European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults

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Introduction

Measurement of blood pressure is the commonest measurement made in clinical practice, and the interpretation of the figure resulting from that measurement has far-reaching implications for the individual in whom the technique is performed. If the measurement is erroneously low, for example, the patient may be denied the most valuable drug treatment to prevent future stroke and heart attack, whereas if, on the other hand, the measurement is erroneously high, the individual may be commenced on lifelong blood pressure lowering drugs unnecessarily. It is imperative, therefore, that the device being used to measure blood pressure is accurate and, because blood pressure is a complex haemodynamic variable, it is accepted that all blood pressure measuring devices must be validated independently in the clinical setting.

Validation of blood pressure measuring devices began in the 1980s with a series of *ad hoc* validation protocols on devices [1]. From the 1990s onwards, device validation became more structured with the publication of standards and protocols from the Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS) [2–7]. In 2002, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH), which is composed of experts in blood pressure measurement, many of whom have considerable experience in validating blood pressure measuring devices, published the *International Protocol*, which simplified previous protocols and

was based on evidence from a large number of validation studies [8]. The International Protocol was drafted in such a way as to be applicable to the majority of blood pressure measuring devices on the market. The validation procedure was therefore confined to adults over the age of 30 years (who 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 during exercise, or for abnormal pathophysiological circumstances, such as atrial fibrillation, or arterial stiffness as may occur in the elderly. The protocol did not preclude investigators and manufacturers from applying the International Protocol to assessment and validation in these circumstances. For full background information on this revision, it is recommended that investigators familiarise themselves with the original protocol, which can be downloaded directly from *www.dableducational.org*.

Initially, the results of validation studies were published in peer-reviewed journals and, every few years, 'state-of-the-market' papers summarising device accuracy were published in general and specialised journals [9]. However, it became apparent that many of these publications were not accessible to many would-be purchasers of blood pressure measuring devices. To overcome this deficiency, the Working Group of the European Society of Hypertension launched the *www.dableducational.org* website in 2004. This now receives visits from over 5000 organisations in 100 countries in all continents.

Since the International Protocol was published in 2002, 78 reported studies have been analysed and this analysis is the evidence base for the changes being incorporated in the first revision of the International Protocol [1,10].

Because of the increasing ban on the use of mercury-containing sphygmomanometers, there is a need for an equivalent standard device that does not contain mercury.

The following are the basic changes to the revised protocol:

(1) Forms replace free-text results so that all data must be standardised.
(2) The age restriction is reduced from 30 to 25 years to facilitate recruitment.
(3) Phase 1 has been removed, as this is now considered redundant.
(4) As a consequence of improvements in technology, pass levels have been tightened. This is of benefit to manufacturers who strive to produce devices of the highest standard.
(5) Controls on the distribution of observer measurements are introduced to ensure that the intended recruitment ranges are reasonably maintained throughout the full procedure.
(6) Due to difficulties experienced in recruiting subjects in high ranges, the recruitment limits have been relaxed under certain conditions.

Support facilities provided by the dablEducational website to assist validation studies are outlined in Appendix B.

Devices passing the stricter criteria of this revision will be classed as having passed ESH-IP2. It will supersede the original protocol [8] for new studies from 1st July 2010 and for publications from 1st July 2011.

The sphygmocorder [11,12] option described in the previous protocol is not included because no validated model is currently available.

This protocol validation applies only to the recorded measurements and does not extend to average measurements or any other derived statistics.

Validation requirements

General requirements
Environment:

(1) The room should be at a comfortable temperature and there should be no noise or other influences that may cause disturbance, such as telephones and pagers.
(2) Ambient noise should not be at a level that could interfere with the auscultation of blood pressures.

Equipment:

(1) Two standard mercury sphygmomanometers, the components of which have been checked carefully

before the study, are used as reference standards. They should be within 1 m of the observers who should be able to follow the menisci at eye level from 40 mmHg to 180 mmHg.
(2) Bladders must be available so that, on each subject, there is one of sufficient length to encircle 80%–100% of the arm circumference [13].
(3) Good quality nonelectronic stethoscopes with well-fitting earpieces should be used.

Test device:

(1) The test device bladder should be that provided according to the manufacturer's instructions. If different cuff sizes are recommended by the manufacturer, the appropriate cuff/bladder should be used but no other part of the apparatus should be changed.
(2) If the device detects blood pressure by auscultation, the same microphone(s) must be used throughout the validation test.
(3) If the test device requires software, this should be loaded and tested.
(4) A familiarisation session, involving a number of test measurements, should be performed before starting the validation study. This should be reported.
(5) If the device allows blood pressure measurement by more than one method (e.g. oscillometry and auscultation), then separate validation studies for each measurement method must be performed.
(6) If there is an optional feature intended to assist measurement, such as a facility to mark a blood pressure, then separate validation studies must be performed with and without the facility.

Observer requirements
A supervisor and two observers are required. The following should be observed:

(1) Observers should have adequate hearing and sight.
(2) Observers should be trained and experienced in blood pressure measurement [14,15].
(3) Observer measurements must be recorded to the nearest 2 mmHg.

Subject requirements
The requirements stated in this protocol refer to a study in the general adult population. Validation studies in specific groups may necessitate modification of these requirements and all such changes or additions should be clearly laid out in *Form 1 – Device and Study Details*.

Numbers: 33 subjects.
Sex: At least 10 male and 10 female.
Age range: All subjects should be at least 25 years of age
Heart rhythm: Sinus rhythm unless the device is being validated for arrhythmias.

