Evaluation of blood pressure measuring devices with special reference to ambulatory systems

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As ambulatory blood pressure measurement becomes more widely accepted in hypertension research and in the clinical management of high blood pressure, the number of devices available on the market has increased considerably, reflecting the clinical demand. These devices are expensive, both in terms of capital and running costs.

As we rely increasingly on data produced by ambulatory systems, it becomes increasingly important that they be shown to be accurate. Initially protocols for the validation of ambulatory devices were designed on an *ad hoc* basis, so that many studies were inadequately designed and comparison of data between studies was usually impossible. The American National Standard published by the Association for the Advancement of Medical Instrumentation (AAMI) remedied this situation in part, and the recent publication of the British Hypertension Society (BHS) protocol for the validation of ambulatory systems has further advanced the demand for accuracy. The BHS protocol includes most of the AMMI standard recommendations, but in addition there are sections on observer training, in-use assessment and inter-device variability. In addition, performance characteristics, computer facilities and details on such practical matters as cost and maintenance are sought. Finally, the BHS protocol provides a grading system of validation which allows comparisons between devices and studies.

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Introduction

The development of the Remler M2000 system in the early 1960s [1], a device capable of measuring daytime ambulatory blood pressure non-invasively, may now be recognized as a major advance in the clinical management of hypertension. With the advent of ambulatory recorders capable of measuring blood pressure non-invasively over 24 h [2] it becomes possible to study many aspects of blood pressure behaviour relevant to the clinical management of hypertension [3,4]. Assessment of the effects of antihypertensive drugs over the 24-h period became feasible [5], and ambulatory monitoring showed promise in assessing prognosis [6] and also provided data on the physiology of blood pressure behaviour [7]. In fact, ambulatory blood pressure measurement is likely to alter current practice in the diagnosis and management of hypertension to such an extent that physicians will become dependent on the technique. Ambulatory measurement can reliably differentiate subjects with a normal 24-h blood pressure and those with a borderline office elevation of blood pressure [8]; it can also diagnose white coat hypertension [9]. Further, the ability of ambulatory measurement to demonstrate the efficacy of antihypertensive medication in clinical practice [5], quite apart from the many research applications of the technique, has opened up a market with enormous potential for device manufacturers [10].

Market considerations

The United States market for cardiac monitoring equipment was $1.2 billion in 1987, but is expected to rise to $1.7 billion in 1992; non-invasive ambulatory monitoring accounted for nearly $50 million of this market in 1987 [11]. In Europe, where the market for patient monitoring equipment is estimated to reach $379 million by 1993, ambulatory blood pressure monitoring equipment is also likely to form a significant fraction [12].

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The increased manufacture of ambulatory devices in recent years reflects this growing market. Thirteen ambulatory systems are presently available commercially and others are in the later stage of development [13]. These systems are expensive, ranging from about $4000 to over $20 000 for one recorder and decoding system depending on the accessories, computer facilities and software options purchased. The charge for 24-h ambulatory recordings which may vary, of course, in relation to a number of factors, not least among which is the private market, reflects the high cost of ambulatory equipment. There are also substantial costs in running an ambulatory blood pressure service. However, the potential savings associated with ambulatory monitoring must be offset against these costs. It is estimated that the market for cardiovascular drugs in the United States, which is growing by 9% annually, will rise from $4 billion in 1986 to nearly $6 billion in 1991 [14]. Ambulatory blood pressure monitoring may reduce this bill substantially by reducing drug prescribing [15].

Need for validation

However we may feel about the events in the market place, the reality is that market forces will probably have a greater influence than medical opinion on the sale and distribution of ambulatory blood pressure measuring devices. This is already apparent in the large sale of devices to the private sector, at least in Europe, which many of us would regard as premature, if for no other reason than that we are now only coming to terms with the reference values for normal 24-h pressures. We can, however, influence the quality of devices being manufactured by ensuring that they are accurate and reliable so as to prevent the development of a situation like that of the self-measurement market where most blood pressure measuring devices that have been evaluated have been shown to be inaccurate [16]. If high standards of performance and accuracy are not demanded, continued uncontrolled marketing will inevitably result in the manufacture and sale of inaccurate devices. This problem has clear implications for clinical practice, the most important of which is inappropriate diagnostic and management decisions.

