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Interarm differences in blood pressure should be determined by measuring both arms simultaneously with an automatic oscillometric device
Friedrich W. Lohmann\textsuperscript{a}, Siegfried Eckert\textsuperscript{b} and Willem J. Verberk\textsuperscript{c}

**Objective** To compare two methods for screening interarm difference (IAD) of blood pressure.

**Material and methods** This study compared two methods for double-arm measurements: (i) conventional measurement (CM) and (ii) simultaneous automatic measurement (SAM). A total of 118 patients with two or more cardiovascular risk factors and a mean age of 59 ± 17 years were referred to two internal clinics. CM was taken with a validated aneroid manometer in sitting position on the right and left arm subsequently and vice versa. SAM was taken three times in sitting position using a validated automatic oscillometric device equipped with two cuffs for simultaneous double-arm measurements.

**Results** The average absolute IAD of the conventional systolic value (4.9 mmHg) was significantly higher than the average absolute IAD of the SAM pressures averaged from two (3.7 mmHg; \( P < 0.03 \)) and three measurements (3.8 mmHg; \( P < 0.05 \)). The standard deviations of IADs were significantly higher (\( P < 0.05 \)) for the conventional systolic and diastolic measurements (4.1/3.1 mmHg) than for SAM averaged from two and three (3.0/2.3 and 3.2/2.6 mmHg, respectively) measurements. Differences of more than 20 mmHg for systolic pressure and/or 10 mmHg for diastolic pressures averaged from two CMs, two SAMs, and three SAMs were seen in 10 (9%), four (3%), and six (5%) patients, respectively.

**Conclusion** SAM provides smaller and more reproducible IADs than CM and therefore, most likely better estimates a patient’s true IAD. Blood Press Monit 00:000–000 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

**Keywords:** automatic oscillometric device, blood pressure measurement, double-arm measurements, interarm difference, simultaneous measurements

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**Introduction**

It is commonly recognized that a large interarm difference (IAD) in blood pressure (BP) is a good indicator for several cardiovascular diseases. For this reason, many hypertension associations recommend to take double-arm measurements at the first visit [1–5]. When persistent differences greater than 20 mmHg for systolic or 10 mmHg for diastolic pressure are measured on consecutive readings, a patient should be referred to a specialist [6]. However, also when IADs are not that high and not disease related, relevant IADs still are important to know as office measurements consequently taken at the arm with the lowest BP can lead to wrong diagnosis and under-treatment of hypertension [7]. Therefore, it is also recommended to measure the arm with the highest pressure for all future measurements when a significant IAD is diagnosed at the first visit [4,8]. Despite the large-scale recommendation of taking double-arm measurements, the method of how it should be taken is much less clear. This is remarkable as it is most likely that both the procedure (measurement frequency, arm position, simultaneously or subsequently measured) and device (automatic, aneroid) can have a significant influence on the outcome. In the past, many double-arm measurements were taken subsequently, first at one arm and thereafter at the other arm. However, as BP is a variable hemodynamic phenomenon that constantly fluctuates over time subsequent measurements are difficult to compare. In addition, because of a cuff response or a white coat effect the first measurement is often higher than the next measurement [9,10]. Finally, when IAD is determined conventionally with the aneroid device it is not unlikely that an observer bias is introduced as, that is, the second measurement value could be influenced by the knowledge of the first BP value [1]. For these reasons some investigators have taken simultaneous double-arm measurements with two observers [11] or with two automatic monitors [7]. Although the latter seems to be a good idea still a bias can be introduced due to delay between readings and interdevice differences even when devices are from the same brand [12]. Recently, an oscillometric automatic office device has been developed for regular clinical healthcare purposes equipped with two cuffs to allow the possibility of taking simultaneous double-arm measurements: the WatchBP Office (Microlife AG, Widnau, Switzerland). This study aimed at comparing a
method that is commonly used in daily practice for assessing IAD: (i) conventional measurement (CM) in subsequent order using an aneroid device, with an innovative method and (ii) simultaneous automatic measurement (SAM) using a double-cuff automated oscillometric device.

Materials and methods

Blood pressure measurements

BP measurements were taken according to the European Society of Hypertension (ESH) guidelines [6]. CM was taken with a calibrated aneroid manometer (Welch-Allyn Maxi Stabil 3, Speidel and Keller, Skaneateles Falls, New York, USA [13]) by trained nurses. Patients were measured in sitting position with the arm supported at heart level, after 3–5 min of rest on the right arm and subsequently on the left arm. After 2–3 min the same procedure was repeated in opposite order, first the left and thereafter the right arm.

SAM was taken using the WatchBP Office (Microlife), a validated automatic oscillometric device equipped with two cuffs for double-arm measurements [14,15]. Three subsequent double-arm measurements in sitting position (similar to CM) were taken after 3–5 min of rest with 1-min intervals.

SAM and CM were taken in a random order.

Statistical analysis

As SAM was taken three times and as CM was taken twice, the average of both two and three SAMs was compared separately with CM for all tests.

Interarm BP differences and average BP values were compared using paired t-tests with Bonferroni correction for multiple measurements when necessary, and Bland–Altman analysis [16]. Absolute IADs were classified according to their magnitude. Proportions were compared by the \( \chi^2 \)-test. The agreement between different methods was assessed with the Pearson’s correlation tests. All data were analyzed using SPSS version 15.0 (SPSS Inc., Chicago, Illinois, USA).

Results

One hundred and eighteen patients with two or more cardiovascular risk factors and a mean age of 59 ± 17 years were referred to two internal clinics: Neukölln Hospital Berlin, Germany (\( n = 81 \)) and Heart and Diabetes Centre North Rhine-Westphalia, Germany (\( n = 37 \)). The patient characteristics are provided in Table 1.

Blood pressure values

As shown in Fig. 1 systolic BP values, as obtained with CM, were significantly higher at the first measurement than at the second measurement for both the left and right arm. This did not apply for the conventional diastolic BP values. In the case of SAM there were no significant differences between subsequent measurements. On average, systolic BP values were slightly higher on the right arm for both CM and SAM but this was not significant. Overall, CM provided the lowest mean systolic BP values but this only differed significantly from SAM averaged from two measurements for the left arm (\( P < 0.05 \)). For diastolic BP, the average CM value of the left arm was significantly lower than the average SAM values (\( P < 0.05 \)).

Interarm difference values

The average absolute IADs of the conventional systolic value (4.9 mmHg) was significantly higher than the average absolute IAD of the SAM pressures averaged from two (3.7 mmHg; \( P < 0.03 \)) and three measurements (3.8 mmHg; \( P < 0.05 \)). For diastolic BP values there were no significant differences in absolute IADs between CM (3.7 mmHg) and SAM averaged from two (3.1 mmHg) and three measurements (3.1 mmHg). The standard deviations of IADs were significantly higher (\( P < 0.05 \)) for the conventional systolic and diastolic BP measurements (4.1/3.1 mmHg) than for SAM averaged from two and three (3.0/2.3 and 3.2/2.6 mmHg, respectively) measurements.

Table 2 shows IADs and absolute IADs for both CM and SAM. For CM the absolute systolic IAD was significantly higher at the first performance (\( P < 0.05 \)) than at the second performance. For SAM there were no significant differences in IAD values between the assessments. The first systolic and the first and second diastolic absolute IADs obtained with CM were significantly higher than the IAD counterparts as obtained with SAM.

Subsequent and simultaneous measurements with the automatic device

For comparing subsequent and simultaneous measurements as taken with the automatic device, the BP value of one arm was subtracted from the value of the next

### Table 1: Patient characteristics (\( n = 118 \))

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>59 (17)</td>
</tr>
<tr>
<td>BMI (kg/m²), mean (SD)</td>
<td>27 (6)</td>
</tr>
<tr>
<td>Male [n (%)]</td>
<td>66 (56)</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg), mean (SD)</td>
<td></td>
</tr>
<tr>
<td>CM (left arm)</td>
<td>130.4 (22.6)</td>
</tr>
<tr>
<td>CM (right arm)</td>
<td>131.1 (22.7)</td>
</tr>
<tr>
<td>SAM (left arm)</td>
<td>132.1 (19.4)</td>
</tr>
<tr>
<td>SAM (right arm)</td>
<td>132.3 (18.7)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg), mean (SD)</td>
<td></td>
</tr>
<tr>
<td>CM (left arm)</td>
<td>78.7 (13.7)</td>
</tr>
<tr>
<td>CM (right arm)</td>
<td>79.1 (13.1)</td>
</tr>
<tr>
<td>SAM (left arm)</td>
<td>80.7 (13.3)</td>
</tr>
<tr>
<td>SAM (right arm)</td>
<td>80.2 (12.8)</td>
</tr>
<tr>
<td>Smokers [n (%)]</td>
<td>20 (17)</td>
</tr>
<tr>
<td>Heart disease [n (%)]</td>
<td>40 (34)</td>
</tr>
<tr>
<td>Diabetes mellitus II [n (%)]</td>
<td>11 (9)</td>
</tr>
<tr>
<td>Hypertension [n (%)]</td>
<td>90 (76)</td>
</tr>
<tr>
<td>Atrial fibrillation [n (%)]</td>
<td>7 (6)</td>
</tr>
<tr>
<td>( \geq 1 ) risk factors [n (%)]</td>
<td>115 (98)</td>
</tr>
<tr>
<td>( \geq 2 ) risk factors [n (%)]</td>
<td>68 (57)</td>
</tr>
</tbody>
</table>

CM, conventional measurement; SAM, simultaneous automatic measurement; SD, standard deviation.
Thereafter, these ‘automated subsequent IADs’ were compared with the automated simultaneous IADs. This was done for multiple combinations and showed that all subsequent automatic measurements led to significantly larger absolute differences than simultaneous measurements \((P < 0.05)\) for systolic but not for diastolic BP. There was no significant difference \((P = 0.07)\) in ‘regular’ IADs but the variance was significantly larger \((P < 0.001)\) for subsequent than simultaneous measurements.

With SAM the right arm commonly had the highest BP on average but for subsequent measurements the arm that was measured at first always provided the highest BP value.

Table 2  Interarm differences (mmHg) for separate conventional and automatic measurements

<table>
<thead>
<tr>
<th></th>
<th>Differences ± SD</th>
<th>Absolute differences ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CM</td>
<td>SAM</td>
</tr>
<tr>
<td>Systolic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R1 – L1</td>
<td>1.4 ± 8.7</td>
<td>0.1 ± 5.5</td>
</tr>
<tr>
<td>R2 – L2</td>
<td>0.1 ± 7.6</td>
<td>-0.1 ± 5.7</td>
</tr>
<tr>
<td>R3 – L3</td>
<td>0.5 ± 6.8</td>
<td>4.9 ± 4.7</td>
</tr>
<tr>
<td>R1 – L2</td>
<td>1.3 ± 9.2</td>
<td>6.4 ± 6.7</td>
</tr>
<tr>
<td>R2 – L1</td>
<td>-1.3 ± 9.9</td>
<td>6.8 ± 7.3</td>
</tr>
<tr>
<td>R2 – L3</td>
<td>1.4 ± 8.4</td>
<td>6.5 ± 5.5</td>
</tr>
<tr>
<td>R3 – L2</td>
<td>-1.1 ± 8.7</td>
<td>6.5 ± 5.9</td>
</tr>
<tr>
<td>Diastolic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R1 – L1</td>
<td>0.3 ± 5.9</td>
<td>-0.6 ± 4.8</td>
</tr>
<tr>
<td>R2 – L2</td>
<td>0.6 ± 6.0</td>
<td>-0.8 ± 5.5</td>
</tr>
<tr>
<td>R3 – L3</td>
<td>-0.2 ± 7.7</td>
<td>4.4 ± 6.2</td>
</tr>
<tr>
<td>R1 – L2</td>
<td>-1.3 ± 10.8</td>
<td>5.6 ± 9.1</td>
</tr>
<tr>
<td>R2 – L1</td>
<td>-0.1 ± 9.6</td>
<td>4.7 ± 8.3</td>
</tr>
<tr>
<td>R2 – L3</td>
<td>0.1 ± 8.6</td>
<td>4.9 ± 7.0</td>
</tr>
<tr>
<td>R3 – L2</td>
<td>-1.1 ± 10.9</td>
<td>5.8 ± 9.3</td>
</tr>
</tbody>
</table>

R1 – L2 means that the blood pressure value of the second left arm measurement is subtracted from the first right arm measurement value as if these automatic measurements were taken in a subsequent order.

CM, conventional measurement; L2, second left arm measurement; R1, first right arm measurement and so on; SAM, simultaneous automatic measurement.

*P < 0.05.

**P < 0.01.

***P < 0.003 for SAM compared with CM.
Differences of more than 20 mmHg for systolic pressure and/or 10 mmHg for diastolic pressure averaged from two CMs, two SAMs, and three SAMs were seen in 10 (9%), four (3%), and six (5%) patients, respectively.

Differences of 20 and/or 10 mmHg occur at least once out of two CMs in 29% of all patients. For two SAMs the frequency was 8% and for three SAMs this was 17%.

Relevant differences defined as 10 mmHg for systolic pressure and/or 5 mmHg for diastolic pressure is seen frequently (Fig. 3) and decrease with the average of more measurements. The highest frequency (51%) is seen with CM. The biggest decrease was seen from one to two measurements with CM (16%). The least decrease was seen from two to three measurements with SAM (1%). Relevant differences defined of at least 10 mmHg for either systolic and/or diastolic pressure was seen in 19% of all patients with the mean CM and in 9 and 10% of the patients when averaged from two and three SAMs.

The same pattern was seen for 20/10 mmHg differences (Fig. 3). There was much less is still change in the frequency at SAM than at the CM.

There were no relationships seen between IADs and patient characteristics such as age, BMI, sex and, heart disease (data not shown).

There was no significant correlation between the average IADs of CM and SAM ($r = 0.072$ for systolic IAD) within patients.

**Discussion**

Despite lower BP values, CM showed a significant higher IAD and standard deviation of IAD than what was obtained with SAM averaged from both two and three measurements. For CM the IAD obtained at the first comparison was higher than the second. However, this was not shown for SAM not even when the differences were determined from subsequent automated measurements. Overall, SAM showed lower absolute IADs and less variance between measurements than CM. There was poor correlation of IADs within patients as obtained with CM and SAM. Incidental IADs of 20 mmHg for systolic or 10 mmHg for diastolic pressure occur frequently with both CM (29%) and SAMs (± 20%). In both CM and SAM the frequency of relevant (average) IADs ( $\geq$ 20/10, $\geq$ 10/5, and $\geq$ 10 mmHg for systolic and/or diastolic BP) decreases with more measurements with the highest decrease seen within CM. Relevant IADs of 10/5 mmHg occur in 35, 22, and 20% of all patients as averaged from CM and two and three SAMs, respectively. When relevant differences are defined as at least 10 mmHg for systolic and/or diastolic BP these percentages are 19, 8, and 10%.

This study should be interpreted within the context of its limitations. Most patients were referred to a cardiovascular centre because they had two or more risk factors and therefore, the results cannot be extrapolated to the population at large. The CM has been taken by different observers in the different clinics. For this reason it is possible that results are influenced by the different observers. CM was taken using a manual aneroid device, which could make it awkward to compare BP measurement data with the BP values as obtained with the automatic oscillometric method. However, the investigators aimed at imitating the commonly used method in daily clinical practice; the aneroid device is still frequently used by physicians and IAD is commonly determined by subsequent measurements. To compare subsequent automated measurements with simultaneous automated measurements we subtracted, that is, the BP values of the second left arm from the first right arm and compared this with the difference of the BP values of the
third right arm and the second left arm. In this situation we used one BP measurement value twice in the comparison. Although it is expected that this method may have a minor influence on the outcome it is not exactly the same performance as the CM method. This study did not find any relationship of IAD with patient characteristics such as age, sex, BMI, cardiovascular risk factors, and BP value. However, this does not mean that there is no such a relationship but could be attributed to the relatively small population of 118 patients. One might argue that patients with atrial fibrillation (AF) should have been excluded, as the oscillometric technique might not be able to measure reliably in this situation [8]. However, there is no clear evidence for this, guidelines for BP measurement in patients with AF are lacking and the oscillometric technique has shown to be accurate with frequent measurements in patients with chronic AF [17]. In addition, at this study we did not find large differences in BP values and BP pattern between both methods among patients with AF.

To the best of our knowledge this is the first study that compared IADs of CM with SAM taken with the same device. There have already been several studies using two automatic devices [12,18]. Although this method is liable to bias because of interdevice differences and a possible delay between measurements it seems more reliable than CM. Manual measurements lead to errors of interpretation, observer bias, and terminal digit preference. For this reason it is recommended by the ESH guidelines to use an automatic BP monitor whenever possible [6]. The justification of this recommendation is confirmed by the finding in this study that the first IAD obtained with CM is significantly higher than the second whereas this is not the case when the IAD of subsequent measurements are calculated with the automatic device. This shows that the differences in IAD between both methods cannot only be explained by the difference in method (subsequent or simultaneous) but should at least partly be ascribed to the use of the manual aneroid device. There was no correlation in IAD between CM and SAM, which indicates that at least one of both methods did not provide the ‘true’ IAD, when existing.

This study found that with CM, 19% of all patients had relevant differences of at least 10 mmHg. This is similar to the finding of Clark et al. in their meta-analysis. However, the prevalence was lower with SAM, which indicates that CM, at least as taken in this study, tends to overestimate the prevalence of relevant IADs.

Although some oscillometric devices with the capacity to perform simultaneous BP readings have been developed these devices often are expensive and for that reason are mainly used for research purposes only [19]. However, the tested device (WatchBP Office) at this study has been developed for diagnosis in regular healthcare and thus eliminates the practical concern that a device with the possibility to take simultaneous measurements could not be widely distributed among clinics or GP practices [20].

Our finding is consistent with earlier studies, which showed that simultaneous interarm measurements lead to less difference than subsequent interarm measurements [21–23]. The finding in this study that the first measurement consequently is higher than the next measurement irrespective of which arm is measured shows the large bias that is introduced when determining IAD with subsequent measurements.

Although the measurement time was not assessed it was clear to all observers that taking SAM required less time and was easier than CM despite the fact that SAM consisted of three duplicate measurements and the CM consisted of two duplicate measurements.

Conclusion

SAM provides smaller and more reproducible IADs than CM and could prevent unnecessary reference to a
cardiovascular centre as a consequence of erroneously found IADs of at least 20/10 mmHg for many patients. In addition, for CM it seems that two measurements at both arms are not enough for detecting IAD whereas this seems sufficient with SAM, although three measurements are preferred.

**Recommendations**

At each first visit double-arm measurements must be taken as recommended by the ESH guidelines [3]. For the best estimate of a patient’s true IAD, BP measurement should not be taken manually and/or subsequently but should preferentially be determined from at least two simultaneous measurements taken with one automatic oscillometric device.

**Acknowledgements**

Conflict of interest: Willem Verberk is an employee of Microlife Corporation Taipei, Taiwan.

Sponsorships: the automated BP devices have been made available by Microlife Corporation.