Blood pressure range: 10 to 12 subjects in each of the three SBP and three DBP recruitment ranges as shown in *Form 3 – Study Results*.

Blood pressure requirements
(1) Recruitment pressures are intended to ensure a uniform distribution of test pressures across a representative range.
(2) The number of observer test measurements in each pressure range must be between 22 and 44.
(3) The difference between the range with the highest count and that with the lowest count cannot exceed 19.
(4) The overall SBP range must be from ≤ 100 to ≥ 170 mmHg and the overall DBP range must be from ≤ 50 to ≥ 120 mmHg.
(5) Ideally recruitment blood pressures should be in the range 90–180 mmHg for SBP and 40–130 mmHg for DBP. However, if patients with blood pressures outside these ranges are available they may be included but only to a maximum of four such pressures.
(6) The number of subjects in each recruitment range must be from 10 to 12 subjects. All SBP pressures below 130 mmHg and DBP pressures below 80 mmHg are counted as 'Low Range'. All SBP pressures above 160 mmHg and DBP pressures above 100 mmHg are counted as 'High Range'.

Accuracy requirements
The protocol classifies observer-device differences as in *Form 3 – Study Results*. When comparing and categorising these differences, they are categorised into one of four bands according to their rounded absolute values.

Accuracy is determined by the number differences in these ranges both for individual measurements (Part 1) and for individual subjects (Part 2). To pass, a device must achieve all the minimum Pass Requirements shown.

Accuracy is contingent on strict adherence to the protocol, and results from validations not adhering to this protocol may be called into question.

Validation procedure, analysis and report
The validation procedure and report should be carried out according to Forms 1–4. These are designed to produce a standard comprehensive and focussed report.

Form 1 – Device and Study Details should be filled at the outset.

A copy of *Form 2 – Subject Data* is filled for each subject screened. Subject measurements recorded by the observers and, when possible, a test device printout of data recorded for a subject should be attached to each relevant form. Data from these forms should be entered into a computer for appropriate analysis.

The results of the analysis are entered into *Form 3 – Study Results*.

Form 4 – Study Report describes the report layout which includes all the elements from *Form 1 – Device and Study Details* and *Form 3 – Study Results*.

It is imperative that all data are completed so that the report contains all of the information required.

Forms 2 and 3 include numbered clear and shaded boxes. The clear boxes indicate directly recorded data; the shaded ones refer to calculations.

The agreement between the investigator and sponsor should state that a full report of the validation study will be published irrespective of the result.

A photograph of the validated device and cuff against a white background should be provided.

Form 1 – Device and study details

Test device details

Brand Owner _____ Brand _____ Model _____

Internal Model Number_____ Manufacturer _____ Original Equipment Manufacturer (OEM) ☐

Circle the correct option on each of the following or, if required, complete the explanation beside '*Other*'.

Location	*Upper arm*	*Wrist*	*Finger*	*Other* _____
Method	*Oscillometry*	*Auscultation*	*Doppler*	*Other* _____
Purpose	*Clinic measurement*	*Self/Home measurement*	*ABPM*	*Other* _____
Operation	*Automatic*	*Semi-automatic*	*Manual*	*Other* _____

Automatic: Cuff inflation, deflation and blood pressure determination are fully performed by the device automatically;
Semi-automatic: Blood pressure determination is performed automatically but cuff inflation and/or deflation needs manual operation;
Manual: Blood pressure determination is performed by manually irrespective of inflation and deflation control.

Cuff details including arm circumference ranges (as recommended by the device manufacturer).

Arm cuffs *Small adult:* _____ cm to _____ cm   *Standard adult:* _____ cm to _____ cm

Large adult: _____ cm to _____ cm   *Other:* _____ cm to _____ cm

Wrist cuff _____cm to _____cm   Wrist Support Method _____

Other features of the device:

_____

_____

_____

Study details

Population *General* *Elderly* *Children* *Adolescent* *Pregnancy* *Obese*

Other/Further details _____

Method *Two observers with an independent supervisor* ☐

Observers blinded from each other's readings and from the device readings ☐

Enter protocol adjustments, as necessary, when the study population is not general with sex, age, blood pressure distribution and all other population defining details stated carefully. These adjustments should be justified, with references where possible. Because children and adolescents have a wide range of body size and blood pressure levels, the sample size for a validation study should depend on the study inclusion criteria. Thus, for example, a 33-subject study would be appropriate only if a narrow age range of children is included. Larger samples should be analysed proportionally to the 33-subject sample.

_____

_____

_____

_____

_____

Form 2 – Subject data

This form is to be filled by the validation supervisor for each subject. Items in clear boxes are assessed directly. Items in shaded boxes are calculated. All blood pressure measurements are recorded in mmHg and are carried out sequentially on one arm, whichever is more comfortable for the subject. Including any time required to change cuffs, At least 30 seconds should be allowed between each measurement to avoid venous congestion, but not more than 60 seconds or variability may be increased.

Prerequisites

☞ On a separate sheet, keep a running total of the number of subjects recruited in the Low (LL and L), Medium (M), and High (H and HH) ranges for SBP (Box 219) and DBP (Box 220).

