The British Hypertension Society protocol for the evaluation of blood pressure measuring devices

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Background: With the increasing marketing of automated and semi-automated 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 criteria. To fulfil this need, the British Hypertension Society (BHS) published a protocol of requirements for the evaluation of blood pressure measuring devices with special reference to ambulatory devices in 1990. This protocol has been used to evaluate a variety of blood pressure measuring devices, including eight ambulatory devices, and comments have been received from many interested parties. This experience has demonstrated certain deficiencies in the original protocol, which merit modification. Therefore, the BHS Working Party has revised its protocol in the interests of providing a comprehensive procedure for the evaluation of all blood pressure measuring devices, including those for intermittent 24-h blood pressure measurement.

Changes: The major changes in the revised protocol include simplification of the validation methodology, its applicability to all blood pressure measuring devices, consideration of the accuracy of the device in low, medium and high pressure ranges, provision for validation in special groups such as the elderly, and provision for validation under special circumstances, such as during exercise.

Grading: The final report for a device should specify the grading achieved for both systolic and diastolic blood pressures in the overall blood pressure range. This grading will determine the overall accuracy of the device, on which recommendations for clinical use may be based. Grading criteria should also be provided for low, medium and high pressure ranges in order to provide an assessment of accuracy in the different pressure ranges in which the device may be used. An assessment of accuracy and performance for special groups and for validation under special circumstances should also be provided, although it is emphasized that as experience and the data on which to base validation criteria are limited at present, the results of such assessments must be interpreted cautiously.

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Introduction

When the technique of blood pressure measurement was introduced to clinical medicine early in the 20th century, the importance of accuracy and the limitations of the technique were well recognized [1]. The standards demanded by the clinicians and scientists who introduced the technique were relaxed as the 20th century progressed, and the methodology of blood pressure measurement in both clinical practice and hypertension research became a cause for concern [2]. However, in recent years the increasing number of publications on blood pressure measurement, the time allocated at scientific meetings to the discussion of

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the consequences of inaccuracy of measurement and the recent publication of a number of books devoted entirely to blood pressure measurement [3–5] indicate that this trend has been reversed. One of the beneficial consequences of concern with device accuracy and performance has been that manufacturers now recognize that inaccurate devices will no longer be tolerated, and they must be prepared to subject their claims for accuracy and performance to independent validation.

When the British Hypertension Society (BHS) protocol was first drawn up, the Working Party responsible for its drafting was concerned that the rapidly growing market for 24-h blood pressure measurement might lead to the proliferation of expensive, inaccurate measuring systems. The first protocol therefore concentrated on the evaluation of these systems, although the protocol was suitable for evaluating other blood pressure measuring devices [6].

The concern of the Working Party that the market for 24-h blood pressure measuring devices would grow has been justified. Twenty-four-hour blood pressure measurement is now accepted as a useful procedure in the clinical management of hypertension [7,8] and in the assessment of antihypertensive drugs [9]. The increased interest in 24-h blood pressure measurement has resulted in some 15 devices presently being available commercially, and many others are in the planning phase [10]. Of these devices, eight have been evaluated according to the BHS protocol [11–18]. Additionally, the BHS protocol, either in its entirety or partially, has been used to evaluate seven devices for self-measurement of blood pressure [19], and the Hawksley random-zero sphygmomanometer [20]. This experience, together with comments from a number of interested parties, has prompted a first revision of the protocol.

Changes and statements of policy in the revised protocol

Scope

The scope of the protocol has been modified to make it more applicable to the generality of blood pressure measuring devices while continuing to incorporate special provisions for the evaluation of ambulatory systems. In making provisions for validation of devices designed to measure 24-h blood pressure, we have emphasized that at the time of writing none of the devices on the market is capable of measuring blood pressure continuously over 24 h and that by providing intermittent measurements usually taken with the subject at rest they do not provide truly ambulatory measurements of blood pressure. The abbreviation ABPM (ambulatory blood pressure monitoring), although somewhat misleading, is now so well established that recommendations to change it would lead to confusion, but we suggest that the abbreviation ABPM should be qualified as either 'intermittent' ABPM to denote the 24-h profile obtained with available devices or 'continuous' ABPM in anticipation of devices which will provide beat-to-beat analysis over the 24-h period.

Protocol sections

The revised evaluation programme is now divided into two parts. Part I consists of the main validation procedure to which all blood pressure measuring devices should be subjected. There are five phases to Part I: I, before-use device calibration; II, in-use (field) assessment; III, after-use device calibration; IV, static device validation; and V, report of evaluation.

Part II provides validation procedures for special categories (the categories included in this revision are those that seem most appropriate at the time of writing; other categories will need to be addressed in the future, and the same basic principles may be applied): I, special group validation: pregnant women, the elderly and children; and II, device validation in special circumstances: blood pressure measurement during exercise and in various postures. The validation procedures in Part II are undertaken only if a device has successfully completed all phases of Part I and has achieved at least a B grading for accuracy for both systolic and diastolic blood pressure.

The original protocol, although acknowledging the desirability of validating devices for special groups such as pregnant women, did not lay down criteria for such testing. Also, no provision was made for validation during exercise or for the influence of different levels of pressure on the validation analysis. These deficiencies are now addressed.

Validation test

The basis of device evaluation is the comparison of blood pressure measured by the device being tested with measurements made by trained observers using a mercury sphygmomanometer and stethoscope to auscultate the Korotkoff sounds. Whereas the original protocol made provision for simultaneous measurement between the test device and the mercury standard in the same arm, experience has shown that the inflation–deflation characteristics of most devices do not permit simultaneous comparisons in the same arm, and in the revision a sequential comparison in the same arm is used for validation. The validation procedure for comparison simultaneously in the same arm between the test instrument and a mercury sphygmomanometer is therefore no longer included in the protocol.

Intra-arterial comparison

Comparison of blood pressure measuring systems which utilize indirect measurement with direct intra-arterial measurement of blood pressure is not recommended in this protocol. There are several reasons for this. Systolic and diastolic blood pressure values obtained by the direct technique are different from meas-

urements obtained by indirect methods [21]. Clinical practice derives from data obtained by the indirect rather than the direct technique. Importantly, ethical considerations preclude its use for device validation in healthy subjects [10]. There is considerable beat-to-beat variation in blood pressure, which is not reflected in indirect readings; blood pressures measured directly and indirectly from the same artery are rarely (if ever) identical. Discrepancies in systolic blood pressure as great as 24 mmHg for systolic and 16 mmHg for diastolic blood pressure have been observed when blood pressure was measured by both techniques in the same arm at the same time. Furthermore, these differences are random, having no schematic pattern to them [22,23].

Grading of devices

The grading system used in the original protocol has been revised to correspond to the change from simultaneous to sequential comparison in the same arm.

Specification of device

In the original protocol it was stated in the Appendices that when manufacturers incorporate modifications into externally identical or indistinguishable versions of a model, this should be indicated clearly by a number specific for that device and full details concerning how the device differs from earlier versions should be provided. In particular, it was recommended that the probable effect of all such modifications on the performance and accuracy of the device should be stated. In view of the considerable confusion and serious consequences for hypertension research and clinical practice arising from modifications made to automated devices by the manufacturer that are unknown to the user [18,24], we stress at the outset of this revision that it is incumbent upon manufacturers to indicate clearly all modifications in the technological and software components of automated devices by changing the device number. Furthermore, modified devices must be subjected to renewed validation.

Observer training

As in the original protocol, considerable emphasis has been placed on observer training. Observers should be trained before embarking on what is a complex and labour-intensive procedure. In the original protocol, one observer measured blood pressure in half of the subjects and a second observer measured blood pressure in the remaining subjects. By so doing, the need to have two observers measure blood pressure independently throughout the study, as recommended in the standard of the Association for the Advancement of Medical Instrumentation (AAMI) [25], was obviated, with savings in personnel requirements. However, although statistical requirements are fulfilled by this method, commercial consequences for a manufacturer of a device which performs badly in the main validation test are such that we believe the employment of two observers to measure blood pressure simultaneously further strengthens the validity of the result.

Timing of main validation

As in the original protocol, the capability of a number of devices of the model being tested to give consistent measurements is assessed before beginning the validation test, and if substantial differences between instruments of the same device occur further device validation is not appropriate. We have attempted to determine the minimal criteria that would give a statistically valid assessment, while also being alert to the demands that the validation tests impose on an assessment laboratory. Although it might be desirable to perform the main comparative validation when the device is new and repeat this test after a period in use, this would effectively nearly double the time and expense of the study. We have therefore compromised by postponing the main validation test until the device has been in use for a period, and we have arbitrarily chosen a minimum period of 1 month. We believe this to be justified on the basis that the accuracy of a measuring device after use is more relevant than the accuracy immediately after purchase. The before- and after-use calibration tests have also been simplified in the revision.

In addition to the issues discussed above, every effort has been made to minimize unnecessary testing. The revised BHS protocol has been designed so that the device passes through different phases of evaluation, entry to each test phase being dependent on the successful completion of the preceding phase.

Part I: Main validation procedure

Part I has five phases (Fig. 1): I, before-use device calibration; II, in-use assessment; III, after-use device calibration; IV, static device validation; and V, report of evaluation.

