

Validation of the Microlife BP 3BTO-A oscillometric blood pressure monitoring device according to a modified British Hypertension Society protocol

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Background The market for devices for the self-measurement of blood pressure is growing, and as accuracy is of prime importance, there is increasing pressure for manufacturers to provide evidence of independent testing. Recent reviews have shown that only five automated upper arm devices for self-measurement of blood pressure have been recommended for use. We tested the Microlife BP 3BTO-A, a lightweight, upper arm, automated oscillometric device, according to a modified version of the British Hypertension Society protocol and also analysed the computer-generated oscillograms for possible causes of inaccuracy.

Methods One hundred and twenty-six subjects were recruited from general medical and specialist clinics and from amongst the staff at Guy's and St Thomas' Hospital, London, UK. Only 85 of these were included in the final analysis. Nine sequential readings were taken by two trained observers alternating between the mercury sphygmomanometer and the device. The last seven readings were analysed according to the British Hypertension Society protocol. Modifications to the protocol were: (1) the exclusion of patients whose blood pressure varied by more than 15 mmHg between sequential observer readings and (2) limited testing in the low systolic pressure range.

Results The Microlife achieved a grade A for both systolic and diastolic pressure according to the British Hypertension Society protocol. The mean differences (standard deviation) between the observers and the device were -1.6 (7.7) mmHg and -2.1 (6.3) mmHg for systolic and diastolic blood pressure, respectively, therefore also fulfilling the criteria set by the Association for the Advancement of Medical Instrumentation. Sub-analysis for different pressure ranges showed that the device was less accurate in the high-pressure range ($> 160/100$ mmHg).

Conclusion The Microlife can be recommended for clinical use in an adult population. *Blood Press Monit* 7: 319–324 © 2002 Lippincott Williams & Wilkins.

Keywords: self-measurement, blood pressure, British Hypertension Society, Association for the Advancement of Medical Instrumentation, oscillometric

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Introduction

There is an increasing demand for accurate devices for the measurement of blood pressure. The need for alternatives to mercury will certainly become greater as traditional sphygmomanometry is phased out. Over 400 automated devices are available on the market [1], the most recent reviews [2,3] showing that only five of the 21 devices for the self-measurement of blood pressure tested according to the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) protocols are recommended (a list of recommended devices appears on the BHS website: www.hyp.ac.uk/bhs/). Only one of these devices, the Omron HEM-722C, when tested in elderly subjects, achieved the A/A grading according to the BHS protocol [4]. We tested the Microlife 3BTO-A blood pressure monitor, which is a small, lightweight upper arm device designed for home or office use, according to the BHS protocol [5]. We also analysed the computer-generated oscillograms for possible causes of inaccuracy.

Methods

Subjects

The subjects were recruited from amongst the staff and those attending clinics at a large teaching hospital in the

UK. Ethical approval was first obtained from the local ethics committee, and all the subjects were asked to sign a written consent form.

Subjects of 18 years and over were asked to take part in the study. For a subject to be included the classification blood pressure requirements had to be met and a complete set of seven sequential measurements obtained. Subjects excluded were:

1. those with atrial fibrillation and frequent extra systoles;
2. those who had weak Korotkoff sounds, which made acceptable auscultation impossible.

Study design

A validation procedure was performed according to the protocol stipulated by the BHS. Modifications to the protocol were:

1. the exclusion of subjects whose blood pressure varied by more than 15 mmHg between sequential readings by both observers;
2. limited testing in the low systolic pressure range such that instead of having eight subjects with a systolic blood pressure (SBP) of < 90 mmHg and 20 subjects with an SBP in the range 90–129 mmHg, we had eight subjects with an SBP \leq 100 mmHg and 20 subjects whose SBP fell in the range 101–129 mmHg. This modification has also been described in one of our previous studies [6].

The validation procedure consisted of several phases.

Before-use device calibration

Three devices were obtained from the manufacturer, who gave written declaration that they were standard production models. Each underwent dynamic calibration over 30 readings against a mercury sphygmomanometer. This procedure requires three observers. The device is set to calibration mode, with the cuff positioned around a cylinder and connected in parallel to two standard mercury sphygmomanometers. The first observer inflates the cuff to a pressure of 250 mmHg and then, on deflation, calls out at five random points, which are given in the BHS protocol. The second observer notes the mercury reading at each of the calls, and the third observer records the reading on the device. This procedure is repeated for a total of six deflations, the readings of the second observer then being compared with the device readings taken by observer number three. Twenty-eight out of the 30 readings must lie within 3 mmHg of each other in order for the machine to pass the calibration phase.

