Automated blood pressure measurement: state of the market in 1998 and the need for an international validation protocol for blood pressure measuring devices

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The market for blood pressure measuring devices is increasing rapidly. A vast market for self-measuring devices has existed for many years and this continues to grow. There is also a large market for automated devices in specialized hospital areas, such as operating theatres and intensive care units. Since the introduction of ambulatory blood pressure monitoring into clinical practice, a growing market for.devices to measure blood pressure over time has been created. The states of these three markets are reviewed in this paper.

With the likely banning of mercury from clinical use, the traditional sphygmomanometer will disappear and it is inevitable that a new and large market will be created by the demand for an automated alternative to the mercury sphygmomanometer in hospitals and in general practice. It is mandatory that such automated devices are validated independently for accuracy and performance.

At present two validation protocols are widely used to test the accuracy of blood pressure measuring devices – the British Hypertension Society and the Association' for the Advancement of Medical Instrumentation protocols. These protocols have a common purpose and many similarities. It is proposed that a common protocol should be devised for international use. Experience with these protocols allows one to make suggestions concerning how such an international protocol might be simplified and improved. Blood *Press Monit* 3:205–211

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Introduction

When the technique of blood pressure measurement was introduced into clinical medicine during the early years of this century, the importance of accuracy and the limitations of the technique were well recognized [1]. However, the standards called for by the clinicians and scientists who pioneered the technique were relaxed as the 20th century progressed. Now, once again, the methodology of blood pressure measurement both in clinical practice and in research into hypertension is recognized to be a cause for concern [2]. The importance of accurate devices has been voiced more strongly in recent years by individuals involved in research into hypertension, as is evident from the growing number of publications on the subject [3].

During the 1960s and 1970s, individual groups, frustrated by the failure of manufacturers to produce evidence to match their claims, began to validate blood pressure measuring systems according to a variety of protocols and so illustrated the need for independent validation of devices [4]. However well-intentioned such protocols may have been, they had the serious disadvantage of not permitting comparison of one device against- another because of the differing methodologies of validation [5].

In 1987, the Association for the Advancement of Medical Instrumentation (AAMI) published a standard for electronic or automated sphygmomanometers that included a protocol for the evaluation of the accuracy of devices [6] and this was followed in 1990 by the protocol of the British Hypertension Society (BHS) [7]. These protocols, which differed in detail, had a common objective, namely the

standardization of validation to establish minimum standards of accuracy and performance and to facilitate comparison of one device with another [8]. Both protocols have since been revised [9,10]. Although other countries, such as Germany [11] and Australia [12], have included recommendations for testing the accuracy of blood pressure measuring devices in their national standards, no validation studies using these protocols had been published until 1997, when one validation study performed according to the protocol 58130 of the German Institute of Validation was published [13]. Ng and Small [14,15] and Ng [16] have reviewed the differences among national protocols for validation in considerable detail.

State of the market for automated devices in 1998

Automated devices for self-measurement of blood pressure

There is an enormous market for automated devices that permit self-measurement of blood pressure. In Germany, for example, 12 million such devices are sold annually [13]. In 1994, Ng and Small [17] surveyed 423 automated devices, of which 161 were for the self-measurement of blood pressure. Only a fraction of the many hundreds of models available world-wide are subjected to independent validation. A review of the literature in 1998 to determine which automated devices for self-measurement of blood pressure had been validated according to the Bf-IS and AAMI protocols shows that 13 such devices had been validated, of which four were deemed satisfactory, according to the criteria of the BI IS and/or AAMI protocols. 1 lowever, if the intra-arterial comparisons of the AAMI protocol and the new German protocol 'are accepted, a further two devices can be added (Table 1).

In the first validation study in 1989 using an early version of the BHS and AAMI protocols, all seven devices tested (the Omron HEM-400C, Philips HP.5308, Healthcheck 'Cuffless' CX-5 060020, Nissei analogue monitor, Philips HP5306/B, Systema Dr MI-150 and Fortec Dr MI-100) failed to fulfil the accuracy criteria of either protocol, whereas the mercury sphygmomanometer was comfortably within the criteria of both protocols [19]. The Omron company is the first manufacturer of devices for self-measurement of blood pressure to have produced a device fulfilling the requirements of the BHS and AAMI protocols, insofar as we are aware. The Omron HEM-705CP achieved acceptable-grades of B for systolic blood pressure and A for diastolic blood pressure according to the BHS criteria and fulfilled the accuracy criteria of the AAMI protocol, whereas in the same study the Philips HP5332 and the Nissei DS-175 achieved unacceptable BHS grades and failed the AAMI criteria for accuracy [18]. In another study, the Omron HEM 706 achieved BHS grades B and C in the overall pressure range and fulfilled the AAMI accuracy criteria [20]. The Omron HEM 403C has also been evaluated according to the BHS protocol but the protocol was violated by substitution of the 1 lawksley random-zero sphygmomanometer for the standard mercury sphygmomanometer [21]. As our group has shown, devices assessed against the Hawksley sphygmomanometer may be disadvantaged and the C grades obtained both for systolic and for diastolic blood pressure with the Omron HEM 403C are at best questionable [22]. Recently, the Omron M4 and Omron MX2 achieved A-grades according to the BHS protocol and also fulfilled the AAMI criteria [23]. Another device, the DynaPulse 200m fulfilled the 1987 AAMI criteria [24]. The AAMI protocol permits direct intra-arterial comparison with a small number of subjects [Y], whereas the BHS protocol does not allow intra-arterial comparison for a number of reasons, the most important of which is that systolic and diastolic blood pressure values obtained by the direct