☞ If any of the following occur during the study, circle the appropriate item in Box 287 and exclude the subject.
  - Circle <u>Arrhythmias</u> if the subject is not in sinus rhythm throughout the study.
  - Circle <u>Device failure</u> if the device fails to record a measurement after three successive attempts.
  - Circle <u>Poor quality sounds</u> if the Korotkov sounds are difficult to auscultate, regardless of the reason.
  - Circle <u>Observers disagreement</u> if the observers differ by more than 4 mmHg twice in the same subject.
  - Circle <u>Other</u> if the subject does not complete the study for any reason other than those listed and record the reason in Box 288.

☞ Starting with the observers, measurements are recorded sequentially alternating between observers and the device in the order BPA, BPB, BP1, BP2, BP3, BP4, BP5, BP6 and BP7.

☞ Observer measurements should be recorded simultaneously by the observers on separate sheets. They must be checked immediately and, if they differ by more than 4 mmHg, they should be taken again. Only enter final measurements on this sheet. Observers must be blinded from each other's measurements and from the device measurements throughout the study.

☞ If possible, a permanent record of device measurements should be kept. If software is provided, device measurements should be downloaded daily.

Recruitment details

Date and time		201	Study number and Subject number	202 | 203
Date of birth		204	Age	205
Sex	*Male Female*	206	On antihypertensive medication	*Yes No* 207
Arm circumference *cm*		208	Cuff for test device	*Standard Other* / *Small Large* 209
Wrist circumference *cm*		210		

Box 209: This is only required for arm devices. If the arm circumference is such that no suitable cuff is available, circle *Cuff size unavailable* in Box 287 and exclude the subject.

Box 210: This is only required for wrist devices.

Entry measurements

Ask the subject to relax for 10–15 min. Then make sure that the subject is seated with legs uncrossed and back supported. Ensure that the arm is supported at heart level. If a wrist device is being tested, the wrist must be supported according to the manufacturer's instructions. If the subject is not seated as described, the posture used must be recorded as a protocol adjustment.

	Observer 1		Observer 2			Device	
	SBP	DBP	SBP	DBP		SBP	DBP
BPA	211	212	213	214	BPB	215	216

	Observer Mean		Category		Count		
	SBP	DBP	SBP	DBP		SBP	DBP
BPA	217	218	*LL L M H HH* 219	*LL L M H HH* 220		221	222

Boxes 217, 218: Enter the rounded up averages of Boxes 211 and 213 and of Boxes 212 and 214 respectively.

Box 219: Circle the range according to the BP in Box 217. LL: < 90, L: 90–129, M: 130–160, H: 161–180, HH: >180.

Box 220: Circle the range according to the BP in Box 218. LL: < 40, L: 40–79, M: 80–100, H: 101–130, HH: >130.

Boxes 221, 222: Update the running totals, for the ranges (counting LL and L together and counting HH and H together) in Boxes 219 and 220, and enter them respectively.

☞ If both Box 221 and Box 222 are greater than 12 or if an *LL* or *HH* is circled and there are already 4 such items circled, circle *Ranges complete* in Box 287 and exclude the subject.

☞ If one of Box 221 or Box 222 is greater than 12 but the other is not, it may be necessary to include this subject, and remove another, in order to achieve the correct range distribution; in the removed subject, circle *Range adjustment* in Box 287.

Validation measurements

	BP1 SBP	BP1 DBP	BP3 SBP	BP3 DBP	BP5 SBP	BP5 DBP	BP7 SBP	BP7 DBP
Observer 1	223	224	225	226	227	228	229	230
Observer 2	231	232	233	234	235	236	237	238
Observer mean	239	240	241	242	243	244	245	246
Observer difference	247	248	249	250	251	252	253	254

	BP2 SBP	BP2 DBP	BP4 SBP	BP4 DBP	BP6 SBP	BP6 DBP
Device	255	256	257	258	259	260
Device–Previous observer	261	262	263	264	265	266
Device–Next observer	267	268	269	270	271	272
Error group	A B C D 273	A B C D 274	A B C D 275	A B C D 276	A B C D 277	A B C D 278
Observer value	281	282	283	284	285	286

Difference
A   0–5 mmHg
B   6–10 mmHg
C   11–15 mmHg
D   > 15 mmHg

Within 5 mmHg

SBP	DBP
279	280

Boxes 239–246: Enter the rounded up averages of Boxes 223 and 231, of Boxes 224 and 232, of Boxes 225 and 233, of Boxes 226 and 234, of Boxes 227 and 235, of Boxes 228 and 236, of Boxes 229 and 237 and of Boxes 230 and 238 respectively.

Boxes 247–254: Enter the differences Box 223–Box 231, Box 224–Box 232, Box 225–Box 233, Box 226–Box 234, Box 227–Box 235, Box 228–Box 236, Box 229–Box 237, and Box 230–Box 238 respectively.

Boxes 261–266: Enter the 'Device–Previous Observer Mean' differences. These are Box 255–Box 239, Box 256–Box 240, Box 257–Box 241, Box 258–Box 242, Box 259–Box 243, and Box 260–Box 244 respectively.

Boxes 267–272: Enter the 'Device–Next Observer Mean' differences. These are Box 255–Box 241, Box 256–Box 242, Box 257–Box 243, Box 258–Box 244, Box 259–Box 245, and Box 260–Box 246 respectively.

☞ Each device measurement is compared to the nearer of the previous and next observer measurement. As described below, the smaller error is circled and the corresponding observer measurement is copied to aid the analysis.

Box 273:   First, circle the smaller value, in absolute terms, of Boxes 261 and 267 (Box 261 if both are the same). Then circle A if this is less than or equal to 5, B if this is 6–10, C if this is 11–15 or D if this is greater than 15.

