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Home blood pressure measurement with oscillometric upper-arm devices

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ABSTRACT

The market for automated blood pressure measuring devices is growing rapidly. Many patients want to buy a device for blood pressure measurement at home and ask their physician for advice about which one to choose. In this article an overview is given of the different devices available for blood pressure measurement and possible pitfalls in the interpretation of measurements taken at home are pointed out. A second article will specifically address those devices that are used to take blood pressure measurements at the wrist.

INTRODUCTION

The market for automated blood pressure measuring devices is growing rapidly. Home blood pressure measurement (HBPM) is becoming more and more popular. Many of the devices designed for HBPM have now been validated according to different protocols. Most (78%) of the 11 million devices for HBPM sold in 2000 were produced by Japanese manufacturers.[1] Of the sold devices, 64% are upper-arm devices and 35% are wrist devices.[1] HBPM has been shown to have a stronger predictive power for mortality than screening blood pressure (BP).[2] Many patients with hypertension ask their general practitioners and specialists which device they should buy. The purpose of this article is to help physicians to better advise patients in choosing between different devices for HBPM. Moreover, it will help the physician to interpret the readings taken at home better and to pin-point possible pitfalls such as (reverse) white-coat hypertension or white-coat effect. These and many other factors should be taken into account when medication changes are made based on home readings.

OVERVIEW OF VALIDATION PROTOCOLS CURRENTLY IN USE

A number of validation protocols for BP measuring devices have been published in the past years. The most widely used are the British Hypertension Society (BHS) protocol 1990, which was revised in 1993, and the protocol of the Association for the Advancement of Medical Instrumentation (AAMI) published in 1987 and revised in 1992.[3-6] Recently an effort has been made to develop a universal protocol in the form of an 'International Protocol'.[7] In Germany the Deutsches Institut für Normierung (DIN) developed a protocol and in Australia another protocol has been drafted.[8,9] Of these protocols, the BHS protocol 1993, the International Protocol and the AAMI 1992 protocol will be discussed briefly. In the BHS protocol 1993 a mercury sphygmomanometer is used as reference standard. In the main part of the protocol, BP measurements are done in 85 subjects. In each subject seven BP measurements are performed alternately with the device being tested (read by one observer) and by two other observers with the mercury sphygmomanometer (*figure 1*). After calculating the differences between the standard and the test device a grade for both systolic (SBP) and diastolic (DBP) blood pressure can be calculated using *table 1*. Only devices with a grade A or B for both SBP and DBP are recommended for clinical use.

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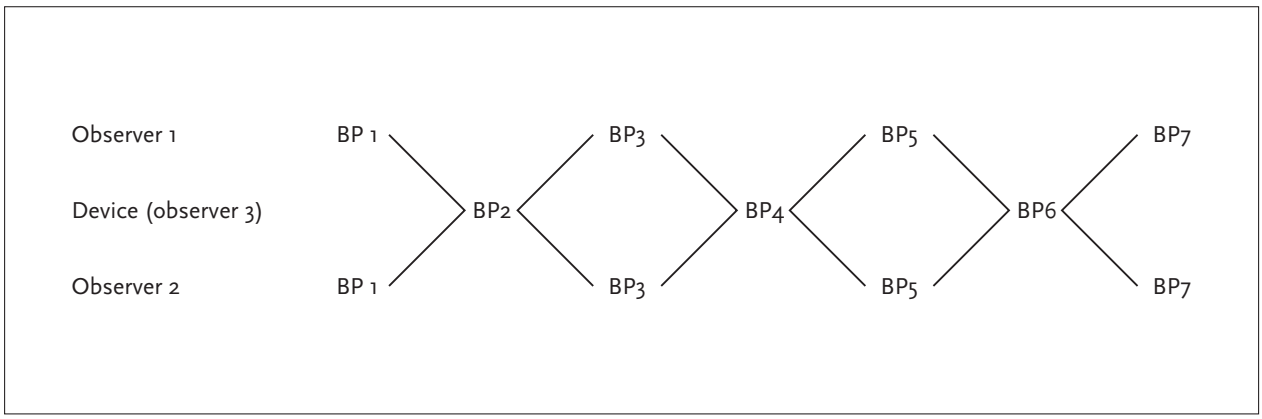