**References**


Are there really differences between home and daytime ambulatory blood pressure? Comparison using a novel dual-mode ambulatory and home monitor

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Several studies compared blood pressure (BP) at home (HBP) with ambulatory BP (ABP), but using different devices, which contribute to differences in measured BP. A novel dual-mode device allowing ABP and HBP monitoring (Microlife WatchBPO3) was validated according to the European Society of Hypertension International Protocol and used to compare the two methods. In the validation study, 33 subjects were assessed with simultaneous BP measurements taken by 2 observers (connected mercury sphygmomanometers) 4 times, sequentially with 3 measurements taken using the tested device. Absolute observer-device BP differences were classified within 5/10/15 mm Hg zones. Measurements with ≤5 mm Hg difference were calculated per participant. In the validation study, the device produced 70/89/96 measurements within 5/10/15 mm Hg, respectively, for systolic BP and 67/95/99 for diastolic BP. Twenty-eight subjects had at least two of their systolic BP differences ≤5 mm Hg and one subject had no difference ≤5 mm Hg, whereas for diastolic BP, it was 22 and 1 subjects, respectively. Mean device-observers BP difference was −0.3 ± 5.6/−2.4 ± 4.8 mm Hg (systolic/diastolic). In the application study, the difference between daytime ABP and HBP was 0.5 ± 7.9 mm Hg for systolic BP (mean ± standard deviation, 95% confidence intervals (CI) −1.9, 2.9, P = NS) and 0.6 ± 5.5 for diastolic BP (95% CI −1.1, 2.3, P = NS). In conclusion, the Microlife WatchBPO3 device for ABP and HBP monitoring fulfils the International Protocol validation criteria. Using this device, no clinically important difference between daytime ABP and HBP was detected. These data justify the use of the same diagnostic threshold for both methods. Journal of Human Hypertension (2010) 24, 207–212; doi:10.1038/jhh.2009.60; published online 16 July 2009

Keywords: ambulatory blood pressure; home blood pressure; self-measurement; comparison; validation; international protocol

Introduction

For the accurate diagnosis and the optimal management of hypertension, current guidelines recommend the assessment of out-of-office blood pressure (BP) using either 24 h ambulatory monitoring (ABP) or self-monitoring by patients at home (HBP). Studies have shown that both these methods allow the detection of the white coat and the masked hypertension phenomena and are more closely related to cardiovascular events than the conventional BP measurements at the office or clinic.

Numerous studies have compared HBP with ABP measurements. In each of these studies, HBP and ABP measurements have been obtained using different devices, usually oscillometric, but of different manufacturers specifically designed for each method. Thus, the observed differences in BP levels between these two methods are attributed, at least in part, to the different devices used.

A novel dual-mode automated oscillometric device (Microlife WatchBPO3) that allows 24 h ABP and also HBP monitoring has been developed. This device aims to provide a complete assessment of the ‘true’ BP of an individual over time at his/her usual environment by combining these two out-of-office monitoring techniques. Furthermore, this device provides a unique opportunity to assess the true difference between HBP and ABP, using the same device for both methods.

This paper presents the results of (i) a validation study of the Microlife WatchBPO3 device according to the European Society of Hypertension International Protocol and (ii) a comparison of daytime ABP versus HBP in the same patients and using the same device.

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Materials and methods

Tested device
The Microlife WatchBPO3 (Microlife, Widnau, Switzerland) is a professional oscillometric device for ABP and also HBP measurement on the upper arm. ABP monitoring can be performed at 20–60 min intervals for 24 h and HBP monitoring for 7 days with duplicate morning and evening measurements per day as recommended by European and American guidelines.1,2 Casual BP measurement might also be obtained at the user’s discretion. The device has a switch to change measurement mode (ambulatory, home, casual). It measures BP at a range 30–280 mm Hg and pulse rate 40–200 beats per minute. Inflation is performed by an automatic electric pumping system and deflation by an automatic pressure release valve. It is powered by four 1.5 V batteries and automated memory and PC link capacity. A PC software is available to report and summarize the recorded BP data (24 h, awake and asleep ABP average according to the individual’s sleeping times and HBP average of days 2–7). Three cuffs are available with the device for arm circumference 17–22, 22–32 and 32–42 cm. The expected retail price in Europe is about 700 euros. Three devices were obtained from the manufacturer for the purpose of the study, with a written declaration that they were standard production models. One of them was randomly selected for the validation procedure.

Validation study
The study was conducted by a supervisor and three trained observers who rotated according to their availability. Before the study initiation, the observers were tested for agreement in BP measurement according to the British Hypertension Society protocol.1,2 Two standard mercury sphygmomanometers (Riester, diplomat-presameter, Rud. Riester GmbH Co. KG, Jungingen, Germany), the components of which have been checked before the study, and a teaching Littman stethoscope were used for simultaneous (Y tube) observer-taken reference BP measurements. The supervisor measured BP with the tested device and also checked the agreement of BP measurements taken by the two observers, who were blinded from each other’s readings and those obtained by the device. Observer readings with a difference >4 mm Hg were repeated until closer agreement was reached. The cuffs of the tested device were used for measurements taken using the tested and the mercury device to fit the arm circumference of each individual. All measurements were taken on the left arm, which was supported at heart level. The protocol was approved by the hospital scientific committee.

According to the International Protocol,16 in phase 1 a total of 15 treated or untreated subjects are included, who fulfil the age, sex and entry BP range requirements (age ≥30 years, ≥5 men and ≥5 women, 5 subjects with entry BP within each of the ranges 90–129, 130–160 and 161–180 mm Hg for systolic and 40–79, 80–100 and 101–130 mm Hg for diastolic BP). If analysis of these data is successful, additional subjects are recruited until 33 subjects fulfil the age, sex and entry BP range requirements for phase 2 (age ≥30 years, ≥10 men and ≥10 women, 11 subjects with entry BP within each of the above-mentioned BP ranges). Subjects with sustained arrhythmia or irregular pulse during the validation procedure were excluded. Signed informed consent was obtained from all subjects who participated in the study.

The validation study was conducted in an isolated room in which noise disturbance was avoided. Age, sex and arm circumference of each participant were recorded, together with the cuff size used and the date and time of the validation procedure. After 10–15 min rest (sitting), BP was measured by the two observers (entry BP). This measurement was used to classify subjects into the low, medium and high range, separately for systolic and diastolic BP, as described above. Device detection measurement was followed by the supervisor to ensure that the device was able to measure BP of each individual. The two observers took readings BP1, BP3, BP5 and BP7 using the double-headed stethoscope and the mercury sphygmomanometers. The supervisor took readings BP2, BP4 and BP6 using the tested device. The validation analysis was based on measurements BP1–BP7.

Application study
Subjects aged ≥25 years attending an outpatients hypertension clinic, untreated or on stable antihypertensive drug treatment for at least 4 weeks were invited to participate in an application study using the tested device. Participants were trained in the conditions of ABP and HBP measurement and the use of the device and were instructed to perform 24 h ABP monitoring and then to switch to the HBP monitoring mode and perform 7 days HBP measurements, or the reverse, according to each individual’s preference. Before study, entry accuracy of the devices was tested against a mercury column in each participant (Y connector).

ABP was monitored on a routine workday at 30 min intervals for 24 h. Participants were instructed to follow their usual daily activities, but to remain still with the forearm extended during each BP reading. HBP was monitored before or after ambulatory monitoring with duplicate morning (0700–1000 h) and evening (1800–2100 h) measurements after 5 min sitting at rest and with 1 min between recordings. Further to the device memory, a form was supplied to the participants to report all their HBP values and also the time they went to bed and arose during ABP monitoring. Clinic BP was measured in two visits in the beginning and the end of the study by three physicians who fulfilled the
British Hypertension Society Protocol criteria for agreement among observers in BP measurement. Triplicate BP measurements were performed during each visit after 5 min sitting at rest and with at least 1 min between recordings using the same device as for ABP/HBP monitoring.

Analysis
For the validation study analysis, each pair of observer measurements was averaged and was then subtracted from the device measurement. The absolute differences between BP2-BP1, BP2-BP3, BP4-BP3, BP4-BP5, BP6-BP5 and BP6-BP7 were calculated and paired according to the device reading. For each pair, the one with the smaller difference was used in the analysis. These BP differences were classified into three zones (within 5, 10 and 15 mm Hg), separately for systolic and diastolic BP, for 15 subjects in phase 1 and for all the 33 in phase 2.1. For each participant, the number of readings with a difference within 5 mm Hg was also calculated (phase 2.2).

For the application study, average HBP was calculated after excluding measurements of the first day, as recommended by current guidelines, and average awake ABP using the sleeping times reported by each individual. Office BP measurements of two visits were also averaged for each individual. Student’s paired t-tests with Bonferroni’s correction for multiple comparisons were used to compare average office, home and awake ambulatory measurements of BP and pulse rate in the same subjects. Standard deviation (s.d.) of mean BP values was compared using F-tests. The variation among repeated BP measurements was quantified using the s.d. of measurements of each subject. The within-subjects s.d. was estimated by one-way analysis of variance for HBP and awake ABP. The BP variation is also reported as within-subjects coefficient of variation (within-subjects s.d./mean BP/100%). The range of BP values (highest–lowest BP reading) obtained by HBP and awake ABP monitoring was also compared. The Bland–Altman approach was used to investigate the degree of similarity between awake ABP and HBP. Statistical analysis was performed using the MINITAB INC Statistical Software (release 13.31) (Stage College, Pennsylvania, PA, USA).

Results
Validation study
Forty-two subjects were recruited from an outpatients BP clinic and from patients and staff of a University Department of Medicine. One subject was excluded because of arrhythmia, 2 because their BP was out of range and 6 because their BP was within the ranges already completed. In 9 readings there was a difference between the observers’ measurements >4 mm Hg and were repeated to reach closer agreement.

The first 15 participants who fulfilled the protocol criteria regarding sex and entry BP were included in the analysis of phase 1 (8 men, mean age 53.4 ± 12.3 years [range 33–75], arm circumference 31.6 ± 3.5 cm [25.5–38], entry systolic BP 142.9 ± 24.5 mm Hg [108–180] and diastolic 89.5 ± 13.7

| Table 1 | Results of the validation analysis |
|------------------------------------------------|
|                  | ≤ 5 mm Hg | ≤ 10 mm Hg | ≤ 15 mm Hg | Recomm. | Mean diff. | s.d. |
| Phase 1          |           |           |           |         |           |     |
| Required         |           |           |           |         |           |     |
| One of           | 25        | 35        | 40        |         |           |     |
| Achieved         | SBP       | 33        | 43        | 44      | Continue  | 0.7  |
|                  |          |           |           |         |           | 5.4  |
| Achieved         | DBP       | 30        | 43        | 45      | Continue  | −3.3 |
|                  |           |           |           |         |           | 4.4  |
| Phase 2.1        |           |           |           |         |           |     |
| Required         |           |           |           |         |           |     |
| Two of           | 65        | 80        | 95        |         |           |     |
| All of           | 60        | 75        | 90        |         |           |     |
| Achieved         | SBP       | 70        | 89        | 96      | Pass      | 0.9  |
|                  |          |           |           |         |           | 6.3  |
| Achieved         | DBP       | 67        | 95        | 99      | Pass      | −1.7 |
|                  |           |           |           |         |           | 5.4  |
| 2/3≤5 mm Hg      |           |           |           |         |           |     |
| 0/3≤5 mm Hg      |           |           |           |         |           |     |
| Recomm.          |           |           |           |         |           |     |
| Phase 2.2        | ≥ 22      | ≤ 3       |           |         |           |     |
| Achieved         | SBP       | 28        | 1         | Pass    |           |     |
|                  | DBP       | 22        | 1         | Pass    |           |     |

Abbreviations: DBP, diastolic blood pressure; Mean diff, mean difference; Recomm, Recommendation; SBP, systolic blood pressure; s.d., standard deviation.
mm Hg [67–113]). Analysis of phase 2 was based on the first 33 participants who fulfilled the criteria regarding sex and entry BP (21 men, mean age 53.4 ± 12.1 years [range 33–79], arm circumference 30.8 ± 3.4 cm [25–38], entry systolic BP 145.3 ± 23.6 mm Hg [106–180] and diastolic 88.5 ± 15.3 mm Hg [63–117]). In 14 subjects, the medium size cuff was used, in 19 the large cuff and the small cuff in none.

The use of the tested device was straightforward with no operational problems during the study. There was one failure of the device to record BP throughout the study, which was successful on repeated measurement. The results of the validation analysis are presented in Table 1. The BP differences between the tested device and the observer readings are presented in Figure 1. The tested device passed all the validation criteria of phases 1 and 2.1 of the European Society of Hypertension International Protocol (Table 1). The first criterion of phase 2.2 was marginally fulfilled for diastolic BP, whereas the second one was comfortably fulfilled for both systolic and diastolic BP.

**Application study**

A total of 49 subjects were recruited and four were excluded because of incomplete HBP or ABP data. Finally, 45 subjects were included in the analysis. Mean age was 56 ± 11.6 years, 29 were men (64%) and 32 (71%) were on antihypertensive drug treatment. Twenty participants (44%) performed HBP monitoring first and then self-started ABP monitoring, whereas the rest 25 (56%) had the ABP monitor fitted by the physician in the office and started HBP monitoring on the next day.

Average office BP was higher than average HBP or awake ABP (systolic and diastolic; Table 2). There was a tendency for pulse rate to be higher in the office than at home or during awake ABP monitoring, which did not reach statistical significance (Table 2). The mean difference between home and awake ambulatory measurements was 0.5 ± 7.7 mm Hg for systolic BP (95% confidence intervals (CI) −1.8, 2.8, \( P = \text{NS} \)), 0.6 ± 5.4 mm Hg for diastolic BP (95% CI −1.1, 2.2, \( P = \text{NS} \)) and −0.6 ± 5.3 beats per minute for pulse rate (95% CI −2.2, 1.0, \( P = \text{NS} \)). The differences between HBP and awake ABP are presented in Figure 2. The home–awake BP difference did not differ in subjects who performed HBP monitoring first and ABP monitoring second (0.10/0.91 mm Hg, systolic/diastolic) compared with those who did the reverse (1.26/0.31 mm Hg).

Strong correlations were found among office BP, HBP and awake ABP measurements (\( P < 0.001 \) for all \( r \) values). Although the correlation coefficients between systolic HBP and awake ABP (\( r = 0.77/0.81 \), systolic/diastolic) were higher than those between office BP and awake ABP (\( r = 0.59/0.80 \) or HBP (\( r = 0.67/0.83 \)), these differences did not reach statistical significance.

The first clinic BP measurement was by 3.3/2.1 mm Hg (systolic/diastolic) higher than the first HBP measurement, whereas the first ABP measurement was by 5.6/3.6 mm Hg higher than the first HBP measurement. None of these differences reached statistical significance, probably because of the small number of subjects analysed (25 subjects started ABP monitoring in the clinic). The first office BP measurement was strongly correlated with the first HBP (\( r = 0.68/0.81 \)) and the first awake ABP measurement (\( r = 0.54/0.62; P < 0.01 \) for all \( r \) values).

The s.d. of the mean HBP (10.6/7.8 mm Hg, systolic/diastolic) tended to be lower than that of the mean awake ABP (11.9/9.1 mm Hg); yet these differences did not reach statistical significance. The within-subjects s.d. was lower for HBP (systolic/diastolic, 9.3/5.4 mm Hg) compared with that of awake ABP (13.7/10.8 mm Hg) (\( P < 0.05/ < 0.001 \).
The within-subjects coefficient of variation was 7.0%/6.7% (systolic/diastolic) for HBP and 10.5%/13.4% for awake ABP. The average lowest and highest BP reading (systolic/diastolic) was 113.4–150.8/71.6–92.3 mmHg for HBP and 103.2–165.7/59.9–109.3 mmHg for awake ABP. The BP range for HBP measurements (37.4 ± 12.9/20.8 ± 8.1 mmHg, systolic/diastolic) was significantly lower than that of awake ABP (62.5 ± 16.6/49.4 ± 18.9 mmHg) (mean difference 25.1 ± 20.5 mmHg/28.6 ± 19.7, \( P < 0.001 \) for both).

**Discussion**

This is the first study allowing the true difference between HBP and ABP measurements to be shown by using the same device for both methods. A formal validation study of a novel device that allows both HBP and ABP monitoring has also been performed. The main findings are that (i) there is no clinically important difference between average home and awake ABP and pulse rate as suggested by 95% CIs and (ii) the dual HBP and ABP monitor fulfils the validation requirements of the European Society of Hypertension International Protocol.

Multiple studies have compared ABP with HBP measurements obtained in the same patients. Some studies found no difference between HBP and daytime ABP, whereas others showed the HBP values to be higher or lower, particularly in children and adolescents. Differences in BP levels between the two methods in these studies are attributed to intrinsic differences between the two methods, but also, at least in part, to the different devices used for each method (ambulatory and home monitoring). Interestingly, despite the relatively small sample size of this study, the 95% CIs excluded any difference between HBP and awake ABP measurements larger than 2.8 mmHg for systolic BP or 2.2 mmHg for diastolic BP, and a difference in pulse rate larger than 2.2 beats per minute. The variability of HBP assessed by different approaches (s.d. of mean BP, s.d. and coefficient of variation of repeated BP readings of individual subjects and range of BP values) was consistently lower than that of awake ABP. This is probably because of the fact that HBP measurements are taken under more standardized conditions of activity and environment (after a few minutes sitting rest and only at home) than ABP measurements (ambulatory conditions, at work, at home and elsewhere). The similarity in HBP and awake ABP levels found in this study justifies the European Society of Hypertension recommendation for using the same diagnostic threshold for both of these methods.

HBP and awake ABP have important similarities because they both provide multiple BP measurements obtained away from the clinic or office setting and in the usual environment of each individual. On the other hand, they have important differences because home measurements are taken only in the sitting posture and at home, whereas ambulatory measurements are taken in ambulatory conditions, at work, at home and during other usual activities. Furthermore, ABP is monitored for 1 to maximum 2 days, whereas HBP is usually monitored for multiple days. Thus, ABP monitoring seems to be more appropriate for the initial assessment of subjects with elevated BP, whereas HBP is regarded as the optimal method for the long-term follow-up of treated hypertension. In other words, these methods seem to be more complementary than competitive and, despite their similar BP levels shown in this study, provide similar, but different, information about the BP behaviour of an individual.

![Figure 2](image_url)  
**Figure 2**  Scatterplots presenting differences between home and awake ABP measurements obtained using the same device. Horizontal lines indicate mean differences between measurements and limits of agreement (±2 s.d.) within which 95% of the differences are expected to lie.
The validation study of the device used for both HBP and ABP monitoring in this study passed the criteria of the International Protocol for systolic and diastolic BP (Table 1). All the criteria were comfortably fulfilled apart from one of the two criteria of phase 2.2 that was marginally fulfilled for diastolic BP. The AAMI criterion of mean difference <5 ± 8 (s.d.) mm Hg was also fulfilled for both systolic and diastolic BP. Therefore, the device can be recommended for clinical use in the adults.

This dual HBP and ABP monitor is a challenging tool for complete out-of-office BP assessment. Owing to its relatively low cost compared with currently available ABP monitors, this device has the potential to facilitate the widespread application of both HBP and ABP monitoring in the management of hypertension in general practice.

Acknowledgements

GS is a consultant to Microlife for the design of blood pressure monitors. The validation study was funded by a grant from Microlife, Widnau, Switzerland and the application study by the Hypertension Center, Third Department of Medicine, University of Athens, Greece.