However, the achievement of high standards is not easily attained. A manufacturer of 24-h measuring devices has to meet national standards of production in countries which have these standards but is not obliged to validate devices for accuracy in clinical situations. The task is all the more difficult as manufacturers often produce an up-dated model every 3–4 years making it difficult for investigators to keep validation abreast of production. Because validation studies are time-consuming to perform, the time-lag between manufacture and publication of an independent evaluation in a reputable journal is often so long that manufacturers may be ready to market a modification of the original device and the outcome of any evaluation is thereby rendered obsolete and of little academic interest. Despite reassurances from manufacturers that the latest model is operationally no different from its predecessor and, therefore, as accurate, all newly marketed models must be fully validated.

Having agreed on the need for the medical profession to ensure that ambulatory devices are accurate and reliable, the question arises of how this can best be achieved. Traditionally, centres with an interest in blood pressure measurement have performed validation studies that have varied greatly in their design and ability to evaluate accuracy and performance. We assessed 25 validation studies of eight automated devices, six of which were used for 24-h ambulatory blood pressure measurement [17–41] to determine whether those criteria that are now considered to be important in the evaluation of accuracy were applied, and also to determine whether it was possible to compare one study with another or make an assessment of the relative merits of ambulatory systems. The devices in these studies were the Pressurometer III, the SpaceLabs 5200, the Copal, the Takeda, the Accutracker I and finger-measuring devices. The description of the device was considered adequate in only 10 studies; bladder dimensions were provided in only two and the arm circumference in only seven studies; the range of blood pressure was given in seven studies, the accuracy of the device after a period in use in one and inter-device variability in two studies; the statistical methods used were varied and often inadequate, with too much reliance being placed on the correlation coefficient, which was used to estimate accuracy in 16 studies. It was impossible to make comparisons between most studies and it was not possible to assess the relative merits of one system against another. On the basis of these findings, it is evident that a standardized approach to the validation procedures used in evaluating ambulatory blood pressure measuring systems is needed.

American Association for the Advancement of Medical Instrumentation (AAMI) Standard

The first body to appreciate the need for a standardized approach to the validation of blood pressure measuring devices was the AAMI [42] which published its recommendations for validation of electronic and automated sphygmomanometers in 1987 as an American National Standard. This standard has been used to evaluate five ambulatory systems, the SpaceLabs 90202, the Medilog [43], the Del Mar Avionics Pressurometer IV [44], the Takeda TM-2420 [45] and the Accutracker II [46]. The SpaceLabs 90202 [42] and the Medilog [43] both fulfilled the criteria of the AAMI standard for both systolic and diastolic pressure, whereas the Pressurometer IV failed to provide measurements of diastolic pressure according to the AAMI standard [44], the Accutracker II failed for both systolic and diastolic pressure [46] and in a vali-

dation study of four Takeda TM-2420 devices only one fulfilled the AAMI criteria [45]. On the basis of the AAMI criteria, therefore, the only systems that can be recommended at present for 24-h ambulatory measurement of blood pressure are the SpaceLabs 90202 and the Medilog; the results of a number of on-going validation studies on other devices will be available shortly.

That the AAMI standard can be effective in influencing the marketing potential of ambulatory devices is evident from the fact that at least one group, the European study of Systolic Hypertension in the Elderly (SystEur), has made the purchase of ambulatory devices conditional upon the standard being satisfied (personal communication, 1990, SysEur Study Co-ordinating Office).

