State of the market for devices for blood pressure measurement

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There is a large market for blood pressure measuring devices, not only in clinical medicine, but also with the public where the demand for self-measurement of blood pressure is growing rapidly. For the consumer, whether medical or lay, device accuracy should be of prime importance in selecting a blood pressure measuring device. However, the majority of devices available have not been evaluated independently for accuracy. In this paper the published evidence for independent validation is reviewed and it is recommended that such reviews should be undertaken regularly by international bodies, such as the European Society of Hypertension. *Blood Press Monit* 6:281–286 © 2001 Lippincott Williams & Wilkins.

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Introduction

Sphygmomanometry has evolved over nearly three centuries, but conventional sphygmomanometry, the technique with which we are all so familiar in clinical practice, was only introduced just over a century ago by Riva-Rocci [1]. As we enter the new millennium, however, a number of developments, not least the availability of accurate automated devices, herald the demise of so-called classic sphygmomanometry and the dawning of a new era in blood pressure measurement. This new age will see the introduction of innovative technologies that will allow not only the accurate non-invasive measurement of blood pressure, but also an assessment of blood pressure as a dynamic phenomenon, the effects of which are as dependent on the waveform and velocity characteristics as on the level of the pressure generated within the cardiovascular system.

The passing of the mercury sphygmomanometer should not in itself be a cause for concern. It might in fact be argued that the sooner we rid ourselves of this most inaccurate technique, on which we base so many important decisions of management, the better. This is not to blame the mercury sphygmomanometer but rather to impugn the most fallible part of the whole procedure – the human observer [2]. But if the mercury column is no longer available, what are the alternatives? In the past, aneroid sphygmomanometers were regarded as a reasonable substitute for mercury sphygmomanometers, but because they become inaccurate with use without the operator being aware of such inaccuracy, and because they have not been subjected to independent validation, they are not generally recommended [3]. Automated devices, in their many guises, have performed badly in validation studies in the past [4], but recently their record in this respect has been improving [5].

The Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) published its recommendations on blood pressure-measuring devices in the *British Medical Journal* in 2001 to guide the would-be purchaser through a complex market-place [5]. In this report, devices were assessed on the basis of published evidence of independent validation according to the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) protocols. The ESH is planning to update the *British Medical Journal* report at regular intervals on its website.

Validation standards

In 1987, the AAMI published a standard for sphygmomanometers that included a protocol for the evaluation of the accuracy of devices, this being followed in 1990 by the BHS protocol. Both protocols have since been revised [6,7], and as the two can be reconciled, the joint criteria are applied in most published validation studies [8]. The criteria for fulfilment of the BHS protocol are that the test devices must achieve at least grade B for systolic and diastolic pressure; the criteria for fulfilment of the AAMI protocol are that the test device must not differ from the mercury standard by a mean difference greater than 5 mmHg or a standard deviation greater than 8 mmHg.

Criteria for recommendation

The following criteria were used to designate devices according to accuracy in the *British Medical Journal* report [5]:

1. '*Recommended*' – a device that fulfils the AAMI criteria for both systolic and diastolic blood pressure and achieves a BHS grade B or A for both systolic and diastolic pressure.
2. '*Not recommended*' – a device that fails the AAMI criteria for either systolic or diastolic pressure and achieves a BHS grade C or D for either systolic or diastolic pressure.
3. '*Questionable recommendation*' – a device for which there is doubt about the strength of evidence, as may occur in the following circumstances:
   (a) when a device fulfils the criteria of one protocol but not the other, when it may be best not to recommend the device for clinical use until a confirmatory study has been performed;
   (b) when the validation results are presented in abstract form only without sufficient detail being available to appraise the methodology, when it may be preferable to withhold an opinion until the full results have been published or at least provided to a would-be purchaser by the manufacturer;
   (c) when the conditions of the protocols have not been fully adhered to (listed as 'protocol violation');
   (d) when a device fulfils the AAMI criteria for intra-arterial validation, when it may be best to await a validation against indirect blood pressure measurement before recommending the device for general clinical use; the BHS protocol does not advocate validation using direct intra-arterial measurement.