References

Validation of the Microlife WatchBP O3 device for clinic, home, and ambulatory blood pressure measurement, according to the International Protocol

Fabio Ragazzo, Francesca Saladini and Paolo Palatini

To determine the accuracy of the Microlife WatchBP O3 blood pressure measuring device tested according to the requirements of the International Protocol of the European Society of Hypertension. The WatchBP O3 is designed to provide clinic, ambulatory, and self blood pressure (BP) measurements. Device evaluation was performed in 33 participants with a mean ± standard deviation age of 56.1 ± 20.7 years (range 30–95 years). Their systolic BP (SBP) was 144.7 ± 24.1 mmHg (range 90–180 mmHg), diastolic BP (DBP) was 86.8 ± 18.3 mmHg (range 50–120 mmHg), and arm circumference was 28.1 ± 2.9 cm (range 22.0–34.0 cm). Blood pressure measurements were performed in the sitting position. The WatchBP O3 passed all three phases of the European Society of Hypertension protocol for SBP and DBP. Mean blood pressure differences for the WatchBP O3 (device observer) were −1.7 ± 6.9 mmHg for SBP and −1.1 ± 4.3 mmHg for DBP. In conclusion, these results indicate that the Microlife WatchBP O3 monitor can be recommended for clinical use in the adult population.

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Keywords: ambulatory blood pressure, device, hypertension, self measurement, validation

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Introduction
To obtain a careful assessment of an individual blood pressure (BP) profile, current international guidelines recommend repeated measurements of BP using the traditional sphygmomanometric technique, self-measurement of BP at home, and the use of ambulatory BP monitoring for some clinical conditions [1,2]. This implies the use of a specific device in each setting and the production of several clinical reports. Mercury is progressively being banned in several European countries [3,4] and a modern approach is to abandon the auscultatory technique and use electronic devices for clinical BP assessment as well. Recently, the Microlife Company (Microlife AG, Widnau, Switzerland) produced the WatchBP O3, a device provided with three different function modes for clinic, home, and ambulatory BP measurement. The aim of this study was to verify the accuracy and reliability of this device according to the recommendations of the International Protocol of the European Society of Hypertension (ESH) [5].

Methods
Participants
We evaluated the WatchBP O3 in 33 adult participants (18 women) with a mean ± standard deviation (SD) age of 56.1 ± 20.7 years (range 30–95 years). Their systolic BP (SBP) was 144.7 ± 24.1 mmHg (range 90–180 mmHg), diastolic BP (DBP) was 86.8 ± 18.3 mmHg (range 50–120 mmHg), and arm circumference was 28.1 ± 2.9 cm (range 22.0–34.0 cm). Blood pressure measurements were performed in the sitting position. Twenty-five participants were excluded because BP ranges were complete (n = 23), Korotkoff sounds were of poor quality (n = 1), or there was atrial fibrillation (n = 1). The study was approved by the Ethics Committee of the University of Padua, and written informed consent was given by the participants.

Device
The WatchBP O3 is a fully automated monitor that measures BP at the upper arm using the oscillometric technique. The device offers three measurement modes for clinic, home, or ambulatory BP. The proper operational mode can be selected using a switch on the side of the device. In the ‘ambulatory’ mode, the device takes measurement at fixed intervals of 15, 20, 30, or 60 min, as programmed by the physician. In the ‘home’ mode, the patient is assumed to take measurements in accordance with the recommendations of the ESH [6], collecting a double measurement in the morning and the evening for 7 consecutive working days. When measurements have been carried out for the full 7-day period, a symbol will flash on the screen and the patient is invited to return to the clinic. In the ‘casual’ mode, the device functions as a regular automatic monitor and the stored readings can be reviewed by the physician at a later date.

The cuffs provided by the manufacturer are suitable for arm circumferences ranging from 22 to 42 cm. Other characteristics of the device are reported in the Appendix.
Device validation

The validation team consisted of three persons. The two observers used for the present validation (FR and FS) had received adequate training by an expert in BP measurement. They were tested according to the suggestions of the ESH protocol and the agreement between the two observers was 0.4 ± 2.0 mmHg for SBP and 0.2 ± 2.6 mmHg for DBP. Device evaluation was performed according to the ESH protocol [5]. Sequential same-arm measurements were performed with the participant in the sitting position. The two observers took BP measurement with a mercury sphygmomanometer at the upper arm using an adult cuff, the bladder of which covered at least 80% of the arm circumference. Four sequential readings were taken by observers 1 and 2 (BP1, BP3, BP5, and BP7), and three BP readings were taken by the supervisor with the test instrument (BP2, BP4, and BP6). The discrepancy

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Required</th>
<th>Achieved</th>
<th>SBP</th>
<th>DBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>One of</td>
<td>≤ 5 mmHg</td>
<td>≤ 10 mmHg</td>
<td>≤ 15 mmHg</td>
<td>Grade</td>
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<td></td>
<td>25</td>
<td>35</td>
<td>40</td>
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</tbody>
</table>

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

Plot of the systolic (upper plot) and diastolic (lower plot) WatchBP O3 observer blood pressure differences. The x-axis represents the mean of the device and observer measurements. The y-axis represents the difference between the device and observer measurements. A positive value indicates that the device measurement is greater than the observer’s measurement.
between the reading provided by the sphygmomanometer and the mean of observers’ measurements was allocated in four zones of accuracy following the recommendations of the ESH protocol [5]. Pearson’s test was used for correlations and Bonferroni correction was used to compute statistical significance. A P value of less than 0.05 or less was considered statistically significant.

Results
In the first phase, 15 participants (seven women) were assessed and five participants had their SBP and DBP in each of the three BP ranges required by the ESH protocol. In total, 45 measurements (three measurements × 15 participants) were available for analysis. The results were in concordance with the requested criteria of the International Protocol for the primary phase (Table 1). In addition, the second phase encompassing 18 participants (11 women) was successfully completed, including the second part of phase 2 (phase 2.2) of the ESH protocol (Table 1). In total, 99 readings (three measurements × 33 participants) were obtained. Mean differences ± SD between the WatchBP O3 and the observer were –1.7 ± 6.9 mmHg for SBP and –1.1 ± 4.3 mmHg for DBP (Fig. 1). Visual inspection of the graphs shows that the device tended to underestimate BP at the upper extreme of the BP distribution. Indeed, a significant correlation was found between the BP discrepancies and the participants’ DBP (P < 0.001). The correlation was of borderline significance for SBP (P = 0.07).

Discussion
These results provide information on the accuracy of the Microlife WatchBP O3 device, which allows assessment of BP in three different settings. The study showed that the device passed all the validation requirements of the ESH protocol [5]. In addition, the SDs of the device-observer differences were within the AAMI requirement of a SD of less than 8 mmHg [7]. In this study, we observed a tendency for the device to slightly underestimate BP obtained with the mercury sphygmomanometer, especially in participants with high BP at entry. A similar trend has been observed with most noninvasive devices [8,9] and the overall results fulfilled the validation criteria of the ESH protocol.

The design of this device seems to be particularly useful for a modern and comprehensive approach to the patient with high BP. The WatchBP O3 is provided with three operational modes for clinic, home, and ambulatory measurements. The home mode is designed to collect BP readings in accordance with the recent recommendations of the ESH according to which home BP should be monitored for 7 days, with at least two morning and two evening measurements [6]. This monitoring schedule is useful for deciding on whether to start antihypertensive treatment or for evaluating the effect of therapeutic adjustments. When BP is controlled, the device can be programmed for long-term monitoring according to a more flexible schedule. Obviously, this device should be used under strict medical supervision.

We conclude that the Microlife WatchBP O3 is an accurate device that can provide a thorough assessment of the patient’s BP profile in clinical practice.

Acknowledgements
This study was funded by a grant from Microlife WatchBP AG, Espenstrasse 139, CH 9443, Widnau, Switzerland.

Conflicts of interest: none declared.

References

Appendix
In this Appendix the basic information of the WatchBP O3 monitor is reported, following the suggestions of the ESH protocol [8].

Device identification
*Microlife 3MZ1*
Microlife WatchBP AG, Espenstrasse 139, CH 9443, Widnau, Switzerland.

This device is a fully automatic, upper-arm type, blood pressure monitor with measuring range of 30–280 mmHg for BP.

The device is equipped with three modes (casual/home/ambulatory blood pressure monitoring) and suitable for home, office, and ambulatory blood pressure monitoring measurement requirements.

The applied cuffs (medium–large size) are suitable for arm circumferences ranging from 22 to 42 cm.
Further cuff sizes are available as accessories.

Two hundred and fifty data memory with date and time for casual and ambulatory mode.

**Dimensions**
Width 80 × Height 115 × Diameter 35 mm.
Weight: 260 g, including batteries.

**List of components**

**Device including**
Cuffs: WatchBP O3 D ring (medium size, 240 × 133 mm bladder), (large size, 300 × 145 mm bladder), washable, cuff plugs (for sealing during washing).

Power: 4 × AAA size batteries.

Wearing accessory: pouch, straps, tube holder, 50 cm tube × 1, 100 cm tube × 1, shoulder strip, waist belt, shoulder sling, and anchor strip.


Software: WatchBP O3 Analyzer software.

**Costs**
Retail price around €700 – in Europe.

**Compliance with standard**
Class IIa medical device after European MDD 93/42 EEC + amendments.

Applicable standards for performance and safety.

**Validation studies**

**Instructions for use, care, and maintenance**
These are reported in detail in the instruction manual.

**Power supply**
4 × 1.5 V batteries; size AAA.

**Service facilities**
Microlife distributors – refer to www.microlife.com or Microlife European Headquarter: Microlife WatchBP AG, Espenstrasse 139, CH 9443, Widnau, Switzerland.

**Method of blood pressure measurement**
Oscillometric, corresponding to Korotkoff method: phase I systolic, phase V diastolic.

**Factors affecting accuracy**
Movement artefacts, arrhythmias.

**Operator training requirements**
Users should follow the recommendations and instructions in the supplied manual. The monitor does not require specific expertise because it is very easy to operate.
Self-Monitoring of Ambulatory Blood Pressure by the Microlife WatchBP O3 – An Application Test

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Abstract

Ambulatory blood pressure monitoring (ABPM) is not widely used in clinical practice, because the measuring procedure is complex and the devices are expensive and need to be fitted by skilled medical technologists. The Microlife WatchBP O3 (Microlife AG, Widnau, Switzerland), which was developed for self blood pressure monitoring at home and adapted for ABPM, is highly affordable for an ABPM device and easy to manipulate. We performed an application test of the WatchBP O3 to confirm reliability of the device. Thirty-seven volunteer participants (age 30.4 ± 13.5 y) underwent blood pressure (BP) measurements every 30 min for 24 h, and were asked to complete a questionnaire about the user-friendliness and acceptability of the device. The participants were asked to attach the device and to detach it the next morning by themselves. The quality of recordings was assessed in terms of percentage of valid readings. The mean number of 24-h BP readings per participant was 46.6 ± 5.3. The percentage of valid readings was 90%, which was similar to that reported for traditional ambulatory devices. Eighty-six percent of participants found it is “easy” or “very easy” to attach the device by themselves. The WatchBP O3, which is easy to manipulate, may be convenient and acceptable for users. The percentage of valid readings is similar to that reported previously. A new era of self-monitoring of ambulatory BP is anticipated in the near future.

Keywords: blood pressure measurement, ambulatory blood pressure monitoring (ABPM), application test, Microlife WatchBP O3, hypertension

INTRODUCTION

Ambulatory blood pressure monitoring (ABPM) and home blood pressure measurement (HBPM) are reportedly more reliable than conventional blood pressure (BP) measurement, as they avoid both observer and regression dilution biases and eliminate the white-coat effect (1). These measurements provide valuable information for the diagnosis and treatment of hypertension. Ambulatory and home BP have a stronger predictive power for target organ damage (2), morbidity (2–4), and mortality (2, 5) than conventional BP measurement (2–7). Ambulatory BP monitoring is usually measured every 15 to 30 min for 24 h or more, providing 50 to 100 BP readings together with the time of each measurement. If home BP is measured once every morning and once every evening, HBPM will provide at least 60 measurements a month with information on the measurement time. Information on BP as a function of time, as well as an increased frequency of measurements, improves the quality of information available with ABPM. Moreover, ABPM has so far been the principal method for assessing nocturnal BP during sleep. Despite the above-mentioned advantages, ABPM is less widely used in clinical practice than HBPM, because conventional ABPM systems are complex and expensive, and need to be attached and detached by skilled medical technologists. Conversely, the Microlife WatchBP O3 (8), which was developed for HBPM and was adapted for ABPM, is highly affordable for an ABPM device, and is easy to manipulate.
because the device (9) was originally based on the validated Microlife WatchBP home device (10) for HBPM. Therefore, the WatchBP O3 is an innovative and promising device, and is expected to encourage the widespread use of self-ABPM. Stergiou et al. tested the device, and concluded that no clinically important difference between daytime ABPM and HBPM was detected (0.5 ± 7.9 mmHg for systolic, 0.6 ± 5.5 for diastolic) (10). Thus, the purpose of this study was to perform an application test exclusively for ABPM mode of the device, and to confirm reliability of the device in terms of frequency of validated readings as well as frequency of artifactual readings during 24-h ABPM.

**METHODS**

**Participants**

From March 2008 to May 2008, 37 volunteers between the ages of 20 and 60 years were recruited from students and staff of Tohoku University, Sendai, Japan. Exclusion criteria of this study were the subjects who had serious diseases such as cardiovascular, neurologic, or metabolic disorder. Among the 37 subjects, none had sustained arrhythmia, paroxysmal atrial fibrillation, secondary hypertension, diabetes mellitus, concomitant cardiovascular disease, or renal disease. All participants provided informed consent. Finally, the total number of subjects included in the present analyses was 37. At the end of ABPM, the participants were asked to complete a questionnaire about the usefulness and acceptability of the device and the use of alcohol and smoking during ambulatory measurements.

**Device**

The Microlife WatchBP O3 (Microlife AG, Widnau, Switzerland) is a cuff-oscillometric device (Figure 1) designed to provide self-monitoring of ambulatory (Figure 2a) as well as home BP (Figure 2b) (12). The device was designed by Microlife Switzerland in consultation with the Departments of Clinical Pharmacology and Therapeutics, Tohoku University Graduate School of Pharmaceutical Sciences and Medicine, Japan. This device (9) was originally based on the validated Microlife WatchBP home device (10) for self-HBPM, and also includes an embedded, 7-day HBPM function that strictly follows European Society of Hypertension (ESH) (1) and the American Heart Association (AHA) (13) measurement guidelines (10) (Table 1). The WatchBP O3 is lightweight (260 g including batteries) and compact (115 × 80 × 35 mm). It measures BP at the upper arm between 30 and 280 mmHg and pulse rate between 40 and 200 beats/min. Inflation is performed by an automatic electric pumping system and deflation by an automatic pressure release valve. The device is powered by four 1.5-V batteries or an AC adaptor. Using a free software program available from the website of Microlife Corporation (http://www.watchbp.com/software/), the WatchBP O3 transmits BP measurement data to any PC via USB connectivity. The individual BP and other reference data can be exported as a PDF file for printing. These data can be also exported as a Microsoft Excel file (Figure 3).
Blood Pressure Measurements
Ambulatory BP was monitored using the WatchBP O3 preset to measure BP every 30 min throughout a 24-h period. We briefly (in 5 min) instructed participants on how to select the “ambulatory” mode using the Mode Switch, and how to position the cuff, anchor strap, and device. They were asked to attach the device and then to detach it the next morning by themselves, to conduct normal activities of daily living, and to keep their arm still only during inflation and deflation of the cuff. Ambulatory hypertension was defined as a 24-h BP of at least 135 mm Hg systolic blood pressure (SBP) or 85 mm Hg diastolic blood pressure (DBP) (13). We defined daytime as the interval ranging from 6 AM to 8 PM, taking the daily pattern of activities of study participants into account. Mean 24-hour, daytime, and nighttime BP values were calculated for each participant.

We identified ambulatory readings as erroneous, artifactual, or valid in two steps. First, the device automatically omitted erroneous readings during ABPM and reported them as errors according to an unpublished algorithm created by Microlife Corporation. Second, among the remaining readings, we further computed artifactual readings according to predefined criteria: (1) systolic BP <60 mmHg and/or mean BP <40 mmHg; (2) abrupt increase or decrease in SBP and/or DBP by ≥30% from the value both immediately before and after respective readings; (3) abrupt increase or decrease in SBP, DBP, and/or mean BP by ≥40%

Table 1. Features and advantages of the Microlife WatchBP O3

<table>
<thead>
<tr>
<th>Feature/Advantage</th>
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<tbody>
<tr>
<td>1. Clinically validated blood pressure measurement device.</td>
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<tr>
<td>2. Lightweight (260 g) and compact (115 × 80 × 35 mm).</td>
</tr>
<tr>
<td>3. Measurement reminder for the next measurement by partial inflation and beeps.</td>
</tr>
<tr>
<td>4. A repeat measurement is performed automatically if an error occurs.</td>
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<td>5. The possibility to disable the display of BP values after measurement.</td>
</tr>
<tr>
<td>6. Three functional modes: ‘Ambulatory’ for 24-h ambulatory blood pressure monitoring, “Home” for embedded self-home blood pressure monitoring schedule according to ESH-WG recommendations (7 days, duplicate morning and evening measurements), and “Casual” for casual home blood pressure measurements.</td>
</tr>
<tr>
<td>7. PC connectivity: transmit blood pressure measurement data to any PC via USB connectivity.</td>
</tr>
<tr>
<td>8. Observer bias is removed by automated monitoring (‘Ambulatory’ mode) or self-measurement (“Home” mode).</td>
</tr>
</tbody>
</table>

Figure 3. The individual BP and other reference data can be exported as a PDF file for printing or as a Microsoft Excel file.
from the value either immediately before or after respective readings; or (4) | pulse pressure – mean of pulse pressure | > 3 × standard deviation of pulse pressure in individual subjects. Pulse pressure was automatically calculated as SBP–DBP, and the mean BP was calculated as DBP plus one-third of the pulse pressure. The quality of recordings was indicated as follows: Percentage of valid readings (%) = number of valid readings ×100 / (number of valid readings + number of erroneous readings according to manufacturer + number of artifactual readings according to our criteria).

RESULTS

Participant Characteristics
The 37 participants included 11 women (29.7%); mean age was 30.4 ± 13.5 years (range 20–58 y). Two participants had ambulatory hypertension (5.4%), one of whom was taking antihypertensive drugs. At enrollment, three participants (8.1%) were current smokers, and seven (18.9%) reported drinking alcohol during monitoring. The 24-h, daytime, and nighttime BP values were 116.7 ± 16.9/72.7 ± 12.6, 120.0 ± 17.5/75.5 ± 12.6, and 112.2 ± 16.0/68.8 ± 12.6 mmHg, respectively. Among the 37 study participants, three subjects have an experience of ABPM with conventional devices. None of the subjects had any serious diseases. They had enough ability to perform common activities of daily living. No subjects worked irregular night shifts.