General considerations

In the protocol we use the term 'device' to denote a particular model of sphygmomanometer which, in practice, would be identified by a name and number or letter specific for that device, and we use the term 'instrument' to denote individual sphygmomanometers.

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 it has been shown to be inaccurate in comparison with conventional sphygmomanometry [20]. Until the manufacturers modify the design, its use cannot be recommended in validation studies. All blood pressures should be recorded to the nearest 2 mmHg as recommended by the BHS [26].

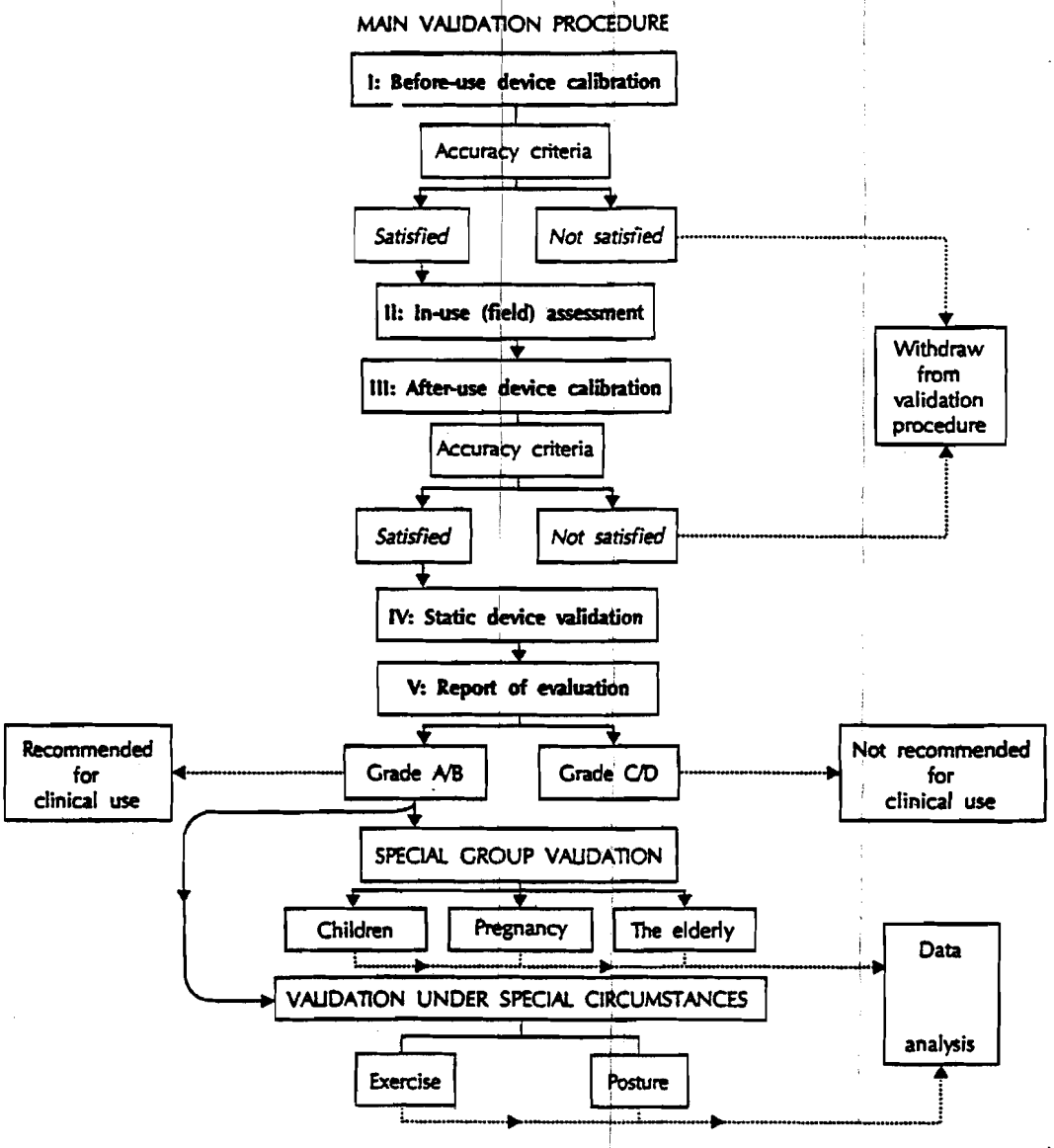

Fig. 1. Validation procedure.

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, such as the Littmann, is recommended.

Familiarization session

As automated devices for blood pressure measurement are complex, familiarization is important. The observers who have satisfied the training criteria should next be instructed in the use of the devices and computer software to be tested. Practice measurements should be made on a number of subjects.

Phase I: Before-use device calibration

If only one instrument is tested for validation, then it is possible, in the event of the assessment proving unfavourable to the test device, that the instrument selected is unrepresentative of the product. Inaccuracy might have been due to poor calibration or some other fault that might occur only occasionally [27]. It is also possible that the first instrument to be tested might be accurate but unrepresentative. Because of these potential differences between instruments, we suggest that at least three instruments for each device should be tested for variability before proceeding to validation. If differences emerge between instruments, further testing should not be conducted until the manufacturer has identified the source of error and provided three instruments which are in agreement. The recommendation to select three instruments is based on economic and feasibility considerations.

Ideally, three instruments should be acquired at random from retail outlets without the manufacturers being aware of which instruments are being chosen. However, in practice, especially when expensive automated blood pressure measuring devices are being evaluated, it is not feasible to obtain instruments in this way. If the manufacturer provides the instruments for validation, it should be stipulated that these be chosen from the production line at random. The manufacturer should give written confirmation of this.

Semi-automated devices for blood pressure measurement should have a facility permitting connection to a mercury sphygmomanometer to check device calibration. It is anticipated that future models of devices which currently do not readily lend themselves to calibration will provide this facility. The details of the calibration procedure are peculiar to each blood pressure system, but the test is usually performed by connecting the device to a mercury sphygmomanometer with a Y-connector. The automatic pressure system and the blood pressure detection mechanism (microphone, oscillometry, etc.) are disabled so that the device acts simply as a manometer. Pressures within the system are then compared throughout the pressure range on the mercury column (0–300 mmHg).

The test requirements are three instruments and three observers. Three observers are blinded from each other by being placed in separate booths. Observer 1 reads a recently calibrated mercury column to provide control values and observer 2 reads the test instrument. The manometers are connected by Y-connectors to a further mercury manometer which is read by a third observer (the 'director'). All three manometers are connected to the test instrument cuff wrapped around a cylinder (Fig. 2). The director observer deflates the cuff at 2 mmHg/s and calls out 'now' (according to pressures shown in Table 1) to denote the moment for the two observers to record pressure. There should be five calls per deflation, to ensure that all sphygmomanometers receive the same pressure calls but in an order that is not discernible to the observers. To use the table, choose the widest range of pressures applicable to the device being tested (for example, if the device being tested measures pressures from 40 to 285 mmHg select the 50–270 mmHg column) and make calls for instruments A, B and C on six deflations (1–6) according to the figures in the appropriate columns.

Test methodology

(1) Three instruments.
(2) Three observers blinded in booths.
(3) Observer 1: calibrated mercury column, control measurement.
(4) Observer 2: test instrument.
(5) Observer 3: director, calibrated mercury column.
(6) Director calls 'now' at pressures shown in Table 1.
(7) Five calls per deflation, dependent on the range of blood pressure.
(8) Six deflations per instrument.
(9) Thirty readings per instrument.
(10) Ninety readings per device.

Test criteria

(1) At least 28/30 control and test measurement pairs must be within 3 mmHg of each other.
(2) Failure: no further testing.

Phase II: In-use (field) assessment

The three instruments used for device calibration are next used to test the accuracy and performance of the device during and after the use for which it was designed. The purpose of this phase is to subject the blood pressure device to a period of fairly strenuous use before performing the main validation test. Each of the three instruments is subjected to 1 month of the use for which it is designed. This phase will therefore be influenced by the device being tested. For example, devices designed for self-measurement of blood pressure should be used in the home environment, devices for theatre use should be put to use in the operating theatre, and so on (see special considerations for ambulatory devices, below). Each of the three instruments should be exposed to routine use for at least 1 month and should complete at least 400 inflations. Documentation of the number of inflations is obtained by placing a 15- to 20-cm strip of white adhesive tape

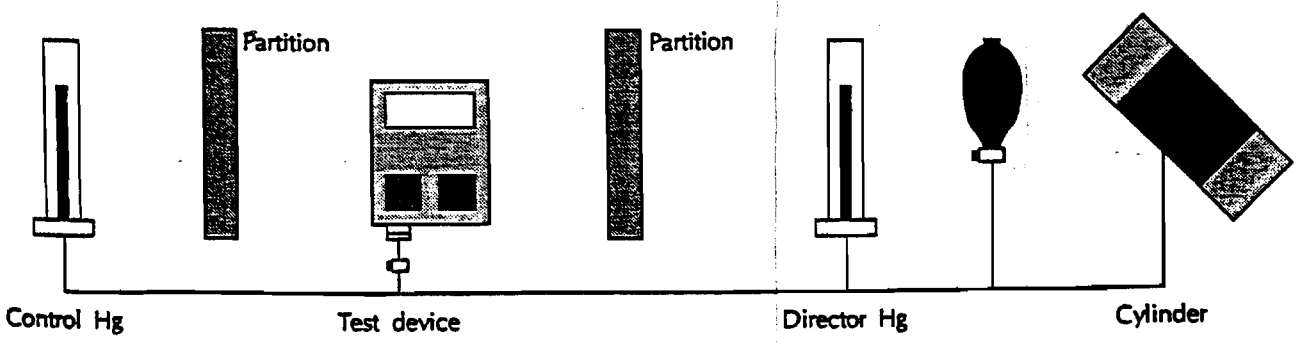

Fig. 2. Procedure for device calibration.