Boxes 274–278: Circle A, B, C or D, as described for Box 273, based on the smallest absolute values (also circled) of Boxes 262 and 268, Boxes 263 and 269, Boxes 264 and 270, Boxes 265 and 271and Boxes 266 and 272 respectively.

Box 279:   Enter the number of 'A's circled in Boxes 273, 275 and 277.

Box 280:   Enter the number of 'A's circled in Boxes 274, 276 and 278.

☞ The numbers of 'A's, 'B's and 'C's will be used in the analysis to calculate the number of device-observer differences within 5 mmHg, 10 mmHg and 15 mmHg.

Box 281:   Enter the value in Box 239 if Box 261 is circled or Box 241 if Box 267 is circled.

Box 282:   Enter the value in Box 240 if Box 262 is circled or Box 242 if Box 268 is circled.

Box 283:   Enter the value in Box 241 if Box 263 is circled or Box 243 if Box 269 is circled.

Box 284:   Enter the value in Box 242 if Box 264 is circled or Box 244 if Box 270 is circled.

Box 285:   Enter the value in Box 243 if Box 265 is circled or Box 245 if Box 271 is circled.

Box 286:   Enter the value in Box 244 if Box 266 is circled or Box 246 if Box 272 is circled.

Signoff

Please use the comments to explain unlisted subject exclusion or any problems during the procedure

Excluded	*Ranges complete* *Poor quality sounds*	*Range adjustment* *Cuff size unavailable*	*Arrhythmias* *Observer disagreement*	*Device failure* *Distribution*	*Other*	287

Comments	288

Supervisor signature	289

☞ Note: Subjects initially included may be excluded due to changes in pressure. See *observer measurements in each recruitment range* in *Form 3 − Study Results.*

If a printout of test device data is possible, print the device data for this subject and attach it to this form.

Form 3 – Study results

The data from *Form 2 – Subject Data* for each subject should be appropriately analysed so that the results on this form can be completed. All references to boxes 201–289 refer to values obtained from all of the Forms 2 from the relevant subjects. All blood pressure measurements are in mmHg.

Table 1 Screening and recruitment details

Screening and recruitment

Total screened	301
Total excluded	302
Ranges complete	303
Range adjustment	304
Arrhythmias	305
Device failure	306
Poor quality sounds	307
Cuff size unavailable	308
Observer disagreement	309
Distribution	310
Other reasons*	311
Total recruited	312

Recruitment ranges

	mmHg		All	On Rx
SBP	Low	< 90	314	
		90–129	315	324
	Medium	130–160	316	325
	High	161–180	317	
		> 180	318	326
DBP	Low	< 40	319	
		40–79	320	327
	Medium	80–100	321	328
	High	101–130	322	
		> 130	323	329

*Explanation summary

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Box 301: The total number of subjects screened, regardless of whether or not they were included in the study.

Box 302: The total number excluded. This equals the sum of Boxes 303–311.

Box 303: The number of subjects excluded with *Ranges complete* circled in *Box 287* (*Form 2 for each excluded subject*).

Box 304: The number of subjects excluded with *Range adjustment* circled in *Box 287*.

Box 305: The number of subjects excluded with *Arrhythmias* circled in *Box 287*.

Box 306: The number of subjects excluded with *Device failure* circled in *Box 287*.

Box 307: The number of subjects excluded with *Poor quality sounds* circled in *Box 287*.

Box 308: The number of subjects excluded with *Cuff size availability* circled in *Box 287*.

Box 309: The number of subjects excluded with *Observer disagreement* circled in *Box 287*.

Box 310: The number of subjects excluded with *Distribution* circled in *Box 287*.

Box 311: The number of subjects excluded with *Other reasons* circled in *Box 287*. A summary of those reasons must be provided in Box 313.

Box 312: The total recruited equals the number screened (Box 301) less the number excluded (Box 302). This should equal 33 except in validations in some specific populations.

Box 313: A summary of why those counted in Box 311 were excluded (*Box 288*).

Boxes 314–323: In a completed study in a general adult population, the sum of Boxes 314 and 315, Box 316, the sum of Boxes 317 and 318, the sum of Boxes 319 and 320, Box 321 and the sum of Boxes 322 and 323 must each be between 10 and 12. The sum of Boxes 314, 318, 319 and 323 must be at most 4. The sum of Boxes 314–318 and the sum of Boxes 319–323 must each be exactly 33. Studies in specific populations may have different restrictions and totals (*Boxes 219* and *220 – Form 2 for each included subject*).

Boxes 324–329: The number of subjects in each range on antihypertensive medication (*Boxes 207, 219* and *220*).

Table 2 Subject details

Sex	Male : Female	330	
Age (years)	Range (Low : High)	331	
	Mean (SD)	332	
Arm circumference (cm)	Range (Low : High)	333	
	Mean (SD)	334	
Cuff for test device (Upper arm devices only)	Small	335	____ –____ cm
	Standard	336	____ –____ cm
	Large	337	____ –____ cm
	Other	338	____ –____ cm
Wrist circumference (cm) (Wrist devices only)	Range (Low : High)	339	
	Mean (SD)	340	

		SBP	DBP
Recruitment BP (mmHg)	Range (Low : High)	341	342
	Mean (SD)	343	344

Note: The values in Boxes 314–380 refer only to the final recruited subjects, each of whom contributes SBP and DBP measurements for analysis. Excluded subjects are not included in any of this analysis.

