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

Eoin O'Brien[a], Neil Atkins[b], George Stergiou[c], Nikos Karpettas[c], Gianfranco Parati[d], Roland Asmar[e], Yutaka Imai[f], Jiguang Wang[g], Thomas Mengden[h] and Andrew Shennan[i]; on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension

Blood Pressure Monitoring 2010, **15**:23–38

Keywords: blood pressure, blood pressure measurement, device validation, European Society of Hypertension, International Protocol, protocol

[a]The Conway Institute of Biomolecular and Biomedical Research, University College Dublin, Ireland, [b]dabl Ltd., Blackrock Co., Dublin, Ireland, [c]Hypertension Center, Third University Department of Medicine, Sotiria Hospital, Athens, Greece, [d]Istituto Scientifico Ospedale San Luca, IRCCS, Instituto Auxologico Italiano, Milan, Italy, [e]Société Française d'Hypertension Artérielle, Filiale de la Société Française de Cardiolgie, Paris, France, [f]The Department of Clinical Pharmacology and Therapeutics, Tohoku University Graduate School of Pharmaceutical Science and Medicine, Sendai, Japan, [g]Centre for Epidemiological Studies and Clinical Trials, Ruijin Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, China, [h]University Clinic Bonn, Department of Internal Medicine, Bonn, Germany and [i]Guy's and St Thomas' Hospitals, London, UK

Correspondence to Professor Eoin O'Brien, Blood Pressure Unit, St. Michael's Hospital, Dún Laoghaire, Co. Dublin, Ireland
Tel: +353 1 2803865; fax: +353 1 2803688; e-mail: eobrien@iol.ie

Received 23 July 2009 **Revised** 18 August 2009
Accepted 18 August 2009

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.

1359-5237 DOI: 10.1097/MBP.0b013e3283360e98

Since the International Protocol as 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 strict criteria (Phase 1 F.9(e0.201.7(ta[(Device 29(re i)-9.2(tion)-40(ill)]TJ0 -1.1779 TD[(be)-296.9(lpass) requests protocol is now considered validated

ments and (the r)3413.3dteined sts

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, the are categorised into one of four bands according to their recommended 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

☐

Other.

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

Automatic:
Semi-automatic: /
;
Manual: .

).

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

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

_____*cm to* _____*cm*

:

Study details

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

Other/Further details _____

Two observers with an independent supervisor ☐

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

,
.
,
,
.
33-
33- .

Form 2 – Subject data

30 60

P

, ( ), ( ), ( )
P (219) P (220).

287

- *Arrhythmias*
- *Device failure*
- *Poor quality sounds* ,
- *Observers disagreement* 4
- *Other* 288.

P , P , P1, P2, P3, P4, P5, P6 P7.

4

Recruitment details

201

202 203

204

205

Male *Female* 206

Yes *No* 207

cm 208

Standard *Other* *Small* *Large* 209

cm 210

209: *Cuff size unavailable* 287

210:

Entry measurements

10 15

1 2

P P P P P P

P 211 212 213 214 215 216

P P P P P P

P 217 218 *LL L M H HH* 219 *LL L M H HH* 220 221 222

217, 218: 211 213 212 214 .

219: P 217. : < 90, : 90 129, : 130 160, : 161 180, : > 180.