Table 1 Alternative to mercury sphygmomanometers

Validated	Non-validated
Modified OMRON HEM-705CP (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Greenlight 300
Modified A & DUA-767	Accusphyg
OMRON HEM-907 (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Finometer
Welch Allyn Vital Signs Monitor BPM-100	

Identification of devices

The *British Medical Journal* review was based on a follow-up of two previous surveys, and computerized search programs were used to identify validation studies in the literature up to December 1999. Blood pressure-measuring devices were divided into two broad categories: manual sphygmomanometers, which included mercury and aneroid devices, and automated sphygmomanometers, including devices for clinical use in hospitals, for self-blood pressure measurement and for ambulatory blood pressure measurement. With increasing pressure for a ban on mercury, a large market for alternatives to the mercury sphygmomanometer has been created. Some devices for the self-measurement of blood pressure have been successively modified for clinical use by increasing the length of tubing, and others are being developed but have not yet been validated; these devices are listed in Table 1.

Table 2 Manual devices that have been subjected to validation by the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI)*** protocols**

Device	AMI	BHS	Circumstance	Recommendation
PyMah Mercury (TRIMLINE Medical Products, Branchburg, New Jersey, USA)	Passed	A/A	At rest	Recommended
Hawksley RZS: US model (Hawksley & Sons Limited, Lancing, Sussex, UK)	Failed	B/D	At rest	Not recommended
Hawksley RZS: UK model (Hawksley & Sons Limited, Lancing, Sussex, UK)	Failed	C/D	At rest	Not recommended
Aneroid device	NA	Failed	In use; abstract only	Questionable recommendation

RZS, random zero sphygmomanometer; NA, not applicable.
Grades A–D according to the BHS protocol: A, best agreement with mercury standard; D, worst agreement with mercury standard.
**Criteria for fulfilment of BHS protocol: devices must achieve at least grade B/B.
***Criteria for fulfilment of AAMI standard: mean difference 5 mmHg, SD 8 mmHg.
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Table 3 **Automated blood pressure-measuring devices for clinical use in hospitals that have been subjected to validation by the British Hypertension Society (BHS)** and Association for the Advancement of Medical Instrumentation (AAMI)*** protocols [5]**

Device	Mode	AAMI	BHS	Circumstance	Recommendation
Datascope Accutorr Plus (Tascope Corp, Paramus, New Jersey, USA)	Osc	Passed	A/A	At rest	Recommended
CAS Model 9010 (CAS Medical Systems, Inc., Branford, Connecticut, USA)	Osc	Passed	NA	At rest in adults Neonates	Recommended Recommended
Tensionic Mod EPS 112	Osc	Passed	B/A	At rest; abstract only	Questionable recommendation
Colin Pilot 9200 (Colin Medical Instruments, San Antonio, Texas, USA)	Tonometry	Passed	NA	At rest; intra-arterial	Questionable recommendation
Dinamap 8100 (Johnson & Johnson Medical Inc., Tampa, Florida, USA)	Osc	Failed	B/D	At rest	Not recommended

Osc, oscillometric mode; NA, not applicable.
Grades A–D according to the BHS protocol: A, best agreement with mercury standard; D, worst agreement with mercury standard.
**Criteria for fulfilment of BHS protocol: devices must achieve at least grade B/B.
***Criteria for fulfilment of AAMI standard: mean difference 5 mmHg, SD 8 mmHg.

Manual (mercury and aneroid) sphygmomanometers

These devices are listed in Table 2 [5]. One model of the many mercury sphygmomanometers available, the PyMah (TRIMLINE Medical Products, Branchburg, New Jersey, USA), has been validated according to both protocols and was given the designation 'recommended'. As mercury sphygmomanometers generally adhere to a simple basic design with standard components, it is probably reasonable to assume that most, if not all, mercury sphygmomanometers will be of similar accuracy. The standard aneroid sphygmomanometer has been formally validated only recently according to the calibration procedure of the BHS protocol, the results supporting reservations concerning aneroid devices because of their susceptibility to becoming inaccurate with use without this being apparent to the user.