Box 330: Enter the number of males, a colon and the number of females. They should total 33 except in validations in some specific populations. If the minimum requirements (10 for a general population) are not met, subjects must be replaced as necessary (*Box 206*).

Box 331: Enter the age of the youngest subject, a colon and the age of the oldest subject e.g. *31:74*. Subjects outside the required range (25 and over for a general population) are not permitted (*Box 205*).

Box 332: Enter the mean and, in parentheses, the SD of the subject ages. Values should be rounded up to one decimal place e.g. *52.3 (11.9)* (*Box 205*).

Box 333: Enter the smallest arm circumference, a colon and the largest arm circumference e.g. *24:34* (*Box 208*).

Box 334: Enter the mean and, in parentheses, the SD of the subject arm circumferences. Values should be rounded up to one decimal place e.g. *29.0 (3.1)* (*Box 208*).

Box 335: If a small cuff was supplied, enter the number of subjects on whom it was used. If it was not supplied, enter an 'X'. Enter the arm sizes for which it is recommended beside it. (Applicable only for arm devices) (*Box 209*).

Box 336: Enter the number of subjects on whom a standard (or medium) cuff was used. Enter the arm sizes for which it is recommended beside it. (Applicable only for arm devices) (*Box 209*).

Box 337: If a large cuff was supplied, enter the number of subjects on whom it was used. If it was not supplied, enter an 'X'. Enter the arm sizes for which it is recommended beside it. (Applicable only for arm devices) (*Box 209*).

Box 338: If a different size cuff was supplied, enter the number of subjects in whom it was used. If no such cuff was supplied, enter an 'X'. Enter the arm sizes for which it is recommended beside it. (Applicable only for arm devices) (*Box 209*).

Box 339: Enter the smallest wrist circumference, a colon and the largest wrist circumference e.g. *15:22* (Applicable only for wrist devices) (*Box 210*).

Box 340: Enter the mean and, in parentheses, the SD of the subject wrist circumferences. Values should be rounded up to one decimal place e.g.*18.1(2.3)* (Applicable only for wrist devices) (*Box 210*).

Boxes 341–342: Enter the lowest pressure, a colon and the highest pressure from BPA measurements only e.g.*104:180*. (*Boxes 217* and *218*).

Boxes 343–344: Enter the mean and, in parentheses, the SD of the subject pressures from BPA measurements only. Values should be rounded up to one decimal place e.g. *140.4 (20.3)*. (*Boxes 217* and *218*).

Table 3 Distribution

SBP		DBP	
Overall range (Low : High)	345	Overall range (Low : High)	350
Low (<130)	346	Low (<80)	351
Medium (130–160)	347	Medium (80–100)	352
High (>160)	348	High (>100)	353
Maximum difference	349	Maximum difference	354

This section analyses the distribution of comparative measurements.

Box 345: Enter the lowest pressure, a colon and the highest SBP from the observer measurements (Boxes 281, 283 and 285).

Boxes 346–348: The observer measurements (three per subject) for SBP are categorised similarly to the recruitment ranges. Enter the counts of measurements falling into each range. These must total 99 (Boxes 281, 283 and 285).

Box 349: Subtract the smallest value from Boxes 346 to 348 from the largest one and enter the result.

Box 350: Enter the lowest pressure, a colon and the highest DBP from the observer measurements (Boxes 282, 284 and 286).

Boxes 351–353: The observer measurements (three per subject) for DBP are categorised similarly to the recruitment ranges. Enter the counts of measurements falling into each range. These must total 99 (Boxes 282, 284 and 286).

Box 354: Subtract the smallest value from Boxes 351 to 353 from the largest one and enter the result.

☞ In order to ensure a uniform distribution, there must be at least 22 measurements and at most 44 measurements (Boxes 346 to 348 and 351 to 353) in each of the low, medium and high ranges and the maximum differences (Boxes 349 and 354) must be at most 19. If not, further recruitment will be necessary. Subjects to be excluded will be those whose pressures drifted from recruitment pressures.

☞ The overall SBP range must be from ≤ 100 mmHg to ≥ 170 mmHg and the overall DBP range must be from ≤ 50 mmHg to ≥ 120 mmHg. If not, further recruitment will be necessary. Subjects to be excluded will be the last recruited within the relevant ranges.

☞ The minimum number of replacements should take place. If a subject is replaced for either of these reasons, circle *Distribution* in *Box 287 of Form 2* for that subject.

☞ In validations carried out in specific populations requiring more than 33 subjects but with similar blood pressure distributions, similar proportions should be used. If the blood pressure distribution in the specific population differs from the standard distribution, ignore this table but comment on the distribution in the discussion.

Table 4 Observer differences

This section is for the differences in pressures between the two observers

		SBP	DBP		
Observer 2–Observer 1	Range (Low : High)	355	356	Repeated measurements	
	Mean (SD)	357	358		359

Boxes 355–356: Enter the lowest difference, a colon and the highest difference between the observers. Include the signs e.g. − 3 : + 4. *(Boxes 247, 249,* 251 and *253 and Boxes 248, 250, 252 and 254).* If the range is outside − 4 : + 4, then this is a violation. Relevant subjects should be excluded, by reason of Observer Disagreement, and replaced.

Boxes 357–358: Enter the mean and, in parentheses, the SD of the observer differences. Values should be rounded up to one decimal place e.g. *0.3 (1.2) (Boxes 247, 249, 251* and *253 and Boxes 248, 250, 252 and 254).*

Boxes 359: Enter the number of measurements that were repeated in the included subjects because observers were more than 4 mmHg apart.