Table 1. Table for calibration values for the interdevice variability test.

	50–250 mmHg			50–270 mmHg			50–290 mmHg			30–250 mmHg			30–270 mmHg			30–290 mmHg			10–250 mmHg			10–270 mmHg			10–290 mmHg		
	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
	228	246	238	242	268	258	262	284	276	226	244	240	244	266	260	260	286	278	220	248	236	240	264	256	258	282	274
	172	200	194	186	216	208	196	230	222	164	196	190	178	212	200	188	226	218	158	188	184	172	204	198	182	220	214
1	132	168	154	144	180	166	152	190	172	120	156	144	132	170	156	138	182	164	112	148	132	120	162	144	130	172	154
	94	100	112	98	104	120	104	112	126	78	86	102	80	90	106	84	98	114	62	68	84	66	78	92	72	80	102
	68	72	78	66	76	84	72	80	86	50	58	62	48	56	64	52	60	72	28	36	48	32	42	46	34	44	50
	246	228	214	268	242	228	284	262	246	244	226	208	266	244	226	286	260	242	248	220	206	264	240	220	282	258	236
	194	180	186	208	194	198	222	206	212	190	174	178	200	186	196	218	200	206	184	168	174	198	178	188	214	190	200
2	160	146	168	170	156	180	180	164	190	150	138	156	160	148	170	170	158	182	144	128	148	152	136	162	162	144	172
	126	120	94	136	126	98	144	132	104	112	108	78	124	116	80	132	124	84	100	94	62	112	100	66	118	108	72
	88	78	52	90	84	54	96	86	56	72	62	36	76	64	34	80	72	32	56	48	16	58	46	14	60	50	12
	238	232	246	258	252	268	276	272	284	240	234	244	260	248	266	278	268	286	236	230	248	256	246	264	274	270	282
	200	186	172	216	198	186	230	212	196	196	178	164	212	196	178	226	206	188	188	174	158	204	188	172	220	200	182
3	142	154	146	150	166	156	160	172	164	128	144	138	140	156	148	150	164	158	116	132	128	126	144	136	136	154	144
	108	126	108	110	136	110	116	144	116	92	112	92	96	124	96	106	132	106	80	100	80	82	112	82	90	118	90
	78	68	60	84	66	62	86	72	64	62	50	40	64	48	44	72	52	46	48	28	20	46	32	22	50	34	26
	232	214	222	252	228	236	272	246	252	234	208	216	248	226	234	268	242	254	230	206	214	246	220	228	270	236	248
	206	172	200	222	186	216	240	196	230	204	164	196	216	178	212	234	188	226	198	158	188	212	172	204	232	182	220
4	168	142	160	180	150	170	190	160	180	156	128	150	170	140	160	182	150	170	148	116	144	162	126	152	172	136	162
	120	112	120	126	120	126	132	126	132	108	102	108	116	106	116	124	114	124	94	84	94	100	92	100	108	102	108
	52	88	68	54	90	66	56	96	72	36	72	50	34	76	48	32	80	52	16	56	28	14	58	32	12	60	34
	222	238	232	236	258	252	252	276	272	216	240	234	234	260	248	254	278	268	214	236	230	228	256	246	248	274	270
	186	206	180	198	222	194	212	240	206	178	204	174	196	216	186	206	234	200	174	198	168	188	212	178	200	232	190
5	146	160	132	156	170	144	164	180	152	138	150	120	148	160	132	158	170	138	128	144	112	136	152	120	144	162	130
	112	94	100	120	98	104	126	104	112	102	78	86	106	80	90	114	84	98	84	62	68	92	66	78	102	72	80
	72	60	88	76	62	90	80	64	96	58	40	72	56	44	76	60	46	80	36	20	56	42	22	58	44	26	60
	214	222	228	228	236	242	246	252	262	208	216	226	226	234	244	242	254	260	206	214	220	220	228	240	236	248	258
	180	194	206	194	208	222	206	222	240	174	190	204	186	200	216	200	218	234	168	184	198	178	198	212	190	214	232
6	154	132	142	166	144	150	172	152	160	144	120	128	156	132	140	164	138	150	132	112	116	144	120	126	154	130	136
	100	108	126	104	110	136	112	116	144	86	92	112	90	96	124	98	106	132	68	80	100	78	82	112	80	90	118
	60	52	72	62	54	76	64	56	80	40	36	58	44	34	56	46	32	60	20	16	36	22	14	42	26	12	44

on the occluding arm cuff, and each time an inflation is made the user indicates this by making a stroke mark on the adhesive strip. This strip should be removed weekly, the number of inflations recorded and a fresh adhesive strip applied to the cuff. For automated devices that produce a printed record of measurements the tape procedure is not necessary, but daily printouts should be retrieved and filed. Problems encountered by those using the device during this phase should be documented.

Test methodology

(1) Three instruments.
(2) One month of use for which device designed.
(3) Minimum 400 inflations per instrument.
(4) Document manual inflations by marking tape on cuff.
(5) Change tape weekly.

Test criteria

(1) Comments of users (subjects or operators) noted.
(2) Not an elimination phase.

In-use assessment of 24-h blood pressure measuring systems

Special considerations apply to validating systems for measuring 24-h blood pressure. We have already drawn attention to the importance of distinguishing between ambulatory systems that measure blood pressure intermittently over 24 h and those that may measure pressure continuously over the 24-h period. Two further distinctions, which may influence validation of these systems, are also important. The first concerns the activity that the instructional literature permits during blood pressure measurement. If instructions are explicitly given for the subject to cease activity when a warning bleep is activated and to hold the arm steady during blood pressure measurement, static device validation as outlined below will be satisfactory. If the instructional literature claims that the ambulatory system will provide accurate blood pressure measurements during activity, then exercise validation (as outlined in Part II) will be required in addition to the static validation outlined below. The second consideration is that of posture. Even if the instructional literature recommends that the subject be seated during blood

pressure measurement, it is not usually feasible for active subjects to comply with such a recommendation and, moreover, during the night the subject will be supine. It may therefore be desirable to incorporate a test for the effect of posture within the validation for ambulatory systems as described in Part II.

The three instruments used for the interdevice assessment are next used to test the accuracy and performance of the device during 24-h blood pressure monitoring. The purpose of this phase is to subject the system to a period of fairly strenuous use before performing the main validation test. The three instruments are placed on 12 normotensive and 12 hypertensive subjects over a 4-week period so that each instrument is worn by eight subjects to give a total of 24 recording days. Each subject is instructed to cease activity during waking hours when the warning bleeps indicate that measurement is about to occur, to sit down and to ensure that the arm is supported on a firm surface such as a table. A diary card is provided for completion after each measurement, in which there is space to record preceding activity and posture. At the end of this period the performance of each of the three instruments and patient acceptability are assessed.

Requirements for the in-use phase

(1) Three instruments to be worn for 24 h in 24 subjects (one instrument × eight subjects) with a range of pressures.
(2) Twenty-four-hour blood pressure measurements are programmed for 30-min intervals for 24 h 30 min, giving 50 measurements per individual.
(3) Four hundred recordings per instrument.
(4) Twelve hundred recordings per device.

Performance requirements

(1) Most 24-h blood pressure systems have programmed editing criteria, and these are left in operation for this phase. If the instructions allow the operator to modify the editing program, the program recommended by the manufacturer is chosen.
(2) The measurements obtained over each 24-h period and separately for daytime (0800–2159 h) and night-time (2200–0759 h) are classified as follows (Table 2):
    (a) Inflations. The total number of inflations made by the instrument.
    (b) Valid readings. Those readings accepted by the instrument as genuine blood pressure measurements.
    (c) Invalid readings. This includes both rejected and aborted readings.
    (d) Rejected readings. Those blood pressure readings which are rejected either by the recorder or decoder as not being genuine blood pressure measurements.
    (e) Aborted readings. Those occasions when an inflation fails to produce a reading of any kind.

The purpose of this phase is to ensure that a period in use does not make the system inaccurate and to gather information on its performance. It is not an eliminating phase. However, there is little point in proceeding to the main validation test if the device performs so badly as to be unacceptable for clinical use.

Patient/subject acceptability

In this assessment each subject is asked to comment on the aspects of device performance according to Fig. 3. This information can be helpful later in making an overall assessment of performance, and the comments may indicate areas of improvement for the manufacturer.

