

## Blood pressure measuring devices: recommendations of the European Society of Hypertension

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There is a large market for blood pressure measuring devices not only in clinical medicine but also among the public where the demand for self measurement of blood pressure is growing rapidly. For consumers, whether medical or lay, accuracy should be of prime importance when selecting a device to measure blood pressure. However, most devices have not been evaluated for accuracy independently using the two most widely used protocols: the British Hypertension Society (BHS) protocol and the standard set by the US Association for the Advancement of Medical Instrumentation (AAMI).<sup>1,2</sup> The Working Group on Blood Pressure Monitoring of the European Society of Hypertension has decided to review blood pressure measuring devices regularly to guide purchasers.<sup>3</sup> For this first report devices for which there is published evidence of independent validation using these protocols have been surveyed. Because most blood pressure devices have not been independently validated, only a fraction of the many devices available have been surveyed. Devices that have been validated recently for which results have not yet been published were not included, but this shortcoming should be addressed in future.

### Methods

#### Validation standards

In 1987, the American Association for the Advancement of Medical Instrumentation published a standard for sphygmomanometers which included a protocol for evaluating the accuracy of devices.<sup>4</sup> In 1990 a protocol was devised by the British Hypertension Society.<sup>5</sup> Both protocols have since been revised.<sup>1,2</sup> Since the two protocols can be reconciled the joint criteria are applied in most validation studies.<sup>6</sup> The criteria for fulfilling the BHS protocol are that devices must achieve at least grade B (where A denotes greatest agreement with mercury standard and D denotes least agreement) for systolic and for diastolic pressures (table 1); the criteria for fulfilling the AAMI protocol are that the test device must not differ from the mercury standard by a mean difference > 5 mm Hg or a standard deviation > 8 mm Hg.<sup>2</sup>

#### Criteria for recommendation

The following criteria have been used to designate devices according to accuracy. A device is classed as

### Summary points

Two manual sphygmomanometers have been validated, one is recommended

Five devices for clinical use in hospitals have been validated, two are recommended

23 devices for self measurement of blood pressure have been validated, five are recommended

24 devices for ambulatory measurement of blood pressure have been validated, 16 are recommended

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recommended if it fulfils the AAMI criteria for both systolic and diastolic pressures (denoted as passed) and received a grade of A or B under the BHS protocol for both systolic and diastolic blood pressures. A device is not recommended if it fails the AAMI criteria for either systolic or diastolic pressure and achieves a grade of C or D for either systolic or diastolic pressure under the BHS protocol. A questionable recommendation is made when there is doubt about the strength of evidence. This may occur when a device fulfils the criteria of one protocol but not the other, and it may be best not to recommend the device for clinical use until a confirmatory study has been performed; when the

**Table 1** Grading criteria used by the British Society of Hypertension.<sup>1</sup> Grades represent the cumulative percentage of readings falling within 5 mm Hg, 10 mm Hg, and 15 mm Hg of the mercury standard. All three percentages must be greater than or equal to the values shown for a specific grade to be awarded. Values are mm Hg

Grade	Absolute difference between standard and test device (%)		
	≤5	≤10	≤15
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

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validation results were presented only in an abstract without sufficient detail to appraise the methodology, and it may be best to withhold an opinion until the full results have been published or at least provided to a potential purchaser by the manufacturer; when the conditions of the protocols have not been fully adhered to (listed as a protocol violation in our scheme); or when a device fulfils the AAMI criteria for intra-arterial validation (the BHS protocol does not advocate validation using direct intra-arterial measurement<sup>1</sup>), but it may be best to await a validation against indirect blood pressure measurement before recommending the device for general clinical use.

**Identification of devices**

This review was based on two previous surveys (which should be consulted for early validation studies that are not reproduced in this review),<sup>7, 8</sup> and computerised search programs were used to identify validation studies in the literature published up to December 1999. Blood pressure measuring devices were divided into two broad categories: manual sphygmomanometers, which include mercury and aneroid devices; and automated sphygmomanometers, which include devices for clinical use in hospitals, for self measurement of blood pressure, for ambulatory blood pressure measurement, and for measuring blood pressure in community settings. (Information on manufacturers appears on the *BMJ's* website.)