Table 1 **Automated blood pressure measuring devices for self-measurement available on the market which have been subjected to validation by the British Hypertension Society (BHS)[a] and Association for the Advancement of Medical instrumentation (AAMI)[b] protocols**

Device	Mode	AAMI	BHS	Circumstance
Omron HEM-400C [18]	Oscillometric	Failed	Failed	Rest
Philips HP5306 [18]	Auscultatoiy	Failed	Failed	Rest
Healthcheck CX-5 060020 [18]	Oscillometric	Failed	Failed	Rest
Nissei Analogue Monitor [18]	Auscultatory	Failed	Failed	Rest
Philips HP5306/B [18]	Oscillometric	Failed	Failed	Rest
Systema Dr MI-1 50 [18]	Oscillometric	Failed	Failed	Rest
Fortec Dr MI-1 00 [18]	Oscillometric	Failed	Failed	Rest
Omron HEM-705CP [19]	Oscillometric	Passed	B/A	Rest
Philips HP5332 [19]	Oscillometric	Failed	CIA	Rest
Nissei DS-175 [19]	Oscillometric	Failed	DIA	Rest
Omron HEM 706 [20]	Oscillometric	Passed	B/C	Rest
Omron HEM 403C [21]	Oscillometric	Passed	??	Protocol violation
Omron HEM-703CP [25]	Oscillometric	Passed	NA	Intra-arterial
Omron R3 [13]	Wrist	Passed	NA	Intra-arterial/German
Omron M4 [23]	Oscillometric	Passed	A/A	Rest
Omron MX2 [23]	Oscillometric	Passed	A/A	Rest
DynaPulse 200m [24]	Oscillomelric	Passed	NA	Rest

Grades A-D according to BHS protocol; A, best agreement, D, worst agreement with mercury standard. Note that for the first seven devices grading criteria had not been established even though BHS protocol was in operation. "For fulfilment of BHS protocol devices must achieve at least grade B/B. [b]For fulfilment of AAMI standard mean difference must be ≤ 5 and SD ≤ 6 mmHg. NA, not applicable.

technique are different from measurements by indirect methods and clinical practice derives from data obtained by the indirect rather than the direct technique [10]. Using intra-arterial comparison, the Omron HEM-703CP was shown to fulfil the criteria of the AAMI protocol [25]. The German protocol for validation also permits intra-arterial comparisons and, using this protocol [11], the Omron R3, a device that measures blood pressure oscillometrically on the wrist, has fulfilled the protocol's requirements [13]. It is estimated that wrist measuring devices have gained 50% of the market share of the 1.2 million blood pressure devices sold annually in Germany for self-measurement of blood pressure [13].

Automated devices for measurement of ambulatory blood pressure

A review of the state of the market for ambulatory blood pressure measuring devices in 1995 showed that, of 43 devices on the market, 18 had been validated according to the protocol either of the AAMI or of BHS and, of these, nine had failed to adhere to the protocols thereby rendering the results questionable, and a further nine devices fulfilled their requirements [4]. A further review of the literature in 1998 has yielded 25 validation studies performed on 16 ambulatory systems according to the BHS and AAMI protocols, of which 12 devices fulfilled the criteria for one protocol or both (Table 2). These are the A&D TM 2420 Models 6 and 7 and TM 2421, CH-Druck, Daypress 500, DIASYS Integra, Nissei ABPM DS-240, Profilomat, QuietTrak, Schiller BR, SpaceLabs SL-90202 and SpaceLabs SL-90207 [26–49]. It is interesting and commendable to note that many of these devices have now been validated for varying populations, such as the elderly and pregnant women, and under special circumstances, such as with subjects in varying postures and during exercise.