Automated sphygmomanometers

Devices for clinical use in hospital

These devices are listed in Table 3 [5].

Devices for self-measurement of blood pressure

There are a large number of automated devices for the self-measurement of blood pressure, virtually all of which use the oscillometric technique. These devices formerly used the automated inflation and deflation of a cuff applied to the upper arm over the brachial artery, although the technique has recently been used to measure blood pressure over the radial artery at the wrist, but as the devices become inaccurate if the arm is not kept at heart level during measurement, there is a reluctance to recommend them regardless of their accuracy [5]. Devices for measuring blood pressure by occluding a digital artery in the finger are also available, but because the problem of limb position is even more critical here and there is the additional problem of peripheral vasoconstriction affecting accuracy, this technique is no longer recommended, and these devices are not considered in this review.

Automated devices for upper arm measurement

These are listed in Table 4 [5].

Automated devices for wrist measurement

Such devices are listed in Table 5 [5]. They have been validated against brachial arterial measurements.

Devices for ambulatory blood pressure measurement

There are two techniques for measuring ambulatory blood pressure: the commonly used method of the intermittent measurement of blood pressure over the 24 h period, and the developing method of continuous waveform analysis.

Devices dependent on intermittent blood pressure measurement

These devices are listed in Table 6 [5]. Many have been validated in special groups, such as the elderly and pregnant women, and in differing circumstances, such as during exercise and in various postures.

Devices for continuous, non-invasive finger blood pressure monitoring

The Portapres (TNO, Amsterdam), a portable recorder for 24 h ambulatory monitoring, can provide beat-to-beat blood pressure monitoring that gives waveform measurements similar to intra-arterial recordings [5].

An automated alternative to mercury

From a review of the literature, it is evident that there are very many devices on the market and that the accuracy of most of these has not been determined. Furthermore, of those which have been evaluated, rather few have fulfilled the requirements of the BHS and AAMI validation protocols.

The manufacturers of blood pressure-measuring devices have failed to identify the need for reasonably priced, accurate automated devices in clinical practice, a need that becomes all the more acute with the impending

Table 4 Automated blood pressure-measuring devices for self-measurement of upper arm blood pressure that have been subjected to validation by the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI)*** protocols [5]**

Device	Mode	AAMI	BHS	Circumstance	Recommendation
Omron HEM-400C (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Failed	Failed	At rest	Not recommended
Philips HP5308	Aus	Failed	Failed	At rest	Not recommended
Philips HP5306/B	Osc	Failed	Failed	At rest	Not recommended
Healthcheck CX-5 060020	Osc	Failed	Failed	At rest	Not recommended
Nissei Analogue Monitor (IDT France, Perpignan, France)	Aus	Failed	Failed	At rest	Not recommended
Systema Dr MI-150	Osc	Failed	Failed	At rest	Not recommended
Fortec Dr MI-100	Osc	Failed	Failed	At rest	Not recommended
Philips HP5332]	Osc	Failed	C/A	At rest	Not recommended
Nissei DS-175 (IDT France, Perpignan, France)	Osc	Failed	D/A	At rest	Not recommended
Omron HEM-705CP (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	B/A	At rest	Recommended
Omron HEM 706 (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	B/C	At rest	Not recommended
Omron HEM 403C (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Failed	C/C	Protocol violation	Not recommended
Omron HEM-703CP (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	NA	Intra-arterial	Questionable recommendation
Omron M4 (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	A/A	Abstract only; detail missing	Questionable recommendation
Omron MX2 (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	A/A	Abstract only; detail missing	Questionable recommendation
Omron HEM-722C (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	NA	A/A	Protocol violation	Questionable recommendation
Omron HEM-722C [34]	Osc	Passed	A/A	Rest/elderly	Recommended
Omron HEM-735C (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	B/A	Rest/elderly	Recommended
Omron HEM-713C (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	B/B	At rest	Recommended
Omron HEM-737 Intellisense (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Osc	Passed	B/B	At rest	Recommended
Visomat OZ2	Osc	Passed	C/B	At rest	Not recommended