**Table 2** Manual blood pressure measuring devices validated using the protocols of the Association for the Advancement of Medical Instrumentation and the British Hypertension Society

Device	Protocol		Use	Recommendation
	AAMI*	BHS (systolic/diastolic)†		
PyMah mercury <sup>9</sup>	Passed	A/A	At rest	Recommended
Hawksley RZS (US model) <sup>10, 11</sup>	Failed	B/D	At rest	Not recommended
Hawksley RZS (UK model) <sup>10, 11</sup>	Failed	C/D	At rest	Not recommended
Aneroid device <sup>12</sup>	NA	Failed	At rest; only abstract available	Questionable recommendation

AAMI=Association for the Advancement of Medical Instrumentation; BHS=British Hypertension Society; RZS=random zero sphygmomanometer; NA=not applied.  
\*To meet AAMI criteria the mean difference between the device and the mercury standard must be ≤5 mm Hg or the standard deviation must be ≤8 mm Hg.  
†To meet BHS criteria devices must achieve a grade of at least B for both systolic and diastolic measurements. Grade A denotes greatest agreement with mercury standard and D denotes least agreement.

**Table 3** Automated blood pressure measuring devices for clinical use in hospitals validated using the protocols of the Association for the Advancement of Medical Instrumentation and the British Hypertension Society. Devices were validated in oscillometric mode unless otherwise indicated

Device	Protocol		Use	Recommendation
	AAMI*	BHS (systolic/diastolic)†		
Datascope Accutorr Plus <sup>17</sup>	Passed	A/A	At rest	Recommended
CAS Model 9010 <sup>18</sup>	Passed	NA	At rest in adults In neonates	Recommended
Tensionic Mod EPS 112 <sup>18</sup>	Passed	B/A	At rest; only abstract available	Questionable recommendation
Colin Pilot 9200 <sup>19</sup> (tonometric mode)	Passed	NA	At rest; intra-arterial	Questionable recommendation
Dinamap 8100 <sup>20, 21</sup>	Failed	B/D	At rest	Not recommended

AAMI=Association for the Advancement of Medical Instrumentation; BHS=British Hypertension Society; NA=not applied.  
\*To meet AAMI criteria the mean difference between the device and the mercury standard must be ≤5 mm Hg or the standard deviation must be ≤8 mm Hg.  
†To meet BHS criteria devices must achieve a grade of at least B for both systolic and diastolic measurements. Grade A denotes greatest agreement with mercury standard and D denotes least agreement.

**Results**

**Manual sphygmomanometers**

These devices are listed in table 2.<sup>9-12</sup> One model of the many mercury sphygmomanometers available, the PyMah (PyMah Corporation, Flemington, NJ), has been validated according to both protocols and is recommended.<sup>9</sup> Because mercury sphygmomanometers are generally of a simple basic design with standard components, it is probably reasonable to assume that most would be of similar accuracy. The standard aneroid sphygmomanometer has only been formally validated according to the calibration procedure of the BHS protocol,<sup>12</sup> and the results support reservations about aneroid devices because they are susceptible to becoming inaccurate without this being apparent to the user.<sup>13</sup>

**Automated sphygmomanometers**

*Devices for use in hospitals*

Devices for clinical use in hospitals are listed in table 3.<sup>14-18</sup>

*Devices for self measurement of blood pressure*

There are a large number of automated devices for self measurement of blood pressure, virtually all of which use the oscillometric technique. Formerly these devices used automated inflation and deflation of a cuff applied to the upper arm over the brachial artery. Recently this technique has been used to measure blood pressure over the radial artery at the wrist, but since these devices become inaccurate if the arm is not kept at heart level during measurement, the working group is reluctant to recommend them regardless of accuracy.<sup>19</sup> Devices that measure blood pressure by occluding a digital artery in the finger are also available, but because the problem of limb position is even more critical and there is the additional problem of peripheral vasoconstriction affecting accuracy, this technique is no longer recommended. These devices have not been considered in this review.<sup>19</sup>

Automated devices for upper arm measurement are shown in table 4.<sup>9, 20-29</sup> Automated devices for wrist measurement are listed in table 5.<sup>29-32</sup> These have been validated against brachial arterial measurements.