In-use field assessment

The three devices were put into clinical use, undergoing at least 400 inflations.

After-use device calibration

The three devices were then re-calibrated as before to ensure that their accuracy was maintained.

Static device validation

Observer training and assessment

Two observers were trained in mercury sphygmomanometry using a BHS CD-ROM. They were then tested against each other and against an expert observer. Throughout the main validation procedure, the two observers' readings were compared for accuracy after every 20 patients. Eighty per cent of the observer measurements should fall within 5 mmHg of each other and 95% within 10 mmHg.

Validation procedure

One hundred and twenty six subjects were recruited. Each subject was seated in a warm quiet room and allowed to rest for at least 5 min before the start of the procedure. Selection was made in order to fulfil the criteria for blood pressure range specified by the BHS protocol. Demographic information (age, height, weight and gender) was recorded for each subject.

The measurements were taken using a correctly sized cuff, the arm circumference being measured at the approximate mid-point of the upper arm. The standard cuff was used if the arm circumference was < 31.5 cm, and a large cuff was used for arm circumferences greater than this up to 42 cm.

Measurements were taken with the subject in the sitting position with the cuff at heart level. An initial auscultatory blood pressure measurement was taken for classification purposes, and one reading was taken with the device in order to allow the device to familiarize itself with the subject. These initial readings were not used in the analysis. Seven sequential same-arm measurements were subsequently taken by two trained, blinded observers alternating between mercury sphygmomanometry and the device (four from the observers and three from the device). Measurements were taken at intervals of > 30 s in order to minimize venous congestion, but < 1 min to minimize variability in blood pressure.

Auscultation was performed using an electronic stethoscope, the Welch Allyn[®] Meditron[™] sensor-based stethoscope model 5079-400, connected to a distributor with an additional headset for the second observer. In order to obtain a record of the mercury readings, the falling mercury column was recorded using a Sony Camcorder, the Korotkoff sounds being simultaneously recorded by connecting

the distributor to the microphone input on the camcorder. Each reading could then be replayed using the Sony DV gate software.

The differences between each test device reading and the observer readings before and after it were then calculated for each observer for both SBP and DBP. The set of differences (i.e. the three before or the three after the device readings) closest to the test device was chosen for each observer. The readings of the better observer were used in the final grading, as per the protocol.

The device was connected to a laptop computer and the oscillograms were recorded using the Labview software package, which had been adapted by engineers at Microlife to enable compatibility with the device. Following the main validation procedure, we selected cases in which there was a poor correlation between the observers' readings and the device and compared these oscillograms qualitatively with those of a normal cuff pressure-pulse signal plot.

Basic information about the device

Device number: BP 3BTO-A. Standards: the device corresponds to the requirements of the European standard for non-invasive blood pressure monitors EN1061-1/12:95, EN1060-3/09:97. Weight: 465 g (with batteries). Size: 131 (width) × 174 (length) × 73 (height) mm. Measuring range: 30–280 mmHg. Memory: stores last measurement automatically. Power source: four dry cells (batteries) UM-3, size AA, 1.5V or mains adaptor 6V DC 600 mA. Cuffs: a medium cuff for arm circumference 22–32 cm is supplied as standard with the device, and a large cuff for arm circumference 32–42 cm. Further information can be obtained from www.microlife.com.

Results

Subjects

One hundred and twenty-six patients were recruited into the study. Fifteen of these were excluded on the basis of predefined criteria (see below). Twenty-six patients were excluded because their classification blood pressures did not fit into the ranges needed. Eighty-five subjects were thus included in the final analysis, their blood pressure ranging from 84 to 214 mmHg and 42 to 136 mmHg for SBP and DBP, respectively. The median age of the group was 44 (range 22–90) years, and there were 51 women and 34 men. Arm circumference ranged from 22.5 to 41 cm, with a median of 28.5 cm.

Observer agreement

The observer agreement levels are shown in Table 1, demonstrating that the observers were within the required levels of agreement.

Device calibration

All three devices selected for testing were in close agreement with the mercury standard. Two of the three devices passed the re-calibration phase, one being used for the static validation.