Percentage of Valid Readings
The mean number of 24-h BP readings per participant was 46.6 ± 5.3. The mean number of valid readings was 42.2 (90%). The mean number of erroneous readings according to manufacturer and that of artifactual readings by our criteria was 2.3 (4.9%) and 1.6 (3.4%), respectively (Table 2). One subject (ID number 30) had a poor result (24 erroneous readings among 45 readings, Table 2). This participant abandoned ambulatory measurement without switching off the device. With two participants (ID number 14 and 31), ambulatory measurements were incomplete because of a low battery. They did not replace the low batteries.

When we excluded these three participants because of incomplete measurements, the number of erroneous readings according to the manufacturer was slightly decreased (3.7%), and the percentage of valid readings was hence marginally improved (92.8%). The remaining participants showed a relatively high percentage of valid readings (≥80% in 33 subjects, ≥70% in 1 subject) (Table 3).

User-Friendliness and the Acceptability of the Device
The main findings of the questionnaire about the user-friendliness and user acceptability of the device were shown in Table 4. Eighty-six percent of participants found it “easy” or “very easy” to attach the ABPM device by themselves. These results suggested that the device was user-friendly and well accepted. On the other hand, 29% of participants detached the device more than three times by themselves (when bathing [83%], changing clothes [49%], or driving [16%]).

DISCUSSION

The present study provided information on the quality of recordings and acceptability of the “Ambulatory” mode of the Microlife WatchBP O3, which has three modes of function for clinical use (“Ambulatory,” “Home,” and “Casual”) (Table 1). The percentages of valid readings, erroneous readings according to the manufacturer, and artifactual readings according to our criteria were 90%, 4.9%, and 3.4%, respectively. Eighty-six percent of participants found it “easy” or “very easy” to attach the device by themselves.

Quality of Recordings
The percentage of valid readings (90%) was similar to that reported previously (11, 14–16). Among previously examined devices (14–16), the percentage of valid readings ranged from 71.3% with the TM-2420 (A&D, Tokyo, Japan) (14) to 95.7% with the TM-2421 (A&D, Tokyo, Japan) (14). When we excluded the three participants (ID 14, 30, and 31) with incomplete measurements, the remaining 34 showed a relatively high percentage of valid readings (≥80% in 33 subjects, ≥70% in 1 subject) (Table 3).

Self-Measurement of ABPM
In the past, patients who used conventional ABPM devices did not attach and detach the devices by themselves, because this had to be done by a skilled medical technologist. However, in the present study, after programming the interval of measurements (if necessary), we asked the participants to perform ambulatory monitoring by themselves, since the device was based on the Microlife WatchBP Home device (9, 10) for self-measurement. The device therefore needed to combine both user-friendliness and accuracy. Most participants (86%) found it “easy” or “very easy” to attach the device by themselves, and the questionnaire also revealed that self-measurement of ABPM had a high level of acceptance among the participants. The present study indicated that, even when users attached the device by themselves, the WatchBP O3 provided accurate ambulatory readings with the exception of the three subjects (ID 14, 30, and 31) previously mentioned.

Study Limitations
First, all participants in this study were Japanese. In Japan, HBPM is more widespread in clinical practice than in other countries (17). In fact, 94% of participants...
reported previous experience with HBPM devices. This could lead to more favorable answers regarding acceptance of the device. Second, the device was tested almost exclusively in normotensive subjects. In hypertensive subjects, the acceptance rate might be lower due to different characteristics of this population and due to higher cuff pressures which may cause discomfort. Third, during self-measurement of ABPM, users may not hesitate to detach the device. In the present study, 29% of participants detached the device more than three times for their own convenience in an arbitrary manner. Hence, self-measurement could be associated with unexpected behaviors among users. However, self-measurement of ABPM makes the activity of daily life such as bathing more convenient for the participants.

**CONCLUSION**

The WatchBP O3, which is easy to manipulate, may be convenient and acceptable for users. The percentage of valid readings is similar to that reported
Table 4. Results of the questionnaire about the user-friendliness and user acceptability of the Microlife WatchBP O3

1. Eighty-six percent of participants found it “easy” or “very easy” to attach the ABPM device by themselves.
2. Seventy-eight percent reported that the device did not interrupt their sleep.
3. Fifty-eight percent found that the size of the device was optimal.
4. Fifty-eight percent answered that the device was reliable.
5. Twenty-nine percent of participants detached the device more than three times by themselves (when bathing [83%], changing clothes [49%], or driving [16%]).
6. Ninety-four percent of participants reported previous experience with a HBPM device.

Previously, Ambulatory BP has a stronger predictive power for target organ damage, morbidity, and mortality than conventional BP measurement (2–7). Ambulatory BP monitoring also provides a more reliable diurnal variability of BP than casual or HBPM. It is therefore expected that the WatchBP O3 will encourage wider use of ABPM in the monitoring of hypertension. The current market price of the ABPM device is greater than US $2000. A new era for self-monitoring of ABPM would arise in the near future, if the price of the equipment is no greater than that of HBPM devices.

ACKNOWLEDGMENTS
This work was supported by a Grant-in-Aid from Microlife. This study was also supported in part by Grants for Scientific Research (15790293, 16590433, 17790381, 18390192, 18590587, 19509292, and 19790423) from the Ministry of Education, Culture, Sports, Science, and Technology, Japan; Grants-in-Aid (H17–Kenkou-007, H18–Junkankitou [Seishuu]-Ippan-012, and H20–Junkankitou [Seishuu]-Ippan-009, 013) from the Ministry of Health, Labor and Welfare, Japan; Grants-in-Aid for Japan Society for the Promotion of Science (JSPS) fellows (16.54041, 18.54042, 19.7152, 20.7198, 20.7477, and 20.54043); Health Science Research Grants and Medical Technology Evaluation Research Grants from the Ministry of Health, Labor and Welfare, the Ministry of Education, Culture, Sports, Science, and Technology, Japan; Japan Atherosclerosis Prevention Fund; Uehara Memorial Foundation; Takeda Medical Research Foundation; National Cardiovascular Research Grants; and Biomedical Innovation Grants.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

REFERENCES


A stroke may be the first manifestation of atrial fibrillation (AF). The percentage of patients who develop a stroke due to AF without a previous diagnosis of AF depends on the method used to screen for it. From the Framingham study, 4% of stroke patients were found to have newly diagnosed AF on hospital admission. A review of published studies evaluating Holter monitoring following a stroke found new AF in 3.8–6.1% of patients. Event loop recorders used for up to a week found AF in 5.7–7.7% of patients. Assuming that 4% of stroke patients were found to have AF on hospital admission as in the Framingham study, then the additional 5.7–7.7% of patients found to have AF in the studies using event loop records makes the total percentage of patients with newly diagnosed AF following a stroke to be 9.7–11.7%. This may still be an underestimation of the total stroke risk due to AF because AF may not recur for over 3 months in some patients with intermittent AF. This suggests that >10% of all strokes are due to asymptomatic AF.

Screening for asymptomatic AF and treating newly diagnosed AF patients with warfarin should help prevent most of these strokes. A recent study suggested that episodes of AF that last less than a few hours do not carry the same risk of stroke as longer episodes. This suggests that intermittent screening for AF may be adequate to identify the patients who are at high risk of developing a stroke due to AF. Home screening for asymptomatic AF by self-assessment of the pulse irregularity has been recommended by the National Stroke Association (http://www.strokeheart.org/CYPA/basics.html). However, application of this approach in the community has shown only limited success, with a sensitivity and specificity of ~70% in the elderly. Another method of screening for AF uses an automatic blood pressure monitor to detect the pulse irregularity. Because hypertension is the most common risk factor associated with AF, using an automatic blood pressure monitor to detect AF would benefit the large number of hypertensive patients who monitor their blood pressure at home. The first blood pressure monitor modified to detect AF was shown to have a very high sensitivity but a relatively lower specificity. This device was given to outpatients who had a previous episode of AF to monitor their heart rhythm at home on a daily basis. Out of the 19 subjects in the study, the device detected seven episodes of recurrent AF with three false positive readings. A new algorithm was developed for this device to improve the specificity by reducing the effect of premature beats. This study was a two center trial designed to assess the sensitivity and specificity of an automated oscillometric device using a new AF algorithm. A secondary aim of the study was to evaluate the effect of specific rhythm abnormalities on the specificity for AF.

Detection of Atrial Fibrillation Using a Modified Microlife Blood Pressure Monitor

Joseph Wiesel, Lorenzo Fitzig, Yehuda Herschman and Frank C. Messineo

BACKGROUND
Hypertension is a major risk factor for the development of atrial fibrillation (AF) and for stroke due to AF. Asymptomatic AF can result in a stroke, in patients with risk factors, if it is not detected and treated appropriately. This study evaluated the sensitivity and specificity of an automatic oscillometric sphygmomanometer designed to detect AF.

METHODS
The sphygmomanometer incorporates an algorithm for detecting AF while reducing false positive readings due to premature beats. A total of 405 unselected outpatients seen in two cardiology offices were evaluated by taking three sequential device readings and one electrocardiogram (EKG) on each patient.

RESULTS
For detecting AF, the sensitivity was 95% and the specificity 86% with a positive predictive value of 68% and a negative predictive value of 98% for single device readings. For the three sequential device readings grouped together, the sensitivity was 97% and the specificity was 89%. The device correctly categorized most of the non-AF, abnormal rhythms. The specificity for those in sinus rhythm was 97%.

CONCLUSIONS
This device is able to detect AF with high sensitivity and specificity. Use of this device by patients who monitor their blood pressure at home may help detect asymptomatic AF and allow for treatment prior to the development of a stroke.
METHODS
An oscillometric automatic blood pressure monitor (model BP3MQ1-2D; Microlife USA, Dunedin, FL) with an irregular heartbeat detection feature was modified such that the irregular heartbeat icon flashes when AF was detected. The device measures the last 10 pulse intervals during cuff deflation and calculates the mean and standard deviation of the intervals. An irregularity index is defined as the standard deviation divided by the mean of the time intervals. In order to reduce the effect of premature beats on the irregularity index, a cutoff value of 25% was chosen so that each of the ten pulse beat intervals that is 25% greater than or 25% less than the mean time interval is deleted. The remaining time intervals are used to calculate the irregularity index. If the irregularity index exceeds a threshold value of 0.06, the rhythm is considered irregular. The number of beats analyzed, and the irregularity index threshold value of 0.06 were chosen to maximize sensitivity for detecting AF. This was done by analyzing heartbeat time intervals from 12-lead electrocardiograms (EKGs) obtained in hospitalized patients as described in the previous study by Wiesel et al.8 The cutoff value was selected by analyzing the pulse beat time intervals obtained from the patients in this previous study. The cutoff value was chosen to improve the specificity while maintaining a high sensitivity for AF. Despite the use of the cutoff values, a premature beat whose time interval is close to the mean time interval would not be deleted and may result in a rhythm that would be considered irregular.

Unselected general cardiology outpatients seen for scheduled visits in two different cardiology offices in Queens, NY were enrolled in the study. Patients with pacemakers or defibrillators were excluded from the study. Demographic data and the presence of risk factors for stroke due to AF, including diabetes mellitus, hypertension, congestive heart failure, and coronary artery disease, were documented. Medication use was not documented because this did not impact on the accuracy of the device based on our previous experience. After informed consent, a standard 12-lead EKG and three sequential device readings were obtained within a few minutes of each other on each patient by a trained technician. EKGs were usually done within 2 min of the device reading but in all cases the EKG was done during the same 15 min office visit as the device reading. The EKGs were read by a board certified cardiologist who was only given the EKGs and had no knowledge of the device readings. The device readings were compared to the EKG readings for each of the three readings individually and for the three sequential readings combined. For the three-sequential readings, the final reading was considered to be irregular if two or three of the individual readings were irregular. If none or only one of the three readings was irregular, the combined three-sequential reading was considered regular.

For the individual readings, 95% confidence intervals were calculated using a bootstrap approach. Bootstrapping is a statistical procedure in which the sample of data is treated as if it were the true population.13 Bootstrap samples are created by repeatedly sampling with replacement from the original sample. This was done a large number of times (1,999 times) and then estimates of sensitivity and specificity were derived. Because the bootstrap samples are derived by sampling the data with replacement, the derived estimates vary across the bootstrap samples. Through this repeated sampling procedures, statistical tests can be conducted that, practically, do not involve any assumptions about the data. The large resampling based approach says the average of these bootstrap estimates will converge to the true estimates. Confidence intervals for the three-sequential readings were calculated according to the efficient-score method (corrected for continuity) described by Newcombe, based on the procedure outlined by Wilson.12,13 As Newcombe notes, the familiar normal approximation is ill suited to situations where the proportion is quite small, as is often the case with prevalence measures, or quite large, as is optimally the case with measures of sensitivity and specificity.

The study was also designed to evaluate the non-AF arrhythmias that may cause false positive readings with the device. The non-AF EKGs were classified as sinus rhythm if no abnormal rhythm was seen on the 12-lead EKG. If any abnormal rhythm was noted on the 12-lead EKG, the EKG was classified based on that abnormal rhythm.

The study was approved by the New York Hospital Queens institutional review board. Written informed consent was obtained from all patients before participation in the study.

RESULTS
A total of 405 patients were enrolled in the two sites, 205 from the first site and 200 from the second site. Demographic data and selected cardiac risk factors are listed in Table 1. The study population is representative of those patients who are at risk for AF: the elderly and those with hypertension or underlying heart disease. Over 50% of the patients had hypertension. Eighteen percent of the patients were nonwhite.

Of the 405 patients, 93 (i.e., 23%) patients had AF based on the EKG readings. The association between the EKG readings and both the individual and the three-sequential device readings were analyzed using the $\chi^2$-test. The $\chi^2$-test resulted in a

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient demographics and cardiac risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (no.)</td>
<td>405</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>73.0</td>
</tr>
<tr>
<td>Age range (years)</td>
<td>34–98</td>
</tr>
<tr>
<td>Male (%)</td>
<td>51</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White (%)</td>
<td>82</td>
</tr>
<tr>
<td>Black (%)</td>
<td>8</td>
</tr>
<tr>
<td>Other (%)</td>
<td>10</td>
</tr>
<tr>
<td>CHF</td>
<td>27</td>
</tr>
<tr>
<td>HTN</td>
<td>209</td>
</tr>
<tr>
<td>DM</td>
<td>60</td>
</tr>
<tr>
<td>CAD</td>
<td>151</td>
</tr>
</tbody>
</table>

CAD, coronary artery disease; CHF, congestive heart failure; DM, diabetes mellitus; HTN, hypertension.
significant association of both the individual readings and the
three-sequential readings to the EKG readings (P < 0.0001).
The individual device readings compared to the EKG read-
ings are shown in Table 2 (ref. 14) The individual device read-
ings resulted in a sensitivity of 95% and a specificity of 86%. In
this population of patients with a very high prevalence of
AF, for individual device readings the positive predictive value
was 68% and the negative predictive value was 98%. The three-
sequential device readings compared to the EKG are shown in
Table 3. The mean sensitivity and specificity for the three-
sequential readings is higher than for individual readings but
it is not statistically different.

The most frequent abnormal non-AF rhythm was ventricu-
lar premature contractions occurring in 7% of the non-AF
patients (Table 4). The next most common arrhythmia was
atrial premature contractions which occurred in 6% of non-AF
patients. The remaining arrhythmias, which include atrial flut-
er, sinus arrhythmia, wandering atrial pacemaker, supraven-
tricular tachycardia and second degree atrio-ventricular block,
each occurred in ≤2% of the non-AF patients. For the indi-
vidual readings, the device was able to classify 62% of EKGs
with premature ventricular contractions correctly as non-AF
rhythms. It was less specific with the premature atrial con-
tractions classifying only 43% correctly as non-AF rhythms.
Overall, the algorithm was able to correctly classify over 50%
tractions classifying only 43% correctly as non-AF rhythms.
It was less specific with the premature atrial con-
tractions correctly as non-AF rhythms. The specificity of this device in the general population is
likely to differ from the results of this study. In this study pop-
ulation, 14% of the patients were found to have false positive
results with single device readings. Because the study popula-
tion was recruited from cardiology offices, these patients can
be expected to have a higher prevalence of underlying heart
disease than the general population and are, therefore, more
likely to have abnormal heart rhythms. The true specificity for
the general population can be expected to fall between the 86%
found in this population of heart patients and the 97% that was
calculated from those without documented abnormal rhythms
on EKG. The majority of patients with AF in this study had
persistent AF. Whether the device would have the same sen-
sitivity for patients with paroxysmal AF is not known and will
need to be determined in future studies.

Patients with premature beats were found to have a relatively
low specificity of ~50%. Therefore, some might suggest that
patients with these arrhythmias be told not to use this device.
However, restricting this device to those without premature
beats means that the half of the patients with premature beats
that could use this device would not get to benefit from it. In
addition, screening all the patients by first obtaining an EKG
prior to using this device would, likely, be more costly than
having all the patients use this device and then obtaining an
EKG on the small percentage with abnormal readings.

There is a subgroup of patients that would benefit the most
from using this device. Because the device is designed to detect
AF prior to the development of a stroke, it would make sense to
limit its use to only those at risk of a stroke from AF. Those are
patients with hypertension, diabetes mellitus, congestive heart
failure, a previous stroke or those aged ≥65 years. A study

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**Table 2 | Comparison of individual device readings to the rhythm as determined by the EKG readings**

<table>
<thead>
<tr>
<th>EKG</th>
<th>AF Sensitivity (%)</th>
<th>Non-AF Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device reading</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irregular</td>
<td>266</td>
<td>127</td>
</tr>
<tr>
<td>Regular</td>
<td>13</td>
<td>809</td>
</tr>
</tbody>
</table>

Sensitivity and specificity with 95% confidence intervals in parentheses are shown in the last two columns. AF, atrial fibrillation; EKG, electrocardiogram.

**Table 3 | Comparison of the three-sequential device readings to the rhythm as determined by the EKG readings**

<table>
<thead>
<tr>
<th>EKG</th>
<th>AF Sensitivity (%)</th>
<th>Non-AF Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device reading</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irregular</td>
<td>90</td>
<td>35</td>
</tr>
<tr>
<td>Regular</td>
<td>3</td>
<td>277</td>
</tr>
</tbody>
</table>

Sensitivity and specificity with 95% confidence intervals in parentheses are shown in the last two columns. AF, atrial fibrillation; EKG, electrocardiogram.

**Table 4 | Specificity for AF in patients with non-AF rhythms**

<table>
<thead>
<tr>
<th>Rhythm</th>
<th>Number</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VPC</td>
<td>23</td>
<td>62</td>
</tr>
<tr>
<td>APC</td>
<td>20</td>
<td>43</td>
</tr>
<tr>
<td>A flutter</td>
<td>7</td>
<td>48</td>
</tr>
<tr>
<td>WAP</td>
<td>5</td>
<td>53</td>
</tr>
<tr>
<td>SVT</td>
<td>2</td>
<td>83</td>
</tr>
<tr>
<td>AV block</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>SA</td>
<td>6</td>
<td>33</td>
</tr>
<tr>
<td>Sinus</td>
<td>248</td>
<td>97</td>
</tr>
</tbody>
</table>

The number column lists the number of patients with that specific rhythm noted on electrocardiogram. A flutter, atrial flutter; AF, atrial fibrillation; APC, atrial premature contraction; AV, atrio-ventricular block; SA, sinus arrhythmia; SVT, supraventricular tachycardia; VPC, ventricular premature contraction; WAP, wandering atrial pacemaker.
needs to be conducted to evaluate the specificity and sensitivity of this device in these high-risk patients. In addition, long-term studies following patients using this device at home needs to be conducted to determine the number of new episodes of AF detected and the cost of the false positive readings.