*Devices for ambulatory measurement of blood pressure*

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

*Intermittent measurement*—Devices dependent on intermittent measurement are listed in table 6.<sup>33-68</sup> Many of these devices have been validated for use in specific groups, such as elderly people and pregnant women, and in differing circumstances, such as during exercise and in different postures. Validating devices for use in ambulatory conditions presents many methodological difficulties, and some evidence suggests that inaccuracies found during static conditions may be amplified in ambulatory conditions.<sup>69</sup>

*Devices for continuous non-invasive blood pressure monitoring of a finger*—The Portapres (TNO, Amsterdam), a portable recorder for 24 hour ambulatory monitoring, can provide beat to beat monitoring which

gives waveform measurements similar to intra-arterial recordings. However, the technique is subject to various inaccuracies, which the use of correction factors and digital filters in the latest model may remove; this model is awaiting formal validation.<sup>70 71</sup>

#### *Devices for measuring blood pressure in a community setting*

There is little information available on the accuracy of automated devices that are installed in public retail areas—such as pharmacies, supermarkets, health clinics, and companies in a variety of industries—which permit the public to measure blood pressure without charge in an unsupervised, crowded setting with high ambient noise. Evaluations of one such device, the Vita Stat 90550 (Spacelabs Medical, Redmond, WA), have had conflicting results.<sup>72 73</sup>

## Discussion

Manufacturers of blood pressure measuring devices use innovative technology to provide an array of systems that can analyse, store, and display features of a haemodynamic variable in ways that would have been beyond the dreams of the pioneers of the technique. Although the selection of a blood pressure measuring device may be influenced by many factors, a fundamental requirement must be that it gives accurate measurements; too often accuracy has been sacrificed for technological ingenuity.

The evidence from validation studies is accumulating, and devices are being scrutinised more critically; this has been the case with ambulatory devices used in specific populations, such as in children, elderly people, and pregnant women. However, the evidence is not always clear cut. There may have been protocol violations; the data published may have been inadequate, such as sometimes occurs when only abstracts have been published; and there may be disagreement between validation studies of the same device. None the less certain recommendations can be made to assist potential purchasers.

In interpreting the recommendations made by this survey the following factors should be considered. A device fulfilling the AAMI criteria and graded A or B for both systolic and diastolic pressure under the BHS protocol has been recommended on grounds of accuracy without equivocation; one that fails the AAMI protocol for either systolic or diastolic pressure and has a grade of C or D for either systolic or diastolic pressure under the BHS protocol cannot be recommended on the grounds of accuracy. Devices are given a questionable recommendation if there is an element of doubt in interpreting the results of a validation study. One circumstance that a purchaser should also consider, but for which we cannot make a recommendation, is the occasional conflict that arises when a device fulfils the criteria of the protocols when validated at one centre but not another. When this occurs the details of the methodology may need to be scrutinised to determine if differences in the selection of participants, for example, might explain the conflict; it may be best to await the results of a confirmatory study before deciding whether the device is accurate.

Only a fraction of the devices available worldwide have been independently validated. This is especially

**Table 4** Automated blood pressure measuring devices for self measurement at the upper arm validated using the protocols of the Association for the Advancement of Medical Instrumentation and the British Hypertension Society. For the first seven devices grading criteria had not been established although the British protocol was in use.<sup>13</sup> Devices were validated in oscillometric mode unless otherwise indicated