Figure 1
Sequential blood pressure measurements according to the British Hypertension Society protocol 1993 (also used in the International Protocol)

Table 1
Grading criteria for sequential measurements according to the British Hypertension Society (BHS), the International Protocol and the Association for the Advancement of Medical Instrumentation (AAMI). All calculations should be done separately for systolic and diastolic blood pressure[4,6,7]

BHS PROTOCOL (1993)

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

[*] *To achieve a certain grade all percentages must be equal to or greater than those in the table, n=255.*

INTERNATIONAL PROTOCOL (2002)

Phase 1: Measurements[1]	<5 mmHg	<10 mmHg	<15 mmHg
At least one of	25	35	40
Phase 2.1: Measurements[2]	<5 mmHg	<10 mmHg	<15 mmHg
All of	60	75	90
Two of	65	80	95
Phase 2.2: Measurements[3]	2/3 <5 mmHg	0/3 within 5 mmHg	
Two of	22		
All of		3	

[1] *After measurements in 15 subjects (45 comparisons) at least 25 comparisons should lie within 5 mmHg or at least 35 within 10 mmHg or at least 40 within 15 mmHg to proceed to phase 2.* [2] *After measurements in all 33 subjects 60, 75 and 90 comparisons should lie within 5, 10 and 15 mmHg, respectively. Also, 65 comparisons should lie within 5 mmHg and 80 within 10 mmHg or 65 within 5 mmHg and 95 within 10 mmHg or 80 within 10 mmHg and 95 within 15 mmHg.* [3] *To complete phase 2.2 in 22 of the 33 subjects at least two out of three comparisons should lie within 5 mmHg and at most 3 of the 33 subjects can have all three comparisons over 5 mmHg apart.*

AAMI[1]

Mean difference	Absolute value ≤5 mmHg and standard deviation of differences ≤8 mmHg

[1] *In 85 subjects, 3 readings/subject, n=255.*

In the International Protocol adjustments have been made to simplify the validation procedure of the BHS protocol 1993. This was done by using the data from 19 validation studies performed according to the BHS protocol. A two-phased approach is used. During phase 1 sequential BP measurements are carried out in 15 subjects (according to the scheme shown in *figure 1*). Requirements shown in *table 1* must be met in order to proceed to phase 2. This approach will help to eliminate very inaccurate devices in an early phase. When the device tested enters phase 2, measurements are done in an additional 18 subjects. Differences between test device and mercury sphygmomanometer have to be within the requirements shown in *table 1* in order to pass. So a pass/fail system has replaced the A,B,C and D grading system of the BHS protocol 1993. Analysis is done separately for systolic and diastolic BP. Only a few devices have been tested according to this new protocol so far.

In the AAMI protocol mean differences and standard deviation of differences (SDD) are calculated. BP measurements are done in 85 subjects with three sets of comparative BP measurements for each subject. Measurements are taken by two trained observers. Simultaneous measurements are preferred, but sequential measurements are also allowed. To pass the AAMI protocol the absolute mean difference has to be ≤5 mmHg and SDD ≤8 mmHg (*table 1*) for both systolic and diastolic BP. Comparisons with intra-arterial measurements are also allowed: ten measurements should be done simultaneously in a minimum of 15 subjects. The upper limits of acceptance (mean and SDD) are the same as for noninvasive measurements.[6]

INSTRUCTIONS FOR HOME MEASUREMENT AND FACTORS INFLUENCING BLOOD PRESSURE

To obtain reliable results patients and/or their relatives should be instructed on how to perform home measurements. Many factors influence the BP that is measured at a given moment and in a given situation.[10,11] There are factors that influence the actual BP level and factors that are related to the method of BP measurement itself. These are shown in *figure 2*. Patients should be aware of a number of these factors when measuring BPs at home. Each measurement should be done only after proper preparation, i.e. patients should begin measurements only after at least five minutes of rest.[12] Measurements should preferably be done while sitting in a comfortable chair. Care should be taken to position the centre of the cuff at heart level. The cuff size should be appropriate for the size of the arm and placed with the centre over the brachial artery. During measurements there should be no talking. A device properly validated and found accurate enough for home measurement should be used.

