Accuracy of Microlife WatchBP Office ABI monitor assessed according to the 2002 European Society of Hypertension protocol and the British Hypertension Society protocol

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Objective **To determine the accuracy of the WatchBP Office ABI monitor for blood pressure measurement developed by the Microlife Company.**

Methods **The device accuracy was tested in 85 subjects with a mean age of 54 ± 19 years. Their systolic and diastolic blood pressure (SBP/DBP) at entry was 141 ± 30/86 ± 19 mmHg, and upper arm circumference was 28 ± 5 cm. Initially, the data from 33 participants were examined according to the 2002 version of the European Society of Hypertension (ESH) protocol. An additional 52 subjects were then enrolled to fulfill the requirements of the British Hypertension Society (BHS) protocol. In all participants, sequential same arm measurements were performed by two trained observers.**

Results **The device passed all three phases of the ESH protocol for SBP and DBP. For the BHS protocol the device was graded A for both SBP and DBP. The A/A grade was achieved in the low blood pressure category (<130/80 mmHg), the B/A grade in the medium category (130–160/80-100 mmHg) and the A/A grade in the high category (>160/100 mmHg). Mean blood pressure difference between device and observers in the first 33 subjects was −0.9 ± 5.5 mmHg for SBP and −2.2 ± 4.5 mmHg for DBP and in the 85 participants it was −1.2 ± 6.5 mmHg and −2.3 ± 5.1, respectively.**

Conclusion **These data show that the Microlife WatchBP Office ABI monitor satisfied the recommended ESH accuracy levels and achieved A/A grade of the BHS protocol across a wide range of BP.** ***Blood Press Monit*** **16:258–261** © **2011 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

Current guidelines for the management of hypertension recommend the use of automated devices for self blood pressure (BP) measurement [1,2]. Electronic monitors that measure BP using the oscillometric principle have dominated the market and many such devices are available today. Obviously, the accuracy of BP measuring devices is of prime importance and a validation study is mandatory before clinical use. In the last few years, most devices have been tested according to the recommendations of the 2002 protocol of the Working Group on BP Monitoring of the European Society of Hypertension (ESH), which permitted a simplification of validation procedures compared with earlier protocols but only provides a pass/fail result [3]. The British Hypertension Society (BHS) protocol requires a much larger sample and thus allows a more rigorous assessment of the device under investigation [4]. In addition, the BHS protocol is provided with a grading system which allows a qualitative evaluation of a device for three different BP ranges. Therefore, in this study we initially assessed the WatchBP Office ABI monitor using the 2002 ESH protocol [3] and then proceeded to recruit the overall number of 85 participants to meet the requirements of the BHS protocol [4].

Methods

Subjects

Thirty-three subjects with the range of BP required by the ESH rules (11 participants in each of the three pressure bands: 90–129/40–79, 130–160/80–100, and 161–180/101–130 mmHg) were initially studied. Their mean ± SD age was 54 ± 19 years (range 30–91), lying systolic blood pressure (SBP) was 141 ± 25 mmHg, diastolic blood pressure (DBP) was 87 ± 17 mmHg, and arm circumference was 29 ± 4 cm. Seven subjects were excluded because BP ranges were complete ($n = 4$), BP was out of range ($n = 2$), or there was atrial fibrillation ($n = 1$). A further 52 subjects were then recruited to fulfill the criteria of the BHS protocol. Mean age of the 85 participants was 54 ± 19 years. Their SBP/DBP at entry was 141 ± 30/86 ± 19 mmHg, and arm circumference was 28 ± 5 cm. BP measurements were performed in the sitting position. The study was approved by the Ethics Committee of the University of Padua, and written informed consent was given by the participants.

Device

The Microlife WatchBP Office ABI model is an oscillometric fully automatic device for BP measurement at the upper arm. The measuring range spreads over 20–280 mmHg for

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BP. The applied cuffs are suitable for arm circumferences ranging from 22.0 to 31.5 cm (standard cuff) and from 32.0 to 42.0 cm (large cuff), respectively. SBP, DBP, and heart rate are displayed on a liquid crystal digital display. The inflation is performed using a fuzzy logic electric pumping system and the deflation by an automatic pressure release valve. Additional characteristics of the device, such as simultaneous measurement of the left–right BP difference, measurement of the ankle-brachial index, and a specific algorithm for the detection of atrial fibrillation during oscillometric measurement are reported in the appendix. The manufacturer supplied three test devices and confirmed that they had been selected from a normal production line.