Device	Protocol		Use	Recommendation
	AAMI*	BHS (systolic/diastolic)†		
Omron HEM-400C <sup>9</sup>	Failed	Failed	At rest	Not recommended
Philips HP5308 (auscultatory mode) <sup>9</sup>	Failed	Failed	At rest	Not recommended
Philips HP5306/B <sup>9</sup>	Failed	Failed	At rest	Not recommended
Healthcheck CX-5 060020 <sup>9</sup>	Failed	Failed	At rest	Not recommended
Nissei analogue monitor (auscultatory mode) <sup>9</sup>	Failed	Failed	At rest	Not recommended
Systema Dr MI-150 <sup>9</sup>	Failed	Failed	At rest	Not recommended
Fortec Dr MI-100 <sup>9</sup>	Failed	Failed	At rest	Not recommended
Philips HP5332 <sup>20</sup>	Failed	C/A	At rest	Not recommended
Nissei DS-175 <sup>20</sup>	Failed	D/A	At rest	Not recommended
Omron HEM-705CP <sup>20</sup>	Passed	B/A	At rest	Recommended
Omron HEM-706 <sup>21</sup>	Passed	B/C	At rest	Not recommended
Omron HEM-403C <sup>22</sup>	Failed	C/C	Protocol violation	Not recommended
Omron HEM-703CP <sup>23</sup>	Passed	NA	Intra-arterial	Questionable recommendation
Omron M4 <sup>24</sup>	Passed	A/A	Only abstract available; details missing	Questionable recommendation
Omron MX2 <sup>24</sup>	Passed	A/A	Only abstract available; details missing	Questionable recommendation
Omron HEM-722C <sup>25</sup>	NA	A/A	Protocol violation	Questionable recommendation
Omron HEM-722C <sup>26</sup>	Passed	A/A	At rest in elderly people	Recommended
Omron HEM-735C <sup>26</sup>	Passed	B/A	At rest in elderly people	Recommended
Omron HEM-713C <sup>27</sup>	Passed	B/B	At rest	Recommended
Omron HEM-737 Intellisense <sup>28</sup>	Passed	B/B	At rest	Recommended
Visomat OZ2 <sup>29</sup>	Passed	C/B	At rest	Not recommended

AAMI=Association for the Advancement of Medical Instrumentation; BHS=British Hypertension Society; NA=not applied.

\*To meet AAMI criteria the mean difference between the device and the mercury standard must be  $\leq 5$  mm Hg or the standard deviation must be  $\leq 8$  mm Hg.

†To meet BHS criteria devices must achieve a grade of at least B for both systolic and diastolic measurements. Grade A denotes greatest agreement with mercury standard and D denotes least agreement.

**Table 5** Automated blood pressure measuring devices for self measurement at the wrist validated using the protocols of the Association for the Advancement of Medical Instrumentation and the British Hypertension Society

Device	Protocol		Use	Recommendation
	AAMI*	BHS (systolic/diastolic)†		
Omron R3 <sup>30</sup>	NA	NA	Intra-arterial comparison	Questionable recommendation
Omron R3 <sup>29</sup>	Failed	D/D	At rest	Not recommended
Boso-Mediwatch <sup>31</sup>	NA	C/C	At rest; protocol violation	Not recommended
Omron Rx <sup>32</sup>	Failed	B/B	At rest; only abstract available	Questionable recommendation

AAMI=Association for the Advancement of Medical Instrumentation; BHS=British Hypertension Society; NA=not applied.

\*To meet AAMI criteria the mean difference between the device and the mercury standard must be  $\leq 5$  mm Hg or the standard deviation must be  $\leq 8$  mm Hg.

†To meet BHS criteria devices must achieve a grade of at least B for both systolic and diastolic measurements. Grade A denotes greatest agreement with mercury standard and D denotes least agreement.

true of devices used for self measurement. In 1994, Ng and Small surveyed 423 automated devices, of which 161 were designed for self measurement.<sup>74</sup> Since then the number of devices available for self measurement has increased greatly but comparatively few have been validated. The situation is even worse for automated devices designed for use in specialised areas of hospitals, such as operating theatres and intensive care units, where accuracy should be a priority. Only five of the

**Table 6** Ambulatory blood pressure measuring devices validated using the protocols of the Association for the Advancement of Medical Instrumentation and the British Hypertension Society