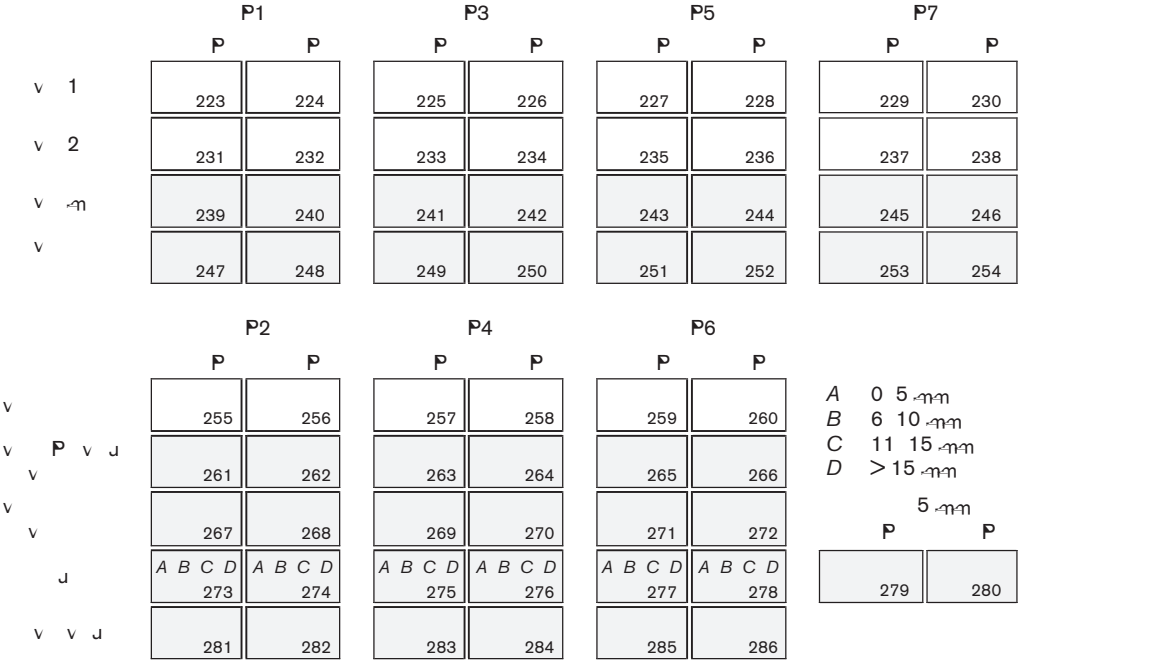
220: P 218. : < 40, : 40 79, : 80 100, : 101 130, : > 130.

221, 222: ( ) 219 220, .

221 222 12 *LL* *HH* 4 , *Ranges complete* 287 .

221 222 12 , , ; , *Range adjustment* 287.

Validation measurements



239 246: 223 231, 224 232, 225 233, 226 234, 227 235, 228 236, 229 237 230 238 .

247 254: 223 231, 224 232, 225 233, 226 234, 227 235, 228 236, 229 237, 230 238 .

261 266: 255 239, 256 240, 257 241, 258 242, 259 243, 260 244 .

267 272: 255 241, 256 242, 257 243, 258 244, 259 245, 260 246 .

273: , 261 267 (261). 5, 6 10, 11 15 15.

274 278: , , , 273, ( ) 262 268, 263 269, 264 270, 265 271 266 272 .

279: 273, 275 277.

280: 274, 276 278.

281: 239 261 241 267 .

282: 240 262 242 268 .

283: 241 263 243 269 .

284: 242 264 244 270 .

285: 243 265 245 271 .

286: 244 266 246 272 .

Signoff

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

288

289

: *observer measurements in each recruitment range*

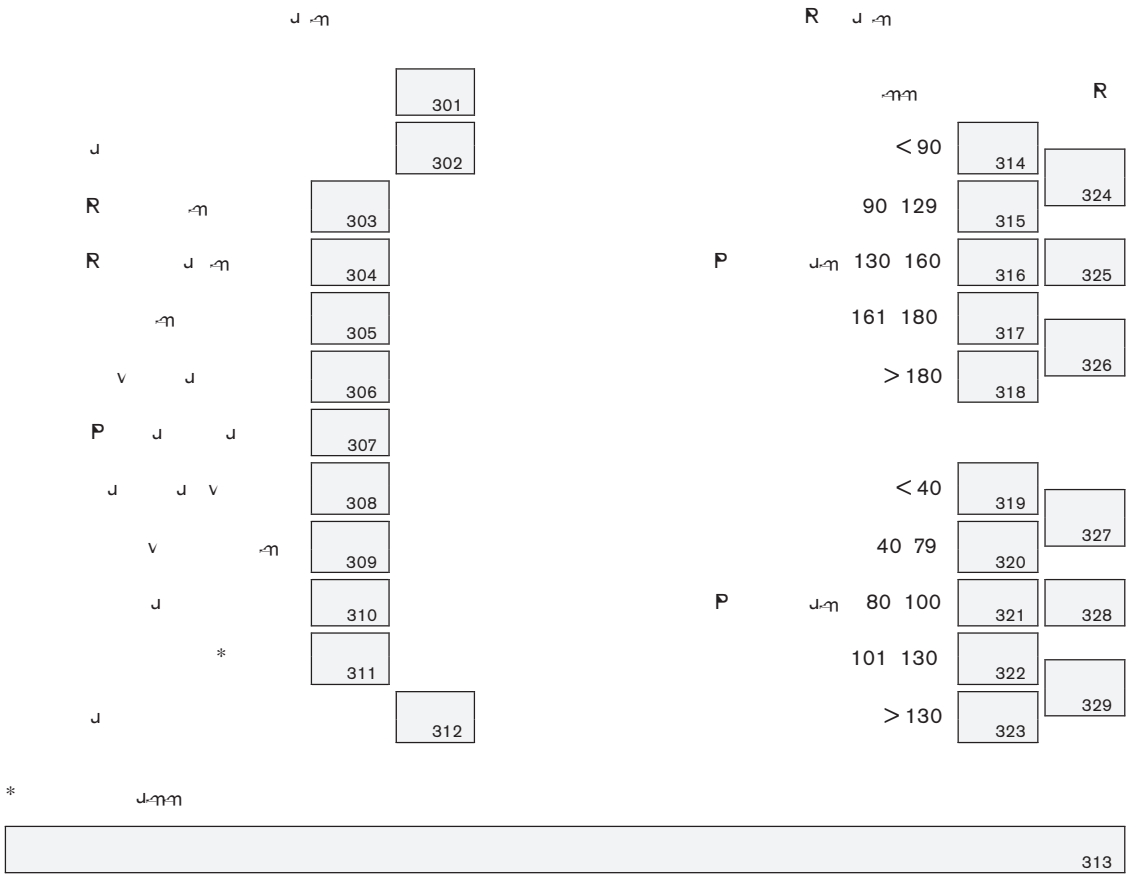
Form 3 – Study Results.