Observer–device agreement

The results of the static validation are given for both observers in Table 1. The mean differences (standard deviation) between observer and device were -1.7 (7.4) mmHg and -2.1 (6.3) mmHg for systolic and diastolic measurements, respectively. The Microlife therefore achieved a grade A for both systolic and diastolic measurements according to the BHS protocol and also achieved a pass according to the AAMI criteria [7].

The data were also analysed separately in the low-, medium- and high-pressure ranges (Table 2). The device achieved a grade A for both systolic and diastolic measurements in the low and medium ranges of blood pressure. In the high-pressure range, however, it achieved a grade C for systolic and a grade B for diastolic measurement.

The data are represented in Figures 1 and 2 in Bland–Altman plots [8], which demonstrate good agreement between the device and the standard in the low-to-medium pressure range, although this worsened at higher systolic pressures.

Excluded subjects

A total of 15 subjects were excluded by predefined criteria from the analysis. Four subjects were excluded because of rhythm irregularities. Five subjects were not included in the study because they had a difference of 15 mmHg or more between sequential observer readings. One of these individuals had a difference of up to 42 mmHg between sequential observer systolic readings and up to 24 mmHg between sequential diastolic readings by both observers. This subject had a classification blood pressure of 240/124 mmHg. Four subjects were excluded because of very quiet Korotkoff sounds, which made it difficult to determine the exact point of phase V. One subject abandoned the procedure because of cuff discomfort, and in one case there was visible excess arm movement. One of the subjects suffered with Parkinson's disease and had a fine tremor of his hands. No recordings were excluded because of differences found between the observer and the device, or following qualitative analysis of the oscillograms.

Oscillogram analysis

Following the static validation, we examined the data for cases in which there was poor agreement between the device and the standard. We then qualitatively analysed the corresponding oscillograms to look for possible causes of inaccuracy.

Table 1 British Hypertension Society grading, cumulative percentages of test device readings differing from the mercury standard by <5, <10, <15 mmHg, mean and mean of differences (between test device and mercury standard) for the test device, and analysis for overall pressure levels for both observers

	Grade	Difference between standard and test device (mmHg)			Mean ± SD (mmHg)	Mean ± SD of differences (mmHg)
		<5	<10	<15		
Observer 1						
SBP	A	63	87	96	134.9 ± 28.1	-1.6 ± 7.7
DBP	A	68	89	97	84 ± 19.7	-2.1 ± 6.3
Observer 2						
SBP	A	64	87	96	134.9 ± 28.1	-1.7 ± 7.4
DBP	A	64	90	97	84.3 ± 19.6	-2.2 ± 6.2
Final grading						
SBP	A	64	87	96	134.9 ± 28.1	-1.7 ± 7.4
DBP	A	68	89	97	84 ± 19.7	-2.1 ± 6.3
Observer comparison						
SBP	A	93	99	100		-0.02 ± 2.7
DBP	A	94	100	100		2.7 ± 2.8

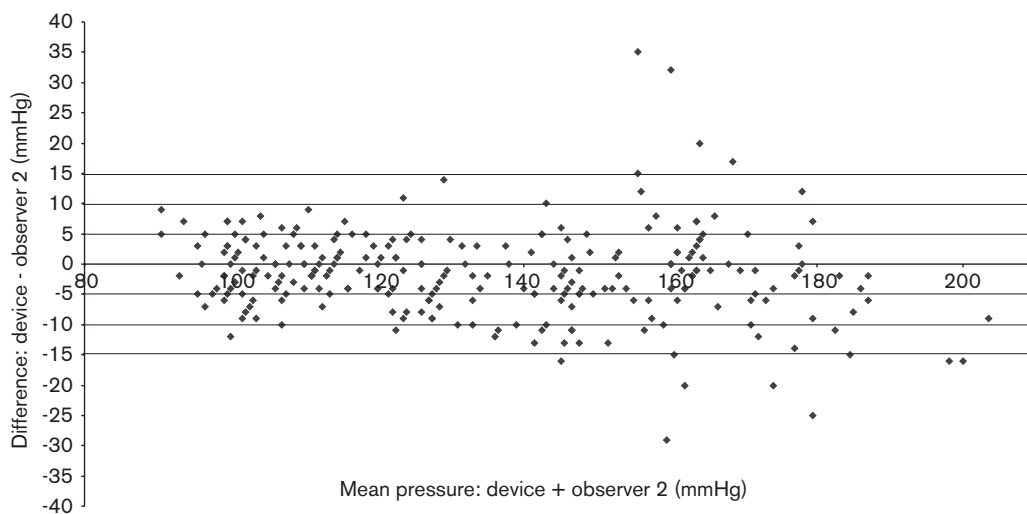
SBP, systolic blood pressure; DBP, diastolic blood pressure. Pressure range: SBP 84–214 mmHg; DBP 42–136 mmHg, n = 255 per observer for SBP and DBP.

