5 Validation and Reliability of Blood Pressure Monitors

Eoin O'Brien, MD
and Neil Atkins, MA

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INTRODUCTION

With the increasing marketing of automated and semiautomated devices for the measurement of blood pressure, there is a need for potential purchasers to be able to satisfy themselves that such devices have been evaluated according to agreed-upon criteria *(1)*. With this need in mind, the Association for the Advancement of Medical Instrumentation (AAMI) published a standard for electronic or aneroid sphygmomanometers in 1987 *(2)*, which included a protocol for the evaluation of the accuracy of devices; this was followed in 1990 by the protocol of the British Hypertension Society (BHS) *(3)*. Both protocols

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were revised in 1993 *(4,5)*. These protocols, which differed in detail, had a common objective, namely the standardization of validation procedures to establish minimum standards of accuracy and performance and to facilitate comparison of one device with another *(6)*.

Since their introduction, a large number of blood pressure measuring devices have been evaluated according to one or both protocols (*see* www.dableducational.org). However, experience soon demonstrated that the conditions demanded by these protocols were extremely difficult to fulfill because of the large number of subjects that needed to be recruited and the ranges of blood pressure required. The time required to complete a validation study according to the BHS protocols had become such that it proved increasingly difficult to recruit trained staff for the duration of a study. These factors made validation studies difficult to perform and very costly, with the result that fewer centers were prepared to undertake them.

When the BHS dissolved its Working Party on Blood Pressure Measurement, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) undertook to produce an updated protocol, named the International Protocol, which was published in 2002 *(7)*. In setting about its objective, the ESH Working Group has recognized the urgent imperative to provide a simplified protocol that does not sacrifice the integrity of the earlier protocols. When the AAMI and BHS protocols were published *(2–5)*, the relevant committees did not have evidence from previous studies on which to base their recommendations. The ESH Working Group had the advantage of being able to examine and analyze the data from 19 validation studies performed according to the AAMI and BHS protocols at the Blood Pressure Unit in Dublin *(8–24)*. Critical assessment of this database of evidence permitted rationalization and simplification of validation procedures without losing the merits of the much more complicated earlier protocols.

The International Protocol was drafted so as to be applicable to the majority of blood pressure measuring devices on the market. The validation procedure was confined, therefore, to adults over the age of 30 yr (as these constitute the majority of subjects with hypertension), and it did not make recommendations for special groups, such as children, pregnant women, and the elderly, or for special circumstances, such as exercise. The protocol did not preclude manufacturers of devices from subjecting their products to more rigorous assessment and validation.

INTERNATIONAL PROTOCOL VALIDATION PROCEDURE

The validation team should consist of four persons experienced in blood pressure measurement: two observers and a supervisor (generally nurses) and an "expert" (a doctor overseeing the entire procedure). If the doctor can be present throughout the entire validation procedure, he or she can take over the role of supervisor, thereby reducing the number of personnel to three. The validation procedure consists of the following steps:

1. Observer training and assessment: Two observers are trained in accurate blood pressure measurement.
2. Familiarization session: The validation team becomes familiar with the workings of the device and accompanying software.
3. Validation measurements: Observer and device measurements are recorded on subjects in two phases. In the first phase, 15 subjects are recruited; devices passing this primary phase proceed to the secondary phase, in which a further 18 subjects are recruited.
4. Analysis: Analysis of the recorded measurements is carried out after each phase.
5. Reporting: The results are presented in tabular and graphical forms.

OBSERVER TRAINING AND ASSESSMENT

Consideration must first be given to the technique of blood pressure measurement, which should be as follows throughout the validation procedure.

Blood Pressure Measurement Technique

A standard mercury sphygmomanometer, the components of which have been checked carefully before the study, is used as a reference standard. It is appreciated that terminal digit preference is a problem with conventional mercury sphygmomanometry, and care should be taken to reduce this in the observer training session. The Hawksley random-zero sphygmomanometer only disguises digit preference, and its accuracy has been questioned *(8,25)*; therefore, its use is not recommended in validation studies. All blood pressures should be recorded to the nearest 2 mmHg.

Blood pressure should be measured with the arm, supported at heart level *(26)*; the manometer level does not affect the accuracy of measurement, but it should be at eye level and within 1 m of the observer.

The quality of the stethoscope is also crucial to performing the evaluation procedure. Stethoscopes with badly fitting earpieces and poor-quality diaphragms preclude precise auscultation of Korotkoff sounds. A well-maintained quality stethoscope is recommended.

Observer Training

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 next. However, it is possible that observers who fulfill these criteria at the outset of the study will not do so at the end of the study, and if this happens the observers must be reassessed for accuracy. To avoid this occurrence, 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 British Hypertension Society (http://www.abdn.ac.uk/medical/bhs/).
2. By formal training and assessment *(27,28)*.

Alternatively, an audiovisual device, such as the Sphygmocorder *(29,30)*, can be used for validation.

FAMILIARIZATION SESSION

Because automated devices for blood pressure measurement may be complex, it is important that the personnel performing a validation study be fully conversant with the equipment. The observers, having satisfied the training criteria, should next be instructed in the use of the device to be validated and any accompanying computer software. For uncomplicated devices designed to provide a straightforward blood pressure measurement, the familiarization session should consist of performing a series of practice measurements on volunteers. However, a more formal session should be applied to complex devices, such as systems for measuring 24-h blood pressure. This session has two functions: (1) it serves as a familiarization period for the personnel performing the validation study and (2) any technical peculiarities of the device being tested, which might influence the validation procedure, may be identified.

VALIDATION MEASUREMENTS

General Considerations

Device validation should be performed at room temperature without disturbing influences, such as telephones and bleeps.

Some automated devices have more than one method of measuring blood pressure. For example, it may be claimed for a particular device that electrocardiogram gating may be used when more accurate measurement is required. In these circumstances, validation must be performed with and without electrocardiogram gating. Similarly, some Korotkoff sound-detecting devices provide an oscillometric backup when sound detection fails. When both systems generate simultaneous readings, only one comparative validation is required with analysis of both methods, but when the oscillometric method is a backup to the auscultatory method and provides a separate measurement, both systems of measurement must undergo individual validation.

Arm Circumference and Bladder Dimensions

The circumference of the arms should be measured to ensure that the bladder being used is adequate for the subject. Measurements made with the test device should use the appropriate bladder according to the manufacturer's instructions. The standard mercury manometer measurements must be taken with a bladder of sufficient length to encircle 80% of the arm circumference *(31)*. Where a test device recommends different cuff sizes, the appropriate cuff/bladder should be used, but no other part of the apparatus should be changed. It is important to ensure that, when assessing auscultatory devices, the same microphones be used throughout the validation test.

Devices for Measuring Blood Pressure at the Wrist

The International Protocol may be used to validate devices that measure blood pressure at the wrist by comparing the wrist-recorded measurements against auscultatory blood pressure measured at the arm. (Devices that measure blood pressure at the finger for self-measurement are not recommended because vasoconstriction of the digital arteries can introduce substantial errors.)

There is little literature regarding the accuracy of devices for wrist measurement, and most studies have shown these devices to be inaccurate *(1)*. Generally, measurements of blood pressures at the wrist with oscillometric devices overestimate blood pressure compared to conventional sphygmomanometry on the upper arm, and the differences can be substantial *(32,33)*.