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

Form 2 – Subject Data 201 289 2 .

Table 1 Screening and recruitment details



301: , .

302: . 303 311.

303: *Ranges complete* *Box 287* (*Form 2 for each excluded subject*).

304: *Range adjustment* *Box 287*.

305: *Arrhythmias* *Box 287*.

306: *Device failure* *Box 287*.

307: *Poor quality sounds* *Box 287*.

308: *Cuff size availability* *Box 287*.

309: *Observer disagreement* *Box 287*.

310: *Distribution* *Box 287*.

311: *Other reasons* *Box 287*. 313.

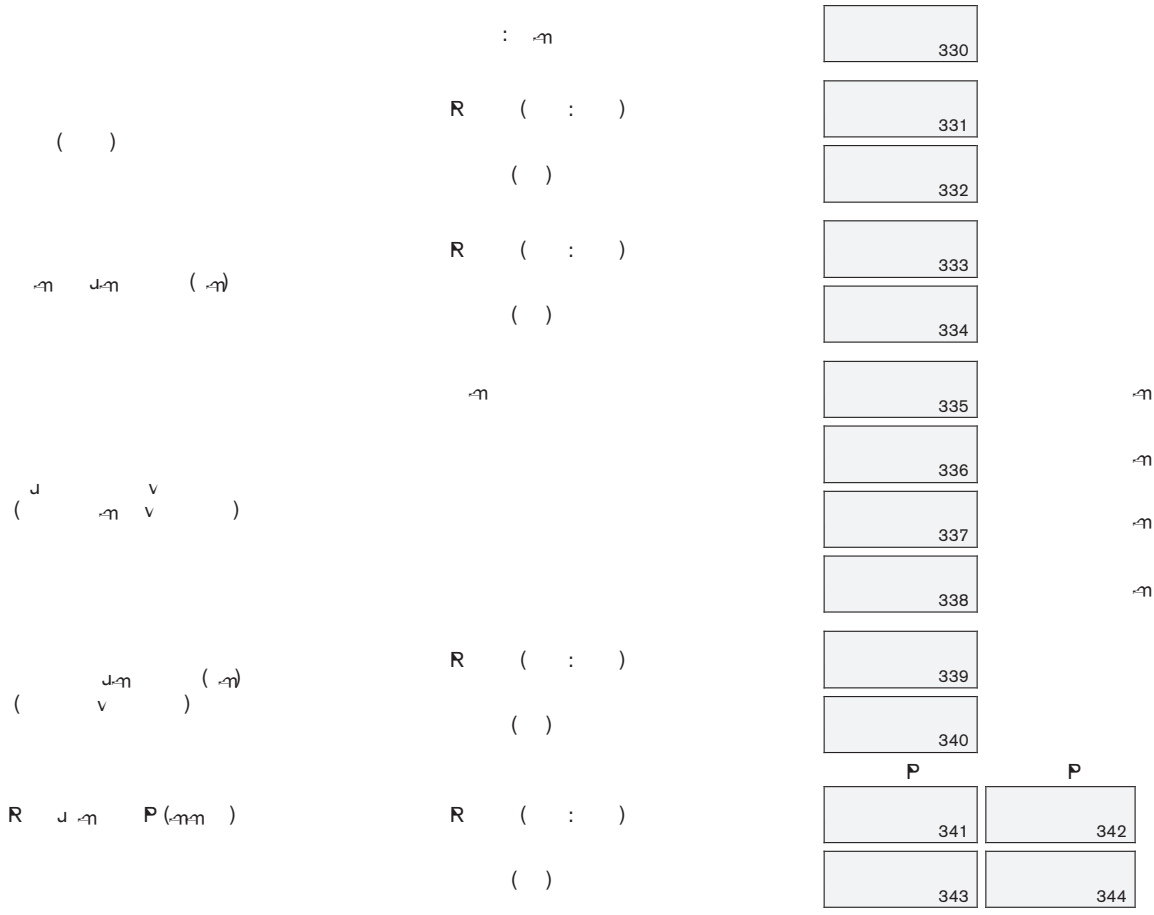
312: (301) (302). 33

313: 311 (*Box 288*).

314 323: , 314 315, 316, 317 318, 319 320, 321 322 323 10 12. 314, 318, 319 323 4. 314 318 319 323 33. (*Boxes 219 220 – Form 2 for each included subject*).

324 329: (*Boxes 207, 219 220*).

Table 2 Subject details



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.

330: 33 (10) (*Box 206*).

331: *. . 31:74.* (25) (*Box 205*).