Automated devices for specialized hospital use

Many automated devices for use in specialized areas of hospitals, such as operating theatres and intensive care units, and during the transport of patients are available, but these are rarely subjected to independent validation studies. Ng [16] has reviewed the operational methodology and listed 258 such devices. A review of the literature in 1998 indicates that only two devices designed primarily for specialized hospital use (though these devices may be applied to other uses, such as epidemiological studies) have been validated according to the BHS

Table 2 Automated devices **for ambulatory blood pressure measurement available on the market that have been subjected to validation by the British Hypertension Society (BHS)[a] and Association for the Advancement of Medical Instrumentation (AAMI)[b] protocols**

Device	Mode	AAMI	BHS	Circumstance
Accutracker II (30/23) [26]	Auscultatory	Passed	A/C	Rest
CH-DRUCK (103)[c] [27]	Auscultatory	Passed	A/A	Rest/pressure ranges
Daypress 500 [28]	Oscillometric	Passed	A/B	Rest
DIASYS 200 [29]	Auscultatory	Passed	C/C	Rest
DIASYS Integra [30]	Auscultatory	Passed	B/A	Rest/pressure ranges
	Oscillomelric	Passed	BIB	Rest/pressure ranges
Nissei OS-240 [31]	Oscillometric	Passed	BIA	Rest
Profilomat" [32]	Auscultatory	Passed	BIA	Rest/pressure ranges
Profilomat[c] [33]	Auscultatory	Passed	B/C	Pregnancy
Profilomat II [34]	Oscillometrio	Failed	D/C	Rest/pressure ranges
QuietTrak[c] [35,36]	Auscultatory	Passed	BIB	Rest
QuietTrak[c] [37]	Auscultatory	Failed	BIB	Pregnancy
QuietTrak[c] [38]	Auscultatory	Passed	A/A	Rest
				Exercise
				Posture
				Elderly
				Children
				Pregnancy
Schiller BR [39]	Auscultatory	Passed	B/B	Rest/pressure ranges
	Oscillomelric	Failed	D/B	Rest/pressure ranges
SpaceLabs 90202 [40]	Oscillometric	Passed	B/B	Rest
SpaceLabs 90207 [41]	Oscillometric	Passed	BIB	Rest/pressure ranges
SpaceLabs 90207 [42]	Oscillometric	Passed	A/C	Pregnancy
SpaceLabs 90207 [43]	Oscillometric	Passed	BIB	Pregnancy
SpaceLabs 90207 [44]	Oscillometrio	Passed	B/C	Pregnancy
SpaceLabs 90207 [45]	Oscillometrio	SBP passed	C	Children
		'DBP failed	D	Children
SpaceLabs 90207 [46]	Oscillometric	Passed	A/C	Elderly
				Posture
TM-2420 model 5 [47]	Oscillometric	Passed	C/C	Rest
TM 2420 model 6 [48]	Oscillometric	Passed	B/B	Rest
TM 2420 model 7 [48]				
TM-2421 [49]	Oscillometric	Passed	B/A	Rest

Grades A-D according to BHS protocol; A, best agreement, D, worst agreement with mercury standard. "For fulfilment of BHS protocol devices must achieve a! least grade B/B. [b]For fulfilment of AAMI standard mean difference must be ≤5 and SD ≤8 mmHg. NA, not applicable. "Model number not denoted. SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 3 Automated blood pressure measuring devices for specialized hospital use available on the market that have been subjected to validation by the British Hypertension Society (BHS)[a] and Association for the Advancement of Medical Instrumentation (AAMI)[b] protocols

Device	Mode	AAMI	BHS	Circumstance
Dinamap model 8100 [50,51]	Oscillometric	Failed	BID	Rest
Colin Pilot 9200 [52]	Tonometric	Passed	NA	Intra-arterial

Grades A-D according to BHS protocol; A, best agreement. D, worst agreement with mercury standard. [a]For fulfilment of BHS protocol devices must achieve at least grade B/B; [b]For fulfilment of AAMI standard mean difference must be ≤5 and SD ≤8 mmHg. NA, not applicable.

and AAMI protocols. The Dinamap portable monitor, model 8100, one of the most popular automated devices in use in clinical practice and hypertension research, despite there having been reports demonstrating its inaccuracy, achieved an acceptable Grade B for systolic blood pressure (66% of blood pressures being within 5 mmHg of the mercury sphygmomanometer's value) but an unacceptable D grade for diastolic blood pressure, less than 50% of blood pressures being within 5 mmHg of the mercury standard's values, using the BHS protocol. The device failed the AAMI accuracy criteria for diastolic blood pressure [50,51]. The AAMI protocol provides for intra-arterial validation of blood pressure measuring devices and using intra-arterial comparisons, the Colin Pilot 9200, a multiparameter monitor of vital signs, fulfilled the accuracy criteria of the protocol [52] (Table 3).