It must, however, be emphasized that although a device designed for measuring blood pressure at the wrist may be accurate when tested according to the International Protocol, it may be inaccurate for

Table 1
Blood Pressure Ranges for BPA (Entry Blood Pressure)

	SBP	*DBP*
Low	90–129	40–79
Medium	130–160	80–100
High	161–180	101–130

For the primary phase, 5 of the 15 subjects should have systolic blood pressures (SBP) in each of the ranges. Similarly 5 of the 15 subjects should have diastolic blood pressures (DBP) in each of the ranges. For the secondary phase, 11 of the 33 subjects (including the first 15 subjects) should have SBP and DBP in each of the ranges. It is recommended that recruitment should commence by targeting subjects likely to have pressures in the low systolic and high diastolic ranges, then progress to complete the high systolic and low diastolic ranges so that it will be easy to complete the recruitment with the remaining medium ranges.

self-measurement of blood pressure if the instructions to have the wrist at heart level during measurement are not strictly followed.

Subject Selection

In selecting 33 subjects (15 for phase 1 and 18 for phase 2) with a wide range of blood pressure, it is likely that there will be a representative range of arm circumference, and subjects should not be selected on the basis of arm circumference. Subjects may be on antihypertensive medication but must not present in atrial fibrillation or any sustained arrhythmia.

Numbers:
Phase 1: 15 subjects
Phase 2: 18 subjects

Sex:
Phase 1: at least 5 male and 5 female
Phase 2: at least 10 male and 10 female
Age range: all subjects should be at least 30 yr
Arm circumference: distribution by chance
Blood pressure range: *see* Table 1

There are three ranges for systolic blood pressure (SBP) and three for diastolic blood pressure (DBP), with 11 subjects in each range, to provide 99 pairs of measurements. To optimize on recruitment, it is recommended that subjects for the high diastolic and low systolic groups should be recruited first. Then the emphasis should be placed on filling the remaining high systolic and low diastolic groups. Finally, the remaining gaps in

the middle groups should be filled. The blood pressure used in this categorization is the entry blood pressure at the time of the validation procedure (BPA), and not any earlier measurement that might have triggered an invitation to the subject to participate in the study.

Observer Measurement

Measurements can be either assessed live using two observers or recorded and later reassessed using the Sphygmocorder *(29,30)*. Measurements made simultaneously by two observers must be checked by the validation supervisor. If the systolic and diastolic measurements are both no more than 4 mmHg apart, the mean value of the two observer measurements for both SBPs and DBPs is used. Otherwise the measurement must be taken again. Where the Sphygmocorder is used, two observers should assess the recording separately. Where they differ they should reassess it together until agreement is reached. Further references to "observer measurement" refer to either the mean of two observer measurements or the agreed measurement using the Sphygmocorder. At least 30 s should be allowed between each measurement to avoid venous congestion, but not more than 60 s so as to minimize variability.

Procedure

1. The subject is introduced to the observers and the procedure is explained. Arm circumference, sex, date of birth, and current date are noted. The subject is then asked to relax for 10–15 min. (This is to minimize anxiety and any white-coat effect, which will increase variability.)
2. Nine sequential same-arm measurements between the test instrument and a standard mercury sphygmomanometer are recorded as follows:
   BPA: entry blood pressure—observers 1 and 2 each with mercury standard. The mean values are used to categorize the subject as low, medium, or high ranges separately for SBP and DBP (*see* Table 1).
   BPB: device detection blood pressure—supervisor. This blood pressure is determined to permit the test instrument to determine the blood pressure characteristics of the subject; more than one attempt may be needed with some devices; this measurement is not included in the analysis. If the device fails to record a measurement after three attempts, the subject is excused and the reason noted.
   BP1: observers 1 and 2 with mercury standard.
   BP2: supervisor with test instrument.
   BP3: observers 1 and 2 with mercury standard.
   BP4: supervisor with test instrument.

BP5: observers 1 and 2 with mercury standard.
BP6: supervisor with test instrument.
BP7: observers 1 and 2 with mercury standard.

Documentation must be provided for data omitted for legitimate technical reasons; once a subject is included, the data for that subject should not be excluded from the study if blood pressure values are obtainable; if blood pressure measurements from either the reference method or the test instrument are unavailable, data entry for that individual may be excluded with an accompanying explanation. Additional individuals must then enter into the study to ensure a sample size of 33.

ANALYSIS

Accuracy Criteria

The BHS protocol introduced the concept of classifying the differences between test and control measurements according to whether these were within 5, 10, 15, or greater than 15 mmHg. Final grading was based on the number of differences falling into these categories. This protocol seeks to keep this concept but expand its flexibility.

Differences are always calculated by subtracting the observer measurement from the device measurement. When comparing and categorizing differences, their absolute values are used. A difference is categorized into one of four bands according to its rounded absolute value for SBP and DBP:

0–5 mmHg	These represent measurements considered very accurate (no error of clinical relevance).
6–10 mmHg	These represent measurements considered to be slightly inaccurate.
11–15 mmHg	These represent measurements considered to be moderately inaccurate.
>15 mmHg	These represent measurements considered to be very inaccurate.

The analysis is based on how values in these bands fall cumulatively into three zones:

Within 5 mmHg	This zone represents all values falling in the 0- to 5-mmHg band.
Within 10 mmHg	This zone represents all values falling in the 0- to 5- and 6- to 10-mmHg bands.
Within 15 mmHg	This zone represents all values falling in the 0- to 5-, 6- to 10-, and 11- to 15-mmHg bands.

Subject Measurements

For accuracy assessment, only the measurements BP1–BP7 are used. The mean of each pair of observer measurements is calculated. This is denoted as observer measurement BP1, BP3, BP5, or BP7. Each device measurement is flanked by two of these observer measurements, and one of these must be selected as the comparative measurement.

From these, further measurements are derived as follows:

1. The differences BP2-BP1, BP2-BP3, BP4-BP3, BP4-BP5, BP6-BP5, and BP6-BP7 are calculated.
2. The absolute values of the differences are calculated (i.e., the signs are ignored).
3. These are paired according to the device reading.
4. Where the values in a pair are unequal, the observer measurement corresponding to the smaller difference is used.
5. Where the values in a pair are equal, the first of the two observer measurements is used.

For each subject there are three device readings for SBP and three for DBP. Each of these six readings has a single corresponding observer measurement, a difference between the two, and a band for that difference as previously described.

Experience with existing protocols has demonstrated that the overall outcome of a device can be apparent from a very early stage. This is particularly so with poor devices and is in accordance with statistical expectancy: the larger the error, the smaller the sample size required to prove it. To persist with validation of a device that is clearly going to fail is an unnecessary waste of time and money and is an inconvenience to participating subjects. Therefore, a mechanism for eliminating poor devices at an appropriate stage is introduced by dividing the validation process into two phases. In a primary phase, three pairs of measurements are performed in 15 subjects in the pressure ranges in Table 1, and a device failing this phase (Table 2A) is eliminated from further testing. One passing it proceeds to a secondary phase, in which a further 18 subjects (total 33) are recruited (Table 2B).

Assessment of Phase 1

Once there are five subjects in the six blood pressure ranges (Table 1), recruitment should be stopped and an assessment is performed. Data from the first five subjects in each range only are used. (In filling these ranges, some ranges may be oversubscribed as a result of subjects

Table 2A
Requirements to Pass Phase 1

Measurements	*Within 5 mmHg*	*Within 10 mmHg*	*Within 15 mmHg*
At least one of	25	35	40

After completing 15 subjects, the data (45 comparisons) should be analyzed to determine the number of comparisons falling within the 5, 10, and 15 mmHg error bands. At least 25 comparisons must be within 5 mmHg or at least 35 comparisons must be within 10 mmHg or at least 40 comparisons within 15 mmHg. If none of these counts reaches the criteria in the table, the device is deemed to have failed.