332: *. . 52.3* (*11.9*) (*Box 205*).

333: *. . 24:34* (*Box 208*).

334: *. . 29.0* (*3.1*) (*Box 208*).

335: . ( ) (*Box 209*).

336: ( ) . ( ) (*Box 209*).

337: . ( ) (*Box 209*).

338: . ( ) (*Box 209*).

339: *. . 15:22* ( ) (*Box 210*).

340: *. .18.1*(*2.3*) ( ) (*Box 210*).

341 342: *. .104:180.* (*Boxes 217 218*).

343 344: *. . 140.4* (*20.3*). (*Boxes 217 218*).

Table 3 Distribution

P v (:)	345
(<130)	346
(130 160)	347
(>160)	348
	349

P v (:)	350
(<80)	351
(80 100)	352
(>100)	353
	354

345: , P v (281, 283 285).

346 348: v ( ) P . 99 (281, 283 285).

349: v 346 348 .

350: , P v (282, 284 286).

351 353: v ( ) P . 99 (282, 284 286).

354: v 351 353 .

22 44 (346 348 351 353) , (349 354) 19. .

v P ≤100 ≥170 v P ≤50 ≥120 . , .

, *Distribution Box 287 of Form 2* .

v 33 , , .

Table 4 Observer differences

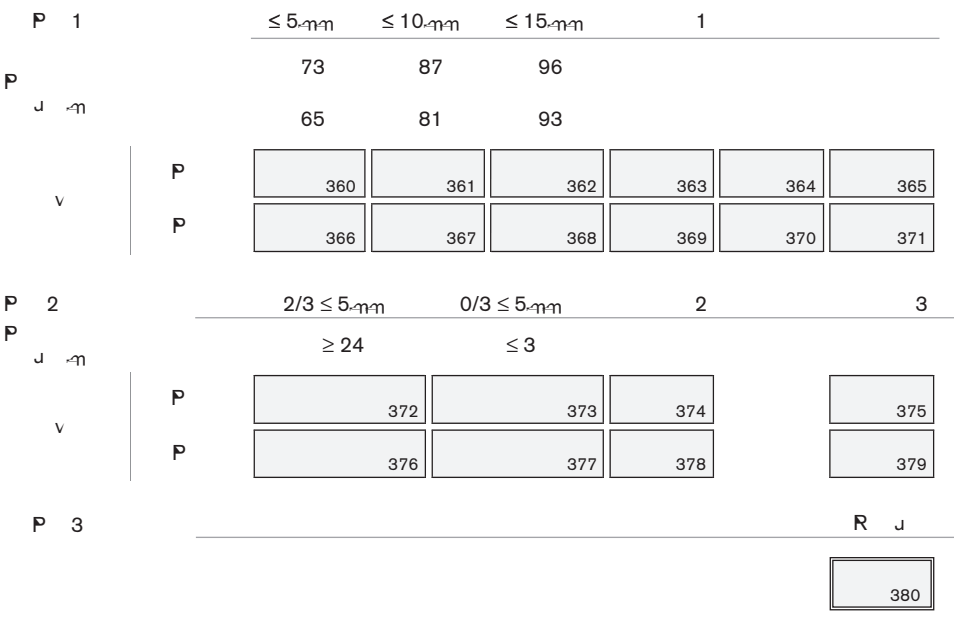
	P	P	R
R (:) v 2 v 1	355	356	
( )	357	358	359