It could be argued that BP measurements should only be

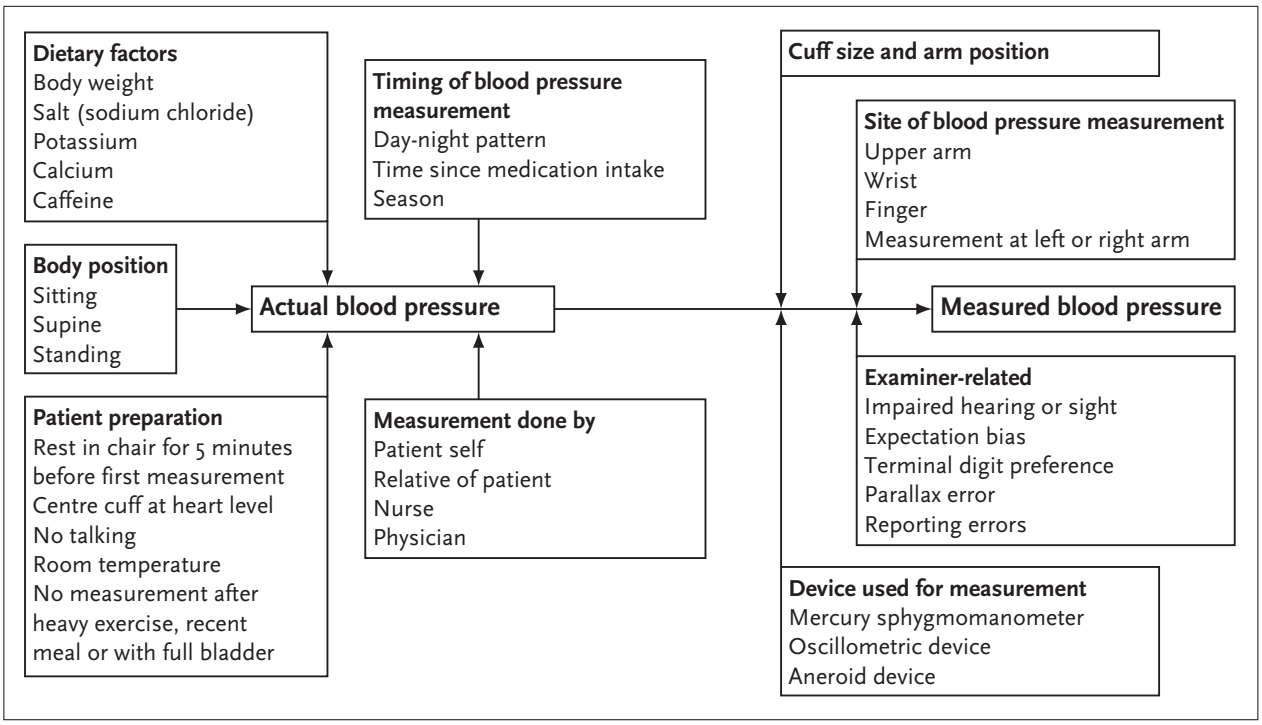

Figure 2

Factors influencing the actual blood pressure level and factors accounting for the difference between actual blood pressure and measured blood pressure level

done by those who are equipped to do so, i.e. healthcare professionals. However one should keep in mind the following citation: '*Indirect BP measurement is one of the most frequently performed healthcare procedures. Because BP measurement is a simple procedure, it is taken for granted that all graduates from medical training programmes have the ability to record accurate, precise and reliable BP readings. However, research since the 1960s has shown this assumption to be false. Most health professionals do not measure BP in a manner known to be accurate and reliable. If you doubt this statement, watch as BPs are taken in your own clinical setting to determine whether the guidelines are followed, and then examine recorded readings for signs of observer bias.*'[10] So, adequate training and education in BP measurement are pivotal and more important than the person who performs the measurements.