Table 2 British Hypertension Society grading, cumulative percentages of test device readings differing from the mercury standard by <5, <10, <15 mmHg, mean and mean of differences (between test device and mercury standard) for the test device at high, medium and low pressure levels for the better observer

	Grade	Difference between standard and test device (mmHg)			n
		≤5	≤10	≤15	
Low pressure range (<130/80 mmHg)					
SBP	A	80	98	100	99
DBP	A	77	93	95	108
Medium pressure range (130–160/80–100 mmHg)					
SBP	A	61	89	99	72
DBP	A	70	89	100	63
High pressure range (>160/100 mmHg)					
SBP	C	50	73	88	84
DBP	B	56	85	98	84

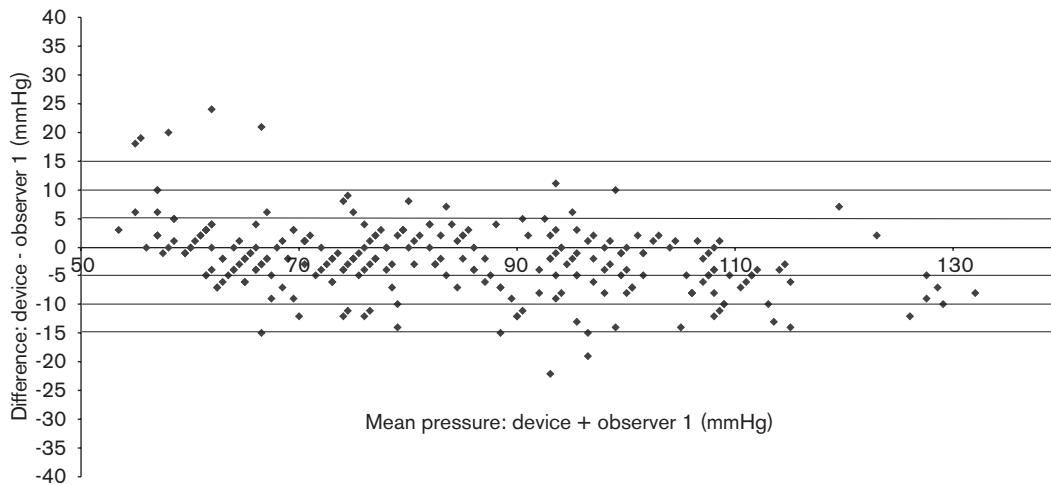
SBP, systolic blood pressure; DBP, diastolic blood pressure.

Fig. 1



Plot of pressure difference between the better observer and the test device, and mean pressure for the test device and that observer, in 85 subjects for systolic pressure (n = 255, [some data points superimposed]).

Fig. 2



Plot of pressure difference between the better observer and the test device, and the mean pressure for the test device and that observer, in 85 subjects for diastolic pressure ($n=255$, [some data points superimposed]).

In two subjects, the cuff pressure plot suggested that the subjects had moved during the procedure. In another case, there was a cyclical variation in the envelope of the oscillogram with a frequency of 5–6 s. This might have been an effect of breathing. One of the patients, aged 58 years, who suffered with systemic lupus erythematosus (a collagen vascular disorder) and Raynaud's disease as well as hypertension, showed flattening of the oscillogram trace. Although the diastolic pressures correlated well, the systolic pressures showed differences of up to 30 mmHg. We suspect that this might have been due to the altered waveform caused by arterial disease.

The subject with Parkinson's disease had a waveform with a 'double peak'. The systolic pressures were in close agreement, although the device overestimated the diastolic pressure by up to 40 mmHg. The first peak was taken as the mean arterial pressure by the machine, whereas the second peak equated well with the mean arterial pressure derived from the observer measurements. The reason for this extra first peak is unclear, but it may be a result of mitral regurgitation.