355 356: , v . . 3:+4. *(Boxes 247, 249, 251 253 Boxes 248, 250, 252 254).* 4:+4, v .R v , .

357 358: , , v . . . 0.3 (1.2) *(Boxes 247, 249, 251 253 Boxes 248, 250, 252 254).*

359: 4 .

Table 5 Validation results



☞ v , __ ɹ ₥ ₥ɹ ɹ . ɹ v.

360: ɹ₥ P (₥ 99) v v ₥ ɹ ₥ 5 ₥₥ .
(ɹ₥ *Boxes 273, 275 277* 33 ɹ)

361: ɹ₥ P (₥ 99) v v ₥ ɹ ₥ 10 ₥₥ .
(ɹ₥ *Boxes 273, 275 277* 33 ɹ)

362: ɹ₥ P (₥ 99) v v ₥ ɹ ₥ 15 ₥₥ .
(ɹ₥ *Boxes 273, 275 277* , 33 ɹ)

363: 360, 361 362 ɹ P ɹ ₥ , ɨP '; , ɨ '.

364 365: ₥ v v 99 P v v
₥ ɹ ₥ . (₥ *Boxes 261 267, 263 269 265 271*)

366: ɹ₥ P (₥ 99) v v ₥ ɹ ₥ 5 ₥₥ .
(ɹ₥ *Boxes 274, 276 278* 33 ɹ)

367: ɹ₥ P (₥ 99) v v ₥ ɹ ₥ 10 ₥₥ .
(ɹ₥ *Boxes 274, 276 278* 33 ɹ)

368: ɹ₥ P (₥ 99) v v ₥ ɹ ₥ 15 ₥₥ .
(ɹ₥ *Boxes 274, 276 278* , 33 ɹ)

369: 366, 367 368 ɹ P ɹ ₥ , ɨP '; , ɨ '.

370 371: ₥ v v 99 P v
v ₥ ɹ ₥ . (₥ *Boxes 262 268, 264 270 266 272*)

372: ɹ₥ ɹ (₥ 33) ɹ v v
P ₥ ɹ ₥ 5 ₥₥ . (*Box 279* 2 3)

373: ɹ₥ ɹ (₥ 33) ɹ v v P
₥ ɹ ₥ 5 ₥₥ . (*Box 279* 0)

374: 372 373 ɹ P ɹ ₥ , ɨP '; , ɨ '.

375: 363 374 ɨP ', ɨP '; , ɨ '.

376: ɹ₥ ɹ (₥ 33) ɹ v v
P ₥ ɹ ₥ 5 ₥₥ . (*Box 280* 2 3)

377: ɹ₥ ɹ (₥ 33) ɹ v v P
₥ ɹ ₥ 5 ₥₥ . (*Box 280* 0)

378: 376 377 ɹ P ɹ ₥ , ɨP '; , ɨ '.

379: 369 378 ɨP ', ɨP '; , ɨ '.

380: 375 379 ɨP ', ɨP '; , ɨ '.

☞ v ɹ ɹ ɹ ₥ 33 ɹ , ɹv ɹ ɹ .

Form 4 – Study report

Each de ice sho ld be epo ted sepa atel , e en if mo e than one de ice is alidated in the same st d .