Table 2B
Requirements to Pass Phase 2.1

Measurements	*Within 5 mmHg*	*Within 10 mmHg*	*Within 15 mmHg*
Two of	65	80	95
All of	60	75	90

After completing all 33 subjects, the data (99 comparisons) should be analyzed to determine the number of comparisons falling within the 5, 10, and 15 mmHg error bands. For the device to pass, there must be a minimum of 60, 75, and 90 comparisons within 5, 10, and 15 mmHg, respectively. Furthermore, there must be a minimum of either 65 comparisons within 5 mmHg and 80 comparisons within 10 mmHg or 65 comparisons within 5 mmHg and 95 comparisons within 15 mmHg or 80 comparisons within 10 mmHg and 95 comparisons within 15 mmHg.

Table 2C
Requirements to Pass Phase 2.2

Subjects	*2/3 within 5 mmHg*	*0/3 within 5 mmHg*
At least	22	
At most		3

The data should now be analyzed per subject to determine the number of comparisons per subject within 5 mmHg. At least 22 of the 33 subjects must have at least two of their three comparisons within 5 mmHg. (These include those who have all three comparisons within 5 mmHg.) At most 3 of the 33 subjects can have all three of their comparisons more than 5 mmHg.

having different SBP and DBP ranges.) This will yield 45 sets of measurements for both SBP and DBP.

1. The number of differences in each zone is calculated using the difference bands as previously described.
2. A Continue/Fail grade is determined according to Table 2A (*see also* Table 3).

Table 3
Example of Device Validation Table[a]

Phase 1		*≤5 mmHg*	*≤10 mmHg*	*≤15 mmHg*	*Grade*
Required	One of	25	35	40	
Achieved	SBP	**22**	**35**	**43**	**Continue**
	DBP	**35**	**42**	**44**	**Continue**

Phase 2.1		*≤5 mmHg*	*≤10 mmHg*	*≤15 mmHg*	*Grade*	*Mean*	*SD*
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	**52**	**79**	**90**	**Fail**	3.4 mmHg	8.4 mmHg
	DBP	**77**	**90**	**94**	**Pass**	–0.6 mmHg	6.9 mmHg

Phase 2.2		*2/3 ≤5 mmHg*	*0/3 ≤5 mmHg*	*Grade*
Required		≥22	≤3	
Achieved	SBP	**17**	**4**	**Fail**
	DBP	**28**	**2**	**Pass**

[a]The device passes for diastolic blood pressure but fails for systolic blood pressure, thereby failing overall.

If the device fails, the validation is complete; if it passes, it proceeds to phase 2.1.

Assessment of Phase 2

This phase determines how accurate the device will be for individual measurements and for individual subjects by determining the number of differences within 5, 10, and 15 mmHg and then determining the number of subjects with at least two device measurements with differences of less than 5 mmHg. After all ranges have been filled, there will be 99 sets of measurements for both SBP and DBP.

1. The number of comparisons per subject within 5, 10, and 15 mmHg is calculated.
2. A Pass/Fail grade for phase 2.1 is determined according to Table 2B.
3. For each of the 33 subjects, the number of measurements within 5 mmHg is determined.
4. For the 33 subjects, each of whom has three comparative measurements, in at least 22 subjects, at least two comparative differences must be within 5 mmHg, and only 3 subjects can have all three comparative differences more than 5 mmHg (Table 2C).
5. If the device passes both phase 2.1 and phase 2.2, it passes the validation and can be recommended for clinical use. Otherwise it fails and is not recommended for clinical use.

REPORTING

Statistical Report

The report should be prefaced with subject data so as to describe the key characteristics of the subjects in the study. An example of a device validation is shown in Table 3.

Sex distribution: the number of males and females.

Age distribution: the mean, standard deviation, and range of the subjects' ages.

Arm circumference distribution: the mean, standard deviation, and range of the subjects' arm circumferences and, where different cuff sizes are used, the number of subjects on which each size was used.

Blood pressure: the mean, standard deviation, and range of the subjects' entry SBP and DBP (BPA).

The report should then give the results of the validation.

PHASE 1

The number of differences falling within 5 mmHg, 10 mmHg, and 15 mmHg zones (Table 2) together with the requirements should be

reported in text and tabular form as in Table 3. The mean and standard deviation of the observer and device measurements and the differences should be stated. The basis on which the decision to continue or stop at this stage should be stated.

PHASE 2

The number of differences falling within 5 mmHg, 10 mmHg, and 15 mmHg zones together with the requirements should be reported in text and tabular form as in Table 3. The number of subjects with at least two differences and no differences within 5 mmHg should be reported in text and tabular form as in Table 3. The mean and standard deviation of the observer and device measurements and the differences should be stated. The basis on which the decision is made to pass or fail the device should be stated.

GRAPHICAL REPRESENTATION

Difference against mean plots should be presented for the data at the phase at which the study ceased. Phase 1 data should be plotted for devices failing at that stage, and phase 2 data for those passing. The *x*-axis of these plots represents blood pressures in the systolic range 80–190 mmHg and the diastolic range 30–140 mmHg and the *y*-axis values from –30 to +30 mmHg. Horizontal reference lines are drawn at 5-mmHg intervals from +15 to –15 mmHg. Vertical reference lines are drawn at the range changeover points, which are at 130 and 160 mmHg for SBP and at 80 and 100 mmHg for DBP. The mean of each device pressure and its corresponding observer pressure is plotted against their difference with a point. Differences greater than 30 mmHg are plotted at 30 mmHg. Differences less than –30 mmHg are plotted at –30 mmHg. The same scales should be used for both SBP and DBP plots. An example is shown in Fig. 1 *(34)*.

PROBLEMS

Any problems encountered during the validation procedure, the date of their occurrence, date of any repairs to the device, the effect of these on the validation procedure should be recorded.

Operational Report

The following information should be provided with blood pressure measuring devices, and the final report should acknowledge that such information is available. Although this need not be presented in detail, any deficiencies should be listed in the report.