In 1987, the Working Party on Blood Pressure Measurement of the British Hypertension Society was asked to review the need for recommendations on ambulatory blood pressure measuring devices, in view of the growing demand for these devices. The more the Working Party examined the issues involved, the more apparent it became that recommendations were indeed required, especially in relation to the evaluation of devices for measuring ambulatory blood pressure. The Working Party originally hoped to be able to merely adopt the AAMI standard [42] for use in the United Kingdom and Ireland, but on consideration concluded that while this standard was the most comprehensive recommendation on validation available, it had a number of deficiencies. The Working Party decided, therefore, to prepare a new protocol to serve as a standardized procedure for the evaluation of ambulatory blood pressure measuring devices [47]; the procedure adopted can be applied to any automated or semi-automated blood pressure device.

British Hypertension Society (BHS) protocol

The validation of blood pressure measuring devices is a complex and labour-intensive procedure and this is particularly so with ambulatory devices. The basis of device evaluation is the comparison of blood pressure measured by the device being tested with simultaneous measurements made by an established technique. Because of the complexity of design in ambulatory systems, this ideal form of validation is usually not always possible and test methods must allow for variation in the design and technology of ambulatory measuring devices [47].

Since the AAMI standard was published methods of statistical analysis in the evaluation of devices have changed. Most notably, the correlation coefficient, once regarded as the best statistic for comparison of one device against another, has been largely abandoned because it may suggest close accuracy when there are, in fact, gross differences between the devices being compared [48,49]. Therefore, more suitable statistical methods are recommended in the BHS protocol.

We regard the AAMI criteria of acceptable inaccuracy (mean difference of ± 5 mmHg with a standard deviation of 8 mmHg) [42] as too liberal. We devised, therefore, a system of grading; although grade A has not yet been achieved by any device we hope that future ambulatory devices may meet this standard [47].

Unlike the AAMI standard [42], direct intra-arterial measurement is not included in the BHS protocol because these values differ from measurements obtained by indirect methods [50,51], and because clinical practice uses indirect measurements rather than the invasive direct methods. Direct intra-arterial measurement may have a role in the validation of certain performance aspects of non-invasive systems, such as during exercise. It should be stressed, however, that if such studies are to be performed, they should be carried out on small numbers after evaluation of ethical considerations and only in centres with established expertise in intra-arterial ambulatory measurements.

The Working Party was conscious of the onerous task of following the recommendations in this protocol and it has endeavoured to keep the procedures as simple as possible. The entire procedure has been designed to ensure that expensive and time-consuming tests are not performed on devices which do not meet certain basic accuracy criteria. The expense involved is also substantial. It is our policy to organize such studies so that the entire procedure is completed within 1 month as this facilitates the organization and standardization of the various tests, leading ultimately to a greater accuracy of performance than can be obtained by performing the validation piecemeal over a long period of time. We have estimated that to validate one ambulatory system according to the BHS protocol requires the time of a research supervisor for 97 h, 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 for 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 industrial charges; we estimate that the cost of a full validation is about £20 000 and manufacturers will have to make provision in their production costs for independent validation.

A standard mercury sphygmomanometer is used as a reference standard for all tests rather than a random zero sphygmomanometer [52] because the random zero sphygmomanometer may underestimate diastolic pressure [53–56].

Principles of validation

The BHS Protocol for evaluation of ambulatory systems consists of six phases [47]: phase I: Observer training and assessment; phase II: Before-use interdevice variabil-

ity; phase III: In-use assessment; phase IV: After-use interdevice variability; phase V: device validation; and phase VI: Preparation of the report (Fig. 1). A device must complete each phase successively before it can proceed to the next phase. The programme is designed so as to prevent unnecessary testing. A brief description of each phase is given below.