Self-measurement of BP is feasible for the majority of hypertensive patients.[13] Proper instruction with, for example, a short teaching session at the outpatient clinic should preferably be given to all patients performing home measurements. After thorough instruction, mercury and aneroid sphygmomanometers could also be used for self-measurement. However aneroid devices have been shown to become inaccurate over time.[14] Patients should be instructed to report all measurements. No values should be discarded. Memory-equipped devices could help to check the values reported by patients.[15]

To obtain reliable results a sufficient number of measurements should be done. Three successive measurements two times a day (before meals, between 06.00 and 08.00 and between 18.00 and 20.00) for at least three to four days are recommended.[16]

BP measured at home will not automatically give the same results as BP measured at the office. About 10 to 15% of hypertensive patients will have isolated office hypertension (widely known as 'white-coat hypertension'), in which persistent office hypertension is accompanied by home BP values below 130/85 mmHg.[17] Indeed many factors influence the BP measured in the two situations. As with ambulatory blood pressure measurement (ABPM), one would expect to measure lower BPs at home as compared with in the office. However the opposite is also commonly seen.[18] Wing *et al.* showed that in a group of 713 older hypertensives, 21 to 41% of patients had higher daytime systolic or diastolic ambulatory BPs than office readings. This was confirmed by research at our own institution (Aksoy, unpublished data).

BP measurement is not easy and the interpretation of the values measured is not at all easy, indeed it is rather complex. The development of automated BP measuring devices for use in the office and at home has actually made interpretation even more difficult, because different devices are commonly used in these different settings. To help interpret the BP values obtained during self-measurement, thresholds for normality of self-measured BP have been proposed as shown in *table 2*.[19] These values are mainly based on cross-sectional studies and not yet related to cardiovascular prognosis.

(DIS)ADVANTAGES OF HOME MEASUREMENT

Different devices can be used for HBPM: the mercury sphygmomanometer, aneroid devices and oscillometrically measuring devices. The last category of devices has won the 'contest' for HBPM, because of their ability to perform measurements automatically. HBPM has several advantages. It can provide us with more measurements than office readings. It can help to diagnose isolated office hypertension, to quantify the 'white-coat effect' and it may help to improve compliance to therapy, improving BP control. Terminal digit preference and expectation bias is no longer a problem. Measurements are independent of the hearing of the observer. The costs of self-measurement are lower than for ABPM.[20]

However, in contrast to ABPM, no BP values can be obtained at night and the prognostic value of self-measurement

Table 2

Proposed thresholds for automated measurements of blood pressure[19]

	BLOOD PRESSURE (mmHG)	95TH PERCENTILES[1]	NORMOTENSION[2]	HYPERTENSION[3]
Ambulatory	24 hour	132/82	≤130/80	>135/85
	Daytime	138/87	≤135/85	>140/90
	Night-time	123/74	≤120/70	>125/75
Self-recorded	Morning	136/85	≤135/85	>140/90
	Evening	139/86	≤135/85	>140/90
	Morning and evening	137/85	≤135/85	>140/90

[1] Mean values for the 95th percentiles for normotensive subjects in large-scale studies. [2] Obtained by rounding off downwards to the next blood pressure ending in 0 or 5 mmHg. [3] Obtained by rounding off upwards to the next blood pressure ending in 0 or 5 mmHg.

needs further investigation.[21] The device used for self-measurement has to be validated and accurate. Thresholds for normal levels are still under investigation. Mengden *et al.* showed that there was a substantial error in the reporting of the BP values obtained during self-measurement by hypertensive patients during two weeks.[15] Some patients omitted high BP readings. This bias may be reduced by using memory-equipped BP devices.[15] Another disadvantage is that it is not possible to control the circumstances in which measurements are taken. Also there is no information about proper cuff position during measurements.