Device validation

The study was performed by two trained observers (F.S. and E.B.) who had each done several validation studies before [5,6]. The two observers 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 these two observers was -1.0 ± 2.0 mmHg for SBP and -0.7 ± 2.3 mmHg for DBP. BP was measured with a mercury sphygmomanometer at the upper arm using adult cuffs, whose bladders had to cover at least 80% of the circumference of the arm. Validation of the device was carried out performing sequential same-arm measurements alternating between the mercury sphygmomanometer and the device. Before starting comparative readings, the two observers took a BP measurement and the mean of these two values was used to determine the BP class in which the subject was allocated. Four sequential readings were taken by observers one and two (BP1, BP3, BP5, and BP7), and three BP readings were taken by the supervisor (P.P.) with the test instrument (BP2, BP4, and BP6). Both ESH and BHS protocols base their evaluation on the number or percentage of differences between device and observer that are within 5, 10, and 15 mmHg [3,4]. The 2002 ESH protocol consists of three phases and the device needs to achieve all the required criteria to pass. The BHS grading system requires the device to achieve grade A or B to pass the test, for both SBP and DBP. In particular, to achieve A grade, 60% of the observer–device discrepancies must be within 5 mmHg, 85% within 10 mmHg, and 95% within 15 mmHg. The procedure used to calculate the set of BP differences for each patient slightly differs between the ESH and the BHS protocols [3,4]. The BHS protocol also includes an analysis of the device accuracy according to the level of BP ($<130/80$, 130–160/80-100, and $>160/100$ mmHg). Data are mean ± SD.

Results

In the first phase of ESH protocol, 15 subjects (10 men) were assessed and five subjects had their SBP and DBP in each of the three BP ranges required by the ESH protocol. The results satisfied the ESH rules (Table 1). In addition, the second phase encompassing 18 subjects (10 men) was successfully completed, including the second part of phase 2 (phase 2.2) of ESH protocol (Table 1). The observer–device disagreement was -0.9 ± 5.5 mmHg for SBP and -2.2 ± 4.5 mmHg for DBP (Fig. 1).

Table 1 Device validation table for the Microlife WatchBP Office ABI assessed according to the ESH protocol

Phase 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade
Required				
One of	25	35	40	
Achieved				
SBP	28	40	45	Passed
DBP	29	42	45	Passed
Phase 2.1				
Required				
Two of	65	80	95	
Achieved				
SBP	68	93	99	Passed
DBP	72	95	99	Passed
Phase 2.2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		
Required	≥ 22	≤ 3		
Achieved				
SBP	24	3		Passed
DBP	29	3		Passed

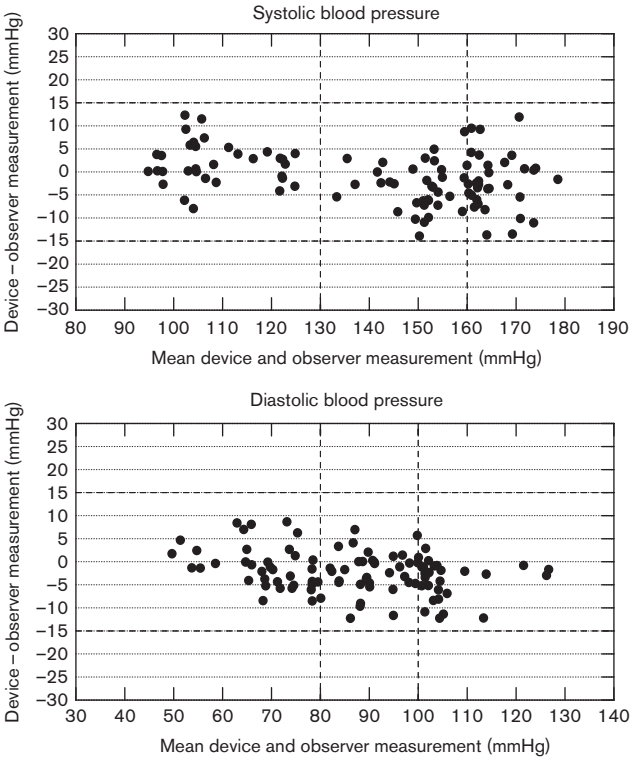
Subjects, $n=33$.
DBP, diastolic blood pressure; ESH, European society of hypertension; SBP, systolic blood pressure.