Discussion

The Microlife achieved an overall grade A for both SBP and DBP according to the BHS protocol and also fulfilled the AAMI criteria. The Microlife can therefore be recommended for clinical use in an adult population. Of the devices recommended by the European Society for Hypertension for the self-measurement of blood pressure, it is only the second device to achieve an A/A grade.

The device was validated for a range from mid-normal blood pressure to severe hypertension. It performed well in

all ranges except in the systolic high-pressure range, for which it achieved a grade C. It should be noted that many of our subjects were recruited from clinics in which many of the patients had severe hypertension. The average pressures in the high-pressure range group were 168 and 106 mmHg for SBP and DBP respectively. It is not uncommon for oscillometric monitors to have a tendency to underestimate the systolic pressure and show a wider standard deviation at higher pressures [9]. It is possible that, in the higher-pressure range, the error is greater purely because of the larger figures involved. This also could be a function of the vascular compliance, which will be reduced in subjects with arterial disease, causing alterations of the waveforms and rendering the algorithms inaccurate. Further work is needed to define the characteristics of the oscillometric waveform in relation to different medical conditions so that we can improve the accuracy of these devices. Some of the cuff pressure plots suggested that there had been some movement during the readings even though the device gave a valid reading, and there was no visible excess movement noted during the measurements. We suggest that if devices were programmed to register all movement artefacts as a coded error, inaccuracy caused by subtle movements could be minimized. Similarly, these devices must be used with caution in conditions such as Parkinson's disease in which excess movement is unavoidable.

It has been suggested that although a large intrasubject variability in blood pressure can disadvantage machines, in practice 97% of sequential measurements lie within 15 mmHg of each other [10]. We felt that the exclusion of subjects with a variation of over 15 mmHg was justified in our study because some subjects had an extremely labile blood pressure (up to 40 mmHg between readings in some

subjects), which precludes a satisfactory comparison of the two methods.

The second modification made to the BHS protocol in our study was changing the low systolic pressure range from having eight subjects with an SBP of less than 90 mmHg to having eight subjects with an SBP of below 100 mmHg, and from having 20 subjects with an SBP in the range 90–129 mmHg to having 20 subjects in the range 101–129 mmHg. It is, in practice, extremely difficult to find subjects with a systolic pressure of less than 90 mmHg, which makes the validation very time-consuming and costly. We have found this to be an accepted modification in our previous published studies [6], and, given the rarity of such pressures in the general population, it is unlikely that the device will be used clinically over these low-pressure ranges.

We used the camcorder and Welch Allyn stethoscope to provide a record of observer readings simultaneously with sound. This allows a review of the readings if necessary and is invaluable for training.

The Microlife BP 3BTO-A is thus one of only a few devices that can be recommended for use in clinical practice and is therefore a welcome addition to the market.

References

- 1 Ng K-G, Small CF. Survey of automated non-invasive blood pressure monitors. *J Clin Eng* 1994; **19**:452–475.
- 2 O'Brien E, Waeber B, Parati G, Staessen J, Myers M, on behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring. Blood pressure measuring devices: recommendations of the European Society of Hypertension. *BMJ* 2001; **322**:531–536.
- 3 O'Brien E. State of the market in 2001 for blood pressure measuring devices. *Blood Press Monit* 2001; **6**:171–176.
- 4 Bortolotto LA, Henry O, Hanon O, Sikias P, Mourad J-J, Girerd X. Validation of two devices for self-measurement of blood pressure by elderly patients according to the revised British Hypertension Society Protocol: the Omron HEM-722C and HEM-735C. *Blood Press Monit* 1998; **4**:21–25.
- 5 O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, Altman DG *et al*. The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; **11**(suppl 2):S43–S62.
- 6 Jones CR, Taylor K, Chowienzyk P, Poston L, Shennan AH. A validation of the Mobil O Graph (version 12) ambulatory blood pressure monitor. *Blood Press Monit* 2000; **5**:233–238.
- 7 Association for the Advancement of Medical Instrumentation. *American national standard for electronic or automated sphygmomanometers*. ANSI/AAMI SP10-1992. Arlington, VA: AAMI; 1993.
- 8 Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; **1**:307–310.
- 9 Geddes LA, Voelz M, Combs C, Reiner D, Babbs CF. Characterization of the oscillometric method for measuring indirect blood pressure. *Ann Biomed Eng* 1982; **10**:271–280.
- 10 O'Brien. Validation up-date. *Blood Press Monit* 2001; **6**:275–280.