Device	Mode	Protocol			Recommendation
		AAMI*	BHS (systolic/diastolic)†	Use	
Accutracker II (30/23) <sup>33</sup>	Auscultatory	Passed	A/C	At rest	Not recommended
CH-DRUCK <sup>34</sup>	Auscultatory	Passed	A/A	At rest	Recommended
Daypress 500 <sup>35</sup>	Oscillometric	Passed	A/B	At rest	Recommended
DIASYS 200 <sup>36</sup>	Auscultatory	Passed	C/C	At rest	Not recommended
DIASYS Integra <sup>37</sup>	Auscultatory	Passed	B/A	At rest	Recommended
	Oscillometric	Passed	B/B	At rest	Recommended
ES-H531 <sup>38</sup>	Auscultatory	Passed	A/A	At rest	Recommended
	Oscillometric	Passed	B/B	At rest	Recommended
Medilog ABP <sup>39</sup>	Auscultatory	Passed	NA	At rest	Questionable recommendation
Meditech ABPM-04 <sup>40</sup>	Oscillometric	Passed	B/B	At rest	Recommended
Nissei DS-240 <sup>41</sup>	Oscillometric	Passed	B/A	Only abstract available; details missing	Questionable recommendation
OSCILL-IT <sup>42</sup>	Oscillometric	Passed	C/B	At rest	Not recommended
Pressurometer IV <sup>43</sup>	Auscultatory	Failed	C/D	At rest	Not recommended
Profilomat <sup>44</sup>	Auscultatory	Passed	B/A	At rest	Recommended
Profilomat <sup>45</sup>	Auscultatory	Passed	B/C	In pregnancy	Not recommended
Profilomat II <sup>46</sup>	Oscillometric	Failed	C/B	At rest	Not recommended
QuietTrak <sup>47</sup>	Auscultatory	Passed	B/B	At rest	Recommended
QuietTrak <sup>48</sup>	Auscultatory	Passed	B/B	At rest; only abstract	Questionable recommendation
QuietTrak <sup>49</sup>	Auscultatory	Failed	D/D	In pre-eclampsia	Not recommended
QuietTrak <sup>50</sup>	Auscultatory	Failed	B/B	In pregnancy	Not recommended
QuietTrak <sup>51</sup>	Auscultatory	Passed	A/A	At rest	Recommended
			A/A	During exercise	Recommended
			A/A	Different postures	Recommended
			A/A	In elderly people	Recommended
			A/A	In children	Recommended
			A/A	In pregnancy	Recommended
Save 33, Model 2 <sup>52</sup>	Oscillometric	Passed	B/B	At rest	Recommended
Schiller BR-102 <sup>53</sup>	Auscultatory	Passed	B/B	At rest	Recommended
	Oscillometric	Failed	D/B	At rest	Not recommended
SpaceLabs 90202 <sup>54</sup>	Oscillometric	Passed	B/B	At rest	Recommended
SpaceLabs 90207 <sup>55</sup>	Oscillometric	Passed	B/B	At rest	Recommended
SpaceLabs 90207 <sup>56</sup>	Oscillometric	Passed	A/C	In pregnancy	Not recommended
SpaceLabs 90207 <sup>57</sup>	Oscillometric	Passed	B/B	In pregnancy	Recommended
SpaceLabs 90207 <sup>45</sup>	Oscillometric	Passed	B/C	In pregnancy	Not recommended
SpaceLabs 90207 <sup>49</sup>	Oscillometric	Failed	D/D	In pre-eclampsia	Not recommended
SpaceLabs 90207 <sup>58</sup>	Oscillometric	Passed	C/C	In pre-eclampsia	Not recommended
SpaceLabs 90207 <sup>59</sup>	Oscillometric	SBP Pass	C	In children	Not recommended
SpaceLabs 90207 <sup>59</sup>	Oscillometric	DBP Fail	D	In children	Not recommended
SpaceLabs 90207 <sup>60</sup>	Oscillometric	Passed	B/A	Elderly people standing and sitting (SBP ≤160 mmHg)	Recommended
SpaceLabs 90207 <sup>60</sup>	Oscillometric	Passed	D/A	Elderly people supine; tested at all pressures	Not recommended
SpaceLabs 90207 <sup>61</sup>	Oscillometric	Passed	C/B	During haemodialysis	Not recommended
SpaceLabs 90217 <sup>62</sup>	Oscillometric	Passed	A/A	At rest	Recommended
TM-2420/TM-2020 <sup>63</sup>	Oscillometric	Failed	D/D	At rest	Not recommended
TM-2420 Model 6 <sup>64</sup>	Oscillometric	Passed	B/B	At rest	Recommended
TM-2420 Model 7 <sup>65</sup>	Oscillometric	Passed	B/B	At rest	Recommended
TM-2421 <sup>66</sup>	Oscillometric	Passed	B/A	At rest	Recommended
TM-2421 <sup>67</sup>	Oscillometric	NA	A/B	In children aged 7-8 years sitting	Questionable recommendation
			A/B	In children of all ages sitting	Questionable recommendation
TM-2421 <sup>67</sup>	Auscultatory	NA	C/C	In children in different postures	Not recommended
Takeda 2430 <sup>68</sup>	Oscillometric	Passed	A/A	At rest	Recommended