The natural inclination, for someone who has an abnormal heart rhythm reading when taking their blood pressure, is to repeat the reading. Based on our data, repeating the reading three times improves both the sensitivity and specificity for AF detection. Those who have multiple abnormal pulse readings would be told to visit their physician to assess their rhythm with an EKG. Those with newly diagnosed AF can then be treated appropriately. Those found to have a non-AF abnormal rhythm would be informed that they cannot use the device to monitor for AF. Those found to have a normal rhythm at the time of the office visit would require further evaluation to determine the cause of the abnormal device reading. In a previous study of patients with a history of AF, 2 out of 19 patients had intermittent abnormal device readings that were diagnosed by use of an EKG event monitor.10 This is similar to the evaluation that these patients would have if they were seen by their physicians complaining of intermittent palpitations that was not diagnosed by the office 12-lead EKG. Though visiting their physician for a false positive reading may be inconvenient and add some cost, it does not result in any harm to the patient. Typical medical costs of a false positive reading would be $80 for an office visit and an EKG with the possibility of an additional $250 if an EKG event monitor was needed to diagnose the arrhythmia. There may be some anxiety experienced by patients with an abnormal reading prior to seeing their physician, due to concern about having AF. This is inevitable with any home screening technique, such as breast self-examination for women. Yet, if the technique can save lives or prevent strokes, then it is still reasonable to recommend it.

Anticoagulation is recommended prior to cardioversion for patients with AF for over 48 h.1 Based on the recent TRENDS study, AF needs to be present longer than 5.5 h to increase the risk of stroke.5 The precise amount of time that is required for a thrombus to form in a patient with AF has not yet been determined. However, it is clear that AF needs to be present for hours before the risk of a stroke increases. Therefore, intermittent monitoring for AF using this blood pressure device would be reasonable. The maximum time period between readings that would ensure detection of AF that could cause a stroke has yet to be determined. Until this period is determined, taking once daily readings is a reasonable compromise for maintaining patient compliance while providing a good likelihood of detecting AF that could cause a stroke.

In some patients, AF is transient and lasts for only a few minutes or hours. However, current recommendations suggest anticoagulation for patients with AF and stroke risk factors, independent of the length of the AF episode. The reason for this is that patients with brief episodes of AF are at risk of developing prolonged episodes of asymptomatic AF which could result in a stroke. Regular use of this device is likely to detect prolonged asymptomatic episodes of AF. Whether this device can be used to defer treatment with anticoagulation in these patients until a prolonged episode of AF is detected will need to be determined by future clinical trials.

Home monitoring of blood pressure for patients with hypertension has been shown to be of clinical value.13 Because hypertension is the most common risk factor associated with AF, the use of a home blood pressure monitor to detect asymptomatic AF could provide additional benefit. The Microlife AF detection blood pressure monitor with the new algorithm has high sensitivity and is able to correctly classify the majority of non-AF rhythms. Use of this oscillometric blood pressure monitor with AF detection by high-risk patients may have the potential to significantly reduce the risk of strokes due to asymptomatic AF.

Acknowledgment: This study was supported by a grant from: Microlife USA, Inc., Dunedin, FL.

Disclosure: J.W. has a patent for the atrial fibrillation algorithm. The other authors declared no conflict of interest.


Validation and Compliance of a Home Monitoring Device in Pregnancy: Microlife WatchBP Home

Yealin Chung, Annemarie de Greeff, and Andrew Shennan

Maternal & Fetal Research Unit, King’s College London, London, UK

Objective. To assess the accuracy and patient compliance in using a novel home blood pressure monitoring device in high-risk pregnancy. Methods. Device accuracy was assessed according to the British Hypertension Society protocol in 45 pregnant women, including 15 with preeclampsia. Twenty-one high-risk pregnant women used the device in addition to their antenatal care. Results. The device achieved a mean difference ± SD of 0.4 ± 7.3/−0.4 ± 5.5 mmHg (pregnancy) and −2.6 ± 7.0/0.8 ± 4.4 mmHg (preeclampsia) for systolic/diastolic pressure. Eighty-one percent of women did at least 6 measurements/day and all women did at least 2 measurements/week. Conclusion. The Microlife WatchBP Home is accurate for use in pregnancy and increases surveillance in compliant patients.

Keywords Blood pressure, Home monitoring, Preeclampsia, Pregnancy, Validation.

INTRODUCTION

Home blood pressure monitoring (HBPM) has superior reproducibility to clinic measurements (1), can detect white coat/masked hypertension and is associated with improved hypertension control (2,3). In addition, it is a more acceptable and practical way of measuring BP, especially when compared to ambulatory blood pressure monitoring (ABPM).

The reliability of HBPM however, has been hampered by patient recording bias (4,5), device accuracy limitations, no agreement on the optimal blood pressure (BP) measurement schedule or the interpretation of the data collected (6,7). Fortunately, emerging technologies have more recently provided devices with a memory function, personal computer (PC) interfaces and increased accuracy (8,9) to overcome these drawbacks. In addition, an optimal
HBPM schedule has been recommended by the European Society of Hypertension (ESH) Working Group on Blood Pressure Monitoring (10,11).

HBPM is increasingly being adopted in pregnancy, with a recent survey (12) reporting that in some populations, more than two thirds of non-proteinuric hypertensive women are already using HBPM in addition to their routine antenatal care.

In the pregnant hypertensive population, the unpredictable and heterogeneous nature of preeclampsia currently necessitates all hypertensive women to be subjected to increased antenatal visits and admissions for surveillance of BP and urine protein level. In fact, antenatal hypertension accounts for up to 24% of all admission to maternity units in the UK (13). Despite such measures, the current evidence suggests that conventional antenatal care is still not adequate in detecting disease deterioration of which inadequate identification of hypertension is likely to contribute (14). Therefore HBPM, particularly in women at risk of preeclampsia, offers the potential of being more than just a superior diagnostic method, through facilitation of maximal surveillance outside of the clinical environment.

Few automated BP devices are accurate compared to auscultation using a recognised validation protocol (9,15) and no studies have evaluated patient compliance to measurement schedules, which is key to the safety of introducing HBPM if it is to replace standard antenatal visits.

The Microlife WatchBP Home is a novel device that has specifically been designed according to the current ESH home monitoring guidelines to promote optimal application of HBPM (16). Its dual mode design allows both scheduled (diagnostic mode) and patient initiated (usual mode) BP measurements. The device allows automatic storage and ESH recommended average calculation of the data as well as a PC interface. It has been validated in an adult population (17) according to International protocol of the ESH (18). However, its accuracy in pregnancy and preeclampsia is yet to be established, as the majority of devices underestimate BP by clinically significant amounts, especially in preeclampsia (19), despite passing an adult validation.

METHODS

The study was performed at St. Thomas’ Hospital (London, UK). Ethical permission was obtained from the local research ethics committee and all subjects were required to give written informed consent for validation of the device.

Accuracy Assessment

The Microlife WatchBP Home device was evaluated according to the British Hypertension Society (BHS) protocol (15). Although the protocol only stipulates
the need for 30 pregnant women, we recruited an additional 15 women with preeclampsia. Preeclampsia was defined as a diastolic blood pressure of ≥90 mmHg on two separate occasions more than 4 hours apart or a single reading >110 mmHg accompanied by proteinuria of >0.3 g on a 24 hour collection (20).

Measurements were taken while women were seated with their arm supported at heart level using a table or the arm of a chair. Arm circumference was measured at the approximate midpoint of the upper arm to determine the appropriate cuff size to be used. Two cuff sizes were available: Standard (22–32 cm) and Large (32–42 cm) and therefore any woman with an arm circumference outside 22–42 cm was excluded from the study. In addition, any woman with an arrhythmia or unclear Korotkoff sounds was also excluded from the study.

Nine sequential same arm blood pressure measurements were taken from each woman, alternating between the reference device (mercury sphygmomanometer) and the test device (Microlife WatchBP Home). Two mercury columns were joined via a Y connector to an upper arm cuff and a bulb. This enabled the trained observers to take simultaneous auscultatory measurements while being blinded to each other’s readings and to the device reading. Device readings were retrieved from the device memory after completing all 9 measurements, which could then be reviewed independently of the observers. At least 30 seconds to 1 minute was allowed between measurements to avoid venous congestion and to minimise variability in blood pressure. The first reading by observer 1 was used to classify subjects into groups specified by the protocol (Table 1) and only the last 7 readings were used in the analysis.

The three sequential mercury measurements with the smallest absolute difference compared to the three device measurements before or after were chosen for the final analysis. The percentage of differences within 5, 10 and 15 mmHg was calculated separately for systolic and diastolic pressure (and for each observer) to determine the grading (A-D grade) according to the BHS criteria (Table 2). The device had to achieve percentages greater than or equal to those in the table to achieve a particular grade. Data was entered and analysed using Excel (Microsoft Office) software. A visual representation of the device accuracy is provided using mean-against-difference plots (21).

<table>
<thead>
<tr>
<th>Table 1: Recruitment criteria.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria</td>
<td>Requirement</td>
</tr>
<tr>
<td>Arm circumference &gt;35cm</td>
<td>8–10</td>
</tr>
<tr>
<td>Second Trimester</td>
<td>10</td>
</tr>
<tr>
<td>Third Trimester</td>
<td>10</td>
</tr>
<tr>
<td>SBP range: 100–115, 116–130, 131–145, 146–160 mmHg</td>
<td>5 in each</td>
</tr>
<tr>
<td>DBP range: 70–80, 81–90, 91–105 mmHg</td>
<td>5 in each</td>
</tr>
</tbody>
</table>
Home Monitoring

A total of 8 Microlife WatchBP Home devices were available and used in this part of the study and loaned to women for use in addition to their current antenatal care. Pregnant women were recruited from the Day Assessment Unit (DAU) and antenatal clinics at St Thomas’ Hospital. On recruitment, they were classified into four distinct categories based on the reasons for home monitoring and to allow for customised instructions depending on patient classification (Table 3). Hypertension was defined as BP of \( \geq 90 \) mmHg on two occasions that were at least four hours apart or a single diastolic reading of \( >110 \) mmHg. Proteinuria was defined as \( >0.3 \) g on a 24-hr collection. Preeclampsia was defined as confirmed hypertension and proteinuria (20).

Table 2: Grading criteria according to the British Hypertension Society protocol.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Absolute pressure difference between standard and test device (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( \leq 5 )</td>
</tr>
<tr>
<td>A</td>
<td>60</td>
</tr>
<tr>
<td>B</td>
<td>50</td>
</tr>
<tr>
<td>C</td>
<td>40</td>
</tr>
<tr>
<td>D</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cumulative percentage of readings (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>C</td>
</tr>
<tr>
<td>D</td>
</tr>
</tbody>
</table>

Table 3: Summary of patient classification.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Monitor</th>
<th>Seek Advice if:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension Alone / High Risk Patients</td>
<td>Hypertension (chronic or gestational) + No Protein OR High Risk for PET</td>
<td>DIAG &amp; USUAL BP ( \geq 140/90 ) mmHg AND ( \geq 1+ ) Protein OR BP ( \geq 160/100 ) mmHg</td>
<td>BP ( \geq 160/100 ) mmHg</td>
</tr>
<tr>
<td>Proteinuria Alone</td>
<td>No Hypertension + Protein (( \geq 0.3 )g/dL)*</td>
<td>DIAG &amp; USUAL BP ( \geq 140/90 ) mmHg AND ( \geq 1+ ) Protein OR BP ( \geq 160/100 ) mmHg</td>
<td>BP ( \geq 160/100 ) mmHg</td>
</tr>
<tr>
<td>Mild Preeclampsia</td>
<td>Hypertension + Protein (( 0.3-0.5 )g/dL)*</td>
<td>DIAG &amp; USUAL BP ( \geq 160/100 ) mmHg</td>
<td>BP ( \geq 160/100 ) mmHg</td>
</tr>
<tr>
<td>Uncertain BP</td>
<td>To improve BP characterisation (e.g. to exclude white coat hypertension)</td>
<td>DIAG only BP ( \geq 160/100 ) mmHg</td>
<td>BP ( \geq 160/100 ) mmHg</td>
</tr>
</tbody>
</table>

**Table 2**: Grading criteria according to the British Hypertension Society protocol.

**Table 3**: Summary of patient classification.

*DIAG = Diagnostic mode: 2 consecutive readings between 6 am–12 pm and 6 pm–12 am.
USUAL = Usual mode: Patient initiated single readings at 10 am, 12 pm and 2 pm.
PET = Preeclampsia.
*24-hour urine collection.
Verbal consent was obtained and demographic information such as age, gravidity, parity and gestation were recorded. The patient, health care professionals in charge of management and maternity notes were consulted to obtain the relevant clinical details required for correct categorisation. All patients were loaned a HBPM device with an appropriately sized cuff, based on a measurement of their arm circumference at the approximate mid point of the upper arm. Any woman in the ‘Hypertension only or High Risk’ group was also given urine dipsticks and a urine sample collection bottle. Training was then given for approximately 15 min on how to use the HBPM device; how to obtain a midstream urine sample and how to use the urine dipstick (if indicated). Women were asked to call the DAU if a specified BP threshold was reached. A typed summary of instructions and telephone numbers for the Day Assessment Unit (DAU), Birth Centre and for the research office was provided.

All women were asked to use the diagnostic (DIAG) function of the device. In this function, two BP measurements were taken consecutively at a patient initiated time between 6 am–12 pm and again between 6 pm–12 am. Women were encouraged to do this for 7 consecutive days to fulfil the ESH guidelines. In addition, some women were also asked to take a single BP measurement at 10 am, 12 pm and 2 pm using the USUAL mode.

A schedule of review was agreed with each individual woman according to her scheduled antenatal appointments. All the BP measurements were recorded in the memory storage system of the device and were subsequently downloaded and saved onto a PC from the device at every patient review. At every review, feedback from the patient was recorded, especially with regard to any incidences of high BP reading (above the instructed threshold) and subsequent actions taken or not taken by the patient. Any problems that the patient faced during HBPM (i.e. technical difficulties such as device malfunction) and factors that could have influenced the readings or measurements were also recorded. Each patient carried on using the HBPM device until home monitoring was no longer clinically indicated or the patient decided to withdraw from the study or i.e. delivery or admittance to hospital.

RESULTS

Validation

Demographics of the subjects recruited were similar for pregnancy and preeclampsia (Table 4). The mean systolic and diastolic blood pressures were higher in the preeclamptic population compared to normotensive pregnancy: 135/82 mmHg vs. 119/75 mmHg. The mean value for proteinuria on 24-hr collection in preeclamptic women was 1.1 ± 1.4 g/dL.
Chung, Greeff, and Shennan

In pregnancy (excluding preeclampsia), the Microlife WatchBP Home device achieved an A/A grade with a mean difference ± SD of 0.4 ± 7.3 mmHg for systolic and −0.4 ± 5.5 mmHg for diastolic pressure (Table 5). In preeclampsia the device achieved an overall B/A grade with a mean difference ± SD of −2.6 ± 7.0 mmHg and −0.8 ± 4.4 mmHg for systolic and diastolic pressures respectively (Table 5). The device therefore also passed the AAMI criteria, which stipulates a mean difference ± SD of ≤5 ± 8 mmHg (62). Mean-against-difference plots are shown in Figures 1 and 2.

The inter-observer comparison fulfilled the accuracy criteria stipulated in the BHS protocol with 97% of readings within 5 mmHg and 100% of readings within 10 mmHg for both systolic and diastolic pressures.

During the validation study one woman was excluded, because the device failed to produce a measurement. This was suspected to be due to excess hanging skin folds on the posterior aspect of the upper arm, which may have interfered with correct application of the cuff and subsequent signal acquisition.

Home Monitoring

In all, 21 patients used the 8 home monitoring devices available to take a total of 1141 BP measurements. The average gestation of patients at recruitment

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>Height (cm)</th>
<th>Weight (kg)</th>
<th>Arm circumference (cm)</th>
<th>Gestation (weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy (n = 30)</td>
<td>33 ± 5</td>
<td>165 ± 7</td>
<td>76 ± 16</td>
<td>31 ± 4</td>
</tr>
<tr>
<td>Preeclampsia (n = 15)</td>
<td>32 ± 6</td>
<td>165 ± 5</td>
<td>73 ± 9</td>
<td>31 ± 4</td>
</tr>
</tbody>
</table>

*Values stated are mean ± standard deviation.

Table 5: Device accuracy in pregnancy and preeclampsia according to BHS criteria.

<table>
<thead>
<tr>
<th>Differences between standard and test device (mmHg)</th>
<th>Grade</th>
<th>≤5</th>
<th>≤10</th>
<th>≤15</th>
<th>Mean ± SD mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy (n = 90)</td>
<td>Systolic BP</td>
<td>A</td>
<td>61%</td>
<td>87%</td>
<td>96%</td>
</tr>
<tr>
<td></td>
<td>Diastolic BP</td>
<td>A</td>
<td>74%</td>
<td>93%</td>
<td>98%</td>
</tr>
<tr>
<td>Preeclampsia (n = 45)</td>
<td>Systolic BP</td>
<td>B</td>
<td>67%</td>
<td>89%</td>
<td>93%</td>
</tr>
<tr>
<td></td>
<td>Diastolic BP</td>
<td>A</td>
<td>76%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
was 31 weeks. The majority of patients were recruited under the ‘Hypertension alone/High Risk for Preeclampsia’ Category (76%).

The home monitoring devices were used between 1–54 days. Forty-eight percent of women used home monitoring for up to 1 week and 38% of women used it for more than 4 weeks. Eighty-one percent of patients had their BP monitored every day, with an average of 6 measurements per day. Up to 75% of the remaining patients monitored their BP at least 4 days per week with an average of 3 measurements per day.

Eleven patients acted (i.e. rang the DAU) on raised BP measurements according to the instructions given to them regarding thresholds. Two patients
Chung, Greeff, and Shennan were subsequently admitted before their next scheduled antenatal appointment. The first of these patients had a diagnosis of mild preeclampsia (proteinuria <0.5g/dL) and was being managed as an outpatient at 35 weeks gestation. She had a HBPM of 171/110 mmHg and a repeat measurement of 164/104 mmHg. She sought advice as instructed and was subsequently admitted until delivery. Her 24-hr proteinuria level was 0.56 g/dL. The second patient was chronic hypertensive and was being monitored for 8 weeks (since 23 weeks gestation) showing a gradual increase in BP over time. Methyldopa was prescribed and increased to 500 mg TDS. She had a HBPM of 152/105 mmHg, with repeat readings of 151/102 mmHg and 164/93 mmHg, together with a trace of protein on that day. She sought advice as instructed and was admitted for rapid onset preeclampsia. Her 24-hr proteinuria level was 0.53g/dL.

Ten patients did not respond appropriately to their HBPM according to the instructions given. Three patients rang the DAU for a raised BP at home (although it was below the instructed ‘action’ threshold) and subsequently visited the DAU on the advice of the attending midwife. In contrast there were 33 occasions where a patient’s BP was raised above the instructed action threshold, but they did not ring the DAU to seek advice. On 12 occasions, patients did not call the DAU immediately as a subsequent BP was below the ‘action’ threshold. On 4 occasions patients did not call the DAU, as they already had a hospital appointment the following day. The remaining 17 occasions occurred in two patients who both had a severe language barrier. On consultation, it was clear that the patients had poor understanding of the instructions given and the importance of alerting midwives of their raised BP readings. None of the inappropriate actions were instigated due to home protein dipstick readings.