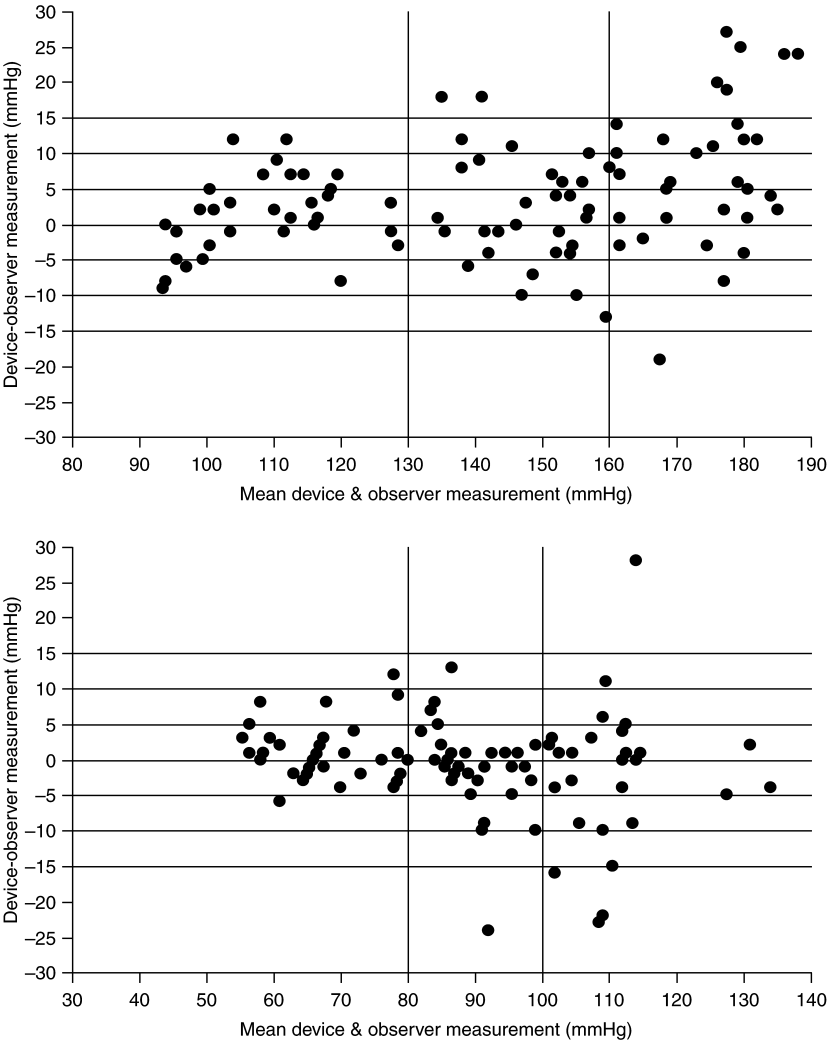

Fig. 1. Devices passing and failing phase 2.1. The *x*-axis represents the mean of the device and observer measurements. Both systolic blood pressure (SBP; upper plot) and diastolic blood pressure (DBP; lower plot) ranges should be plotted on the same scale. Recruitment limits are indicated by the vertical hatched lines. The *y*-axis represents the difference between the device and observer measurements. The 5-mmHg bands from +15 to –15 mmHg are indicated by the horizontal hatched lines. The 99 comparisons are presented in a difference-against-mean scatterplot. In this example, the SBP plot depicts a poor device, whereas the DBP plot depicts an accurate device.

Basic Information

The information provided in operational manuals is often deficient. Without appropriate specifications and operational instructions, it is difficult to obtain optimal performance.

List of Components

All major components of the system should be listed. The dimensions of the bladders supplied and those of the range of bladders available should be indicated.

Method of Blood Pressure Measurement

The basic method of pressure detection (e.g., auscultatory or oscillometric) should be stated, and if more than one method is used the indications for changing methods and the means of denoting this on the recording should be stated. With Korotkoff sound-detecting devices it must be disclosed whether phase IV or V is being used for the diastolic endpoint. If data are derived from recorded measurements, such as mean pressure, the method of calculation must be stated.

Factors Affecting Accuracy

Many factors may affect the accuracy of automated recordings, such as arm movement, exercise, arm position, and cuff or cloth friction. All such factors should be listed by the manufacturer.

Operator Training Requirements

Some automated systems require considerable expertise on the part of the operator if accurate measurements are to be obtained, whereas other systems require relatively little instruction. These requirements should be stated.

Computer Analysis

Some automated systems are compatible with personal computer systems. The exact requirements for linking with computer systems and their approximate cost should be stated. If the automated system is dependent on its own computer for plotting and analysis, this should be made clear and the cost of the computer facility, if it is an optional extra, should be stated. Clear instructions should be provided for setting recording conditions (e.g., frequency of recordings during defined periods and on–off condition of digital display); retrieving recordings and saving data to disk; retrieving data from disk, displaying numerical data and graphics; exporting data to statistical/graphic/spreadsheet software programs; and printing results (partial or complete). Where data

cannot be exported, information on how it is stored should be available to facilitate external analysis of several monitoring events. The manufacturer should list compatible computers (PC or other) and printers together with memory requirements, operating systems, compatible graphic adaptors, and additional software or hardware requirements (including interfaces and cables if these are not supplied).

EXPERIENCE WITH THE INTERNATIONAL PROTOCOL

The International Protocol was published in 2002 *(7)*, and to date (December 2006) 26 validation studies on 23 devices have been performed using this protocol *(35–56)*. It is timely to review the use of the protocol and to identify its shortcomings so that these can be rectified in the next revision and to examine how well the protocol is being used.

Reporting of Basic Characteristics

The protocol states clearly that the mean, standard deviation, and range of the subjects' ages, arm circumferences, and entry blood pressures should be stated along with the number of males and females recruited; only 16 of the 26 studies provided all this information (Table 4). The protocol stipulates that if different cuff sizes are used, the number of subjects on which each size was used should be given. Seven studies involved wrist monitors *(41,43,48,49,54,56)*. In two studies it was stated that only one cuff was available *(36,47)*. A choice of available cuffs was described in 10 studies *(37,40,45,46,50,52,54,55)*, but their use was only described in five of these *(40,46,50,54)*. The remaining seven studies made no references to cuffs.

Subject Recruitment

Most of the studies stated simply that 15 subjects were recruited for phase 1 and a further 18 subjects for phase 2. However, the reality is that studies do not go so smoothly, and it is important that problems with recruitment should be reported. The protocol requires that "documentation must be provided for data omitted for legitimate technical reasons." In particular, the total number of subjects recruited, the numbers rejected and the reasons for rejection, and the number of subjects used for both systolic and diastolic assessments should be stated. Experience with the International Protocol has shown that there are three common reasons for subjects to be excluded: (1) the ranges have been filled and the subjects are no longer needed; (2) the presence of an arrhythmia; (3) the presence of poor quality Korotkoff sounds. It is

Table 4
Recruitment Demographic Details

				Age		*Sex*	*Arm circumference*		*Recruitment BP*	
Device	*Ref.*	*BP*	*Recruited*[a]	*Mean (SD)*	*Range*	*M:F*	*Mean (SD)*	*Range*	*Mean (SD)*	*Range*
A&D UA-631	*35*	SBP	66						142 (31)	84–206
		DBP		49 (16)	18–76		29 (3)	22–32	85 (18)	54–118
A&D UA-787	*36*	SBP	33						142 (23)	94–180
		DBP		52 (18)		20:13	29 (3)	24–35	84 (11)	64–104
Omron M5-I	*37*	SBP	33							
		DBP		52 (14)		17:16				
Omron 705IT	*37*	SBP	33							
		DBP		54 (13)		18:15				
Rossmax	*38*	SBP	37 (29)	54 (11)	30–81	19:14	30 (3)	22–37	144 (24)	104–180
		DBP		56 (11)	30–81	19:14	30 (3)	22–37	88 (17)	54–144
Tonoport V	*39*	SBP	42 (24)	45 (16)	30–77	16:17	30 (3)	22–37	144 (26)	92–180
		DBP		45 (16)	30–74	19:14	30 (3)	22–37	91 (19)	50–122
Tonoport V	*44*	SBP	35 (31)	54 (11)	30–83	20:13	28 (3)	23–36	147 (24)	12–210
		DBP		55 (11)	30–83	19:14	28 (3)	23–36	88 (13)	67–107
Accoson Green-light 300	*40*	SBP	51 (15)	56 (16)	34–80	15:18	29 (5)	18–42	142 (26)	95–176
		DBP		55 (16)	34–90	19:14	30 (5)	18–42	88 (21)	51–125
Braun BP 2550	*41*	SBP	37						146 (22)	102–181
		DBP		52 (8)	30–82	18:15	24 (6)	16–42	93 (20)	60–127

(Continued)