AAMI=Association for the Advancement of Medical Instrumentation; BHS=British Hypertension Society; NA=not applied; SBP=systolic blood pressure; DBP=diastolic blood pressure.

\*To meet AAMI criteria the mean difference between the device and the mercury standard must be ≤5 mm Hg or the standard deviation must be ≤8 mm Hg.

†To meet BHS criteria devices must achieve a grade of at least B for both systolic and diastolic measurements. Grade A denotes greatest agreement with mercury standard and D denotes least agreement.

hundreds of devices available have been validated using the two protocols, of which only two met the criteria for recommendation in this review.<sup>63-75</sup> The much used anaeroid sphygmomanometer has only recently been

independently evaluated.<sup>12</sup> However, because these devices become inaccurate with use without this inaccuracy being apparent to the user, it is also necessary to validate them after they have been used for some time.<sup>13</sup>

A serious dilemma is how to influence manufacturers to modify devices that have been shown to be inaccurate. The Dinamap Portable Monitor model 8100 (Critikon, Tampa, FL) is an example of this: despite a number of reports of inaccuracy<sup>18 76</sup> it is one of the most popular automated devices used in clinical practice and hypertension research. It seems that purchasers and users of expensive devices for blood pressure measurement in specialised hospital areas are prepared to accept the word of manufacturers with regard to their accuracy and performance and to ignore warnings from the scientific literature as to their shortcomings.

Again, the situation is worse for self measurement devices. Despite the poor accuracy record of devices that measure blood pressure at the wrist and the serious misgivings voiced by clinicians about these devices,<sup>19</sup> their popularity is growing. In Germany, for example, 1.2 million self measurement devices are sold annually.<sup>30</sup>

The European Union and international organisations of specialists in hypertension have unanimously recommended that all devices for measuring blood pressure should be independently validated.<sup>19 77-82</sup> The reality is, however, that most devices are not validated independently. This may be partly due to the expense of conducting validation studies using complex protocols.<sup>1 2</sup> Recently, the European Society of Hypertension Working Party on Blood Pressure Monitoring agreed proposals to simplify the BHS protocol without compromising the integrity of the procedures, and an international protocol for validation is being drafted.<sup>83</sup> This will help manufacturers to market devices worldwide, expedite validation procedures, reduce the expense of performing studies, and permit more centres to undertake validation procedures; all of which would enable manufacturers to have all devices validated independently before they are marketed. Early publication of validation studies might further encourage manufacturers to have their devices evaluated, and the readiness of *Blood Pressure Monitoring* to act as a repository of peer reviewed studies is welcomed. The internet might provide a means of continuously updating information on blood pressure measuring devices.

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Competing interests: EOB is director of the blood pressure unit at Beaumont Hospital, which has been contracted by manufacturers from time to time to conduct validation studies of blood pressure measurement devices; the results of these studies have been published. EOB has advised AccuSphyg, which is developing a non-mercury automated device for use in hospitals, and he holds a minority financial interest in the company.

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## Endpiece

### Importance of compassion

A traditional Chinese doctor is instructing his apprentice: "He said that knowledge was of little use without wisdom, and that there was no wisdom without spirituality, and that true spirituality always included service to others. As he explained many times, the essence of a good physician consisted of a capacity for compassion and a sense of the ethical, without which qualities the sacred art of healing degenerated into simple charlatanism."

Isabel Allende, *Daughters of Fortune*

Submitted by Anna Crown, specialist registrar, Bristol