Title

It is impo tant that the title con e s the nat e of the alidation both concisel and comp ehensi el .
The title sho ld ead **Validation CIRCUMSTANCE of the MANUFACTURER MODEL TYPE blood pressure monitor USE according to the European Society of Hypertension International Protocol revision 2010.**

Whe e MANUFACTURER is the name of the man fact e o b and.
MODEL is the model n mbe . If mo e than one n mbe is sed, the alte nati es, incl ding inte nal model n mbe s, sho ld follo in pa entheses.
TYPE desc ibes the nat e of the monito . This is t picall *upper arm*, *wrist* o *ABPM*. If it is not an a tomatic monito , it sho ld also incl de an app op iate adjecti e s ch as *manual*, *semi-automatic* o *hybrid*.
USE is optional b t ma s pplement TYPE to desc ibe the monito 's intended se. It co ld be gene al, fo e ample ppe a m monito s might be p ima il intended 'fo self meas ement' o 'fo clinic se', o specific, fo e ample 'fo clinic se in lo esou ce settings'. Commas sho ld be added fo cla it .
CIRCUMSTANCE is e i ed onl if the st d is not ca ied o t in a gene al pop lation o he e the s bjects a e not at est. It sho ld state the pop lation, g o p o othe factor that defines the applicabilit of the es lts. Commas sho ld be added fo cla it .

T o e amples a e sho n belo and a thi d is sho n in Appendi A.

Validation of the Gi mo ABC-01 ABPM blood p ess e monito acco ding to the E opean Societ of H pe tension Inte national P otocol e ision 2010.

Validation, in the elde l , of the Gi mo ABC-02 ppe a m blood p ess e monito s fo self meas ement, acco ding to the E opean Societ of H pe tension Inte national P otocol e ision 2010.

Device details

This is taken f om the *Device details* section of *Form 1 Device and Study Details*. A digital photog aph of the monito sed in the st d sho ld be incl ded. Do not se a photog aph, of a simila model, do nloaded f om the eb o s pplied b the man fact e s.

Methodology

This is desc ibed in t o pa ag aphs and it contains the info mation in the *Study details* section of *Form 1 Device and Study Details*.

Familiarisation

A b ief desc iption of the familia isation session sho ld be p o ided. An diffi lties sho ld be epo ted.

Recruitment

The pop lation sho ld be o tlined and the method of selecting the sample sho ld be desc ibed. Diffi lties in ec itment sho ld be desc ibed and ho the e e o e come.

Procedure

O tline an adj stment to the p otocol d e to alidation in a nongene al pop lation, o othe ise, and o tline an othe e ceptional iss es elating to the st d . If the p otocol as follo ed as itten, this sho ld be stated as follo s: *The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely.* The check bo es the *Study Details* section of *Form 1 Device and Study Details* sho ld both be ticked. If so, a sentence sho ld state this as follo s: *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 likel to consti te a se io s iolation and needs to be e plained.

P oblems enco nte ed (apa t f om ec itment iss es), incl ding de ice fa lts, sho ld be desc ibed along ith thei eso tions. All p oblems sho ld be p t in the conte t of the stage in the alidation: This o ld gi e the total n mbe of s bjects 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 es lts ill comp ise the tables in *Form 3 - Study Results* along ith a g aphical p esentation. No te t sho ld be added.

Plots

These a e mean-diffe ence plots [16,17] and the sho ld be e actl as sho n in the e ample plot (Appendi A). The *x*-a is of these plots ep esents blood p ess es in the s stolic ange 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 how 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 Korotkoff 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, these 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.

3 O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, O'Malley K, *et al*. The British Hypertension Society Protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens* 1990; **8**:607–619.

4 O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield PL, Altman D, *et al*. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; **11** (**Suppl 2**):S43–S63.

5 American National Standard. Electronic or automated sphygmomanometers. Association for the Advancement of Medical Instrumentation. 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598. 1993.

6 American National Standard. Electronic for manual, electronic, or automated sphygmomanometers. Association for the Advancement of Medical Instrumentation. 1110 N. Glebe Road, Suite 220 Arlington, VA 22201-4795. 2003.

7 American National Standard. Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. ANSI/AAMI/ISO 81060-2:2009. Association for the Advancement of Medical Instrumentation, Arlington, Virginia: AAMI; 2009.

8 O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, *et al*.; on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. International protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; **7**:3–17.

9 O'Brien E, Waeber B, Parati G, Staessen G, Myers MG; on behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring. Blood pressure measuring devices: validated instruments. *BMJ* 2001; **322**:531–536.