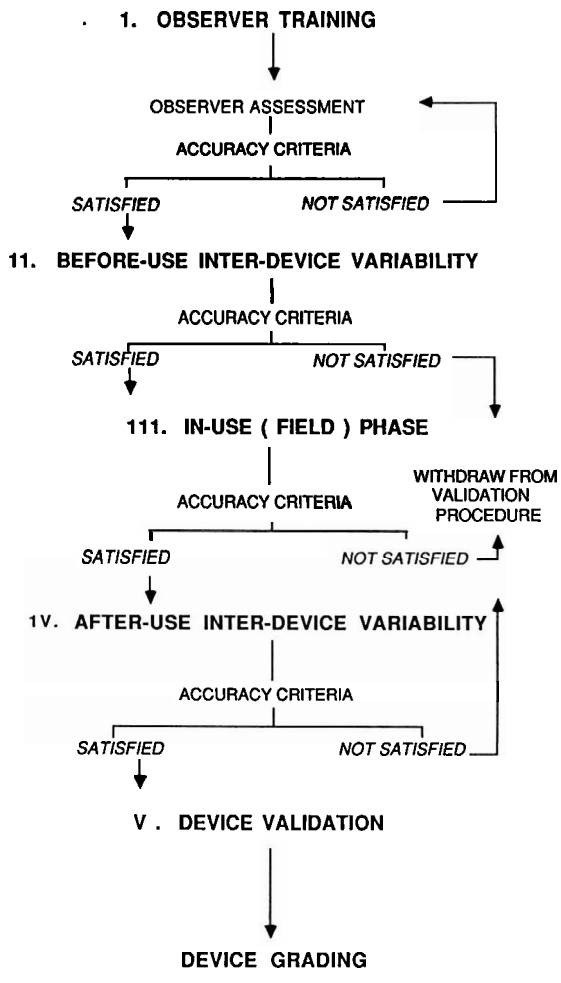

Fig. 1. Validation procedure of the British Hypertension Society protocol.

Phase I: Observer training and assessment
Observers are trained by films [57] and by other experts according to the BHS recommendations for blood pressure measurements [58]. Following training the observers are tested for accuracy against each other and an expert observer by measuring blood pressure in normotensive and hypertensive subjects. Ninety per cent of systolic and diastolic differences between trainees and expert must not differ by more than 5 mmHg and 98% by not more than 10 mmHg and 85% of systolic and diastolic differences between each trainee should not differ by more than 5 mmHg and 95% by not more than 10 mmHg.

Phase II: Before-use interdevice variability assessment
Three devices of each ambulatory system should be assessed according to the manufacturer's stipulations for calibration against a mercury sphygmomenometer.

Phase III: In-use assessment
The three devices used for the interdevice assessment are next used to test the performance of the device during and after 24-h ambulatory monitoring in subjects with a wide range of pressure to give a large number of measurements. The measurements obtained over each 24-h period are characterized according to the number of inflations, valid readings, rejected readings, aborted readings, and the ratio of day to night readings.

Phase IV: After-use interdevice variability
At the end of a month of ambulatory assessment the three devices are retested for interdevice variability to determine if there has been any change in interdevice agreement after use.

Phase V: Device validation
One device is arbitrarily selected from the three devices for the main validation test. Eighty-five subjects aged from 15 to 80 years with a representative range of blood pressures are selected. Simultaneous measurement of blood pressure between a mercury sphygmomanometer and the ambulatory device is recommended, but in practice either simultaneous opposite arm measurements or sequential same arm measurements are usually necessary. Based on an analysis of data from simultaneous opposite-arm and sequential same-arm measurements, the BHS protocol recommends the latter, which can be made as accurate as simultaneous same-arm measurement by using a 'correction' technique [59].

Phase VI: Preparation of the report
Recommendations for the analysis and presentation of data are made in the protocol [47].

Statistical considerations
The percentage of test device measurements differing from the mercury standard by not more than 5, 10 and 15 mmHg forms the basis of grading the test system. The rationale for this is discussed in detail in an appendix to the protocol [47].

The future

The BHS protocol incorporates, therefore, a number of features which may be seen as an advance on the AAMI Standard [42]. However, it should not be seen as a definitive statement and it is important that we continue to improve and develop standards to satisfy the rapidly expanding demand for ambulatory blood pressure measur-

ing devices. Certain inadequacies are already evident in the BHS protocol [47].