Table 5 Validation results

Part 1		≤ 5mmHg	≤ 10mmHg	≤ 15mmHg	Grade 1	Mean	SD
Pass requirement	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	360	361	362	363	364	365
	DBP	366	367	368	369	370	371

Part 2		2/3 ≤ 5mmHg	0/3 ≤ 5mmHg	Grade 2		Grade 3
Pass requirement		≥ 24	≤ 3			
Achieved	SBP	372	373	374		375
	DBP	376	377	378		379

Part 3						Result
						380

☞ In order for the device to pass, <u>all</u> protocol requirements must be fulfilled. A fail in any part will result in an overall fail

Box 360: Enter the number of SBP differences (at most 99) between observer and device measurements falling within 5 mmHg. (The total number of *Boxes 273*, *275* and *277* circled A in the 33 subjects)

Box 361: Enter the number of SBP differences (at most 99) between observer and device measurements falling within 10 mmHg. (The total number of *Boxes 273*, *275* and *277* circled A or B in the 33 subjects)

Box 362: Enter the number of SBP differences (at most 99) between observer and device measurements falling within 15 mmHg. (The total number of *Boxes 273*, *275* and *277* circled A, B or C in the 33 subjects)

Box 363: If Boxes 360, 361 and 362 fulfil the Pass requirements, then this is 'Pass'; otherwise, it is 'Fail'.

Boxes 364–365: Enter the mean and standard deviation respectively of the 99 SBP differences between observer and device measurements. (Use data from circled *Boxes 261* or *267*, *263* or *269* and *265* or *271*)

Box 366: Enter the number of DBP differences (at most 99) between observer and device measurements falling within 5 mmHg. (The total number of *Boxes 274*, *276* and *278* circled A in the 33 subjects)

Box 367: Enter the number of DBP differences (at most 99) between observer and device measurements falling within 10 mmHg. (The total number of *Boxes 274*, *276* and *278* circled A or B in the 33 subjects)

Box 368: Enter the number of DBP differences (at most 99) between observer and device measurements falling within 15 mmHg. (The total number of *Boxes 274*, *276* and *278* circled A, B or C in the 33 subjects)

Box 369: If Boxes 366, 367 and 368 fulfil the Pass requirements, then this is 'Pass'; otherwise, it is 'Fail'.

Boxes 370–371: Enter the mean and standard deviation respectively of the 99 DBP differences between observer and device measurements. (Use data from circled *Boxes 262* or *268*, *264* or *270* and *266* or *272*)

Box 372: Enter the number of subjects (at most 33) with two or three of the absolute differences between observer and device SBP measurements within 5 mmHg. (*Box 279* is 2 or 3)

Box 373: Enter the number of subjects (at most 33) with none of the absolute differences between observer and device SBP measurements within 5 mmHg. (*Box 279* is 0)

Box 374: If Boxes 372 and 373 fulfil the Pass requirements, then this is 'Pass'; otherwise, it is 'Fail'.

Box 375: If Boxes 363 and 374 are both 'Pass', then this is 'Pass'; otherwise, it is 'Fail'.

Box 376: Enter the number of subjects (at most 33) with two or three of the absolute differences between observer and device DBP measurements within 5 mmHg. (*Box 280* is 2 or 3)

Box 377: Enter the number of subjects (at most 33) with none of the absolute differences between observer and device DBP measurements within 5 mmHg. (*Box 280* is 0)

Box 378: If Boxes 376 and 377 fulfil the Pass requirements, then this is 'Pass'; otherwise, it is 'Fail'.

Box 379: If Boxes 369 and 378 are both 'Pass', then this is 'Pass'; otherwise, it is 'Fail'.

Box 380: If Boxes 375 and 379 are both 'Pass', then this is 'Pass'; otherwise, it is 'Fail'.

☞ In validations carried out in specific populations requiring more than 33 subjects, proportionally equivalent passing criteria should be used.

Form 4 – Study report

Each device should be reported separately, even if more than one device is validated in the same study.

Title

It is important that the title conveys the nature of the validation both concisely and comprehensively.

The title should read **Validation CIRCUMSTANCE of the MANUFACTURER MODEL TYPE blood pressure monitor USE according to the European Society of Hypertension International Protocol revision 2010.**

Where MANUFACTURER is the name of the manufacturer or brand.

MODEL is the model number. If more than one number is used, the alternatives, including internal model numbers, should follow in parentheses.

TYPE describes the nature of the monitor. This is typically *upper arm*, *wrist* or *ABPM*. If it is not an automatic monitor, it should also include an appropriate adjective such as *manual*, *semi-automatic* or *hybrid*.

USE is optional but may supplement TYPE to describe the monitor's intended use. It could be general, for example upper arm monitors might be primarily intended 'for self measurement' or 'for clinic use', or specific, for example 'for clinic use in low resource settings'. Commas should be added for clarity.

CIRCUMSTANCE is required only if the study is not carried out in a general population or where the subjects are not at rest. It should state the population, group or other factor that defines the applicability of the results. Commas should be added for clarity.

Two examples are shown below and a third is shown in Appendix A.

Validation of the Gizmo ABC-01 ABPM blood pressure monitor according to the European Society of Hypertension International Protocol revision 2010.