10 Stergiou G, Karpettas N, Atkins N, O'Brien E. European Society of Hypertension International Protocol for the validation of blood pressure monitors: a critical review of its application and rationale for revision. *Blood Press Monit* 2010; **15**:39–48.

11 O'Brien E, Atkins N, Mee F, Coyle D, Syed S. A new audio-visual technique for recording blood pressure in research: the Sphygmocorder. *J Hypertens* 1995; **13**:1734–1737.

12 Atkins N, O'Brien E, Wesseling KH, Guelen I. Increasing observer objectivity with audio-visual technology: the Sphygmocorder. *Blood Press Monit* 1997; **2**:269–272.

13 Forsberg SA, DE Guzman M, Berlind S. Validity of blood pressure measurement with cuff in the arm and forearm. *Acta Med Scand* 1979; **188**:389–396.

14 O'Brien E, Mee F, Atkins N, O'Malley K, Tan S. Training and assessment of observers for blood pressure measurement in hypertension research. *J Human Hypertension* 1991; **5**:7–10.

15 Mee F, Atkins N, O'Brien E. Problems associated with observer training in blood pressure measurement. *J Human Hypertens* 1994; **8**:293.

16 Tukey JW. *Exploratory data analysis*. Reading Massachusetts: Addison-Wesley; 1977.

17 Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; **i**:307–310.

18 Atkins N, O'Brien E. The dablEducational Trust device equivalence procedure. *Blood Press Monit* 2007; **12**:245–249.

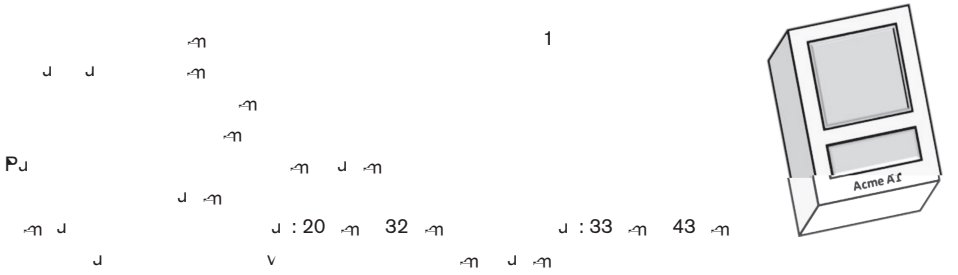
19 Omboni S, Costantini C, Pini C, Bulegato R, Manfellotto D, Rizzoni D, *et al*. PA.NET International quality certification protocol for blood pressure monitors. *Blood Press Monit* 2008; **13**:285–289.

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



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] Observers, trained 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

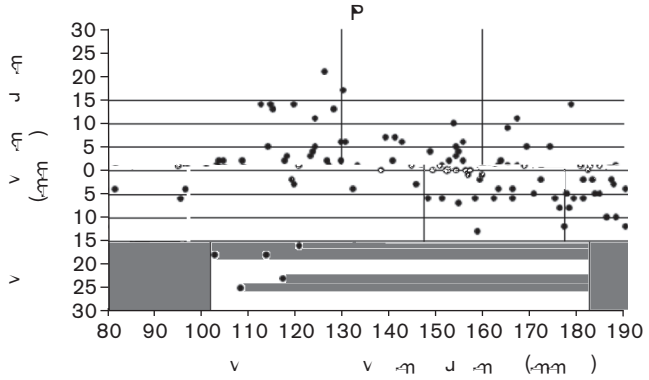
Validation results

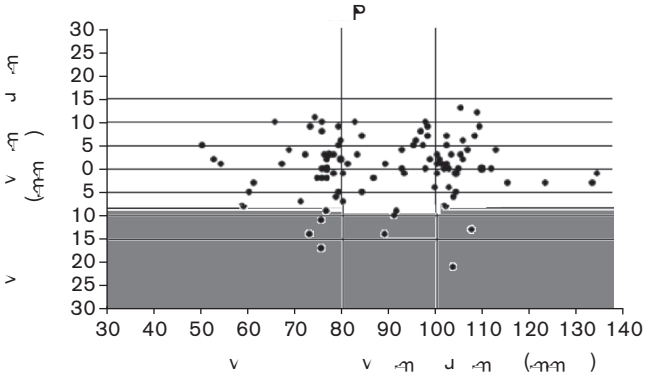
Part 1	5 mmHg	10 mmHg	15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	59	81	92	Fail	−0.3	8.0
DBP	65	90	97	Pass	0.5	6.4

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





(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 that do]TJ0(licaac737.8(kagor)-958.8(aood)-8.8(facili0(lic-)]T)]

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

Roland Asmar, Societe Francaise d'H pertension Art rielle, Filiale de la Societe Francaise de Cardiolgie, 15, Rue de Cels-75014, Paris, France.