Though the BHS protocol provides an assessment of performance in the subject's normal environment, blood pressure measurements are usually made with the subject at rest and an ambulatory device that meets the criteria of this protocol cannot be assumed to be accurate during physiological manoeuvres, such as exercise, isometric handgrip, Valsalva manoeuvre, etc. It is difficult to show how this aspect of validation can readily be provided for. One solution is to simultaneously measure ambulatory pressure intra-arterially in the opposite arm to the non-invasive test device during ambulatory use or exertional procedures. However, as already stated, ethical considerations preclude this procedure in many countries. Indeed, invasive measurements of blood pressure cannot easily be justified in healthy volunteers, and even if official ethical approval can be obtained the occurrence of a complication arising from the invasive procedure would be likely to carry serious medico-legal consequences.

The lack of an accurate non-invasive method of measuring blood pressure during exercise makes the performance of laboratory validation during, for example, treadmill walking, questionable. However, these are difficulties that must be addressed, and may in time be overcome.

Other aspects that merit consideration are the positional changes that may occur during ambulatory use of a device and the effect of extreme heart rate levels and arrhythmias. It should be possible to devise tests to assess the effect of these factors on the accuracy of ambulatory devices without adding excessively to what is already a taxing procedure to perform.

Technological developments may make device validation less costly and easier to perform. The development of an accurate automated blood pressure measuring device, which could replace the mercury sphygmomanometer and trained observers, would simplify the validation procedure and make it unnecessary to have expensive personnel involved for lengthy periods in the validation procedure.

Another technological advance would be the development of a bionic arm which might replace the need for such large numbers of volunteers. At least one such device, suitable for testing devices that measure blood pressure oscillometrically, is being developed (personal communication, Dynatech Nevada Inc., Nevada, USA, 1990).

Making standards effective can also be a problem. The adoption of standards by manufacturers of blood pressure measuring devices is not easily effected in the United Kingdom and Ireland. Unfortunately, even the presence of a national standard is not a guarantee of accuracy and it will be many years before a standard is accepted in the United Kingdom and Ireland. The British Standards Institution recently published revised standards for mercury and aneroid sphygmomanometers [60]; it is also preparing a standard for automated devices and the BHS has made an application to the British Standards Institution for a standard for semi-automated devices (personal communication, BSI, 1989). However, even if a standard for ambulatory devices was available, manufacturers would not be obliged to comply with it and there would still be a need for independent evaluation. Manufacturers cannot be obliged to guarantee the accuracy of their product, though it is likely that the legislative harmonization being prepared by the Commission of the European Communities with regard to essential safety requirements of medical devices will be extended to other aspects of device performance, such as accuracy [61]. Also, we expect that reputable manufacturers will welcome the opportunity of having ambulatory devices evaluated independently according to a generally accepted protocol. This process, which will necessarily take time, could be influenced beneficially if editors of general medical, clinical pharmacology and hypertension journals critically evaluated the evidence supporting the accuracy of ambulatory blood pressure measurement systems used in research studies. Health authorities and sponsoring organizations should not continue to purchase equipment which has not been evaluated adequately.