NB: in the first seven devices, grading criteria had not been established even though the BHS protocol was in operation.
Osc, oscillometric mode; Aus, auscultatory mode; NA, not applicable.
Grades A–D according to the BHS protocol: A, best agreement with mercury standard; D, worst agreement with mercury standard.
**Criteria for fulfilment of BHS protocol: devices must achieve at least grade B/B.
***Criteria for fulfilment of AAMI standard: mean difference 5 mmHg, SD 8 mmHg.

ban on mercury. Soundings from the manufacturing industry suggest that notice is now being taken of the requirement for an accurate automated device for hospital and general practice – or to put it another way, manufacturers are becoming aware of the enormous potential market that will exist if mercury sphygmomanometers are phased out. There is therefore an urgent need for those involved in the management of

Table 5 Automated blood pressure-measuring devices for the self-measurement of blood pressure at the wrist that have been subjected to validation by the British Hypertension Society (BHS) and Association of Advancement of Medical Instrumentation (AAMI)*** protocols [5]**

Device	AMI	BHS	Circumstance	Recommendation
Omron R3 (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	NA	C/C	At rest; protocol violation	Not recommended
	Fail	D/D	At rest	Not recommended
Boso-Mediwatch	NA	C/C	At rest; protocol violation	Not recommended
Omron Rx (Omron Healthcare, Inc. Vernon Hills, Illinois, USA)	Failed	B/B	At rest; abstract publication	Questionable recommendation

NA, not applicable.
Grades A–D according to the BHS protocol: A, best agreement with mercury standard; D, worst agreement with mercury standard.
**Criteria for fulfilment of BHS protocol: devices must achieve at least grade B/B.
***Criteria for fulfilment of AAMI standard: mean difference 5 mmHg, SD 8 mmHg.

Table 6 Ambulatory blood pressure-measuring devices that have been subjected to validation by the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI)*** protocols [5]**