Table 4 ***(Continued)***

				Age		*Sex*	*Arm circumference*		*Recruitment BP*	
Device	*Ref.*	*BP*	*Recruited*[a]	*Mean (SD)*	*Range*	*M:F*	*Mean (SD)*	*Range*	*Mean (SD)*	*Range*
Oscar 2	*42*	SBP	104	56 (12)	31–86	19:14	31 (5)	25–49		96–180
		DBP	48 (18)	51 (13)	22–78	17:16	30 (-)	21–49		63–125
Omron RX3	*43*	SBP	33						141 (24)	
		DBP		53 (13)		18:15	29 (2)		86 (15)	
SunTech Agilis	*45*	SBP	33						143 (23)	93–173
		DBP		54 (12)	31–74	13:20	29 (3)	23–40	87 (17)	55–108
Seinex SE-9400	*46*	SBP	≈37						138 (15)	
		DBP		54 (14)		18:15	29 (3)	23–36	85 (14)	
Microlife BP 3AC1-1	*46*	SBP	38						137 (21)	
		DBP		53 (14)		19:14	30 (3)	23–38	90 (16)	
Colson MAM BP 3AA1-2	*47*	SBP	33						142 (27)	100–180
		DBP		47 (10)	32–71	15:18	28 (3)	24–32	88 (16)	61–120
Omron 637-IT (Adult)	*48*	SBP	59						141 (28)	99–180
		DBP		51 (10)	30–71	18:15	28 (2)	26–36	88 (15)	62–119
Omron 637-IT (Obese)	*48*	SBP	72						144 (27)	98–180
		DBP		52 (11)	34–73	14:19	38 (4)	34–48	88 (16)	55–121
Omron 637-IT (Elderly)	*49*	SBP	76						146 (23)	104–180
		DBP		72 (5)	65–80	16:17	31 (5)	25–38	86 (16)	62–112

(Continued)

Table 4 *(Continued)*

				Age		*Sex*	*Arm circumference*		*Recruitment BP*	
Device	*Ref.*	*BP*	*Recruited*[a]	*Mean (SD)*	*Range*	*M:F*	*Mean (SD)*	*Range*	*Mean (SD)*	*Range*
BPLab	*50*	SBP	42						145 (32)	82–208
		DBP		51 (12)	30–75	24:18	32 (3)	26–37	88 (21)	56–132
Omron MX3 Plus	*51*	SBP	33						139 (22)	102–178
		DBP		50 (11)	31–73	18:15	30 (3)	24–37	85 (15)	58–112
Microlife BP A 100 Plus	*52*	SBP	44						143 (27)	97–178
		DBP		49 (14)	30–75	17:16	29 (4)	22–40	90 (18)	57–130
PMS Mandaus	*53*	SBP	33						147 (30)	97–206
		DBP		46 (14)	21–73	15:21(sic)	29 (4)	22–39	90 (19)	54–123
Omron M6	*54*	SBP	41							
		DBP		57 (13)		18:15	30 (4)	23–42		
Omron R7	*54*	SBP	35							
		DBP		53 (15)		19:14	30 (2)	26–32		
DINAMAP ProCare	*55*	SBP	38						140 (24)	99–183
		DBP		49 (12)	24–68	17:16	31 (4)	23–38	88 (17)	55–123
Oregon Scientific BPW810	*56*	SBP	33						144 (21)	92–190
		DBP		53 (13)	30–78	19:14	27 (2)	24–31	95 (15)	66–126

[a]In five studies where there were some subjects in which only one pressure (SBP or DBP) was used, the number of subjects in which at least one pressure was used is shown followed in parentheses by the number of subjects in which both pressures were used. For the Oscar 2, there were 104 subjects recruited to get the 48 included. The demographics for the BPLab are for all 42 subjects.

unlikely that these difficulties were not experienced, but this was described in only five studies *(41,42,49,52,55)*. One study stated that no subjects were excluded *(45)*. Many implied that more subjects were recruited, but this was not stated explicitly.

The International Protocol has simplified subject recruitment so as to facilitate the validation process. However, recruitment remains a major problem, with particular difficulty recruiting subjects with low systolic and high diastolic pressures *(46)*. The protocol allows for the use of either systolic or diastolic pressures in different subjects; because only five studies availed of this facility, it may be assumed that this issue should be highlighted in future revisions of the protocol.

A particularly frustrating aspect of recruitment is the fall in blood pressure that may occur between the measurement in clinic and laboratory. A number of factors such as the effect of medication, a white-coat reaction, or anxiety in the clinic may account for this, but the protocol requirement for the subject to relax for 15 min before measurement to reduce variability is the most significant factor. Regression to the mean during the validation procedure will reduce pressures further. It can be anticipated, therefore, that the initial recruitment blood pressure will inevitably be lower during validation. Unless a broad range of subjects with high pressures are recruited, these phenomena tend to result in most of the entry pressures in the high range clustered at the lower end of that range, with the plots showing markedly fewer pressures in the high ranges than would be expected. There should be at least 22 points (two-thirds of the expected number) in each range in the plot. Despite relaxing the range of pressures in the International Protocol, as compared with the BHS and AAMI protocols, the successful treatment of hypertension has reduced the availability of subjects with high blood pressures. Yet this is a critical sector of the population for device validation because this is the range in which monitors are more likely to be inaccurate.

On the other hand, the difficulty of recruiting subjects in the low blood pressure range could be somewhat alleviated by allowing recruitment from a younger population in a future revision of the protocol. The cutoff age of at least 30 yr in the protocol was based on the principle that hypertension is uncommon below this age. A corollary of this argument must be that low blood pressures are more likely in a younger population. A lower limit of 20 yr would be pragmatic without detracting from the principles of the protocol.

The International Protocol stipulated strict criteria for recruitment according to blood pressure ranges so that by standardizing subjects in

this manner validation studies from different centres would be comparable with each other. In this respect the International Protocol has realized this aim. In the 21 studies that provided mean entry blood pressure measurements, the systolic pressures ranged from 137 to 147 mmHg, with an overall mean blood pressure of 143 mmHg; the median pressure was 143 mmHg and there were two mode pressures at 142 and 144 mmHg. This is considerably higher than validation studies performed according to the AAMI standard in which blood pressures tend to be some 20 mmHg lower. The mean diastolic pressures in these studies ranged from 84 to 95 mmHg, with an overall mean of 88 mmHg, a level that reflects the difficulty in recruiting subjects with high diastolic pressures; median and mode pressures were both 88 mmHg. In the studies examined, both systolic and diastolic overall mean pressures were close to the target mean pressures of 145 and 90 mmHg. It would seem, therefore, that the subjects recruited for device validation according to the International Protocol are for the greater part hypertensive, thus providing validation for devices in the circumstances most likely to be met in clinical practice.

Results From Validation Studies Using the International Protocol

Overall, the pass rate from studies using the International Protocol was extremely high, with only 2 of 26 devices failing to meet the protocol recommendations *(18,39)*. (One of these subsequently passed a later study *[44]*.)

The International Protocol introduced two innovative phases to facilitate the validation process. Phase 1 allowed assessment of a device after 15 subjects had been evaluated so that clearly inaccurate devices could be identified in order not to have to proceed with unnecessary validation. Phase 2.2 was introduced with the purpose of ensuring that accurate measurements were distributed randomly rather than being subject dependent. It is timely, therefore, to examine the validation results to determine if these innovative phases are serving the purposes for which they were designed.