Only 50% of diagnosed hypertensive pregnant women could be confirmed to be hypertensive according to HBPM (average BP ≥135/85 mmHg). There was 1 incidence of device malfunction due to a deflation valve error on a large cuff. A few women expressed difficulty in reaching midwives when phoning the DAU and some expressed difficulty in carrying out the full BP measurement schedule due to clashes with work-related commitments.

DISCUSSION

The Microlife WatchBP Home monitor is a novel oscillometric device, designed to comply with the HBPM schedule recommended by the ESH Working Group on Blood Pressure monitoring (10,16). The device has previously been shown accurate in adults (17) and this study shows the device to also be accurate in pregnancy and preeclampsia according to the BHS protocol. This achievement has only been reached by two other devices: the Microlife 3BTO-A (22) and the Omron MIT (23) (this device has been discontinued). Although the device was not assessed in severe preeclampsia, its purpose is to diagnose around a
threshold, and in this regard our definitions and study population are suited to validating its use for home monitoring. We followed a recognised protocol, and recruited more patients than recommended.

In addition this study shows the feasibility of implementing a novel technology in HBPM in addition to antenatal care in pregnancies at risk of preeclampsia. In the adult population it has certainly been suggested that self-monitoring may improve BP control by improving compliance through increased patient involvement (24,25). The Microlife WatchBP Home device has the facility to monitor compliance by downloading measurements onto a PC, which we have shown to be necessary by the high levels of non-compliance to instructions in this study. This is in contrast to the only other study assessing home BP measurement in hypertensive pregnancy, which showed good compliance using self-reporting diaries (26). In this study only 3 out of 72 women did not have accurate results comparing device readings with their diaries, with one patient fabricating measurements. The advantage of our device is that self-reporting is not required, due to the PC interface.

It is important to note that with an overall increase in BP surveillance, women who were compliant with monitoring instructions had a far greater surveillance of their BP than they would’ve had in the routine hospital environment. Our results also support the findings of previous reports that questions the reliability of clinic measurements (CBPM) in diagnosing hypertension in pregnancy, as in this study half the ‘hypertensive’ patients were found to be normotensive according to their HBPM. The use of HBPM in pregnancies at risk of hypertensive disorders would theoretically allow for earlier disease detection and/or disease progression and therefore has the potential to facilitate optimal antenatal care and to reduce the risk of poor obstetric outcome.

Despite the small numbers of this study, appropriate self referral and earlier admission was shown in at least two patients (10%). If the results from Ross-McGill’s randomised controlled trial27 in low risk pregnancies were to be extrapolated to high risk pregnancies such as the population in this study, it would be reasonable to assume that replacement of additional antenatal visits (purely for BP monitoring) with HBPM would reduce the total number of antenatal visits required, without being compensated for by an increase in visits for other reasons. However given the high number of failures to respond to instructions, we do recommend compliance assessment before instigating reduced antenatal schedules, which is achievable with this new technology.

Admission for bed rest in hypertensive pregnancy may aid optimal monitoring of BP, but has been shown to be of no value in preventing the disease process of pregnancy induced hypertension (i.e. no improvement in fetal growth or neonatal mortality) (28). Therefore in pregnant women with/at risk of hypertensive disorders, HBPM offers an alternative management option that provides greater surveillance of BP and has far less social and emotional encumbrance, as long as other risks such as severe hypertension do not occur.
The biggest challenge with HBPM implementation in this study was patient education, with the language barrier proving to be the greatest hurdle, and perhaps the only aetiological factor for women’s non-compliance. If patients are trusted and relied upon with their own surveillance of BP, it is vital that they understand the importance of BP measurements and the rationale behind the instructions. More than a third of patients recruited to this study presented with some degree of a language-related communicative barrier, which may reflect the diverse population in which this study was performed. In addition, the suggested BP measurement schedule clashed with either personal or work-related commitments. Home monitoring is only of benefit if the patient is able to take their own BP correctly, measure it as frequently as necessary and act on readings as instructed. If a woman is unable to carry out any of the above for any reason, whether it is due to inadequate understanding or work-related difficulty, addition of HBPM would be of no little value. In light of the fact that we live in a society where multi-ethnicity is becoming increasingly common, a holistic approach by the midwife and/or clinician is vital.

Despite the small sample size, important clinical principals are demonstrated from this study. Almost two thirds of all suspected preeclampsia referrals to a DAU are BP related and may benefit from the use of home monitoring.

In conclusion, implementation of HBPM in addition to current antenatal care is feasible and compliance can be monitored through improved device memory function and PC interface capabilities. Use of validated devices such as the Microlife WatchBP Home could be considered in replacing additional antenatal visits and hospital admissions prompted purely for the surveillance of BP and proteinuria in patients that are compliant in HBPM.

ACKNOWLEDGMENT

The authors would like to thank the DAU midwives and the patients for their assistance with this study.

Declaration of Interest: Microlife Corporation provided loan devices (Microlife WatchBP Home) for the study.

REFERENCES


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Validation of the Microlife Watch BP Office professional device for office blood pressure measurement according to the International protocol
George S. Stergiou, Dimitris Tzamouranis, Athanasios Protogerou, Efthimia Nasothimiou and Christos Kapralos

**Objective** To assess the accuracy of oscillometric and auscultatory blood pressure (BP) measurement taken using the professional electronic device Microlife Watch BP Office according to the European Society of Hypertension International Protocol.

**Methods** Thirty-three participants were included for the assessment of each measurement mode (oscillometric and auscultatory). Simultaneous BP measurements were taken by two observers (mercury sphygmomanometers) four times, sequentially with three measurements taken using the tested device. Absolute observer device BP differences were calculated. For each participant the number of measurements with a difference within 5 mmHg was calculated.

**Results** In phase 1 the device produced 32, 40 and 40 oscillometric systolic BP (SBP) measurements within 5, 10 and 15 mmHg, respectively and diastolic BP (DBP) 30, 40 and 43 (for auscultatory SBP 29, 42, 45 and DBP 33, 43, 45). In phase 2.1 the device produced 71, 90 and 96 SBP measurements within 5, 10 and 15 mmHg, respectively and DBP 71, 88 and 97 (for auscultatory SBP 72, 96, 99 and DBP 83, 96, 99). Twenty-four participants had at least two of their SBP differences within 5 mmHg and one participant had no difference within 5 mmHg, and DBP 23 and three participants, respectively (for auscultatory SBP 29 and 0 and DBP 29 and 1). Mean SBP difference was $-1.4 \pm 6.3$ mmHg and DBP $-0.8 \pm 6.0$ mmHg (auscultatory SBP $-1.8 \pm 4.5$ and DBP $-0.4 \pm 4.0$).

**Conclusion** The Microlife Watch BP Office device used in the oscillometric or the auscultatory mode fulfills the validation criteria of the International protocol and therefore can be recommended for clinical use.


Keywords: accuracy, European Society of Hypertension, International protocol, Microlife, office blood pressure, professional device, validation

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**Introduction**

The use of a conventional mercury device and the auscultatory technique is still recommended as the standard method for office blood pressure (BP) measurement [1]. This method, however, has important drawbacks [1,2], such as the white-coat phenomenon that often leads to BP overestimation [1], the observer bias and terminal digit preference [1] and the fact that physicians rarely follow the recommended methodology for BP measurement [3]. Furthermore, aiming for environmental protection, mercury is progressively being banned from medical use in several European countries [4].

Therefore, after a century of use, office BP measurement enters an era of transformation aiming to resolve several of its drawbacks and to maintain a central role in hypertension management [2–7]. Several non-mercury professional devices that differ from the conventional technique in several respects are currently being developed and tested. No agreement is still, however, present on what will replace the mercury device for the office measurement [5].

An interesting and technologically modern approach is to abandon the auscultatory technique and use validated electronic devices as currently accepted for ambulatory and home BP monitoring [1]. These devices avoid the terminal digit preference and the observer bias [1] and might minimize the white-coat effect if used in the office in the absence of an observer [7,8]. Interestingly, the French Hypertension Society recently recommended the use of electronic devices for office BP measurement [9].

This study presents the results of a validation study of the Microlife Watch BP Office professional device [10] according to the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults [11].
Methods

Tested device

The Watch BP Office (Microlife AG, Widnau, Switzerland) is a mercury-free BP monitor designed for professional use in the office or clinic [10]. The device has three function modes, which allow automated oscillometric measurement in one arm, simultaneous automated oscillometric measurement in both arms and auscultatory measurement by an observer using a stethoscope. The concept of the device design and a pilot application study of the simultaneous both arms measurement has been published [10]. The device is powered by four 1.5 V batteries or a 7.5, 2.0 AC adaptor. The dimensions of the device are 19 × 12.5 × 9 cm and its weight is 801 g without batteries. It has a liquid crystal digital 7 × 9 cm screen where systolic, diastolic and mean BP, pulse rate and pulse pressure are displayed. Inflation is performed by an automatic electric pump and deflation by an automatic pressure release valve. Three cuffs are available for use with the device: small (17–22 cm), standard (22–32 cm) and large (32–42 cm). A bluetooth PC link enables data export. Two identical devices were obtained from the manufacturer together with a written declaration that they were standard production models.

Familiarization phase

To be familiar with the auscultatory mode of the device that uses a digital countdown display in measuring BP, the supervisor used the device in several participants in the BP clinic and then had a pilot phase of simultaneous comparisons (35 measurements) against a trained observer who used a Y-tube connected standard mercury device.

Blood pressure measurements

The study was conducted by a supervisor and three trained observers who rotated according to their availability. All were experienced in BP measurement research and have been recently standardized for their agreement in BP measurement. Before the study initiation the observers were retested for agreement in BP measurement (50 simultaneous readings, Y-tube connected mercury devices) [11]. Because for the validation of the auscultatory mode of the device the supervisor had to use the auscultatory technique, he also performed the above-mentioned standardization procedure against two observers. In the middle of the study, standardization of the supervisor against two observers was repeated, but with half the measurements of the initial standardization. Two standard mercury sphygmomanometers (Riester, diplomat-presameter; Rud. Riester GmbH Co. KG, Jungingen, Germany), the components of which have been checked before the study, and a teaching Littman stethoscope were used for simultaneous (Y tube) observer-taken reference BP measurements. The supervisor measured BP with the tested device and also checked the agreement of BP measurements taken by the two observers, who were blinded from each other’s readings and those obtained by the device. Observer readings with a difference greater than 4 mmHg were repeated until closer agreement was reached. The cuffs of the tested device were used for measurements taken using the tested and the mercury device to fit the arm circumference of each individual. All measurements were taken on the left arm, which was supported at heart level. The protocol was approved by the hospital scientific committee.

Participants

According to the International protocol, in phase 1 a total of 15 treated or untreated participants are included who fulfill the age, sex and entry BP range requirements (age 30 years or older, at least five men and five women, five participants with entry BP within each of the ranges 90–129 mmHg, 130–160 mmHg and 161–180 for systolic and 40–79 mmHg, 80–100 mmHg and 101–130 mmHg for diastolic BP). If analysis of these data is successful, additional participants are recruited until a total of 33 participants fulfill the age, sex and entry BP range requirements for phase 2 (age 30 years or older, at least 10 men and 10 women, 11 participants with entry BP within each of the abovementioned BP ranges for systolic and diastolic BP). Participants with sustained arrhythmia or irregular pulse during the validation procedure were excluded. Signed informed consent was obtained from all participants who participated in the study.

Procedure

The validation study was conducted in an isolated room where disturbing noise was avoided. Age, sex and arm circumference of each participant was recorded, together with the cuff size used and the date and time of the validation procedure. After 10–15 min sitting rest, BP was measured by the two observers (entry BP). This measurement was used to classify participants into the low, medium and high range, separately for systolic and diastolic BP, as described above. Device detection measurement followed by the supervisor, to ensure that the device was able to measure BP of each individual. The two observers took readings BP1, BP3, BP5 and BP7 using the double-headed stethoscope and the mercury sphygmomanometers. The supervisor took readings BP2, BP4 and BP6 using the tested device. The validation analysis was based on the last seven measurements (BP1–BP7).

Analysis

Each pair of observer measurements was averaged and was then subtracted from the device measurement. The absolute differences between BP2–BP1, BP2–BP3, BP4–BP3, BP4–BP5, BP6–BP5 and BP6–BP7 were calculated and paired according to the device reading. For each pair, the one with the smaller difference was used in the analysis. These BP differences were classified into three zones (within 5, 10 and 15 mmHg), separately for systolic and diastolic BP, for 15 participants in phase 1 and for all
the 33 in phase 2.1. For each individual participant, the number of readings with a difference within 5 mmHg was also calculated (phase 2.2). Statistical analysis was performed using the MINITAB Inc., Statistical Software (release 13.31) (State College, Pennsylvania, USA).

Results
Oscillometric mode
For the validation of the oscillometric mode 46 participants were recruited from an outpatients BP clinic and from patients and staff of a University Department of Medicine. Two participants were excluded because their entry BP was out of the International protocol range, one because of arrhythmia, one because of persistent cough during the validation procedure, one because of malformation of the arm because of earlier osteomyelitis, one because of three consecutive (repeated) readings made by the observers had a greater than 4 mmHg difference (difficulty in hearing Korotkoff sounds) and seven because entry BP did not fit within the ranges needed. In 14 BP readings (12 patients) there was a difference between the observers’ measurements greater than 4 mmHg. These were repeated to reach closer agreement.

The first 15 participants (45 BP readings) who fulfilled the protocol criteria regarding sex and entry BP range were included in the analysis of phase 1. Analysis of phase 2 was based on the first 33 participants (99 BP readings), who fulfilled the study inclusion criteria regarding sex and entry BP. Six men and nine women were included in phase 1. Mean age was 49.9 ± 11.7 (SD) years (range 31–65), arm circumference 30.0 ± 3.6 cm (24–38), entry systolic BP 143.8 ± 25.6 mmHg (109–178) and diastolic 90.2 ± 16.9 mmHg (66–116). Twenty men and 13 women were included in phase 2. Mean age was 51.4 ± 12.2 years (range 31–72), arm circumference 30.4 ± 3.5 cm (24–38), entry systolic BP 143.4 ± 25.2 mmHg (98–179) and diastolic 90.1 ± 16.6 mmHg (60–116). The standard cuff was used in 21 participants, the large in 12 and the small in none.

The use of the tested device was straightforward and there were no operational problems during the study. No failures of the device to record BP throughout the study were observed. The requirements of the International protocol and the results of the validation analysis are presented in Table 1. The BP differences between the tested device and the observer readings (99 readings) are presented in Fig. 1. Tendency for larger device–observer systolic BP differences at higher pressures was observed.

The tested device satisfied all the criteria of both phases 1 and 2.1 for systolic and diastolic BP (Table 1). The mean BP differences between the device and the

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>≤ 5 mmHg</th>
<th>≤ 10 mmHg</th>
<th>≤ 15 mmHg</th>
<th>Recom-</th>
<th>Mean differ-</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required</td>
<td>One of</td>
<td>25</td>
<td>35</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Achieved</td>
<td>SBP</td>
<td>32</td>
<td>40</td>
<td>42</td>
<td>Continue</td>
<td>–3.3</td>
</tr>
<tr>
<td></td>
<td>DBP</td>
<td>30</td>
<td>40</td>
<td>43</td>
<td>Continue</td>
<td>–1.7</td>
</tr>
<tr>
<td>Phase 2.1</td>
<td>Two of</td>
<td>65</td>
<td>80</td>
<td>95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required</td>
<td>All of</td>
<td>60</td>
<td>75</td>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Achieved</td>
<td>SBP</td>
<td>71</td>
<td>90</td>
<td>96</td>
<td>Pass</td>
<td>–1.4</td>
</tr>
<tr>
<td></td>
<td>DBP</td>
<td>71</td>
<td>88</td>
<td>97</td>
<td>Pass</td>
<td>–0.8</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Phase 2.2</th>
<th>≤ 5 mmHg</th>
<th>≤ 5 mmHg</th>
<th>Recom-</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Required</td>
<td>≥ 22</td>
<td>≤ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Achieved</td>
<td>SBP</td>
<td>24</td>
<td>1</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>DBP</td>
<td>23</td>
<td>3</td>
<td>Pass</td>
</tr>
</tbody>
</table>

Table 1 Results of the oscillometric measurement validation analysis

Fig. 1

Scatterplots presenting differences in blood pressure (BP) between the observer readings and the tested device using the oscillometric mode (99 readings). Recruitment limits regarding entry BP ranges (low, medium and high) are indicated by the vertical lines.

DBP, diastolic blood pressure; SBP, systolic blood pressure.
reference method in all the 33 participants were −1.4 ± 6.3 mmHg for systolic and −0.8 ± 6.0 mmHg for diastolic BP. In phase 2.2, the device also passed all the protocol criteria for systolic and diastolic BP.

**Auscultatory mode**

For the validation of the auscultatory mode 40 patients were recruited as mentioned above. One was excluded because entry BP was out of the International protocol range and six because entry BP did not fit within the ranges needed. The two validation procedures for the oscillometric and the auscultatory measurement of the device were regarded as independent studies but run in parallel and 25 participants participated in both. In 12 BP readings (10 participants) there was a difference between the observers’ measurements greater than 4 mmHg. These were repeated to reach closer agreement.

The first 15 participants who fulfilled the protocol criteria regarding sex and entry BP range were included in the analysis of phase 1 and the first 33 in the analysis of phase 2. Eight men and seven women were included in phase 1. Mean age was 51.4 ± 12.7 years (range 32–70), arm circumference 29.6 ± 3.5 cm (24–38), entry systolic BP 138.9 ± 25.5 mmHg (93–172) and diastolic 86.9 ± 16.5 mmHg (53–109). Twenty-two men and 11 women were included in phase 2. Mean age was 52.3 ± 13.8 years (range 31–74), arm circumference 29.7 ± 3.8 cm (23.5–38), entry systolic BP 140.4 ± 25.1 mmHg (93–178) and diastolic 86.9 ± 16.7 mmHg (53–116). The standard cuff was used in 24 participants, the large in nine and the small in none.

The supervisor had no operational problems in using the auscultatory mode of the device during the study. The results of the validation analysis are presented in Table 2. The BP differences between the tested device and the observer readings (99 readings) are presented in Fig. 2.

The tested device again satisfied all the criteria of both phases 1 and 2.1 for systolic and diastolic BP (Table 2). The mean BP differences between the device and the reference method in all the 33 participants were −1.8 ± 4.5 mmHg for systolic and −0.4 ± 4.0 mmHg for diastolic BP. In phase 2.2, the device again passed all the protocol criteria for systolic and diastolic BP.

**Discussion**

This study provides information on the accuracy of the professional mercury-free device Microlife Watch BP Office, which allows both automated oscillometric and auscultatory BP measurement by an observer [10]. The study showed that using both the measurement methods the device comfortably passed all the validation requirements of the International protocol.
The design of this device seems to be particularly useful for professional use in the clinic or office. Apart from obtaining accurate automated oscillometric BP measurement, the device allows simultaneous both-arm BP measurement as recommended for the initial assessment of participants with elevated BP [1]. A pilot application study of this function has been published [10]. In addition, the device allows BP measurements to be taken by an observer using the auscultatory method and a stethoscope. This feature is particularly useful for patients with arrhythmias such as atrial fibrillation and for individuals in whom oscillometric measurement cannot give an accurate measurement [1,11].