References

1. Hinman AT, Engel BT, Bickford AF: **Portable blood pressure recorder: accuracy and preliminary use in evaluating intradaily variations in pressure.** *Am Heart J* 1962, 63:663–668.
2. Harshfield GA, Pickering TG, Laragh JH: **A validation study of the Del Mar Avionics ambulatory blood pressure system.** *Ambul Electrocardiol* 1979, 1:7–12.
3. Pickering TG, Harshfield GA, Kleinert HD, Blank S, Laragh JH: **Blood pressure during normal daily activities, sleep and exercise.** *JAMA* 1982, 247:992–996.
4. Mancia G: **Clinical use of ambulatory blood pressure monitoring.** *Am J Hypertens* 1989, 2:505–545.
5. O'Brien E, Cox J, O'Malley K: **Editorial review: Ambulatory blood pressure measurement in the evaluation of blood pressure lowering drugs.** *J Hypertens* 1989, 7:243–247.
6. Perloff D, Sokolow M, Cowan RM, Juster RP: **Prognostic value of ambulatory blood pressure measurements: further analysis.** *J Hypertens* 1989, 7 (suppl 3):S3–S10.
7. Drayer JIM, Weber MA, De Young JL, Wyle FA: **Circadian blood pressure patterns in ambulatory hypertensive patients: effects of age.** *Am J Med* 1982, 73:493–499.
8. O'Brien E, O'Malley K: **Overdiagnosing hypertension.** *Br Med J* 1988, 297:1211–1212.
9. Pickering TG, James GD, Boddie C, *et al.*: **How common is white coat hypertension?** *JAMA* 1988, 259:225–228.
10. O'Brien E, O'Malley K, Sheridan J: **The need for a standardized protocol for validating ambulatory blood pressure measuring devices.** *J Hypertens* 1989, 7 (suppl 3):S19–S20.
11. Anonymous: *Cardiac Monitor Equipment and Supplies Markets in U.S. Hospitals and Physicians Offices, to 1992. (A1946).* New York: Frost and Sullivan, 1987.
12. Anonymous: *The Patient Monitoring Equipment Market in Europe (E901).* New York: Frost and Sullivan, 1987.
13. O'Brien E, O'Malley K: **Twenty-four-hour ambulatory blood pressure monitoring: a review of validation data.** *J Hypertens* 1990 (suppl, in press).