AUTOMATED DEVICES VALIDATED FOR HOME USE

A substantial number of devices for self-measurement have been validated according to the British Hypertension Society protocol, the International Protocol or the protocol of the Association for the Advancement of Medical Instrumentation. Most of these devices measure BP oscillometrically. The development of the oscillometric technique goes back to the late 19th century. It is based on the assumption that the maximal oscillation in the cuff air pressure observed during deflation corresponds to the mean arterial pressure. Systolic and diastolic BP values are then computed through a specific algorithm.[22] These algorithms are kept secret, differ per device and can be changed easily.

Table 3 shows the devices that have been validated for self-measurement at the upper arm.[22] A device can be either recommended (i.e. fulfilling the AAMI criteria for both systolic and diastolic BPs and achieving a BHS grade B or A for both systolic and diastolic blood pressures) or not recommended (i.e. failing the AAMI criteria and achieving a BHS grade C or D for either systolic or diastolic pressure). A device achieves a 'questionable recommendation' when there is uncertainty about the strength of evidence (e.g. protocol violation, results presented only in abstract form etc.)[23]

Table 3

Automated blood pressure measuring devices for self-measurement at the upper arm that have been validated using the protocols of the British Hypertension Society (BHS), the International Protocol or the protocol of the Association for the Advancement of Medical Instrumentation (AAMI) – devices measure blood pressure oscillometrically unless otherwise stated (adapted with permission)[23]

	PROTOCOL			
DEVICE	AAMI	BHS[1]	YEAR	RECOMMENDATION
Omron HEM-400C	Failed	Failed[2]	1990	Not recommended
Philips HP5308 (Au)	Failed	Failed[2]	1990	Not recommended
Philips HP5306/B	Failed	Failed[2]	1990	Not recommended
Healthcheck CX-5 060020	Failed	Failed[2]	1990	Not recommended
Nissei analogue monitor (Au)[3]	Failed	Failed[2]	1990	Not recommended
Systema Dr MI-150	Failed	Failed[2]	1990	Not recommended
Fortec Dr MI-100	Failed	Failed[2]	1990	Not recommended
Philips HP5332	Failed	C/A	1996	Not recommended
Nissei DS-175	Failed	D/A	1996	Not recommended
Omron HEM-705CP	Passed	B/A	1996	Recommended
Omron HEM-706	Passed	B/C	1994	Not recommended
Omron HEM-403C	Failed	C/C	1995	Not recommended
Omron HEM-703CP	Passed	NA4	1994	Questionable
Omron M4	Passed	A/A	1998	Questionable
Omron MX2	Passed	A/A	1998	Questionable
Omron HEM-722C	Passed	A/A	1997	Questionable
Omron HEM-722C	Passed	A/A	1999	Recommended
Omron HEM-735C	Passed	B/A	1999	Recommended
Omron HEM-713C	Passed	B/B	1996	Recommended
Omron HEM-737 Intellisense	Passed	B/B	1998	Recommended
Visomat OZ2	Passed	C/B	1998	Not recommended

[1] According to the BHS protocol separate judgements are given to systolic and diastolic blood pressures, e.g. A/A both very good, C/A insufficient for systolic, but good for diastolic blood pressure. [2] In the first seven devices grading criteria had not yet been established. [3]Au = auscultatory. [4]NA = not applied.

Most devices become more inaccurate at higher BP levels. This has been shown for ambulatory blood pressure measuring devices, but in general applies for most automated BP measuring devices.[24] This is in part attributable to the design of the BHS protocol: independent of the BP level the absolute difference is used to calculate the grades.

CONCLUSION

As can be seen in *table 3*, many devices have been tested so far. However, only a few have achieved at least a grade B for both systolic and diastolic BP according to the BHS protocol or have passed the International Protocol. Based on the results shown in this table one of the Omron devices graded B/B or better could be advised for HBPM. The field of BP measurement is developing rapidly. Recently the Omron-MIT has been validated: this device measures oscillations during inflation instead of deflation.[25] Wrist devices are also becoming more and more popular and will be addressed in a separate article.
O' Brien *et al*. periodically publish an update on validated devices in the British Medical Journal.[23] Devices that have passed the BHS protocol can also be found on the website of the British Hypertension Society: http://www.hyp.ac.uk (blood pressure monitors).

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