Relationship Between Phase 1 and Phase 2.1

The relationship between phase 1 and phase 2.1 for the 26 studies is shown in Table 5. The values in parentheses are the projected phase 2.1 values derived from phase 1. Allowing for band-dependent tolerances, 55% of the 156 values are accurately predicted (shown in boldface),

Table 5
Phase 1 and Phase 2.1 Results

Device	*Study*	*Phase*	*BP*	*Within 5 mmHg*	*Within 10 mmHg*	*Within 15 mmHg*	*Result*	*Mean (SD)*
A&D	*35*	1	SBP	32	40	44	Continue	
UA-631			DBP	43	45	45	Continue+	
		2.1	SBP	**72** (70–71)	**89** (87–89)	**96** (96–97)	Pass	2 (5)
			DBP	**93** (94–95)	**99** (98–99)	**99** (98–99)	Pass+	1 (3)
A&D	*36*	1	SBP	38	42	43	Continue+	
UA-787			DBP	35	39	45	Continue	
		2.1	SBP	*65* (83–84)	*80* (92–93)	**95** (94–95)	Pass	1.0 (5.3)
			DBP	**78** (76–78)	*92* (85–86)	**99** (98–99)	Pass	0.7 (5.3)
Omron	*37*	1	SBP	35	43	45	Continue+	
M5-I			DBP	39	43	44	Continue+	
		2.1	SBP	*68* (76–78)	92 (94–95)	**98** (98–99)	Pass	–0.9 (5.8)
			DBP	**83** (85–86)	**95** (94–95)	98 (96–97)	Pass+	–0.8 (4.8)
Omron	*37*	1	SBP	38	43	44	Continue+	
705IT			DBP	31	42	45	Continue	
		2.1	SBP	**83** (83–84)	**96** (94–95)	98 (96–97)	Pass+	–0.2 (4.5)
			DBP	74 (68–69)	**94** (92–93)	97 (98–99)	Pass	–2.0 (4.8)
Rossmax	*38*	1	SBP	21	31	38	Stop	
			DBP	36	43	45	Continue+	
		2.1	SBP	51 (46–47)	*73* (68–69)	*86* (83–84)	Fail	–4.5 (9.5)
			DBP	*71* (79–80)	**93** (94–95)	**98** (98–99)	Pass	–1.8 (5.0)

(Continued)

Table 5 ***(Continued)***

Device	*Study*	*Phase*	*BP*	*Within 5 mmHg*	*Within 10 mmHg*	*Within 15 mmHg*	*Result*	*Mean (SD)*
Tonoport V	*39*	1	SBP	28	37	40	Continue	
			DBP	26	38	44	Continue	
		2.1	SBP	56 (61–62)	78 (81–82)	**88** (87–89)	Fail	–1.4 (8.7)
			DBP	**60** (57–58)	**83** (83–84)	**97** (96–97)	Pass	–0.2 (6.8)
Tonoport V	*44*	1	SBP	38	42	45	Continue+	
			DBP	39	45	45	Continue+	
		2.1	SBP	**83** (83–84)	**93** (92–93)	**98** (98–99)	Pass+	–0.7 (4.6)
			DBP	80 (85–86)	96 (98–99)	97 (98–99)	Pass+	–0.8 (4.4)
Accoson Green-light 300	*40*	1	SBP	40	44	45	Continue+	
			DBP	31	40	44	Continue	
		2.1	SBP	84 (87–89)	**95** (96–97)	**98** (98–99)	Pass+	—
			DBP	74 (68–69)	**90** (87–89)	**96** (96–97)	Pass	—
Braun BP 2550	*41*	1	SBP	32	42	45	Continue	
			DBP	37	44	45	Continue+	
		2.1	SBP	75 (70–71)	**94** (92–93)	**98** (98–99)	Pass	–1.5 (4.8)
			DBP	78 (81–82)	**98** (96–97)	**99** (98–99)	Pass	2.2 (3.8)
Oscar 2	*42*	1	SBP	33	40	44	Continue	
			DBP	34	41	44	Continue	
		2.1	SBP	**71** (72–73)	**86** (87–89)	*94* (*96–97*)	Pass	0.9 (2.3)
			DBP	**72** (74–75)	88 (90–91)	**96** (96–97)	Pass	–0.5 (2.2)
Omron RX3	*43*	1	SBP	40	44	45	Continue+	
			DBP	43	45	45	Continue+	
		2.1	SBP	**86** (87–89)	**95** (96–97)	**99** (98–99)	Pass+	0.8 (4.1)
			DBP	**92** (94–95)	**99** (98–99)	**99** (98–99)	Pass+	–0.4 (3.0)

(Continued)

Table 5 ***(Continued)***

Device	*Study*	*Phase*	*BP*	*Within 5 mmHg*	*Within 10 mmHg*	*Within 15 mmHg*	*Result*	*Mean (SD)*
SunTech	*45*	1	SBP	35	42	45	Continue+	
Agilis			DBP	35	44	45	Continue+	
		2.1	SBP	**78** (76–78)	**91** (92–93)	*96* (98–99)	Pass	–0.7 (4.7)
			DBP	*70* (76–78)	*92* (96–97)	*96* (98–99)	Pass	–3.0 (4.1)
Seinex	*46*	1	SBP	34	40	45	Continue	
SE-9400			DBP	40	40	45	Continue+	
		2.1	SBP	**76** (74–75)	92 (87–89)	**98** (98–99)	Pass	–0.9 (5.2)
			DBP	*79* (87–89)	*93* (87–89)	97 (98–99)	Pass	–1.7 (4.7)
Microlife	*46*	1	SBP	36	40	44	Continue+	
BP			DBP	32	41	43	Continue	
3AC1-1		2.1	SBP	74 (79–80)	**87** (87–89)	98 (96–97)	Pass	–1.3 (5.6)
			DBP	*81* (70–71)	93 (90–91)	*97* (94–95)	Pass+	–0.4 (4.8)
Colson	*47*	1	SBP	37	44	45	Continue+	
MAM			DBP	35	45	45	Continue+	
BP		2.1	SBP	76 (81–82)	93 (96–97)	**99** (98–99)	Pass	–1.0 (5.0)
3AA1-2			DBP	**79** (76–78)	**97** (98–99)	**99** (98–99)	Pass	–1.1 (4.1)
Omron	*48*	1	SBP	29	39	41	Continue	
637-IT			DBP	39	44	45	Continue+	
(Adult)		2.1	SBP	69 (63–64)	88 (85–86)	*95* (90–91)	Pass	0.5 (6.2)
			DBP	**86** (85–88)	**98** (96–97)	**99** (98–99)	Pass+	0.1 (3.7)
Omron	*48*	1	SBP	32	41	44	Continue	
637-IT			DBP	37	45	45	Continue+	
(Obese)		2.1	SBP	**69** (70–71)	*86* (90–91)	95 (96–97)	Pass	1.8 (6.6)
			DBP	77 (81–82)	95 (98–99)	**98** (98–99)	Pass	1.6 (4.7)

(Continued)