14. ANONYMOUS: *The cardiovascular drugs market in the U.S. (A1931).* New York: Frost and Sullivan, 1987.
15. JOINT NATIONAL COMMITTEE: **Hypertension prevalence and the status of awareness, treatment, and control in the United States: final report of the Subcommittee on Definition and Prevalence of the 1984 Joint National Committee.** *Hypertension* 1985, 7:457–468.
16. O'BRIEN E, MEE F, ATKINS N, O'MALLEY K: **Inaccuracy of seven popular sphygmomanometers for home measurement of blood pressure.** *J Hypertens* 1990, 7:621–634.
17. PALATINI P, SPERTI G, CORDONE L, *ET AL.*: **Reliability of indirect blood pressure monitoring for the evaluation of hypertension.** *Clin Exp Hypertens [A]* 1985, 7:437–443.
18. FITZGERALD DJ, O'DONNELL D, BRENNAN M, O'MALLEY K, O'BRIEN E: **Accuracy and reliability of the Del Mar Avionics Pressurometer III.** *J Hypertens* 1982, 48:572–579.
19. GOULD BA, HORNUNG RS, CASHMAN PMM, ALTMAN D, RAFTERY EB: **An evaluation of the avionics pressurometer III 1978 at home and in the hospital.** *Clin Cardiol* 1986, 9:335–343.
20. GERMANO G, DAMIANI S, FERRUCI A, CIAVARELLA M, ROMEO F, CALCAGNINI G; **Reliability and reproducibility of a new device for ambulatory blood pressure recording.** *Ann Med Int* 1988, 139:140–141.
21. THURM RH, GRANEY WF: **Twenty-four hour blood pressure monitoring in the evaluation of once daily treatment of essential hypertension with captopril.** *Clin Exp Hypertens [A]* 1985, 7:283–290.
22. PAGNY JY, CHATELLIER G, DEVRIES C, JANOD JP, CORVOL P, MÉNARD J: **Comparison of ambulatory blood pressure measured by the Remler and the Spacelabs apparatus [in French].** *Arch Mal Coeur* 1986, 6:901–906.
23. PAGNY JY, CHATELLIER G, DEVRIES C, JANOD JP, CORVOL P, MÉNARD J: **Evaluation of the Spacelabs ambulatory blood pressure recorder: comparison with the Remler M2000.** *Cardiovasc Rev Rep* 1987, 4:31–36.
24. MODESTI PA, GENSINI GF, CONTI C, NERI SERINI GG: **Clinical evaluation of an automatic blood pressure monitoring device.** *J Clin Hypertens* 1987, 3:631–644.
25. MAHESWARAN R, ZEZULKA AV, GILL JS, BEEVERS DG: **Clinical evaluation of the Spacelabs model 5200 ambulatory blood-pressure monitor.** *J Ambulatory Monitoring* 1987, 1:33–37.
26. CASADEI R, PARATI G, POMIDOSSI G, *ET AL.*: **24-hour blood pressure monitoring: evaluation of Spacelabs 5300 monitor by comparison with intra-arterial blood pressure recording in ambulant subjects.** *J Hypertens* 1988, 6:797–803.
27. SHERIDAN J, BURKE M, MEE F, KENNY RA, O'BRIEN E, O'MALLEY K: **Accuracy of the SpaceLabs 5300 automatic indirect ambulatory blood pressure recorder: a comparison with the Remler M2000.** *J Ir Coll Phys Surg* 1988, 17:31.
28. SANTUCCI S, STEINER D, ZIMLER M, JAMES G, PICKERING T; **Validation study of the Spacelabs models 90202 and 5200 ambulatory blood-pressure monitors.** *J Ambulatory Monitoring* 1988, 1:211–216.
29. GRAETTINGER WF, LIPSON JL, CHEUNG DG, WEBER MA: **Validation of portable noninvasive blood pressure monitoring devices: comparisons with intra-arterial and sphygmomanometer measurements.** *Am Heart J* 1988, 116:1155–1160.
30. PELIKAN G: *The Advantages of Oscillometric Techniques for Measuring Ambulatory Blood Pressure.* Redmond, Washington: SpaceLabs Inc, 1987.
31. CONWAY J, JOHNSTON J, COATS A, SOMERS V, SLEIGHT P: **The use of ambulatory blood pressure monitoring to improve the accuracy and reduce the number of subjects in clinical trials of antihypertensive agents.** *J Hypertens* 1988, 6:111–116.
32. FLAPAN AD, STEWART SE, MCDOUGAL F, PADFIELD P: **Is self home-monitoring of blood pressure as good as 24-hour ambulatory monitoring?** *J Hypertens* 1987, 5 (suppl 5):S491–S493.
33. BENNET P, ANDERSON W, CARROLL D, MAHESWARAN R, ZEZULKA A, BEEVERS DG: **Clinical evaluation of the Pollenex BP-850 automatic sphygmomanometer.** *Int J Psychophysiol* 1988, 6:65–69.
34. TOCHIKUBO O, KANEKO Y, YOKOI H, YUKINARI Y: **A new portable device for recording 24-h indirect blood pressure in hypertensive outpatients.** *J Hypertens* 1985, 3 (suppl 3):S355–S357.
35. TOCHIKUBO O, MINAMISAWA K, MIYAJIMA E, MASAO I, YANAGA A, YUKINARI Y: **A new compact 24-hour indirect blood pressure recorder and its clinical application.** *Jpn Heart J* 1988, 29:257–269.
