each trainee and between trainees and expert should differ by not more than 5 mmHg, and 48 by not more than 10 mmHg.

b. Failure to achieve this degree of accuracy necessitates a repeat training and assessment session for the failed observer(s).

3. By using an audio-visual method for validation, such as the sphygmocorder

Training observers as described above is a labor-intensive procedure, and even when observers are instructed to a high degree of accuracy, there is the problem of maintaining that accuracy throughout the study [B20], [B17].

A need has been recognized, therefore, for an electronic audio visual system to measure blood pressure in validation studies that is not dependent on observers but will nevertheless retain the traditional auscultatory methodology using the mercury sphygmomanometer. An example of such is the sphygmocorder which was developed for this purpose and, since it was first described in 1995 [B19], a number of improvements have been made to the system [B2]. This system is being developed for commercial distribution.

Annex C

(informative)

Bibliography

Bibliographical references are resources that provide additional or helpful material but do not need to be understood or used to implement this standard. Reference to these resources is made for informational use only.

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