Device	Mode	AAMI	BHS	Circumstance	Recommendation
Accutracker II (30/23) (Suntech Medical Instruments Inc., Raleigh, North Carolina, USA)	Aus	Passed	A/C	At rest	Not recommended
CH-DRUCK	Aus	Passed	A/A	At rest	Recommended
Daypress 500	Osc	Passed	A/B	At rest	Recommended
DIASYS 200 (Novacar, Saint-Antoine, Rueil-Malmaison, France)	Aus	Passed	C/C	At rest	Not recommended
DIASYS Integra (Novacar, Saint-Antoine, Rueil-Malmaison, France)	Aus	Passed	B/A	At rest	Recommended
	Osc	Passed	B/B	At rest	Recommended
ES-H531	Aus	Passed	A/A	At rest	Recommended
	Ocs	Passed	B/B	At rest	Recommended
Medilog ABP (Oxford Medical Ltd., Abingdon, Oxon, UK)	Aus	Passed	NA	At rest	Questionable recommendation
Meditech ABPM-04	Osc	Passed	B/B	At rest	Recommended
Nissei DS-240 (IDT France, Perpignan, France)	Osc	Passed	B/A	Abstract only; detail missing	Questionable recommendation
OSCILL-IT	Osc	Passed	C/B	At rest	Not recommended
Pressurometer IV (Del Mar Avionics, Irvine, California, USA)	Aus	Failed	C/D	At rest	Not recommended
Profilomat	Aus	Passed	B/A	At rest	Recommended
Profilomat*[53]	Aus	Passed	B/C	In pregnancy	Not recommended
Profilomat II	Osc	Failed	C/B	At rest	Not recommended
QuietTrak*[47–51]	Aus	Passed	B/B	At rest	Recommended
(Tycos Instruments Inc., Ardern, North Carolina, USA)	Aus	Passed	B/B	At rest; abstract	Questionable recommendation
	Aus	Failed	D/D	In pre-eclampsia	Not recommended
QuietTrak* [57]	Aus	Failed	B/B	In pregnancy	Not recommended
QuietTrak*[58]	Aus	Passed	A/A	At rest	Recommended
QuietTrak*[59]			A/A	During exercise	Recommended
			A/A	Different posture	Recommended
			A/A	In the elderly	Recommended
			A/A	In children	Recommended
			A/A	In pregnancy	Recommended
Save 33, Model 2 (Save 33 Electonique Micale, Bruay Sur Escaut, France)	Osc	Passed	B/B	At rest	Recommended
Schiller BR-102 (Schiller AG, Baar, Switzerland)	Aus	Passed	B/B	At rest	Recommended
	Osc	Failed	D/B	At rest	Not recommended
SpaceLabs 90202 (SpaceLabs Medical Inc., Redmond, Washington, USA)	Osc	Passed	B/B	At rest	Recommended
SpaceLabs 90207 (SpaceLabs Medical Inc., Redmond, Washington, USA)	Osc	Passed	B/B	At rest	Recommended
	Osc	Passed	A/C	In pregnancy	Not recommended
((SpaceLab SpaceLabs 90207 [64]	Osc	Passed	B/B	In pregnancy	Recommended
SpaceLabs 90207 [65]	Osc	Passed	B/C	In pregnancy	Not recommended
SpaceLabs 90207 [53]	Osc	Failed	D/D	In pre-eclampsia	Not recommended
SpaceLabs 90207 [57]	Osc	Passed	C/C	In pre-eclampsia	Not recommended
SpaceLabs 90207 [66]	Osc	SBP pass	D	In children	Not recommended
SpaceLabs 90207 [67]		DBP fail	D	In children	Not recommended
SpaceLabs 90207[68]	Osc	Passed	A/B	Elderly standing and sitting SBP 160 mmHg	Recommended
SpaceLabs 90207 [69]	Osc	Passed	A/D	Elderly supine over all pressures	Not recommended
	Osc	Passed	C/B	During haemodialysis	Not recommended
SpaceLabs 90217 (SpaceLabs Medical Inc., Redmond, Washington, USA)	Osc	Passed	A/A	At rest	Recommended
TM-2420/TM-2020	Osc	Failed	D/D	At rest	Not recommended
TM-2420 Model 6	Osc	Passed	B/B	At rest	Recommended
TM-2420 Model 7	Osc	Passed	B/B	At rest	Recommended
TM-2421	Osc	Passed	B/A	At rest	Recommended
Takeda 2421 [76]	Osc	NA	C/C	In children and in different postures	Not recommended
	Aus	NA	A/B		Questionable recommendation [67]
Takeda 2430	Osc	Passed	A/A	At rest	Recommended

Osc, oscillometric mode; Aus, auscultatory mode; NA, not applicable; SBP, systolic blood pressure; DBP, diastolic blood pressure.
Grades A–D according to the BHS protocol: A, best agreement with mercury standard; D, worst agreement with mercury standard.
**Criteria for fulfilment of BHS protocol: devices must achieve at least grade B/B.
***Criteria for fulfilment of AAMI standard: mean difference 5 mmHg, SD 8 mmHg.

hypertension to impress upon purchasing officers in the health services (whose responsibility it will be to order automated devices to replace traditional sphygmomanometers) that protocols are in existence for validating blood pressure devices and that evidence of independent validation should be demanded from manufacturers.

Soundings from hospital authorities suggest that there is currently a tendency to substitute aneroid for mercury sphygmomanometers without evidence of the accuracy of these devices, especially after a period of time in use. Moreover, aneroid sphygmomanometry is prone to all the problems of the auscultatory technique, namely observer bias and terminal digit preference. Automated devices, by providing timed print-outs of blood pressure, remove these sources of error and thereby improve the overall accuracy of measurement, provided of course that they themselves are accurate.

Automation is obviously not without its problems. As already mentioned, automated devices have been notorious for their inaccuracy [4], and although accurate devices are now appearing on the market, they are not yet designed for hospital use, and their accuracy after a period of time in such use has not been established. Moreover, without the mercury standard against which to compare measurements generated by an algorithmic interpretation of blood pressure, clinicians will become dependent on the consistency and accuracy of such algorithms. It will therefore be necessary to retain the mercury sphygmomanometer in certain laboratories as the gold standard against which algorithms may be checked from time to time.

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