36. VAN EGMOND J, HASENBOS M, CRUL JF; **Invasive v. non-invasive measurement of arterial pressure.** *Br J Anaesth* 1985, 57:434–444.
37. DORLAS JC, NIJBOER JA, BUTIJN WT, VAN DER HOEVEN GMA, SETTELS JJ, WESSELING KH: **Effects of peripheral vasoconstriction in the blood pressure in the finger, measured continuously by a new noninvasive method (the Finapres®).** *Anesthesiology* 1985, 62:342–345.
38. YAMAKOSHI K, KAWARADA A, KAMIYA A, SHIMAZU H, ITO H: **Long-term ambulatory monitoring of indirect arterial blood pressure using a volume–oscillometric method.** *Med Biol Eng Comput* 1985, 23:459–465.
39. IMAI Y, NIHEI M, ABE K: **A new automated volume–oscillometric device for monitoring ambulatory blood pressure in the finger in man.** *J Hypertens* 1986, 4 (suppl 6):S662–S664.
40. IMAI Y, NIHEI M, ABE K, *ET AL.*: **A finger volume–oscillometric device for monitoring ambulatory blood pressure: laboratory and clinical evaluations.** *Clin Exp Hypertens [A]* 1987, 9:2001–2025.
41. WHITE WB, SCHULMAN P, MCCABE EJ, NARDONE MB: **Clinical validation of the Accutracker, a novel ambulatory blood pressure monitor using R-wave gating for Korotkoff sounds.** *J Clin Hypertens* 1987, 3:500–509.
42. ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION: *American National Standard for Electronic or Automated Sphygmomanometers.* Washington DC: AAμI, 1987.
43. HOPE SL, ALUN-JONES E, SLEIGHT P: **Validation of the accuracy of the Medilog ABP non-invasive blood-pressure monitor.** *J Ambulatory Monitoring* 1988, 1:39–51.
44. HARSHFIELD GA, HWANG C, GRIM CE: **A validation study of the Del Mar Avionics Pressurometer IV according to the AAMI guidelines.** *J Hypertens* 1988, 6:913–918.
45. JAMIESON MJ, FOWLER G, MACDONALD TM, *ET AL.*: **Bench and ambulatory field evaluation of the A & D TM-2420 automated sphygmomanometer.** *J Hypertens* 1990, 8:599–605.
46. O'BRIEN E, MEE F, ATKINS N, O'MALLEY K: **An evaluation of the Accutracker II according to the AAMI standard.** *J Ambulatory Monitoring* 1990 (in press).
47. O'BRIEN E, PETRIE J, LITTLER W, *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.
48. CONWAY J: **Home blood pressure recording.** *Clin Exp Hypertens [A]* 1986, A:1267–1294.
49. BLAND JM, ALTMAN DG: **Statistical methods for assessing agreement between two methods of clinical measurement.** *Lancet* 1986, i:307–310.
50. MANCIA G: **Methods of assessing blood pressure values in humans.** *Hypertension* 1983, 5 (suppl III):III5–III13.
51. VARDAN S, MOOKHERJEE S, WARNER R, SMULYAN H: **Systolic hypertension: direct and indirect BP measurements.** *Arch Intern Med* 1983, 143:935–938.
52. WRIGHT BM, DORE CF: **A random zero sphygmomanometer.** *Lancet* 1970, i:337–338.
53. EVANS JG, PRIOR IAM: **Experience with the random-zero sphygmomanometer.** *Br J Prev Soc Med* 1970, 24:10–15.
54. DE GAUDEMARIS R, FOLSOM AR, PRINEAS RJ, LUEPKER RV: **The random-zero versus the standard mercury sphygmomanometer: a systematic blood presure difference.** *Am J Epidemiol* 1985, 121:282–290.
55. PARKER D, LIU K, DYER AR, GIUMETTI D, LIAO Y, STAMLER J: **A comparison of the random zero and standard sphygmomanometers.** *Hypertension* 1988, 11:269–272.
56. O'BRIEN E, MEE F, ATKINS N, O'MALLEY K: **Inaccuracy of the Hawksley random zero sphygmomanometer.** *Lancet* 1990 (in press).

57. JAMIESON M, PETRIE J, O'BRIEN E, PADFIELD P, LITTLER WA, DE SWIET M: *Blood Pressure Measurement.* London video for the British Hypertension Society, British Medical Journal Publication, 1989.
58. PETRIE JC, O'BRIEN E, LITTLER WA, DE SWIET M: **Recommendations on blood pressure measurement.** *Br Med J* 1986, 293:611–615.
59. ATKINS N, O'MALLEY K, MEE F, O'BRIEN E: **The accuracy of simultaneous arm measurement versus opposite arm and sequential measurement.** *J Hum Hypertens* (in press).
60. BRITISH STANDARDS INSTITUTION: *Specification for Anaeroid and Mercury Non-automated Sphygmomanometers: British Standard BS2743:1990.* London: BSI, 1990.
61. JOINT EUROPEAN STANDARDS INSTITUTION: *Proceedings: Workshop on the European Standardization of Medical Devices, Brussels, 12–14 December 1988.* Brussels: CEN/CENELEC, 1989.