Phase III: After-use device calibration

At the end of the month of use the three instruments are retested for calibration variability as in the before-use device calibration test to determine whether there has been any change in device agreement after use.

If all three instruments give measurements that are in agreement at the time of purchase as well as after a period in use, this suggests, at least, that the device is being manufactured to perform consistently. If, conversely, all three instruments give discordant measurements, further assessment is pointless and the model cannot be recommended. However, if one instrument is found to be discordant with the remaining two showing consistency, further evaluation is reasonable on the basis that one inaccurate instrument might have been included by chance. Such an occurrence may indicate, however, that overall production of that device is not satisfactory and should be noted in the final report. If two or three instruments are discordant, no further testing is performed.

Phase IV: Static device validation

If there has been no alteration in device variability after the month of use, one instrument is arbitrarily selected from the three instruments used for the main validation test. In the event of one instrument failing after-use device calibration, one of the two instruments that are in agreement is used for the validation test.

Observer training and assessment

The first prerequisite for this validation test is to ensure that the observers are in agreement and have achieved the required accuracy (see Appendix A). However, it is possible that observers who fulfil these criteria at the outset of the study do not fulfil the criteria at the end of the study, and if this happens the test must be repeated. To avoid this occurrence, analysis should be performed after completion of testing in 20, 40 and 60 subjects to permit detection of any drift in agreement between the observers.

Table 2. Example of in-use assessment.

		24-h			Daytime			Night-time			
Instrument	Subject	Inf.	Valid	Invalid	Inf.	Valid	Invalid	Inf.	Valid	Invalid	Grade
I	1	50	46	4	30	27	3	20	19	1	***
I	2	50	47	3	30	27	3	20	20	0	***
I	7	50	45	5	30	29	1	20	16	4	***
I	9	49	47	2	29	28	1	20	19	1	***
I	16	50	50	0	30	30	0	20	20	0	***
I	18	50	8	42	30	8	22	20	0	20	F
I	20	50	46	4	30	30	0	20	16	4	***
I	24	50	41	9	30	23	7	20	18	2	***
II	3	50	40	10	30	24	6	20	16	4	***
II	5	50	47	3	30	27	3	20	20	0	***
II	10	50	49	1	30	29	1	20	20	0	***
II	11	50	46	4	30	28	2	20	18	2	***
II	12	51	42	9	31	26	5	20	16	4	***
II	15	50	35	15	30	21	9	20	14	6	**
II	21	49	45	4	29	26	3	20	19	1	***
II	22	50	43	7	30	30	0	20	13	7	*
III	4	50	49	1	30	30	0	20	19	1	***
III	6	50	50	0	30	30	0	20	20	0	***
III	8	50	34	16	30	24	6	20	10	10	*
III	13	50	48	2	30	28	2	20	20	0	***
III	14	50	44	6	30	27	3	20	17	3	***
III	17	50	42	8	30	25	5	20	17	3	***
III	19	51	46	5	30	27	3	21	19	2	***
III	23	50	44	6	30	29	1	20	15	5	**
Totals											
3	24	1200	1034 (86%)	166 (14%)	719	633 (88%)	86 (12%)	481	401 (83%)	80 (17%)	

Figures are for 24 recording days in 24 subjects. ***80% minimum = 24 day and 16 night; **70% minimum = 21 day and 14 night; *50% minimum = 15 day and 10 night; F, failed (< 15 day or 10 night). Inf., inflations.

Summary analysis

Instrument	***	**	*	F
I	7	0	0	1
II	6	1	1	0
III	6	1	1	0
All	19	2	2	1

General considerations

Static device validation should be performed in a warm room from which disturbing influences, such as telephones and bleeps, have been removed.

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 static validation must be performed with and without electrocardiogram gating. Similarly, some Korotkoff sound-detecting devices provide an oscillometric backup when
sound detection fails. In these circumstances both systems of measurement must undergo static validation.

For validation of blood pressure measuring devices which measure blood pressure continuously to provide beat-to-beat analysis, the blood pressure value for comparison should be the mean of all beats over a 20-s period before and after the standard measurement; analysis then proceeds as for other systems. When validating devices that measure finger pressure, consideration will need to be given to the differences in blood pressure between distal and proximal limb arteries.

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, i.e. the bladder should be of sufficient length to encircle 80% of the arm circumference [26]. All blood pressure measurements should be performed for both the test device and the standard with the bladder appropriate for the circumference of the arm in which blood pressure is being measured. If only one size of cuff is provided with the test device, this must be used throughout, but for a standard sphygmomanometer a cuff containing a bladder appropriate to the arm in which blood pressure is being measured must be used. When changing the test device cuff, only the cuff should be changed; it is important to ensure that the same microphone(s) is (are) used throughout the validation test.

Subject selection

Subject selection is dependent on the circumstances under which the device will be used. If the device is intended for a special patient population, such as

DEVICE ASSESSMENT FORM

Thank you for participating in this study to assess this new device for measuring ambulatory blood pressure. In order to evaluate your impressions of it we would like you to take a few minutes to complete this form. Please circle the option which most corresponds to your opinion. Feel free to comment as you wish.

(1)	Did you experience any discomfort?	Negligible	Some	Considerable
	Comment			
(2)	Did it cause interference with your activities?	Negligible	Some	Considerable
	Comment			
(3)	Did it cause interference with your sleep?	Negligible	Some	Considerable
	Comment			
(4)	Did you have any problems with noise?	Negligible	Some	Considerable
	Comment			
(5)	Did the device cause any anxiety?	Negligible	Some	Considerable
	Comment			
(6)	Did you have any difficulties with the device?	Negligible	Some	Considerable
	Comment			
(7)	Were the instructions clear?	Yes	No	
	Comment			
(8)	Had you any other problems with the device?	Yes	No	
	Comment			
(9)	What was your overall impression?			
	Comment			
	Overall, into which of the following categories would you place it?	Bad	Fair	Good Very good
(10)	Have you any suggestions as to how it might be improved?			
	Comment			

Device . . . . . .

Date of ABP . . . . . .

Subject code . . . . . .

Fig. 3. *Patient device assessment form.*

pregnant or paediatric patients, it must also be validated in these groups (see Part II). Similarly, patients with arrhythmias (such as atrial fibrillation) should not be included; if validation in these circumstances is required, subject selection must be directed accordingly. Subjects in whom Korotkoff sounds persist to near-zero should be excluded from the study.

In selecting 85 subjects 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.

In the selection of subjects it is not sufficient to specify merely that subjects shall have blood pressures within a specified range of pressure, because there may be a tendency (arising out of convenience) to recruit more subjects in the lower pressure range than those with higher pressures. Pressure ranges are therefore specified. The blood pressure used in the analysis should be the entry blood pressure at the time of the static validation, and not that at the time of recruitment for validation as described below.

Numbers. Eighty-five subjects.
Sex. Distribution by chance.
Age range. Distribution by chance.
Arm circumference. Distribution by chance.
Blood pressure range

SBP (mmHg)	< 90	90–129	130–160	161–180	> 180
n	8	20	20	20	8
DBP (mmHg)	< 60	60–79	80–100	101–110	> 110
n	8	20	20	20	8

SBP, systolic blood pressure; DBP, diastolic blood pressure.

The numbers indicated are the minimum number required for each blood pressure group.

Validation tests

With most automated devices, a number of factors may make it difficult or impossible to perform simultaneous comparison in the same arm. For example, devices that deflate as rates of > 5 mmHg/s do not permit accurate measurement by an auscultating observer, leading to inaccurate comparison between the test and reference device [28]. At fast deflation rates an auscultating observer will tend to underestimate systolic and overestimate diastolic blood pressure by recording the first definite pressure phase at which Korotkoff sounds are audible as the systolic value and the last definite phase of audible sounds as the diastolic value. The device may have a facility for slowing the rate of deflation so that the simultaneous comparison can be performed, but this is not permissible as modification of the usual operational mode may alter the accuracy. Other factors that may preclude simultaneous same-arm testing are confusion of noise from the device with Korotkoff sounds, failure of the inflating mechanism to reach the required pressure and uneven deflation making accurate auscultation impossible.

An alternative procedure to simultaneous measurements in the same arm is to perform simultaneous measurements in opposite arms, but this introduces the substantial error of interarm difference and may not be truly simultaneous.

To overcome the problems associated with simultaneous measurements in either the same or opposite arms, this protocol recommends one sequential testing procedure performed in the same arm to be used for all devices.

Sequential same-arm comparison. Sequential same-arm measurements between the test instrument and a standard mercury sphygmomanometer are carried out as follows in 85 subjects (Fig. 4).

BP*A* Entry blood pressure, observers 1 and 2 each with mercury standard.
This blood pressure determines the blood pressure range to which the subject will be allocated in subsequent analysis; it is not included in the analysis of this phase.

BP*B* Device detection blood pressure, observer 3.
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; it is not included in the analysis.

BP*1* Observers 1 and 2 with mercury standard.
BP*2* Observer 3 with test instrument.
BP*3* Observers 1 and 2 with mercury standard.
BP*4* Observer 3 with test instrument.
BP*5* Observers 1 and 2 with mercury standard.
BP*6* Observer 3 with test instrument.
BP*7* Observers 1 and 2 with mercury standard.