Table 5 ***(Continued)***

Device	*Study*	*Phase*	*BP*	*Within 5 mmHg*	*Within 10 mmHg*	*Within 15 mmHg*	*Result*	*Mean (SD)*
Omron	*49*	1	SBP	31	41	43	Continue	
637-IT			DBP	29	43	45	Continue	
(Elderly)		2.1	SBP	**66** (68–69)	87 (90–91)	**95** (94–95)	Pass	–0.3 (6.5)
			DBP	69 (63–64)	92 (94–95)	97 (98–99)	Pass	2.8 (4.8)
BPLab	*50*	1	SBP	35	42	44	Continue+	
			DBP	38	41	44	Continue+	
		2.1	SBP	*68* (76–78)	**92** (92–93)	98 (96–97)	Pass	–2.2 (5.6)
			DBP	80 (83–84)	93 (90–91)	98 (96–97)	Pass+	–1.5 (4.9)
Omron	*51*	1	SBP	34	41	45	Continue	
MX3			DBP	39	44	45	Continue+	
Plus		2.1	SBP	*68* (74–75)	**90** (90–91)	97 (98–99)	Pass	
			DBP	*75* (85–86)	**96** (96–97)	**98** (98–99)	Pass	
Microlife	*52*	1	SBP	32	42	43	Continue	
BP A			DBP	31	45	45	Continue	
100		2.1	SBP	**71** (70–71)	*87* (92–93)	96 (94–95)	Pass	–2.0 (6.0)
Plus			DBP	**71** (68–69)	**98** (98–99)	**99** (98–99)	Pass	–3.1 (4.1)
PMS	*53*	1	SBP	37	43	45	Continue+	
Man-			DBP	39	44	45	Continue+	
daus		2.1	SBP	76 (81–82)	**94** (94–95)	**99** (98–99)	Pass	–3.2 (3.8)
			DBP	**87** (85-86)	**98** (96–97)	**99** (98–99)	Pass+	–1.8 (2.9)
Omron	*54*	1	SBP	35	43	45	Continue+	
M6			DBP	36	41	44	Continue+	
		2.1	SBP	83 (76–78)	97 (94–95)	**99** (98–99)	Pass+	–0.8 (4.2)
			DBP	84 (79-80)	95 (90-91)	98 (96-97)	Pass+	-1.9 (3.8)

(Continued)

Table 5 ***(Continued)***

Device	*Study*	*Phase*	*BP*	*Within 5 mmHg*	*Within 10 mmHg*	*Within 15 mmHg*	*Result*	*Mean (SD)*
Omron	*54*	1	SBP	35	40	45	Continue+	
R7			DBP	39	44	45	Continue+	
		2.1	SBP	**75** (76–78)	**90** (87–89)	**98** (98–99)	Pass	0.2 (5.6)
			DBP	**88** (85–86)	**98** (96–97)	**99** (98–99)	Pass+	0.2 (3.6)
DINA-	*55*	1	SBP	38	42	43	Continue+	
MAP			DBP	29	43	45	Continue	
ProCare		2.1	SBP	78 (83–84)	**91** (92–93)	96 (94–95)	Pass	−2.5 (5.4)
			DBP	*76* (63–64)	**95** (94–95)	**99** (98–99)	Pass	0.5 (4.5)
Oregon	*56*	1	SBP	32	39	44	Continue	
Scien-			DBP	38	45	45	Continue+	
tific 810		2.1	SBP	*77* (70–71)	*90* (85–86)	**96** (96–97)	Pass	−5.1 (1.6)
BPW			DBP	**81** (83–84)	**98** (98–99)	**99** (98–99)	Pass+	5.0 (4.3)
Phase 1			All of	35	40	43	Continue+	
Phase 2.1			All of	80	90	95	Pass+	

Accurate prediction from Phase 1 **Bold** Within 2 Within 1 Exact
Error in prediction from Phase 1 *Italics* Out by 6 Out by 4 Out by 2

29% are fairly predicted, and 16% are poorly predicted (itaicised). Of these poor predictions, the ratio of final result overestimations to underestimations was 3:2. There were no poor predictions in 12 of the studies, one or two in 11 studies, and three or four in 3 studies.

Only one device, the Rossmax, failed phase 1, but the device was not eliminated in order to test the integrity of phase 1; the results of phase 2.1 confirmed that the device could have been eliminated on the basis of phase 1 results. The Tonoport device, which failed phase 2.1 in the first of its two studies, only marginally passed phase 1. The predicted values also indicated a fail and the device did worse than these predictions. However, a performance slightly better than predicted could have yielded a pass. Given these results, it is clear that passing phase 1 does not guarantee a phase 2.1 pass, but it does tend to give a reasonable indication of how the device will fare, and certainly a comfortable "Continue" will end in a Pass, whereas a fail justifies abandoning further validation.

Relationship Between Phase 2.1 and Phase 2.2

The relationship between phase 2.1 and phase 2.2 is shown in Table 6, which shows the actual spread and the corresponding optimal and worst outcomes based on phase 2.1. In the optimal situation, where a device has at least 66 accurate readings, all subjects will have at least 2 accurate readings. Where the errors are subject based, as many subjects as possible will have all three measurements accurate with a knock-on effect of some subjects having no accurate measurements. Using the data from both phases, it is straightforward to calculate the number of subjects with three, two, one, and no accurate measurements, i.e., those with an error of 5 mmHg or less. The 22 of 33 subjects with at least two accurate measurements was not the most difficult to achieve, but, except where the device was extremely accurate in phase 2.1, there was a potential to fail phase 2.2. One particularly interesting situation was the SBP of the UA-787. With a marginal 65 measurements within 5 mmHg, the potential to fail phase 2.2 was high. But with only four subjects having all three measurements accurate, the phase 2.2 results were very close to optimal. On the other hand, the Oscar 2, which passed phase 2.1 more comfortably, for both SBP and DBP, by a poorer spread of results, went to a whisker of failing phase 2.2.

The only device to pass phase 2.1 and fail phase 2.2 was the Tonoport for diastolic pressure in the first Tonoport study *(39)*. The pass was very marginal with only 60 accurate readings, which needed to be very evenly spread in order to pass phase 2.2, which was not the

case. Although the device had already failed the systolic accuracy, the value of this phase is well demonstrated.

Plots

The description of how the plots should be drawn is given carefully in the protocol along with examples. Yet they were not provided properly in nine studies *(35,36,40–42,44,47,50,51)*. The main errors were the lack of vertical reference points and incorrect blood pressure ranges. Even where plots were provided in a technically correct fashion, they were often of a very poor quality that did not permit counting the points in each range or unnecessary extra lines marking, for example, the mean or two standard deviations were included with the effect of cluttering the plot. These plots are standard, widely used difference against mean scatter plots and should not be described as Bland-Altman plots. (In an article in 1986, Bland and Altman simply recommended this form of plotting as the most appropriate to use when plotting paired measurements hypothesized to be the same *[34]*.)

HOW CAN THE INTERNATIONAL PROTOCOL BE IMPROVED?

Issues of Clarification

In the light of experience with the International Protocol and the above analysis, the following issues can be listed for modification in the next revision of the International Protocol:

Improved reporting: it is important that the details of all stages of the validation process be reported, but clearly this does not always happen, and reviewers of submitted papers may also be unaware that some results have not been detailed. A template for results should be provided so as to facilitate investigators and referees.

Subject recruitment: reducing the age restriction from 30 to 20 yr will facilitate recruitment of subjects with low blood pressures without altering the integrity of the protocol.

Observer measurements: the total number of observer pressures used for assessment (excluding the "Observer A measurements") should be at least 22 for each range. This will allow for some flexibility from the entry pressures but prevent "minimal recruiting."