Interestingly, BP measurements taken using the auscultatory mode of the device seemed to be more accurate than the oscillometric measurements (Tables 1, 2; Figs 1, 2). In the auscultatory mode there was no reading with a greater than 15 mmHg difference from the reference method compared with three systolic and two diastolic BP readings in the oscillometric mode. Likewise, there was only one participant with all three auscultatory diastolic BP readings having a greater than 5 mmHg difference from the reference method compared with three participants for oscillometric measurements. Thus, the oscillometric measurement barely passed phase 2.2 of the International protocol. Furthermore, the standard deviation of the differences from the reference method tended to be lower in the auscultatory (4.5/4.0 mmHg for systolic/diastolic BP) compared with the oscillometric measurements (6.3/6.0 mmHg) and the tendency for larger device–observer systolic BP differences at higher pressures observed with the oscillometric measurement was not observed with auscultation. It should be realized, however, that the auscultatory measurements in this study were taken by an observer experienced in BP monitoring research and in the extremely standardized conditions of the validation room. In routine office BP measurement taken by practitioners in clinical practice the oscillometric measurements of this device will probably be more accurate than the auscultatory one [3].

In conclusion, the Microlife Watch BP Office professional device used either in the oscillometric or the auscultatory mode fulfills the validation requirements of the International protocol and therefore can be recommended for clinical use.

Acknowledgement
Conflict of interest: G.S. was a consultant to Microlife for the design of the Microlife Watch BP Office monitor. This work was funded by a grant from Microlife, Heerbrugg, Switzerland.

References
Automated device that complies with current guidelines for office blood pressure measurement: design and pilot application study of the Microlife WatchBP Office device

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\textbf{Objective} Current guidelines for office blood pressure (BP) measurement recommend mercury devices, both arms measurement in the initial assessment and at least duplicate measurements at follow-up visits. This study presents the design and a pilot application study of an automated device that fulfils American, European, and International guidelines for office BP measurement.

\textbf{Design and functions} The Microlife WatchBP Office is a professional electronic mercury-free device with three function modes designed for: (a) initial assessment: triplicate automated simultaneous oscillometric both arms measurement at 60-s intervals and when there is a consistent interarm difference more than 20 mmHg systolic and/or more than 10 mmHg diastolic, the arm with the higher BP is indicated. (b) Follow-up assessment: triplicate automated oscillometric single arm measurements at 60-s intervals and their average is displayed. (c) Auscultatory measurement: by an observer using a stethoscope and a digital countdown BP display for patients with arrhythmias and other individuals in whom the oscillometric measurement is not accurate.

\textbf{Pilot application study} The ‘initial assessment’ mode was applied by three physicians in 63 patients (189 readings). Average interarm systolic BP difference was 0.04 ± 5.1 mmHg and diastolic 0.4 ± 3.2 mmHg. A value more than 10 mmHg interarm difference in nine systolic BP readings (5\%) and three (2\%) diastolic. No patient had a consistent interarm difference more than 10 mmHg in all three or two of the three readings.


\textbf{Keywords:} automated device, clinic blood pressure, office blood pressure, oscillometric device, professional device

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\textbf{Introduction} American, European, and International hypertension guidelines recommend the use of a mercury device and the auscultatory technique as the standard method for office blood pressure (BP) measurement [1–3]. This method has, however, two major drawbacks. First, it has been shown that physicians rarely follow the recommended methodology for BP measurement [1,4]. Second, as the aim is environmental protection, mercury is progressively being banned from medical use in several European countries [5].

Therefore, office BP measurement has entered an era of transformation and several new solutions for the replacement of the conventional method are currently being developed and tested [6–12]. Electronic monitors that measure BP using the oscillometric principle have dominated the market of ambulatory and home monitoring [2], and some have been designed specifically for professional use in the office [9,10]. These devices avoid the terminal digit preference and the observer bias [2] and might minimize the white coat effect if used in the office in the absence of an observer [8,10].

\textbf{American, European, and International recommendations for office blood pressure measurement} General agreement between American, European, and International guidelines on how BP should be assessed in the office is seen. According to the American Heart Association in the initial visit BP should be measured in both arms and when there is a consistent interarm difference the arm with the higher pressure should be used [1]. Although it is not stated which difference
should be considered as clinically important, it is mentioned that differences of value more than 10 mmHg are not uncommon [1]. The European Society of Hypertension (ESH) recommends bilateral measurements to be taken on the first visit, and if there are reproducible BP differences more than 20 mmHg systolic or more than 10 mmHg diastolic on consecutive readings, to refer the patient to a cardiovascular center for further evaluation [2]. The WHO also recommends both arms measurement in the initial assessment and investigation for vascular stenosis if interarm BP difference is more than 20 mmHg systolic or more than 10 mmHg diastolic [3]. The American Heart Association guidelines recommend a minimum of two readings at intervals of at least 1 min to be taken at each visit and to use their average. If there is more than 5 mmHg difference between the two readings, one or two additional readings should be obtained [1]. The ESH and the WHO also recommend two measurements at 1 min intervals to be taken at each visit, with a repeat measurement if there is uncertainty [2] or elevated BP [3].

Automated oscillometric devices have the potential to meet the requirements of the recommended methodology for office BP measurement and overcome some of the common problems in the application of the method by the practicing physicians. The guidelines appreciate the usefulness of the oscillometric technique particularly for ambulatory and home measurements and mention the recent introduction of oscillometric devices for office measurement [2]. It is, however, emphasized that the auscultatory method is still needed for patients with arrhythmias, such as atrial fibrillation with a rapid ventricular response, and also for individuals in whom oscillometric measurement cannot give an accurate measurement [2].

An automated device designed according to recommendations for office blood pressure measurement

The Microlife WatchBP Office (Microlife AG, Widnau, Switzerland) is a professional electronic mercury-free device (Fig. 1) designed to fulfill the requirements of the American, the European, and the International guidelines for office BP measurement [1,2]. The device has three function modes which allow: (a) single arm automated oscillometric BP measurement, (b) simultaneous both arms oscillometric BP measurement and (c) auscultatory measurement by an observer using a stethoscope. The device is powered by four 1.5 V batteries or a 7.5 V, 2.0 A adaptor. The dimension of the device is 19 × 12.5 × 9 cm and its weight is 801 g without batteries. It has a liquid crystal digital (LCD) 7 × 9 cm screen where systolic, diastolic, and mean BP, pulse rate and pulse pressure are displayed (Fig. 1). Inflation is carried out by an automatic electric pump and deflation by an automatic pressure release valve. Three cuffs are available for use with the device: small (17–22 cm), standard (22–32 cm), and large (32–42 cm). A memory recording for current patient’s set of readings is available. A blue-tooth PC link enables data export.

The three function modes of the device operate as follows (Fig. 2):

1. First visit mode – this mode allows simultaneous both arms automated oscillometric BP measurement using two cuffs (right and left). The deflation rate is...
4–6 mmHg. BP is measured during deflation at a range between 30 and 280 mmHg and pulse rate at a range of 40–200 bpm. Three succeeding measurements are automatically taken with 60 s intervals between readings (erroneous readings are automatically repeated). Then average systolic and diastolic BP for each arm is displayed (Fig. 1), as well as pulse rate, mean BP, and pulse pressure. Values of individual readings are also accessible. Only when in all three measurements there is a consistent interarm BP difference more than 20 mmHg systolic and/or more than 10 mmHg diastolic, the device indicates which arm provided the higher BP to be used for follow-up measurements. The procedure can be repeated at the discretion of the physician.

2. Follow-up mode – in this mode, triplicate automated oscillometric BP measurements are taken as described above, but in one arm that is manually selected on the basis of the first visit measurements. Average systolic, diastolic, and mean BP, pulse pressure and pulse rate are automatically displayed and individual readings are again accessible. The procedure can be interrupted after the first or the second reading and the average of all readings is displayed. The observer might decide to hide the results of individual readings and display the average after triplicate measurement has been completed.

3. Auscultatory mode – this mode allows BP to be measured by an observer using a stethoscope to detect the Korotkoff sounds. Deflation rate is 3–4 mmHg/s. During deflation cuff pressure is digitally displayed on the liquid crystal digital screen (at descending steps of 1 or 2 mmHg) and detected by the operator in real time, allowing recording of systolic and diastolic BP at a range between 20 and 280 mmHg). Memory is not available in this mode.

**Pilot application study**

To test the applicability of the first visit mode, three physicians, after a short familiarization period with the device, performed BP measurements (triplicate simultaneous both-arms) in patients attending an outpatients BP clinic. A total of 65 consecutive patients were included (23, 21, and 21 by each of the three physicians). In two cases data were lost because of memory button misuse by the observers.

Interarm differences between all BP readings and the average BP of each individual were compared using paired t-tests. Absolute interarm differences were classified according to their magnitude. The relationship of interarm BP differences with average BP was assessed using correlation coefficients. Analysis was carried out using the MINITAB INC Statistical Software (release 13.31) (State College, Pennsylvania, USA).

Sixty-three patients (189 readings) were included in the analysis [mean age 60.5 ± 12.9 (SD) years, 34 men, 58 on antihypertensive drug treatment, four diabetics, seven with cardiovascular disease]. Average both arms systolic BP was 137 ± 17 mmHg (range: 103–195) and diastolic 86 ± 12 mmHg (range: 59–118). Left arm circumference was 29.2 ± 2.1 cm (range: 24–33 cm) and right 29.5 ± 2.1 cm (25–33 cm). No patient reported discomfort because of the measurement procedure. In one case, one of the triplicate readings was erroneous and was automatically repeated by the device.

No significant interarm BP differences were found in any of the triplicate readings or their average (Table 1). The average interarm systolic BP difference of all the 189 simultaneous readings was 0.04 ± 5.1 mmHg (95% confidence intervals −0.7, 0.8, P NS) and diastolic 0.4 ± 3.2 mmHg (95% confidence intervals −0.1, 0.8, P not significant). Regarding the systolic BP, there was a value more than 10 mmHg interarm difference in nine readings, one of which was more than 15 mmHg and none more than 20 mmHg (Table 1, Fig. 3). Regarding diastolic BP, there were three readings with a value more than 10 mmHg interarm difference and none with more than 15 mmHg (Table 1, Fig. 3). No patient had an interarm difference more than 10 mmHg in all three readings or even in two of the three readings for systolic or diastolic BP. The interarm BP difference was weakly correlated with the average BP of the two arms (for systolic r = 0.14, P = 0.047 and diastolic r = 0.22, P 0.002). The

---

**Table 1** Left and right arm blood pressure values and differences in 63 patients with simultaneous measurements and classification of patients according to their absolute interarm differences

<table>
<thead>
<tr>
<th>Blood pressure</th>
<th>Reading</th>
<th>0–5 mmHg</th>
<th>6–10 mmHg</th>
<th>11–15 mmHg</th>
<th>16–20 mmHg</th>
<th>More than 20 mmHg</th>
</tr>
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<tbody>
<tr>
<td><strong>Systolic</strong></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>First</td>
<td>138.8 ± 18.4</td>
<td>47 (73)</td>
<td>12 (20)</td>
<td>4 (6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Second</td>
<td>136.8 ± 17.1</td>
<td>48 (77)</td>
<td>13 (20)</td>
<td>2 (3)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Third</td>
<td>135.7 ± 17.8</td>
<td>46 (72)</td>
<td>15 (23)</td>
<td>2 (3)</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Average</td>
<td>136.9 ± 17.2</td>
<td>52 (83)</td>
<td>10 (16)</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
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<tr>
<td><strong>Diastolic</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First</td>
<td>87.6 ± 11.9</td>
<td>58 (92)</td>
<td>3 (5)</td>
<td>2 (3)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Second</td>
<td>85.7 ± 12.2</td>
<td>59 (98)</td>
<td>3 (5)</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Third</td>
<td>85.1 ± 12.4</td>
<td>60 (95)</td>
<td>3 (5)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Average</td>
<td>86.1 ± 11.9</td>
<td>60 (95)</td>
<td>3 (5)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
systolic interarm BP difference was associated with the corresponding difference in diastolic BP \((r = 0.26, P < 0.0001)\).

**Discussion**

This study presents the design of a professional electronic device that has been developed to fulfill the requirements of the American, the European, and the International guidelines for office BP measurement [1,2]. A pilot application study of the first-visit BP measurement is also presented. Although it is still debatable whether electronic devices should replace the conventional mercury device for office BP measurement [4–7,12], it is clear that these devices will probably provide more accurate measurement than those usually obtained in general practice [8,10,12]. Interestingly, the French Hypertension Society recently recommended the use of electronic devices for office BP measurement [13] and large long-term outcome hypertension trials also used electronic devices for office measurement [14].

Further to obtaining accurate BP measurement that is devoid of the observer bias, additional features of automated devices, such as automated triplicate BP measurement, simultaneous both arms measurement and memory and PC link capacity have the potential to improve the performance of physicians in following the recommendations for office BP measurement. It is, however, known that in patients with arrhythmias, such as atrial fibrillation, and other individuals without obvious reason, the oscillometric measurement cannot give accurate BP measurement [1,2]. Owing to this problem, BP measurement using the auscultatory method is still needed in the office or clinic setting. Therefore, the additional feature of the Microlife Office BP device that allows auscultatory measurement seems to be important for a professional device. Both the automated oscillometric and the auscultatory BP measurement taken by this professional device, however, deserve formal validation for accuracy against the reference method (mercury sphygmomanometer) using an established protocol.

Although hypertension guidelines recommend both arms measurement in the initial assessment of hypertensive patients [1,2], this recommendation may not be regularly followed by physicians in practice [15]. It should be mentioned that it is not known whether simultaneous measurements in both arms independently affect the measured BP. The pilot study with both arms measurement presented in this study is unique in that oscillometric measurements were taken simultaneously in both arms with one device. Other studies have used two oscillometric devices [15–17], or two observers using mercury devices [18], or sequential measurements [17–19]. This study confirms earlier reports suggesting that spontaneous interarm BP differences of 10–15 mmHg are not rare [15,17,20,21], but are not reproducible in repeated measurements [15]. Five percent of the systolic and 2% of the diastolic BP readings in this study had an interarm difference more than 10 mmHg. Some earlier studies suggested that there is a small but consistent interarm BP difference (1–3 mmHg), with the right arm BP having the higher pressures [15–17]. Other studies, however, did not confirm this finding [20] and 95% confidence intervals in this study excluded a systematic interarm BP difference of 1 mmHg or greater. In line with earlier reports [15–17], interarm differences of more than 20 mmHg were very uncommon in this study (none of 189 readings) and obstructive arterial disease seems to be characterized by even larger interarm systolic BP difference [15,16]. These data support the ESH guidelines that recommend reproducible BP differences more than 20 mmHg systolic or more than 10 mmHg diastolic on consecutive readings to be regarded as an indication of obstructive arterial disease [2].
A tendency to increased interarm BP difference at higher pressures was observed. We do not have a plausible explanation for this finding that was not reported in earlier studies [8]. It should be mentioned, however, that few patients with very high and very low BP were included in this pilot study. The association between systolic and diastolic interarm BP differences might probably be attributed to the fact that with oscillometry systolic and diastolic BPs are calculated on the basis of the mean BP (the only parameter measured by this method) and the individual device algorithm. Thus, the random variation of mean BP is expected to affect both systolic and diastolic BP.

In conclusion, the technology of automated electronic devices offers challenging solutions, which fulfill the requirements of current guidelines for office BP measurement. In addition, these devices have the potential to overcome several of the problems that limit the reliability of this method when applied in clinical practice. Of course, formal validation of the devices’ accuracy in BP measurement using an established protocol is an essential prerequisite for clinical application.

Acknowledgements
Conflict of interest statement: G.S. is a consultant to Microlife for the design of the Microlife WatchBP Office monitor. C.W.L., C.M.L., S.L.C., and T.M.T. are Microlife employees.

References
A tool for reliable self-home blood pressure monitoring designed according to the European Society of Hypertension recommendations: The Microlife WatchBP Home monitor

George S. Stergioua, Bernd Jaeneckeb, Periklis P. Giovasa, Arron Changc, Yen Chung-Yuehc and Ty-Minh Tanb

Background Self-blood pressure monitoring by patients at home (HBPM) is being increasingly used in clinical practice and has been endorsed by hypertension societies as an important adjunct to the conventional office blood pressure measurements. Several problems, however, exist regarding the application of HBPM in practice, such as device inaccuracy, observer bias and misreporting, variable monitoring schedule and variable method for summarizing measurements. The European Society of Hypertension Working Group (ESH-WG) on Blood Pressure Monitoring has published detailed recommendations on how to apply HBPM in clinical practice.

Objective The Microlife WatchBP Home monitor is designed to provide reliable and unbiased self-blood pressure monitoring by patients at home, strictly according to the ESH-WG recommendations.

Design Dual-function automated oscillometric monitor for HBPM in the arm, with memory, PC link capacity and embedded monitoring schedule. The device has a Usual mode for casual HBPM and a Diag (diagnostic) mode for HBPM strictly according to the ESH-WG proposed schedule (duplicate morning and evening measurements for 7 days). Readings are averaged by the device after exclusion of the initial day according to ESH-WG recommendations and can be transferred to PC for storing or printing. A pilot study in hypertensive patients with previous experience in HBPM suggested that the device is user-friendly and well accepted.

Conclusion The Microlife WatchBP Home monitor is a novel device that provides a reliable and unbiased assessment of home blood pressure strictly according to the ESH recommendations. Blood Press Monit 12:127–131 © 2007 Lippincott Williams & Wilkins.

Keywords: blood pressure measurement, European Society of Hypertension, home blood pressure, hypertension, Microlife, self-measurement

Clinical benefits and current problems of self-home blood pressure monitoring

Self-monitoring of blood pressure by the patients at home (HBPM) is being increasingly used in clinical practice [1]. This method has several advantages compared to the conventional office blood pressure (BP) measurements. HBPM is free of the white coat effect [2–4], can detect the masked hypertension phenomenon [5,6] and, compared to office BP measurements, it is more reproducible [7], correlates more closely to target organ damage [8–11] and better predicts cardiovascular events [6,12–14]. In addition, the use of HBPM has been shown to improve patients’ compliance and hypertension control and is regarded as the optimal method for the long-term follow-up of hypertension [1–5,16–20].