Validation, in the elderly, of the Gizmo ABC-02 upper arm blood pressure monitor, for self measurement, according to the European Society of Hypertension International Protocol revision 2010.

Device details

This is taken from the *Device details* section of *Form 1 – Device and Study Details*. A digital photograph of the monitor used in the study should be included. Do not use a photograph, of a similar model, downloaded from the web or supplied by the manufacturers.

Methodology

This is described in two paragraphs and it contains the information in the *Study details* section of *Form 1 – Device and Study Details*.

Familiarisation

A brief description of the familiarisation session should be provided. Any difficulties should be reported.

Recruitment

The population should be outlined and the method of selecting the sample should be described. Difficulties in recruitment should be described and how they were overcome.

Procedure

Outline any adjustment to the protocol due to validation in a nongeneral population, or otherwise, and outline any other exceptional issues relating to the study. If the protocol was followed as written, this should be stated as follows: *The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely.* The check boxes the *Study Details* section of *Form 1 – Device and Study Details* should both be ticked. If so, a sentence should state this as follows: *Overseen by an independent supervisor, measurements were recorded by two observers blinded from both each other's readings and from the device readings.* If not, it is likely to constitute a serious violation and needs to be explained.

Problems encountered (apart from recruitment issues), including device faults, should be described along with their resolutions. All problems should be put in the context of the stage in the validation: This would give the total number of subjects completed at that time e.g. *the device fell onto a concrete floor after the 25th subject was completed. It was recalibrated and found not to have been damaged.*

Results

The results will comprise the tables in *Form 3 - Study Results* along with a graphical presentation. No text should be added.

Plots

These are mean-difference plots [16,17] and they should be exactly as shown in the example plot (Appendix A). The *x*-axis of these plots represents blood pressures in the systolic range 80 mmHg–190 mmHg and the diastolic

range 30 mmHg–140 mmHg. The y-axes represent errors from –30 mmHg to +30 mmHg. Horizontal reference lines are drawn at 5 mmHg intervals from +15 mmHg to –15 mmHg. 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.

Where points are superimposed, these should be indicated either by proportionately larger points or by different symbols.

Discussion

The possible effect of any problems encountered should be raised – even if this is to state that there was no effect. A brief comment should be given on the sample and, with reference to the plots, the distribution of pressures. This should include an account of how well the population is represented. If this is poor (for example, if the pressures in a blood pressure range are clustered within that range), an explanation of why a better sample could not be obtained must be provided along with justification for the applicability of the results. Where a special population is used, any adjustments not defined by the population should be justified. If Korotkov Phase IV was used, the effect of this on the accuracy of DBP should be discussed. If previously published validation studies exist for this device, their results should be briefly compared and contrasted to those of the current study.

Conclusion

The conclusion as to whether the device is accurate for use in the population should be stated. If the results are particularly sensitive to correct use (e.g. most wrist devices) then this caution must be stated.

Acknowledgements and conflicts of interest

All acknowledgements and any conflict of interest should be provided as appropriate. These include any sources of funding or provision of equipment. The manner by which the test devices were acquired should be stated.

Reference

The paper should be referenced. If there are previous validation studies on this device, they should be referenced.

References

1 O'Brien E, Atkins N. Validation and reliability of blood pressure monitors. In: White W, editor. *Blood pressure monitoring in cardiovascular medicine and therapeutics*. US: Humana Press Inc; 2007, pp. 97–132.

2 Association for the Advancement of Medical Instrumentation. *The National Standard of Electronic or Automated Sphygmomanometers*. Arlington, Virginia: AAMI; 1987.

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Appendices

Appendix A: Example of a completed validation report

Validation of the Acme A1 upper arm blood pressure monitor, for clinic use and self measurement, according to the European Society of Hypertension International Protocol revision 2010.

Device details

Brand	Acme	Model	A1
Manufacturer	Acme		
Location	Upper arm		
Method	Oscillometry		
Purpose	Clinic and self measurement		
Operation	Automatic		
Arm cuffs	Standard adult: 20 cm to 32 cm and Large adult: 33 cm to 43 cm		
Other features	Facility for averaging the last three measurements		
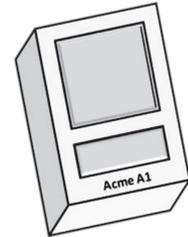
Monitor photograph

Methodology

Familiarisation

Twelve test-measurements were carried out. No problems were encountered.

Recruitment

Hypertensive subjects were recruited from those attending the hypertension clinic in the ABC Hospital. Some participated immediately and without appointment. Others attended the hospital specially. Normotensive subjects were recruited from accompanying relatives or friends and from hospital staff. There was some difficulty in recruiting subjects with DBP in the high range but, other than that, there were no problems. Patients on antihypertensive treatment attending the hospital were generally well controlled and therefore subjects in the high ranges had to be drawn mainly from new patients with some recruitment from those with renal disease.

Screening and recruitment details

Screening and recruitment			Recruitment ranges			
Total screened		51		mmHg	All	On Rx
Total excluded		18	Low	<90	0	4
Ranges complete	11			90–129	11	
Range adjustment	2		SBP Medium	130–160	11	10
Arrhythmias	1		High	161–180	10	6
Device failure	0			>180	1	
Poor quality sounds	1					
Cuff size unavailable	0		Low	<40	0	3
Observer disagreement	0			40–79	11	
Distribution	2		DBP Medium	80–100	12	9
Other reasons[a]	1		High	101–130	10	5
Total recruited		33		>130	0	

[a]Explanation summary. One subject had to leave for personal reasons before completing the sequence.