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. Analysis is done separately for observers 1 and 2, using three pairs of readings from each subject, giving a total of 255 pairs

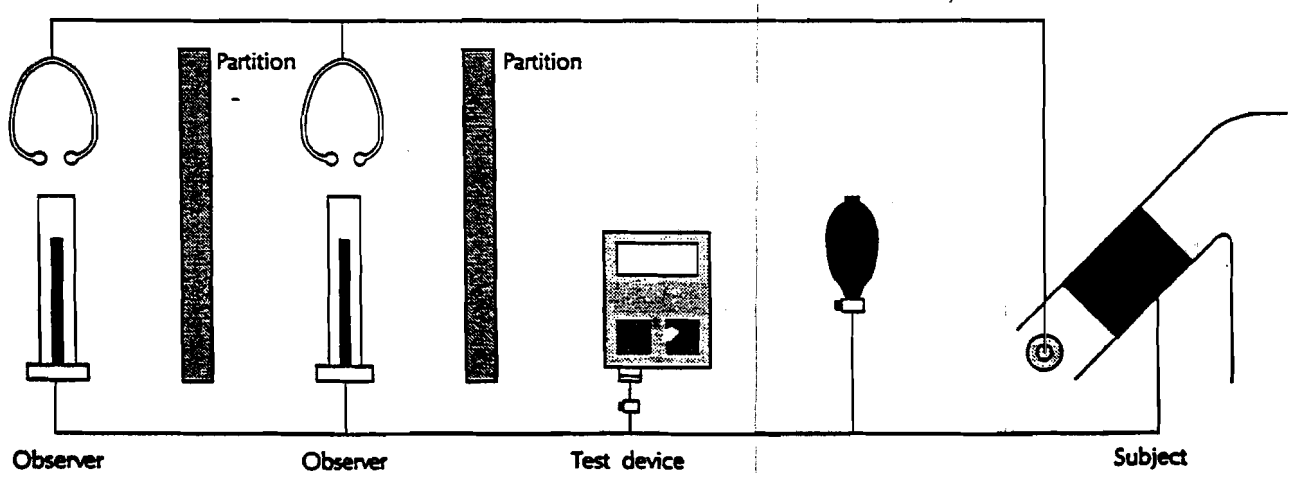

Fig. 4. Procedure for sequential comparison in the same arm.

of readings for each observer. To compare one observer and the test instrument, first analyse the data on the 85 subjects using the pairs BP*1* versus BP*2*, BP*3* versus BP*4* and BP*5* versus BP*6*. Then similarly analyse the data using the pairs BP*2* versus BP*3*, BP*4* versus BP*5* and BP*6* versus BP*7*. The result which is more favourable to the test device is selected.

Documentation must be provided for data omitted for legitimate technical reasons; once a subject is included, before the pressure data-gathering phase, 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 85.

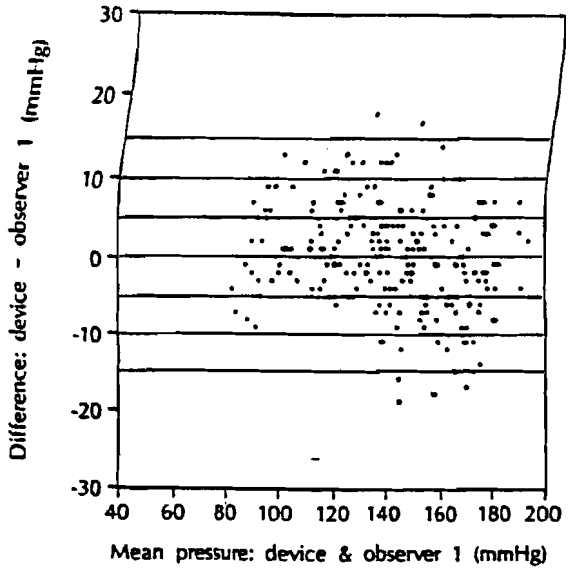

Fig. 5. Plot of pressure difference between the better observer and the test device and mean pressure for the test device and that observer in 85 subjects for systolic pressure (n = 255). Reference lines, 0, ± 5, ± 10 and ± 15 mmHg difference.

Accuracy criteria. The percentages of test instrument measurements differing from the mercury standard by ≤ 5, ≤ 10 and ≤ 15 mmHg are calculated separately for each observer and separately for systolic and diastolic blood pressure. The device is graded *A*, *B*, *C* or *D* separately for each observer, according to the criteria in Table 3. To obtain a particular grade, all three percentages should equal or exceed the tabulated values. An example is shown in Table 4. The final grade for each systolic and diastolic blood pressure is the better of the grades obtained by the two observers. The difference (device − observer), for systolic and diastolic blood pressure separately (using the data on which the final grade is based), should be plotted against the mean of the device pressure and the observer pressure, using all 255 points. Figures 5 and 6 show plots corresponding to the data in Table 4 [29]. The data used for the plots should be for the better observer, although data for both observers should be presented as in Table 4. Eighty per cent of the measurements by the observers should be within 5 mmHg of each other and 95% within 10 mmHg. If this level of agreement between observers is not reached, phase IV must be repeated.

Table 3. British Hypertension Society grading criteria.

	Absolute difference between standard and test device (mmHg)		
Grade	≤ 5	≤ 10	≤ 15
Cumulative percentage of readings			
A	60	85	95
B	50	75	90
C	40	65	85
D		Worse than C	

Grades are derived from percentages of readings within 5, 10 and 15 mmHg. To achieve a grade all three percentages must be equal to or greater than the tabulated values.

Table 4. Grading criteria, mean and mean of differences for test device and a sample analysis for overarll pressure levels for both observers.

		Differences between standard and test device (mmHg)				
	Grade	≤ 5	≤ 10	≤ 15	Mean ± SD (mmHg)	Mean ± SD of differences (mmHg)
Observer 1						
SBP	B	57	87	98	143 ± 28	0 ± 7
DBP	B	53	86	97	91 ± 20	− 2 ± 7
Observer 2						
SBP	B	51	85	94	145 ± 28	− 3 ± 7
DBP	B	55	86	98	89 ± 20	1 ± 7
Final grading						
SBP	B	57	87	98	143 ± 28	0 ± 7
DBP	B	55	86	98	89 ± 20	1 ± 7
Observer comparison						
SBP	A	81	99	100		− 2 ± 3
DBP	A	82	100	100		− 2 ± 3

Pressure range: SBP 93–231 mmHg; DBP 56–124 mmHg. n = 255 per observer for SBP and DBP. SBP, systolic blood pressure; DBP, diastolic blood pressure.

There is now evidence that some blood pressure measuring devices, especially ambulatory systems, have poorer accuracy at higher pressure levels, and this may not become apparent if data analysis is confined to the overall pressure range [30,31]. It is therefore recommended to analyse pressure data in the following ranges (Table 5): low pressure range < 130/80 mmHg; medium pressure range 130–160/80–100 mmHg; high pressure range > 160/100 mmHg. For this analysis each subject is classified by the initial mercury measurement (BP*A*). It must be emphasized that data from this analysis are provided to indicate possible trends in accuracy of the test device, and that the grade for

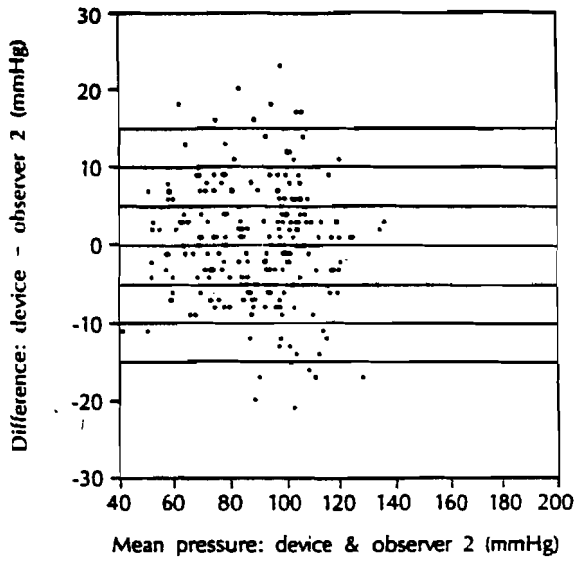

Fig. 6. Plot of pressure difference between the better observer and the test device and mean pressure for the test device and that observer in 85 subjects for diastolic pressure (n = 255). Reference lines, 0, ± 5, ± 10 and ± 15 mmHg difference.

overall accuracy determines whether the device can be recommended for use in clinical practice.

Table 5. British Hypertension Society criteria for test device and a sample analysis for high, medium and low pressure levels for the better observer.

		Difference between standard and test device (mmHg)			
	Grade	≤ 5	≤ 10	≤ 15	n
Low pressure range (< 130/80 mmHg)					
SBP	A	68	88	100	75
DBP	B	56	88	98	81
Medium pressure range (130–160/80–100 mmHg)					
SBP	B	57	88	97	105
DBP	C	49	86	98	99
High pressure range (> 160/100 mmHg)					
SBP	C	47	84	96	75
DBP	C	48	83	97	75

SBP, systolic blood pressure; DBP, diastolic blood pressure.