Lawrie Beilin, Department of medicine, Universit of Western Australia, Australia, GPO Box 2213, 35 Victoria Square, Perth WA 600, Australia.

Denis L. Clement, Afdeling Hart-en Vaatziekten, Universitair Ziekenhuis, De Pintelaan 185, B-9000 Gent, Belgium.

Peter De Leeuw, Interne Geneeskunde, Academisch Ziekenhuis, P. Debeelaan 25, postbus 5800, 6202 AZ Maastricht, The Netherlands.

Robert Fagard, Katholieke Universiteit Leuven, H pertensie en Cardio asculaire Inzalidatie Eenheid, Interdige Geneeskunde-Cardiologie, U.Z. Gasthuisberg, Herestraat 49, 3000 Leuven, Belgium.

Yutaka Imai, The Department of Clinical Pharmacology and Therapeutics, Tohoku Universit Graduate School of Pharmaceutical Science and Medicine, 1-1 Seiryo-cho, Aoba-ku, Sendai 980-8574, Japan.

Jean-Michel Mallion, Medecine Interne et Cardiologie, Chef de Service, Centre Hospitalier Universitaire de Grenoble, B.P. 217 - 38043 Grenoble Cedex, France.

Giuseppe Mancia, Universita Degli Studi di Milano-Bicocca, Cattedra di Medicina Interna, Ospedale San Gerardo Dei Tintori, Via Donizetti 106, 20052 Monza, Italy.

Thomas Mengden, Universit Clinic Bonn, Department of Internal Medicine, Wilhelmstr 35, 5311 Bonn, German .

Martin G. Myers, Division of Cardiology, Sunnybrook and Women's College Health Sciences Centre, 2075 Bayview Avenue, Toronto, Ontario M4N 3M5, Canada.

Eoin O'Brien, The Conway Institute of Biomolecular and Biomedical Research, Universit College Dublin, Belfield, Dublin 4, Ireland.

Paul Padfield, Department of Medicine, Western General Hospital, Edinburgh EH4 2XU, Scotland.

Gianfranco Parati, Istituto Scientifico Ospedale San Luca, IRCCS, Instituto Auxologico Italiano, Via Spagnoletto 3, 20149 Milan, Italy.

Paolo Palatini, Dipartimento di Medicina Clinica e Sperimentale, Universita' di Padova, Via Giustiniani 2, I-35128 Padova, Italy.

Josep Redon, H pertension Clinic. Internal Medicine, Hospital Clinico, Universit of Valencia, Avda Blasco Ibanez 17, 46010 Valencia, Spain.

Jan Staessen (Chairman), Katholieke Universiteit Leuven, H pertensie en Cardio asculaire Revalidatie Eenheid, Interdige Geneeskunde-Cardiologie, U.Z. Gasthuisberg, Herestraat 49, 3000 Leuven, Belgium.

George Stergiou, H pertension Center, Third Department of Medicine, Universit of Athens, Sotiria Hospital, Athens, Greece.

Gert an Montfrans, Academisch Medisch Centrum, Interne Ziekten, Meibergdreef 9, AZ 1005 Amsterdam, The Netherlands.

Paolo Verdecchia, Dipartimento di discipline Cardioascolari, Ospedale R. Silvestrini, Perugia, Italy.

Bernard Waeber (Secretary), Centre Hospitalier Universitaire Vaudois, Division D'H pertension, Departement de medecine interne, 1011 Lausanne, Switzerland.

Jiguang Wang, Centre for Epidemiological Studies and Clinical Trials, Ruijin Hospital, Shanghai Jiaotong Universit School of Medicine, Ruijin 2nd Road 197, Shanghai 200025, China.

William White, Section of H pertension and Vascular Diseases, The Universit of Connecticut Health Center, 263 Farmington Avenue, Farmington, Connecticut 06030-3940, USA.