Altered grading: with improvements in technology, devices will tend to pass the requirements with ease. In the BHS protocol, there was a grading system, and manufacturers had begun to aim for an A/A grade rather than a simple B/B pass. A similar system should be introduced

Table 6
Relationship Between Phase 2.1 and Phase 2.2

				Actual values within 5 mmHg				*Optimal within 5 mmHg*				*Worst within 5 mmHg*				*Results*	
Device	*Ref.*	*BP*	*N*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*Phase 2.2*	*Phase 2.1*
A&D UA-631	*35*	SBP	72	18	4	10	1	6	27	0	0	24	0	0	9	Pass	Pass
		DBP	93	27	6	0	0	27	6	0	0	31	0	0	2	Pass+	Pass+
A&D UA-787	*36*	SBP	65	4	24	5	0	0	32	1	0	21	1	0	11	Pass+	Pass
		DBP	78	18	11	2	2	12	21	0	0	26	0	0	7	Pass	Pass
Omron M5-I	*37*	SBP	68	11	14	7	1	2	31	0	0	22	1	0	10	Pass	Pass
		DBP	83	22	7	3	1	17	16	0	0	27	1	0	5	Pass	Pass+
Omron 705IT	*37*	SBP	83	19	12	2	0	17	16	0	0	27	1	0	5	Pass+	Pass+
		DBP	74	18	8	4	3	8	25	0	0	24	1	0	8	Pass	Pass
Rossmax	*38*	SBP	51	12	4	7	10	0	18	15	0	17	0	0	16	Fail	Fail
		DBP	71	15	11	4	3	5	28	0	0	23	1	0	9	Pass	Pass
Tonoport V	*39*	SBP	56	10	9	8	6	0	23	10	0	18	1	0	14	Fail	Fail
		DBP	60	11	11	5	6	0	27	6	0	20	0	0	13	Fail	Pass
Tonoport V	*44*	SBP	83	22	8	1	2	17	16	0	0	27	1	0	5	Pass	Pass+
		DBP	80	19	10	3	1	14	19	0	0	26	1	0	6	Pass	Pass+

(Continued)

Table 6 ***(Continued)***

				Actual values within 5 mmHg				*Optimal within 5 mmHg*				*Worst within 5 mmHg*				*Results*	
Device	*Ref.*	*BP*	*N*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*Phase 2.2*	*Phase 2.1*
Accoson	*40*	SBP	84	18	15	0	0	18	15	0	0	28	0	0	5	Pass+	Pass+
Greenlight 300		DBP	74	17	10	3	3	8	25	0	0	24	1	0	8	Pass	Pass
Braun	*41*	SBP	75	12	18	3	0	9	24	0	0	25	0	0	8	Pass+	Pass
BP2550		DBP	78	17	12	3	1	12	21	0	0	26	0	0	7	Pass	Pass
Oscar 2	*42*	SBP	71	17	7	6	3	5	28	0	0	23	1	0	9	Pass	Pass
		DBP	72	16	9	6	2	6	27	0	0	24	0	0	9	Pass	Pass
Omron RX3	*43*	SBP	86	21	11	1	0	20	13	0	0	28	1	0	4	Pass+	Pass+
		DBP	92	27	5	1	0	26	7	0	0	30	1	0	2	Pass+	Pass+
SunTech Agilis	*45*	SBP	78	18	9	6	0	12	21	0	0	26	0	0	7	Pass+	Pass
		DBP	70	13	14	3	3	4	29	0	0	23	0	1	9	Pass	Pass
Seinex	*46*	SBP	76	16	12	4	1	10	23	0	0	25	0	1	7	Pass	Pass
SE-9400		DBP	79	18	11	3	1	13	20	0	0	26	0	1	6	Pass	Pass
Microlife	*46*	SBP	74	14	15	2	2	8	25	0	0	24	1	0	8	Pass	Pass
BP 3AC1-1		DBP	81	21	7	4	1	15	18	0	0	27	0	0	6	Pass	Pass+
Colson MAM	*47*	SBP	76	16	12	4	1	10	23	0	0	25	0	1	7	Pass	Pass
BP3AA1-2		DBP	79	28	8	3	2	13	20	0	0	26	0	1	6	Pass	Pass

(Continued)

Table 6 ***(Continued)***

				Actual values within 5 mmHg				*Optimal within 5 mmHg*				*Worst within 5 mmHg*				*Results*	
Device	*Ref.*	*BP*	*N*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*Phase 2.2*	*Phase 2.1*
Omron 637-IT	*48*	SBP	69	15	8	8	2	3	30	0	0	23	0	0	10	Pass	Pass
(Adult)		DBP	86	24	5	4	0	20	13	0	0	28	1	0	4	Pass+	Pass+
Omron 637-IT	*48*	SBP	69	14	9	9	1	3	30	0	0	23	0	0	10	Pass	Pass
(Obese)		DBP	77	19	8	4	2	11	22	0	0	25	1	0	7	Pass	Pass
Omron 637-IT	*49*	SBP	66	12	12	6	3	0	33	0	0	22	0	0	11	Pass	Pass
(Elderly)		DBP	69	15	9	6	3	3	30	0	0	23	0	0	10	Pass	Pass
BPLab	*50*	SBP	68	10	18	2	3	2	31	0	0	22	1	0	10	Pass	Pass
		DBP	80	18	11	4	0	14	19	0	0	26	1	0	6	Pass+	Pass+
Omron	*51*	SBP	68	10	18	2	3	2	31	0	0	22	1	0	10	Pass	Pass
MX3 Plus		DBP	75	17	11	2	3	9	24	0	0	25	0	0	8	Pass	Pass
Microlife	*52*	SBP	71	15	11	4	3	5	28	0	0	23	1	0	9	Pass	Pass
BP A 100 Plus		DBP	71	17	7	6	3	5	28	0	0	23	1	0	9	Pass	Pass
PMS	*53*	SBP	76	15	14	3	1	10	23	0	0	25	0	1	7	Pass	Pass
Mandaus		DBP	87	23	8	2	0	21	12	0	0	29	0	0	4	Pass+	Pass+
Omron M6	*54*	SBP	83	20	10	3	0	17	16	0	0	27	1	0	5	Pass+	Pass+
		DBP	84	24	5	2	2	18	15	0	0	28	0	0	5	Pass	Pass+
Omron R7	*54*	SBP	75	15	13	4	1	9	24	0	0	25	0	0	8	Pass	Pass
		DBP	88	25	6	1	1	22	11	0	0	29	0	1	3	Pass	Pass+

(Continued)

Table 6 *(Continued)*

				Actual values within 5 mmHg				*Optimal within 5 mmHg*				*Worst within 5 mmHg*				*Results*	
Device	*Ref.*	*BP*	*N*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*3*	*2*	*1*	*0*	*Phase 2.2*	*Phase 2.1*
DINAMAP	*55*	SBP	78	19	8	5	1	12	21	0	0	26	0	0	7	Pass	Pass
ProCare		DBP	76	18	9	4	2	10	23	0	0	25	0	1	7	Pass	Pass
Oregon	*56*	SBP	77	18	8	7	0	11	22	0	0	25	1	0	7	Pass+	Pass
Scientific		DBP	81	19	10	4	0	15	18	0	0	27	0	0	6	Pass+	Pass+
BPW810																	
						2/3 within 5 mmHg								0/3 within 5 mmHg			
		Pass+				≥26								0			

The number of subjects with 3, 2, and 1 measurements within 5 mmHg (n_3, n_2 and n_1) can be calculated from the total number of measurements within 5 mmHg (N) and the number of subjects with 2 or 3 measurements and zero measurements within 5 mmHg (n_{2or3} and n_0).

$n_3 = N + n_0 - n_{2or3} - 33$

$n_2 = n_{2or3} - n_3$

$n_1 = 33 - n_{2or3} - n_0$

into the International Protocol so that excellent devices can be distinguished from adequate ones.

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