The mean differences and standard deviation of the differences should also be given to determine whether the device is within the AAMI recommendations, which are that the mean difference shall be ≤ 5 mmHg and the standard deviation ≤ 8 mmHg (Table 4).

Phase V: Report of evaluation

The final report should be prefaced with subject data so as to describe the key characteristics of the subjects in the study; this should include the number of subjects, the ranges of systolic and diastolic blood pressure and a form which should provide the information on any problems encountered, the date of occurrence, date of repair, effect on validation procedure, comments on agency or manufacturer efficiency, estimated costs of service, and this section should conclude with appropriate recommendations to the manufacturer for improving the equipment.

Basic information

The information provided in operational manuals is often deficient. Without appropriate specifications and operational instructions, it is difficult to obtain optimal performance. The information outlined in Appendix B should be provided, and deficiencies in this regard should be listed in the report.

Acknowledgements

The report should state whether the equipment was purchased for the evaluation or donated or loaned by the manufacturer. The data analysis should ideally be done by the laboratory doing the evaluation. If it has been done by the manufacturers, this should be stated. Any consultancies or conflict of interest should be acknowledged by the investigator.

Part II: Validation procedures for special groups and in special circumstances

Procedures in Part II are to be undertaken only if the device has successfully completed Part I and has achieved A or B grading for accuracy.

It is important to emphasize that experience in validating blood pressure measuring devices in these special circumstances is limited, and the proposals put forward here must be regarded as somewhat tentative. However, it is hoped that further use of the protocol along the lines suggested will, in time, provide the data necessary to draw up validation procedures that are more definitive. Thus, we do not provide pass–fail criteria for the Part II section of the protocol. Furthermore, in the Part II sections it is recommended that grading should not be attempted, but rather the results should be stated as the mean difference and standard deviation between the standard and the test device.

The number of subjects required for these groups and circumstances has been reduced from the figure of 85 required for the main validation test in Part I to 30. Although it is accepted that this figure is arbitrary, it nevertheless takes into account that the device has had to complete the Part I validation in 85 subjects and that the categorization of subjects into special groups (for example, the elderly) permits such a reduction in the number of subjects. Furthermore, the number of measurements for analysis in the groups will be repeated three times, providing 90 measurements for analysis.

I: Special group validation

Pregnant women

Numbers. Thirty pregnant women.

Age range. Immaterial.

Arm circumference. Eight to 10 subjects with arm circumference > 35 cm.
Trimester distribution. At least 10 in second and 10 in third trimester.
Blood pressure range
Systolic: 5/30 in 100–115, 116–130, 131–145, 146–160 mmHg.
Diastolic: 5/30 in 70–80, 81–90, 91–105 mmHg.

The numbers indicated are the minimum number required for each blood pressure group.

Elderly subjects
Numbers. Thirty subjects.
Sex. At least 10 male and 10 female.
Age range. Older than 65 years.
Blood pressure range
Systolic: 5/30 < 110 mmHg, 5/30 > 200 mmHg.
Diastolic: 5/30 < 70 mmHg, 5/30 > 110 mmHg.

The numbers indicated are the minimum number required for each blood pressure group.
Arm circumference. At least 5/30 subjects with arm circumference > 35 cm.

Paediatric subjects
It is impossible to measure systolic blood pressure accurately by conventional sphygmomanometry in children aged less than 4 years and diastolic pressure in children aged less than 5 years [32]. It is therefore necessary to validate devices by different methods for children aged less than 5 years and those aged from 5 to 15 years. Because the blood pressure of children is age-related, ranges are specified in relation to age-specific mean and standard deviation.

Young children (0–5 years)
Numbers. Thirty subjects.
Sex. At least 10 male and 10 female.
Age range. Fifteen to be distributed between 0 and 12 months and 15 between 1 and 5 years.
Blood pressure range [33]
Systolic: 5/30 > mean + 1 SD for population.
Diastolic: 5/30 < mean − 1 SD for population.

Arm circumference. The bladder size should be appropriate for the arm circumference of the subject [26].
Validation procedure. This should be as described above except that the Doppler technique should be used rather than conventional sphygmomanometry, and the precautions recommended by de Swiet *et al.* [32] should be followed.

Older children (5–15 years)
Numbers. Thirty subjects.
Sex. Distribution by chance.
Age range. Evenly distributed between 5 and 15 years.
Blood pressure range [33]

Systolic:
5/30 > mean + 1 SD for population.
5/30 < mean − 1 SD for population.

Diastolic:
5/30 > mean + 1 SD for population.
5/30 < mean − 1 SD for population.

Arm circumference
5/30 > 70th centile for weight.
5/30 < 30th centile for weight.

Validation procedure. This should be as described above, using conventional mercury sphygmomanometry against which to compare the test device.

Other groups
Other groups to whom consideration of special validation may have to be given are athletes and patients with hypotension and arrhythmias. Separate validations may need to be performed if the device under consideration claims to be suitable for these groups. The procedure used should be adapted from one of the above special group validations.

II: Device validation in special circumstances
Validation during exercise
The first protocol did not provide for validation during exercise, and the revision provides a test for validation during exercise. This is an optional phase which is applicable only to devices that are manufactured for use during exertion. It is performed only after the device has achieved A or B grading on comparison with a standard mercury sphygmomanometer according to Part I of the BHS protocol, and it is necessary to perform the validation test in only 30 subjects.

The measurement of blood pressure during exercise poses problems of accuracy with all currently available non-invasive electronic monitors [34,35]. It is likely, however, that manufacturers will produce devices designed specifically for this purpose, and there will then be a need to address validation during exercise. Errors of measurement are particularly great when measuring diastolic blood pressure during exercise, and this cannot be assessed reliably without intra-arterial measurement.

The physiological and clinical importance of exercise-induced changes in blood pressure are related solely to systolic blood pressure, there being little change or only a slight fall in diastolic blood pressure during dynamic exercise. The validation is therefore concerned only with measurement of systolic blood pressure, comparing the test device with a standard mercury sphygmomanometer which is reasonably accurate for systolic blood pressure during exercise [34,35]. Moreover, measuring only systolic blood pressure should permit the use of simultaneous comparison for many devices, as the changes in pressure during exercise make this comparison preferable to the sequential technique recommended elsewhere in the protocol.

Testing should be carried out in a similar manner to that outlined above for static validation. Subjects exercise according to a modified Bruce protocol [36], with subjects exercising at level 2 (mild exercise) and level 5 (peak exercise) for approximately 6 min each (or

until blood pressure measurements are completed). Only systolic blood pressure should be recorded simultaneously with the test device and a mercury sphygmomanometer three times at each exercise level in 30 subjects.

Numbers. Thirty subjects.
Sex. Distribution by chance.
Age range. Distribution by chance.
Blood pressure range. Systolic blood pressure only: at least 5/30 > 160 mmHg.
Arm circumference. Distribution by chance.

Exercise testing
(1) Modified Bruce protocol.
(2) Level 2 for 5–6 min (or until blood pressure measurements complete).
(3) Level 5 for 5–6 min (or until blood pressure measurements complete).
(4) Simultaneous same-arm, if feasible; if not, use sequential analysis as in Part I.
(5) Arm to be supported at heart level.

Analysis
Data should be tabulated and plotted as in Part I of the protocol. The report should include a statement indicating whether the instruction manual recommends that the subject remain static while blood pressure is being measured.

Static device validation according to posture
Numbers. Thirty subjects.
Sex. Distribution by chance.
Age range. Distribution by chance.
Blood pressure range. Systolic blood pressure of at least 5/30 < 110 mmHg, 5/30 > 180 mmHg.
Arm circumference. Distribution by chance.

The validation is similar to the validation test in Part I, in that it is based on sequential same-arm measurements between the test device and a standard mercury sphygmomanometer, but it has been modified to permit accuracy assessment for supine, sitting and standing postures.

BP*A* Entry blood pressure, observers 1 and 2 each with mercury standard.
This blood pressure determines the blood pressure range to which the subject will be allocated in subsequent analysis; it is not included in the analysis of this phase.
BP*B* Device detection blood pressure, observer 3.
This blood pressure is determined to permit the device to determine the blood pressure characteristics of the subject; it is not included in the analysis.
(a) Subject seated with arm supported on table.

BP*1(a)* Observers 1 and 2 with mercury standard.
BP*2(a)* Observer 3 with test instrument.
BP*3(a)* Observers 1 and 2 with mercury standard.
BP*4(a)* Observer 3 with test instrument.
BP*5(a)* Observers 1 and 2 with mercury standard.
BP*6(a)* Observer 3 with test instrument.
BP*7(a)* Observers 1 and 2 with mercury standard.

(b) Subject standing with arm by side unsupported.
Repeat the above sequence.
(c) Subject lying supine with arm by side on couch.
Repeat the above sequence.

Analysis is performed separately for each posture (a), (b) and (c), followed by comparative analysis of the three pairings.

Discussion

This revision of the BHS protocol acknowledges the increasing market for blood pressure measuring systems in general and, whereas the original protocol was devoted primarily to the validation of 24-h recording systems, the revised protocol is applicable to all instruments measuring blood pressure.

