Validation of the Microlife Watch BP Office professional device for office blood pressure measurement according to the International protocol

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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 ± 6.3 mmHg and DBP −0.8 ± 6.0 mmHg (auscultatory SBP −1.8 ± 4.5 and DBP −0.4 ± 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.** *Blood Press Monit* **13:299–303 © 2008 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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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].

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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 $19 \times 12.5 \times 9$ 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 ausculatory mode of the device the supervisor had to use the ausculatory technique, he also performed the abovementioned 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

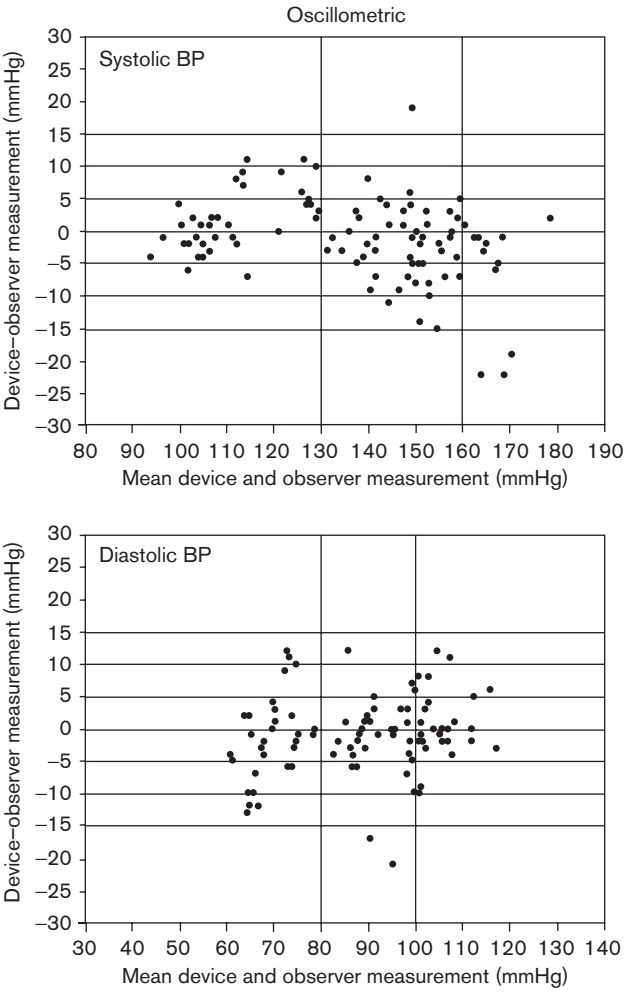
Table 1 Results of the oscillometric measurement validation analysis

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation	Mean difference	SD
Required	One of	25	35	40			
Achieved	SBP	32	40	42	Continue	−3.3	6.6
	DBP	30	40	43	Continue	−1.7	6.3
Phase 2.1							
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	71	90	96	Pass	−1.4	6.3
	DBP	71	88	97	Pass	−0.8	6.0

Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Recommendation
Required		≥ 22	≤ 3	
Achieved	SBP	24	1	Pass
	DBP	23	3	Pass

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

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.

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.

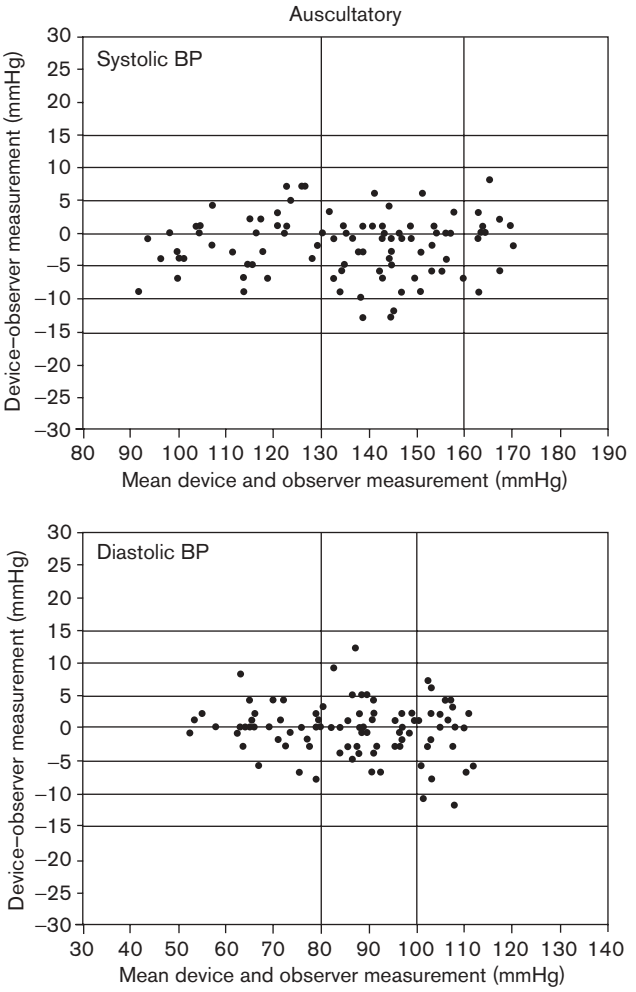
The supervisor had no operational problems in using the auscultatory mode of the device during the study. The results of the validation analysis are presented in Table 2. The BP differences between the tested device and the observer readings (99 readings) are presented in Fig. 2.

Table 2 Results of the validation analysis of the auscultatory measurement

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation	Mean difference	SD
Required	One of	25	35	40			
Achieved	SBP	29	42	45	Continue	−3.3	4.6
	DBP	33	43	45	Continue	−1.3	4.5
Phase 2.1							
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	72	96	99	Pass	−1.8	4.5
	DBP	83	96	99	Pass	−0.4	4.0
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recommendation		
Required		≥ 22	≤ 3				
Achieved	SBP	29	0		Pass		
	DBP	29	1		Pass		

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

Fig. 2



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

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 ausculatory (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.

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