Several problems, however, exist regarding the application of this technique in clinical practice. The inaccuracy of most devices for HBPM [21] and the subjective nature of patients’ reported HBPM measurements (misreporting) [22,23], are major limitations that preclude the reliable and unbiased estimation of the level of BP at home. In addition, there is still no agreement on the optimal schedule (number of measurements-days) for HBPM, nor on the optimal approach to summarize the large amount of BP readings collected by applying this method [24,25]. Therefore, at present HBPM is regarded as a supplementary source of information, which, in case of disagreement with conventional office BP measurements (e.g. white-coat or masked hypertension phenomenon) requires confirmation with ambulatory BP monitoring [1,16,17].
Guidelines for application of self-home blood pressure monitoring in clinical practice

It is important to note that neither the 2003 European Society of Hypertension (ESH) Guidelines [18] nor the US JNC-7 [19] provided detailed recommendations on how to apply HBPM in the management of hypertension in clinical practice. The 2003 ESH guidelines recommend the use of validated, semiautomatic devices that measure BP at the level of the arm, and provided a threshold (135/85 mmHg) for the definition of hypertension on the basis of HBPM [18]. No recommendations, however, were given on how many measurements should be obtained, how often they should be taken, and how they should be summarized. In 2003, the ESH Working Group on Blood Pressure Monitoring (ESH-WG) [1] provided detailed recommendations on the selection of devices for HBPM and proposed a schedule for HBPM monitoring in the initial phase of hypertension diagnosis and in the long-term follow-up of treated hypertension, as well as a method to summarize HBPM measurements (Table 1).

The Microlife WatchBP Home monitor

The Microlife WatchBP Home monitor (Microlife AG, Heerbrugg, Switzerland) is a novel oscillometric device designed to provide reliable and unbiased HBPM (Table 2, Fig. 1). The device was designed by Microlife Switzerland in consultation with the Hypertension Center, Third Department of Medicine, University of Athens, Greece. Effort was put to address all the major issues of HBPM strictly in line with the ESH recommendations (Table 1) [1].

The device measures BP on the upper arm at rest at a range between 30 and 280 mmHg and pulse rate between 40 and 200 beats/min. Inflation is performed by an automatic electric pumping system and deflation by an automatic pressure release valve. The device has a large liquid crystal digital display (7.9 x 5.6 cm) where systolic and diastolic blood pressure and pulse rate are displayed simultaneously (Fig. 1). It is powered by four 1.5 V batteries or an AC adaptor. Three cuffs are available to be used with the device, allowing measurements in a wide range of arm circumference (17–42 cm).

Apart from being an accurate oscillometric monitor for HBPM, the Microlife WatchBP Home has a dual mode function for clinical use. A small switch at the right side of the device (Fig. 2) changes from ‘Usual’ mode to ‘Diag’ mode (diagnostic). In the ‘Usual’ mode patients can take casual BP measurements (multiple measurements any time or day) or measurements to other people. In the ‘Diag’ mode, however, the patient has to follow a strict HBPM schedule in accord with the ESH recommendations (duplicate morning and evening measurements for 7 days) [1]. In the ‘Diag’ mode the device allows for only two BP measurements to be taken in the morning (0600–0900 h) and another two in the evening (1800–2100 h). Additional measurements or measurements out of these time intervals cannot be taken in the ‘Diag’ mode. After completing 7 days of HBPM schedule, the device displays a symbol suggesting that the patient has to consult his/her physician. By pressing the memory button (Fig. 1) the device displays the average of all measure-

Table 1 ESH-WG recommendations for self-home blood pressure monitoring [1]

<table>
<thead>
<tr>
<th>Recommendation</th>
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<tbody>
<tr>
<td>Preference of oscillometric arm measuring monitors</td>
</tr>
<tr>
<td>Independent validation of monitors using established protocols</td>
</tr>
<tr>
<td>Use of appropriate cuff size for individual arm circumference</td>
</tr>
<tr>
<td>Duplicate morning (0600–0900 h) and evening (1800–2100 h) measurements for 7 workdays (minimum of 12 readings)</td>
</tr>
<tr>
<td>Exclusion of first day blood pressure measurements</td>
</tr>
<tr>
<td>Average home blood pressure should be &lt; 135/85 mmHg</td>
</tr>
<tr>
<td>Storage, printing or transmission capacity</td>
</tr>
</tbody>
</table>

ESH-WG, European Society of Hypertension Working Group on Blood Pressure Monitoring.
ments after discarding those of the first day, as recommended by the ESH (Table 1) [1]. Average BP is not displayed unless a minimum of 12 readings has been obtained (ESH recommendation, Table 1). By pressing the memory button again and again, average morning and evening and individual BP readings can be displayed. Up to 250 BP readings can be stored in the device memory (for measurements of both the ‘Diag’ and the ‘Usual’ mode). The device has PC link capacity (USB cable, Fig. 2) to display, store or print through a PC the average BP data and the individual readings (Fig. 3). These data can be exported as a Microsoft Excel file for use with other software (Microsoft, Redmond, Washington, USA).

According to the ESH recommendations, a 7-day HBPM (after discarding the first day) is appropriate for the assessment of home BP in the initial diagnostic phase and in the long-term follow-up of treated hypertension [1]. Thus, patients might be advised to obtain a ‘Diag’ mode HBPM using the Microlife WatchBP Home monitor in the last week before each visit to the physician.

Pilot study of Microlife WatchBP Home monitor

A small pilot study was conducted to assess users’ acceptance and performance of the Microlife WatchBP Home monitor [29]. Twenty consecutive hypertensive patients attending an Outpatients BP Clinic and with previous experience in HBPM were invited to use the Microlife WatchBP Home device for 5 days. Mean age was 65.4 years, range 34–78 years, 13 men and seven women, two with < 7 years of education, six with 7–12 years and 12 with college/university education. Participants were briefly instructed (in 5 min) on the use of the device and received a single-page instructions handout. At the end of each SBPM monitoring session, users were asked to fill in a questionnaire about the usefulness of the device (11 questions, each with five possible answers).
The main findings of this pilot study were the following [29].

- Ninety-five percent of participants effectively used the ‘Diag’ mode (one did not use the device).
- Seventy percent used the ‘Usual’ mode (four participants used only the ‘Diag’ mode).
- Ninety percent found it ‘easy’ or ‘very easy’ to understand the dual function and to use the device.
- Ninety percent found the dual function ‘useful’ or ‘very useful’.
- Sixty percent regarded the ‘Dual’ function as the main advantage of the device and 20% the memory (10% did not answer this question).

Although this was a small pilot study in selected patients (attending a hypertension clinic and previously using HBPM), the above data suggest excellent users’ acceptance and performance.

Conclusions

The Microlife WatchBP Home oscillometric monitor has been designed for the optimal application of HBPM in clinical practice strictly according to the ESH recommendations. The device has novel design (Fig. 1) and function (Table 2) and thereby offers a unique solution for out-of-office BP monitoring (Table 3). Apart from being an accurate device, it has embedded HBPM schedule and data averaging method as recommended by the ESH. Thus, the Microlife WatchBP Home monitor provides a reliable and unbiased assessment of home BP strictly adhering to the ESH recommendations. In a small pilot study, the device appeared to be user-friendly and well accepted by hypertensive patients. It is important to note that, according to the manufacturer, the cost of the device will not much exceed that of previous validated Microlife oscillometric models with memory capacity. If HBPM is to be used in decision making in hypertension, as recently suggested [1–5,15–17], an objective assessment of home BP according to the guidelines, as that provided by the Microlife WatchBP Home monitor, is an essential prerequisite.

Acknowledgement

Conflict of interest statement: G.S. has served as a consultant to Microlife for the design of the Microlife WatchBP Home monitor. B.J., A.C., Y.C. and T.T. are Microlife employees.

References

Validation of the Microlife WatchBP Home device for self home blood pressure measurement according to the International Protocol
George S. Stergiou, Periklis P. Giovas, Charilaos P. Gkinos and John D. Patouras

Objective Current guidelines recommend that self monitoring of blood pressure at home should only be performed using validated devices. This study assessed the accuracy of the Microlife WatchBP Home device for self home blood pressure measurement according to the European Society of Hypertension International Protocol.

Methods Thirty-three participants were included (15 in phase 1 and an additional 18 in phase 2). Simultaneous blood pressure measurements were taken by two observers (Y-tube-connected mercury sphygmomanometers) four times sequentially, with three measurements taken using the tested device. Absolute differences between observer and device measurements were classified into three zones (within 5, 10 and 15 mmHg). The number of measurements with a difference within 5 mmHg was calculated for each individual.

Results In phase 1, the device produced 38, 43 and 43 measurements within 5, 10 and 15 mmHg, respectively, for systolic blood pressure and 35, 45 and 45 for diastolic blood pressure. In phase 2.1, the device produced 75, 91 and 97 measurements within 5, 10 and 15 mmHg for systolic, and 74, 93 and 99 for diastolic blood pressure. In phase 2.2, 30 participants had at least two of their differences within 5 mmHg and two participants had no differences within 5 mmHg for systolic blood pressure, whereas for diastolic blood pressure the number of participants were 27 and three, respectively. Mean difference for systolic blood pressure was \(-0.3 \pm 5.6\) mmHg and for diastolic \(-2.4 \pm 4.8\) mmHg.

Conclusions The Microlife WatchBP Home device for self home blood pressure measurement fulfills all the validation criteria of the International Protocol and can, therefore, be recommended for clinical use in the adult population. Blood Press Monit 12:185–188 © 2007 Lippincott Williams & Wilkins.

Keywords: accuracy, European Society of Hypertension, home blood pressure, International Protocol, Microlife, self-measurement, validation

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Introduction
Self-monitoring of blood pressure (BP) is regarded as a useful adjunct to conventional office BP measurements [1] and several hypertension societies recommend its application in clinical practice for the diagnosis and the long-term follow-up of hypertensive patients [2–5]. Although the accuracy of the devices used for BP measurement is an important prerequisite, few electronic devices for self home BP measurement available on the market have been proved accurate on the basis of independent validation studies [6].

In 2002, the European Society of Hypertension Working Group on Blood Pressure Monitoring developed the International Protocol [7], which, compared with the earlier protocols by the Association for the Advancement of Medical Instrumentation (AAMI) [8] and the British Hypertension Society [9], has been simplified in terms of the sample size required and the entry BP range.

This paper presents the results of a validation study of the Microlife WatchBP Home oscillometric device for self home measurement of BP according to the European Society of Hypertension International Protocol for Validation of Blood Pressure Measuring Devices in Adults [7].

Methods
Tested device
The Microlife WatchBP Home (Microlife, Heerbrugg, Switzerland) is an oscillometric device for self home BP measurement on the upper arm. It measures BP at rest ranging between 30 and 280 mmHg and pulse rate between 40 and 200 beats/min. Inflation is performed...
by an automatic electric release valve. The device has a large liquid crystal digital display that simultaneously displays the systolic and diastolic BP and the heart rate. It is powered by four 1.5 V batteries or an AC adaptor and has a personal computer link capacity and memory for 250 measurements. Three cuffs are available for use with the device: small cuff (for arm circumference 17–22 cm), standard (22–32 cm) and large cuff (32–42 cm). Three devices were obtained from the manufacturer for the purpose of the study, together with a written declaration that they were standard production models. To familiarize themselves with the tested device, the investigators took several BP measurements using all the three devices and one of them was randomly selected for the validation procedure.

Blood pressure measurements

One supervisor and two trained observers experienced in the methodology of BP measurement were involved in this validation study. Before the study initiation, the observers were retested for agreement in BP measurement according to the British Hypertension Society protocol [9]. Two standard mercury sphygmomanometers (Riester, diplomat-presameter, Rud. Riester GmbH Co. KG, Jungingen, Germany), the components of which had been carefully checked before the study, and a teaching Littman stethoscope were used for simultaneous (Y-tube) observer-taken reference BP measurements. The supervisor measured BP with the tested device and also checked the agreement of BP measurements taken by the two observers, who were blinded to each other's readings and to those obtained by the device. Observer readings with a difference greater than 4 mmHg were repeated until closer agreement was reached. Two cuffs of the tested device were used for measurements taken with the tested and the mercury device according to the manufacturers' instructions to fit the arm circumference of each individual. All measurements were taken on the left arm, which was supported at heart level. The protocol was approved by the hospital scientific committee.

Participants

According to the International Protocol, in phase 1, a total of 15 treated or untreated participants are included who fulfill the age, sex and entry BP-range requirements (age 30 years or older, at least five men and five women, five participants with entry BP within each of the ranges 90–129, 130–160 and 161–180 mmHg for systolic and 40–79, 80–100 and 101–130 mmHg for diastolic BP). If analysis of these data is successful, additional participants are recruited until a total of 33 participants fulfill the age, sex and entry BP-range requirements for phase 2 (age 30 years or older, at least 10 men and 10 women, 11 participants with entry BP within each of the above-mentioned BP ranges for systolic and diastolic BP). Participants with sustained arrhythmia or irregular pulse during the validation procedure were excluded. Informed consent was obtained from all participants who took part in the study.

Procedure

The validation study was conducted in an isolated room where disturbing noise was avoided. Age, sex and arm circumference of each participant were recorded, together with the cuff size used and the date and time of the validation procedure. After 10–15 min of sitting rest, BP was measured by the two observers (entry BP). This measurement was used to classify participants into the low, medium and high ranges, separately for systolic and diastolic BP, as described above. Device detection measurement by the supervisor followed, to ensure that the device was able to measure the BP of each individual. The two observers took readings BP1, BP3, BP5 and BP7 using the double-headed stethoscope and the mercury sphygmomanometers. The supervisor took readings BP2, BP4 and BP6 using the test device. The validation analysis was based on the last seven measurements (BP1 to BP7).

Analysis

Each pair of observer measurements was averaged and was then subtracted from the device measurement. The absolute differences between BP2–BP1, BP2–BP3, BP4–BP3, BP4–BP5, BP6–BP5 and BP6–BP7 were calculated and paired according to the device reading. For each pair, the one with the smaller difference was used in the analysis. These BP differences were classified into three zones (within 5, 10 and 15 mmHg), separately for systolic and diastolic BP for 15 participants in phase 1 and for all the 33 in phase 2.1. For each individual participant, the number of readings with a difference within 5 mmHg was also calculated (phase 2.2). Statistical analysis was performed using the MINITAB INC Statistical Software (release 13.31) (Stage College, Pennsylvania, PA, USA).

Results

Study participants

A total of 38 participants were recruited from an Outpatients Blood Pressure Clinic and from patients and staff of a University Department of Medicine. To facilitate the recruitment procedure, emphasis was placed on the recruitment of participants with high diastolic and low systolic BPs first, and those with high systolic and low diastolic BPs next, as recommended by the International Protocol [7]. Four participants were initially excluded because their entry BP was outside the range required for study inclusion. Two of these were included in the study later, after treatment modification. One participant, initially excluded because of Korotkoff sound V persisting down to 0, was later successfully included in the study. A total of 36 participants successfully completed the validation procedure. No participant was excluded because of arrhythmia. In three
BP readings, there was a difference between the observers’ measurements greater than 4 mmHg. These were repeated to reach closer agreement.

The first 15 participants (45 BP readings) who fulfilled the International Protocol criteria regarding sex and entry systolic and diastolic BP ranges were included in the analysis of phase 1. Analysis of phase 2.1 and phase 2.2 was based on the first 33 participants (99 BP readings), who fulfilled the study inclusion criteria regarding sex and entry BP. The characteristics of participants in study phases 1 and 2 are presented in Table 1. The standard cuff was used in 23 of the 33 participants and the large one in the other 10.

Validation criteria

The use of the tested device was straightforward and there were no operational problems during the study. There was only one failure of the device to record BP throughout the study. A successful reading was obtained on repeated measurement. The requirements of the International Protocol for phases 1, 2.1 and 2.2 and the results of the validation analysis are presented in Table 2. The differences in BP between the tested device and the observer readings (99 readings) for systolic and diastolic BP are presented in Fig. 1.

In phase 1, the tested device passed all the three criteria (one required), for both systolic and diastolic BP (Table 2). The mean differences between the tested device and the reference method were -0.3 ± 5.6 mmHg for systolic and -1.1 ± 4.5 mmHg for diastolic BP. In phase 2.1, the device comfortably satisfied all the six criteria (five required), for both systolic and diastolic BP (Table 2). The mean differences between the device and the reference method in all the 33 participants were -0.3 ± 5.6 mmHg for systolic and -2.4 ± 4.8 mmHg for diastolic BP. In phase 2.2, the device also passed all the protocol criteria for systolic and diastolic BP.

Discussion

This study provides information on the accuracy of the Microlife WatchBP Home device for self home BP measurement. It showed that this new oscillometric BP monitor comfortably fulfilled the validation requirements of the International Protocol [7] for both systolic and diastolic BP and could, therefore, be recommended for clinical use in the adult population. The algorithm of this device is identical to that of the Microlife BPA100 Plus device, which has recently been validated using the International Protocol and has been shown to be accurate [10]. As significant changes have been made to the WatchBP Home, compared with the BPA100 Plus device, regarding both the hardware and the software, a new validation study was deemed necessary.

The tested device also satisfied the validation criterion of the AAMI protocol, given that the mean difference in BP between the device and the observer measurement was lower than 5 mmHg with a standard deviation lower than 8 mmHg [8] (Table 2). It should be mentioned, however, that, according to the International Protocol, this study included fewer patients than was required by the AAMI protocol.

### Table 1 Characteristics of participants in study phases 1 and 2

<table>
<thead>
<tr>
<th>Phase</th>
<th>Participants (men/women)</th>
<th>Mean age ± SD years (range)</th>
<th>Mean arm circ. ± SD cm (range)</th>
<th>Entry SBP ± SD mmHg (range)</th>
<th>Entry DBP ± SD mmHg (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>15 (9/6)</td>
<td>50.1 ± 12.6 (31–66)</td>
<td>29.5 ± 3.8 (22–36)</td>
<td>141.2 ± 25.0 (104–178)</td>
<td>86.3 ± 19.6 (50–115)</td>
</tr>
<tr>
<td>Phase 2</td>
<td>33 (19/14)</td>
<td>49.1 ± 15.2 (30–82)</td>
<td>29.6 ± 3.5 (22–36)</td>
<td>142.2 ± 23.2 (104–178)</td>
<td>88.5 ± 17.4 (50–120)</td>
</tr>
</tbody>
</table>

arm circ, arm circumference; DBP, diastolic blood pressure; SBP, systolic blood pressure

### Table 2 Results of the validation analysis

<table>
<thead>
<tr>
<th>Phase</th>
<th>Required</th>
<th>Achieved</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>≤ 5 mmHg</td>
<td>≤ 10 mmHg</td>
<td>≤ 15 mmHg</td>
<td>Recommended</td>
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<tr>
<td>Phase 1</td>
<td>One of</td>
<td>SBP</td>
<td>25</td>
<td>38</td>
<td>35</td>
<td>40</td>
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<td></td>
<td></td>
<td>DBP</td>
<td>38</td>
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<tr>
<td>Phase 2.1</td>
<td>Two of</td>
<td>SBP</td>
<td>65</td>
<td>75</td>
<td>74</td>
<td>95</td>
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<tr>
<td></td>
<td>All of</td>
<td>DBP</td>
<td>80</td>
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<tr>
<td>Phase 2.2</td>
<td>2/3</td>
<td>≥ 22</td>
<td>60</td>
<td>75</td>
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DBP, diastolic blood pressure; SBP, systolic blood pressure
Despite the increasing use of home BP monitoring in clinical practice and its support by hypertension societies [1–5], the vast majority of the devices available on the market have not been subjected to independent validation using the established protocols [6]. One reason for this was the difficulty in conducting validation studies using the earlier cumbersome protocols [8,9]. The application of the International Protocol has significantly facilitated the procedure for the assessment of the accuracy of BP monitors and several validation studies using this protocol have been published [6]. There is an urgent need for more devices available on the market to be properly validated.

Acknowledgement
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