The revised protocol makes provision for validation in special groups such as in the elderly, in pregnancy and in children. Although the protocol provides an assessment of performance during 24-h use, it needs to be emphasized that blood pressure measurements are usually made with the subject at rest, and a device that meets the criteria of the first part of the protocol cannot be assumed to be accurate during physiological manoeuvres, such as exercise, isometric handgrip and Valsalva manoeuvre. The protocol acknowledges the influence that exercise may have on 24-h blood pressure measurement [22,23,34,35], and therefore recommends special procedures for validation during exercise and in different postures [37,38]. These special validations occupy the second part of the protocol and are not undertaken unless a device has been through the main validation procedures in Part I, in which it must achieve grade A or B for accuracy for both systolic and diastolic blood pressure. However, we would emphasize that there are currently few data on which to base the recommendations for validation in these special categories and that the procedures proposed are based on what now seems reasonable. Hence, no pass–fail assessment is proposed, but it is hoped that with experience using the protocol in these circumstances it will soon be possible to produce validation procedures that are more definitive.

The role of intra-arterial blood pressure measurement in the evaluation of blood pressure measuring instruments, especially of 24-h recording systems, has been carefully considered, but again we have decided that such testing has no place as a recommendation in this protocol, although we acknowledge that valu-

able information may continue to be provided by those few centres with long experience and expertise in this area. We caution against direct intra-arterial comparison for device validation, mainly because the values obtained by the direct technique are different from those obtained by indirect methods [21], because clinical practice derives from data obtained by the indirect rather than the direct technique, and because of ethical considerations [10].

A further important modification is that analysis of the validation data makes provision for the influence of different blood pressure levels on device accuracy. Analysis across the pressure range, as recommended in the original protocol, may mask the influence of increasing pressure on device accuracy [30,31]. Again, it should be emphasized that experience of this form of analysis is limited, so this extension of the protocol must be seen as exploratory rather than definitive and the overall grade achieved by the device should be taken as the best indication of accuracy. However, consideration of the effect of blood pressure levels on device accuracy emphasizes the importance of taking into account the accuracy of the system at the blood pressure levels likely to be encountered in the subjects on whom the device is being used.

The final grading for a device must specify the grading achieved for both systolic and diastolic blood pressure in the overall blood pressure range for the better of the two observers. This grading determines the overall accuracy of the device, and only those devices that achieve grade A or B for both systolic and diastolic pressure are recommended for clinical use.

The BHS validation procedure is necessarily lengthy, and requires considerable involvement of trained personnel and careful supervision. The expense involved is also substantial. It is recommended that the validation procedure should be conducted under strict conditions by trained personnel. We have estimated that to perform validation of one automated blood pressure measuring system according to the BHS protocol requires the time of a research supervisor for 97 h, two trained observers for 93 h, an expert observer (doctor) for 8 h, a computer operator for 23 h and consultant supervision for 44 h. To this must be added the cost of out-of-pocket payments to about 150 subjects required for the procedure, and payment towards overheads. The cost of providing the necessary labour and expertise will vary according to salary scales and institutional charges; we estimate the cost of performing a full validation to be about sterling £25 000 and manufacturers will have to make provision in their production costs for independent validation [39]. It is to be hoped, however, that with developing technology such as bionic arms, which will reduce the dependence on hypertensive subjects for validation, and the manufacture of a reliable automated device to reduce the dependence on observer measured blood pressure, it will be possible to simplify the procedure of validation further.

The adoption of standards by manufacturers of blood pressure measuring devices may not be easily effected. Manufacturers are currently not obliged to guarantee the accuracy of their product, although most reputable manufacturers welcome the opportunity of having their devices evaluated independently according to a generally accepted protocol. The European Community has established a working party (CEN/TC 205/WG 10: Non-invasive sphygmomanometers) to draw up a standard for all blood pressure measuring devices, and a directive will be issued in 1994 which will be legally binding on all member states (O'Brien E, personal communication, 1993). The AAMI has recently revised its national standard for automated and electronic devices, and a summary report has been published [40].

Manufacturers of blood pressure systems must be encouraged to have their product evaluated independently by an approved evaluation procedure. This process, which necessarily takes time, has been influenced beneficially by editors of general medical, clinical pharmacology and hypertension journals demanding the evidence supporting the accuracy of automated blood pressure systems used in research studies. Health authorities and sponsoring organizations should not continue to purchase equipment which has not been adequately evaluated. In one instance the large multicentre European Study on Isolated Systolic Hypertension in the Elderly (Syst-Eur Study) has made it conditional in its protocol that automated systems cannot be used in the study unless independently evaluated by an accepted protocol [41].

Acknowledgement

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Appendix A: Observer training and assessment

Observer training

Two trained observers are required for the evaluation of a device. Observer training consists of two phases.

Film training

The observers, each of whom should understand blood pressure measurement, e.g. trained nurses, are retrained in blood pressure measurement using a video film, such as the British Hypertension Society video film 'Blood Pressure Measurement' [42]. The first part demonstrates the technique of blood pressure measurement, and the second part consists of an assessment period in which the 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 this assessment. The video film lasts 30 min.

Expert training

In this phase of training, an expert in blood pressure measurement takes the trainee observers through the different stages of blood pressure measurement as recommended by the BHS [26]. Difficult aspects of interpretation, such as the auscultatory gap and bias, should be discussed and illustrated by example using a multi-aural stethoscope. It is recommended that observers have audiograms to detect any hearing deficit.

Observer assessment

Two (or more) observers are tested for accuracy against each other and an expert observer in the following manner (Fig. A1); an expert observer should have extensive experience in blood pressure measurement and should have correctly interpreted 95% of a test sequence, such as that in the BHS video [42], before each training assessment [43].

(1) 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 from gaining sight of a neighbouring observer's reading. It is therefore necessary to separate observers by a series of partitions.

(2) 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.

(3) Behind a partition five subjects with a range of blood pressure from about 110/60 to 190/110 mmHg are seated. 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 at 2 mmHg/s.

(4) As the inflatable bladder is connected to each of the columns of mercury in the observer booths, all 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.

(5) 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.

(1) Forty-five systolic and diastolic differences between each trainee and between trainees and expert to differ by not more than 5 mmHg and 48 by not more than 10 mmHg.

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

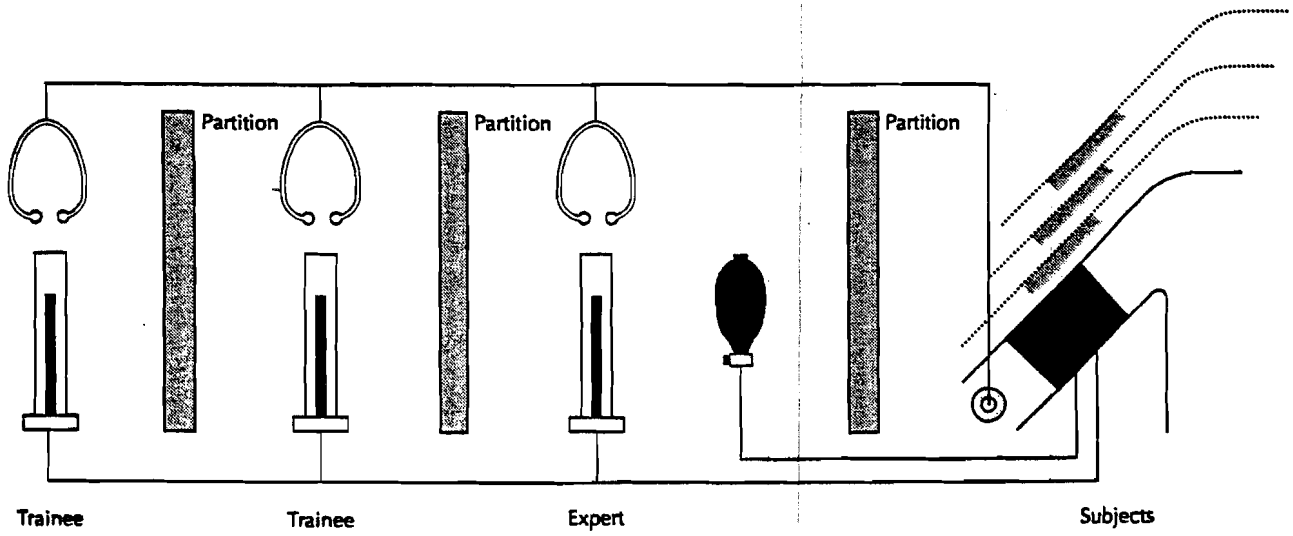

Fig. A1. Procedure for testing observer agreement in two trainees.

Appendix B: Statistical considerations

Introduction

Different observers or devices never agree exactly, in the sense of giving the same blood pressure for all subjects. The comparison of two sets of blood pressure readings thus takes the form of assessing the amount of disagreement. Methods of comparison are described and illustrated in this Appendix. However, statistical methods cannot indicate what is or is not acceptable agreement for an individual subject or a group of subjects; that decision must be based on clinical considerations.