Banning of mercury and creation of demand for an automated 'clinical' sphygmomanometer

After a century of clinical use, the mercury sphygmomanometric technique of blood pressure measurement is under threat. Three important occurrences may be implicated in heralding the demise of the traditional Riva Rocci/Korotkoff technique of blood pressure measurement: mercury is likely to be banned from hospital use because it is toxic (it has already been banned from medical use in Scandinavian countries and the Netherlands); accurate automated devices to replace the mercury sphygmomanometer are now available; and, with the advent of 24 h ambulatory blood pressure measurement into clinical practice, more reliance is being placed on behaviour of blood pressure than on casual measurement of blood pressure levels. Moreover, it is now recognized that, although the mercury sphygmomanometric technique has served us well, it is inherently fraught with many sources of error, paramount among which are the biases and inaccuracies introduced by the observer.

These considerations lead to the almost inevitable conclusion that it is only a matter of some short time before the Riva Rocci/Korotkoff technique disappears from clinical practice. This being so, it is likely that the millimetre of mercury (mmHg) will in time be replaced by the Système Internationale kilopascal (kPa) as the unit of measurement for blood pressure. The argument that clinical practice would be adversely affected by such a change in unitage will be no stronger than that voiced when Système Internationale units were introduced to other measurements affecting clinical practice [53–55].

The message would therefore seem to be that we should begin to prepare for inevitable change. Perhaps a first step might be that when our mercury sphygmomanometers need replacement, we should opt for an accurate independently validated automated device. Manufacturers of automated devices should provide both the mmHg and kPa scales so that we may begin to familiarize ourselves with the latter in anticipation that it will ultimately be adopted as the unit for measurement of blood pressure in medicine.

The disappearance of the traditional sphygmomanometer will create a large market for an alternative device. Aneroid sphygmomanometers traditionally have been the alternative to the mercury device, but aneroid sphygmomanometers become inaccurate with use without the operator being aware of such inaccuracy [3]. Automated devices, which are dependent on an algorithm, cannot develop inherent inaccuracy, though the device can fail to function for other reasons. Efforts to encourage the development of an accurate automated device suitable for use in the hospital environment and general practice are presently being made. (Personal communication from 'Working Party on Blood Pressure Measurement of the BHS). Obviously, independent validation of an automated substitute for the traditional mercury sphygmomanometer in hospital use will be mandatory.

Need to simplify validation protocols

In striving for methodologies that: best test the accuracy of blood pressure measuring devices, both the BHS and the AAMI have designed protocols that are complex, lengthy and expensive to perform. With the experience derived from nearly a decade of using these protocols, there is now evidence demonstrating that a revised common protocol could be simplified in some areas and expanded in others with an overall rationalization of the methodological procedures [56–58].

The most fallible component in blood pressure measurement is the human observer. The traditional technique of measuring blood pressure does not allow the result of the measurement to be checked by independent observers, thereby leaving the method open to bias. The

Sphygmocorder, in which a number of components used to measure blood pressure have been combined with audio-visual recording technology to produce a system that provides recorded data of the comparative measurements and removes the expensive need to employ observers throughout the validation procedure, has greatly facilitated validation of devices (56,571.

Reducing the number of subjects required for validation would simplify the procedure greatly and there is now sufficient data from the many validation studies performed for one to review the number of subjects required [58]. The use of simulators to augment the comparative measurements also shows promise as a means of reducing the number of hypertensive subjects presently demanded by the protocols [14,15,59–61].

Need for a common protocol for validation

Experience with the AAMI and BHS protocols has provided valuable insight into the methodological problems associated with validation of devices [62–66]. The two protocols have many similarities but there are some important differences. These differences merit consideration in order to make things easier for manufacturers seeking to validate devices for acceptance both in Europe and in the USA. Of the two protocols, the BHS protocol is the more elaborate in that it takes particular care to ensure that observers are trained to a very high standard, it makes provision for validation with special groups and it also makes recommendations for in-use validation of all devices. By making modifications to the BHS protocol, it is possible to perform validations of blood pressure measuring devices (with the exception of ambulatory devices, which require special consideration) that satisfy the criteria of both protocols [67,68]. It has been demonstrated in practice that validation studies can be performed in such a way as to fulfil the criteria of both protocols. It would seem timely, therefore, for the AAMI and BHS to join together in producing a revised common protocol for the validation of blood pressure measuring devices that might be acceptable as an international protocol.

Just a decade ago a group of physicians and researchers with an interest in blood pressure measurement, in particular, in the measurement of blood pressure during daily activity, perceived a need for consensus on a number of issues, most especially those relating to ambulatory blood pressure measurement. Such have been the advances in the development of blood pressure measurement in general that the group has recognized the need to formalize its structure, so the group has been established as an official working party of the European Society of Hypertension. It is proposed that the group will seek to become affiliated to the International Society of Hypertension and the American Society of Hypertension [69]. One of the objectives of this group is to investigate the possibility of having a common protocol that would be accepted as the international standard for the validation of blood pressure measuring devices. Such a protocol would be welcomed by manufacturers and by those involved in performing validation procedures.

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