Procedure

The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely. [1] Overseen by an independent supervisor, measurements were recorded by two observers blinded from both each other's readings and from the device readings.

Results

Subject details

Sex		
Male : Female	19 : 14	
Age (years)		
Range (Low : High)	30 : 72	
Mean (SD)	53.4 (10.2)	
Arm circumference (cm)		
Range (Low : High)	22 : 37	
Mean (SD)	29.8 (2.9)	
Cuff for test device		
Standard	29	(22–32 cm)
Large	4	(33–43 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	103 : 178	44 : 123
Mean (SD)	146.3 (25.0)	90.1 (16.8)

Observer measurements in each recruitment range

SBP (mmHg)		DBP (mmHg)	
Overall range (Low : High)	103 : 196	Overall range (Low : High)	52 : 135
Low (<130)	27	Low (<80)	33
Medium (130–160)	35	Medium (80–100)	35
High (>160)	37	High (>100)	31
Maximum difference	10	Maximum difference	4

Observer differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	− 4 : + 2	− 2 : + 3	
Mean (SD)	− 1.1 (1.2)	+ 0.5 (1.1)	3

Validation results

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	59	81	92	Fail	− 0.3	8.0
DBP	65	90	97	Pass	0.5	6.4

Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade 2	Grade 3
Pass requirements	≥ 24	≤ 3		
Achieved				
SBP	25	2	Pass	Fail
DBP	25	3	Pass	Pass

Part 3				Result
				Fail

Plots
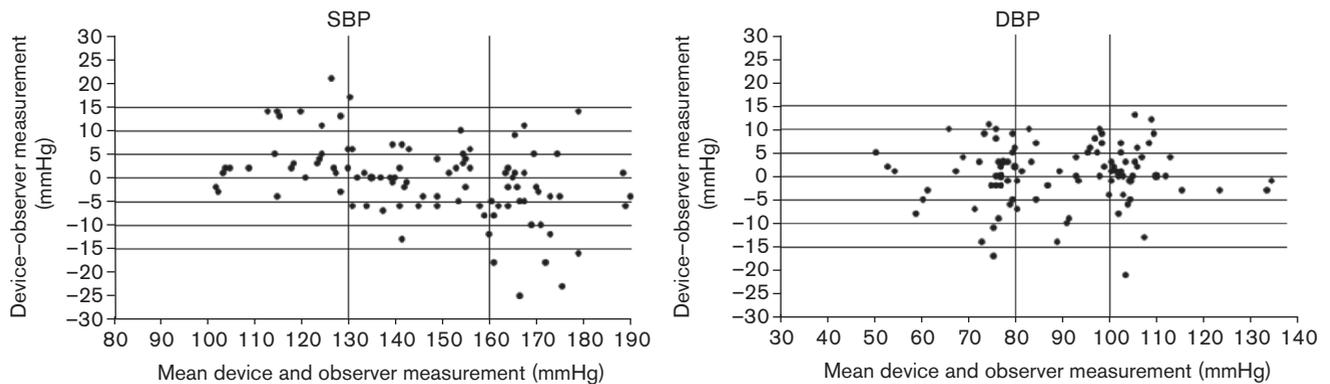
Discussion

Recruitment of subjects with high BP, in particular high DBP, proved to be extremely difficult and accounted for most of the extra screened subjects; this is reflected in the overall distribution, as shown in the DBP plot, in which most of the points are below 115 mmHg. Nevertheless, there is close to a perfect 33 points in each range and the distribution conditions are fulfilled. Therefore, this has had no effect on the result.

Conclusion

As the device has failed to reach the required standards, it is not recommended for personal or clinical use.

Acknowledgements and conflicts of interest

Two A1 monitors were supplied for the purposes of the study by the manufacturers Acme who also funded the study. None of the authors has any association with Acme or has received any personal benefit from Acme.

References

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Appendix B: Support facilities provided by the dablEducational website to assist validation studies

(1) The 2002 ESH International Protocol is available to download as a pdf file from *www.dableducational.org* [8]. This protocol outlines the history and development of validation protocol methodology.

(2) Manufacturers are referred to the device equivalence procedure on *www.dableducational.org* [18]. Manufacturers of blood pressure measuring devices may make modifications to a device, which has previously been successfully validated for accuracy, that do not affect its measurement accuracy. The modified device should not require further validation. The procedure for manufacturers to declare the equivalence of a modified device with a device that has been validated earlier is described.

(3) Manufacturers are referred to the facility for posting validation results on *www.dableducational.org*. This facility speeds up the posting of validation results on the dablEducational Trust website (without compromising later publication of a full paper).

(4) Manufacturers are referred to the facility for applying for performance accreditation for devices that is additional to the accuracy criteria of the International Protocol on *www.dableducational.org* and *www.pressionearteriosa.net* [19]. Although standard validation protocols provide assurance of the accuracy of blood pressure monitors, there is no guidance for the consumer as to the overall quality of a device. The PA.NET International Quality Certification Protocol denotes additional criteria of quality for blood pressure measuring devices. At the end of the certification process, ARSMED attributes a quality index to the device and a quality seal with four different grades (bronze, silver, gold and diamond) which may be used on the packaging of the appliance or in advertising. A quality certification is released to the manufacturer and published on www.pressionearteriosa.net and *www.dableducational.org*.

Appendix C: Membership of European Society of Hypertension working group on blood pressure monitoring

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