Whether we compare two observers or two devices, the philosophy of the recommended approach is to consider the distribution of the differences between the blood pressure obtained for each subject. If more than two sets of measurements are available, the same approach is used to compare each pair. Graphs are particularly useful. There is no place in this analysis for the calculation of correlation coefficients or hypothesis tests [29].

Initial analysis

In the presentation of evaluation data it is common practice to begin by producing a scatter plot of the two sets of blood pressure data (observer and test device). The data used in the plots should be those for the better observer, although data for both observers should be presented as in Table 4.

A conventional scatter plot of devices versus observer can be a useful first step, but it is inefficient as all information is usually clustered near the line of equality. We have therefore used a better way of assessing the discrepancies by plotting the differences between the measurements by the observer and the device against their average, as in Figs 5 and 6. This plot shows the differences in blood pressure explicitly, and indicates whether the distribution of the differences varies according to the blood pressure level. We use the average blood pressure here, as this is the best estimate of the true blood pressure for that patient at that time. This method of plotting, which can can be extended to give more information (see below), is recommended in preference to the conventional scatter plot. When plotting the data it is desirable to avoid data points being superimposed on each other by using small dots to represent single data points and large dots to represent superimposition of data points, the area of the dot representing the number of superimposed points, as has been done in Figs 5 and 6. Alternatively, computer programs may provide a facility for random 'jittering', whereby a small random amount is added to the plotting coordinates of each point, or different symbols may be used to indicate the number of superimposed points.

Quantification of agreement

The assessment of agreement is based on both the average of the difference between the methods of measurement and the variability in the differences. The average agreement between the two sets of blood pressure measurements is the mean of the differences from each subject (and is equal to the difference between the overall means). There are three approaches to the assessment of the variability component of agreement.

(1) The proportion of differences greater than some reference value (such as 10 mmHg) can be calculated. The reference values can be indicated on the scatter diagram as in Figs 5 and 6.
(2) The values outside which a certain proportion (say 10%) of the observations fell can be calculated. This is done simply by ordering the data and taking the range of values remaining after a percentage (say 5%) of the sample is removed from each end. These values can also be superimposed on the scatter diagram.
(3) The SD of the intrasubject differences can be calculated. Assuming that the differences will be normally distributed, which is usually reasonable for blood pressure data, the range of values expected to encompass most intrasubject differences can be calculated. For example, 90% of differences can be expected to lie between the mean − 1.645 SD and the mean + 1.645 SD. These two values are called the 90% limits of agreement [29]. They can also be indicated on the scatter diagram. It is recommended that the AAMI criteria of a mean difference of no more than 5 mmHg and standard deviation of no more than 8 mmHg between the standard and test device should also be applied.

Methods 1 and 2 do not require any assumptions concerning the distribution of the differences, but they are generally less reliable than those obtained using normal distribution theory, especially in small samples. However, if there are one or more outliers (extreme discrepancies between observers or methods), a non-parametric approach may be preferable. In this protocol we have chosen to use the percentage of differences within certain limits (method 1), a simple approach that can be used for all phases of the evaluation. For the device validation phase (phase IV) three of these assessments are made, relating to the percentage of differences within 5, 10 and 15 mmHg.

The device is then graded according to these results using the criteria in Table 3.

Criteria for grading devices

The criteria for agreement between the device and an observer are based on what might be expected for blood pressures if measurement errors follow a normal distribution. The SD of differences between two trained observers using manual sphygmomanometers can be as low as 6 mmHg for sequential measurements. For grade A we estimated the proportion of differences that would lie within 5, 10 and 15 mmHg with this SD, assuming a normal distribution. These percentages were then rounded for convenience, and to allow for occasional aberrant readings we lowered the percentages required within 10 and 15 mmHg. Grades B and C correspond to SD of 8 and 10 mmHg, respectively. The resultant criteria are shown in Table 3.

Accuracy related to blood pressure level

We also need to consider whether the degree of agreement is the same across the range of pressure. Inspection of the plots of difference against the mean will provide the first indication of whether device accuracy is being influenced by pressure level.

There is some evidence that ambulatory systems may be less accurate at higher pressure levels, and this may not become apparent if data analysis is confined to the overall pressure range [30,31]. It is therefore recommended to analyse pressure data in the ranges (Table 5): low pressure range < 130/80 mmHg, medium pressure range 130–160/80–100 mmHg and high pressure range > 160/100 mmHg. For this purpose subjects are classified by their entry blood pressures.

Sample size

The calculation of an appropriate sample size for the device validation (phase IV) is, to some extent, arbitrary. If the observed proportion of differences within 5 mmHg is 80%, then a 95% confidence interval for the proportion will be approximately ± 5% with a sample size of 85 subjects (255 observations), the size recommended in the AAMI Standard [25]. In the validation procedures for special groups and circumstances a sample size of 30 is recommended because the main validation test will have been performed previously in 85 subjects and a smaller sample may, therefore, be permissible. However, this figure may have to be modified when statistical data become available for validation in these groups.

Appendix C: Basic information

Device identification. When manufacturers incorporate modifications into externally identical or indistinguishable versions of a device, this should be indicated clearly by a specific device number and full details concerning how the device differs from earlier versions should be provided. In particular, the probable effect of all such modifications on the performance and accuracy of the device should be stated. Updated and modified devices must be subjected to full independent validation.

Costs. The cost of the recorder, the decoder, computer analysis facilities and all components should be listed. The consumables needed for device operation and their cost should be provided.

Compliance with standard(s). The standard(s) adopted by the manufacturer should be stated.

Validation studies and results. The results of validation assessments by the manufacturer or by independent laboratories, or both, should be summarized so as to provide the following details: the method of validation, the number of subjects, any special features in subject selection, e.g. pregnancy, childhood, the range of blood pressures, the heart rate range, the accuracy requirements and the statistical analysis employed. The full references for all published validation studies should be listed, together with the addresses of the laboratories.

Instructions for use. These should be clearly stated in a step-by-step layout. Illustrations are helpful in this context.

Patient instruction card. A card should be provided for distribution to patients using the ambulatory recorder, which gives simple operational instructions together with instructions on what precautions to take in the event of the device malfunctioning.

Precautions for use. The operator must be alerted to any weaknesses in the system which might affect performance or patient safety. The safety precautions incorporated in the system to prevent the cuff remaining inflated must be clearly stated.

Power supply. The mains voltage and the frequency must be shown, and whether a transformer is needed or not to adapt the decoder. If the latter applies, the frequency must also be converted as the movement of certain parts may be affected with resultant inaccuracies. The most suitable batteries for the device should be listed, and those capable of being recharged should be indicated. The number of recordings obtainable for a set of batteries, or per charge, and the warning system for battery failure should be indicated.

Instructions for care and maintenance. The operator should be given clear instructions on the day-to-day

care of the equipment and the need for regular maintenance. Product warranty information should be provided. Ambulatory devices should have full warranty cover for at least 1 year after the date of purchase.

Service facilities. The location of national and international service facilities should be listed. It is regrettable that some manufacturers appoint agents who, although competent with certain ranges of medical devices, have little or no knowledge of specialized blood pressure measuring equipment. Potential purchasers should be aware of this problem, and check that the agent is competent to provide the necessary facilities. An estimate of the cost of routine servicing out of warranty together with an estimate of the costs of transporting the equipment for such servicing should be given. Maintenance contracts are available for some ambulatory systems, and details of these should be provided.

Dimensions. The dimensions of the recorder and its total weight with batteries, pump, etc., should be indicated. The means of attachment (waist-belt, shoulder-strap, bag, etc.) should also be stated.

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. A 35 × 12 cm bladder is recommended for routine use in most adults by the BHS [26].

Method(s) 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 phase 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.

Artefact editing. Some ambulatory devices have in-built systems for editing artefactual measurements. The method of doing this and the rationale should be stated explicitly. Reliable and accurate devices should require only minimal editing, and this should be performed automatically by the device. It should not be necessary for the operator to have to screen the device measurements for bizarre recordings that are likely to be artefactual. We have therefore refrained from making recommendations on artefact editing.

Facility for device recalibration. The manufacturer should state the intervals at which recalibration becomes necessary, and a simple method for checking accuracy should be provided. If recalibration is required, the manufacturer should state whether this can be done by the owner, and if so, how.

Factors affecting accuracy. Many factors may affect the accuracy of ambulatory recordings, such as arm movement, exercise, arm position, cuff or cloth friction. All such factors should be listed by the manufacturer. In patients with cardiac arrhythmias it is difficult and sometimes impossible to obtain an accurate measurement of blood pressure with a standard mercury sphygmomanometer. In such subjects the probability of obtaining an accurate ambulatory record is remote, and unless sound validation data of accuracy are available for arrhythmias it should be assumed that ambulatory devices are probably inaccurate in these patients. The manufacturer's literature should carry a statement along the following lines: 'This instrument has not been validated in patients with arrhythmias'.

Operator training requirements. Some ambulatory 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 ambulatory systems are compatible with personal computer systems. The exact requirements for linking with computer systems and their approximate cost should be stated. If the ambulatory 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, additional software or hardware requirements (including interfaces and cables if these are not supplied).

Problem list and solutions. Finally, a list of common operational problems should be listed with the means of detection and remedy.