For the BHS protocol the device achieved an overall A grade according to the criteria of the BHS protocol for both SBP and DBP (Table 2). The A grade was obtained throughout the BP range for DBP and in the upper and lower BP classes for SBP. In the middle SBP class, the device was graded as B, as the percentage difference of device–observer within 15 mmHg was 94%, instead of the required 95% for the A grade. The mean and SD of -1.2 ± 6.5 and -2.3 ± 5.1 mmHg for SBP and DBP, respectively, also met the Association for the Advancement of Medical Instrumentation ANSI/AAMI SP10:2002 criteria (Fig. 2).

Discussion

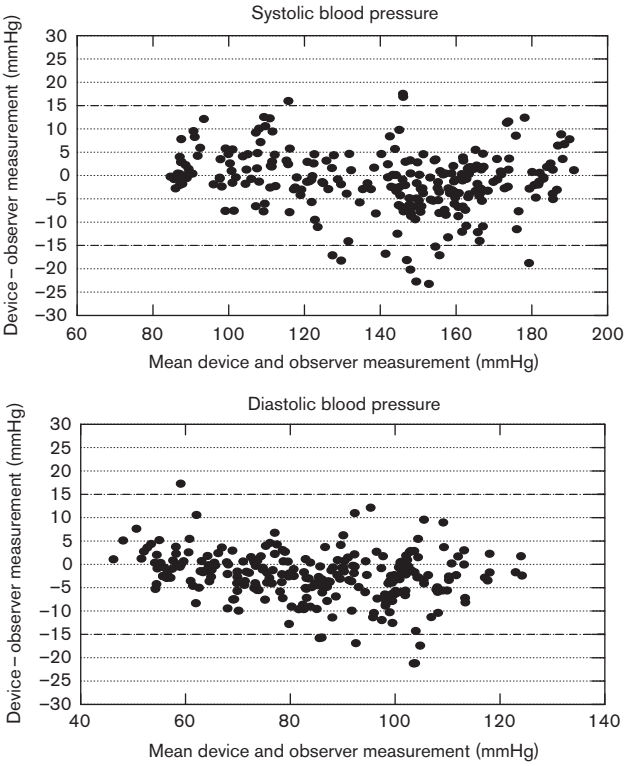
Companies that manufacture automatic monitors for BP measurement have tried to improve the performance of their devices by ameliorating the quality of the materials and elaborating new algorithms [1,7]. The results of this study demonstrate that the Microlife WatchBP Office ABI monitor provides very accurate and reliable BP measurements across a wide range of BP. The device not only satisfied the criteria of the ESH protocol but it also achieved A/A grade of the BHS scoring system. Mean device–observer differences were ≤ 2.3 mmHg, and the SD were well within the Association for the Advancement of Medical Instrumentation requirement of a SD of less than 8 mmHg [8]. The BHS protocol includes a large sample size with great extremes of BPs and provides a scoring system that gives opportunity to compare one

Fig. 1



Plot of the systolic (upper plot) and diastolic (lower plot) WatchBP Office ABI-observer blood pressure differences in the first 33 subjects enrolled in the study. All differences were within 15 mmHg. The *x*-axis represents the mean of the device and observer measurements in mmHg. The *y*-axis represents the difference between the device and observer measurements in mmHg. A positive value indicates that the device measurement is greater than the observer's measurement. A slight random jitter avoids data point superimposition.

Fig. 2



Plot of the systolic (upper plot) and diastolic (lower plot) WatchBP Office ABI-observer blood pressure differences in the whole group ($n=85$). The *x*-axis represents the mean of the device and observer measurements in mmHg. The *y*-axis represents the difference between the device and observer measurements in mmHg. A positive value indicates that the device measurement is greater than the observer's measurement. A slight random jitter avoids data point superimposition.

Table 2 Device validation table for the Microlife WatchBP Office ABI evaluated according to the BHS grading system

	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade
Required % of readings	60%	85%	95%	A
Overall evaluation (255 readings)				
Achieved				
SBP	71%	89%	96%	A
DBP	75%	94%	98%	A
Low pressure range (<130/80 mmHg)				
Achieved				
SBP ($n=99$)	77%	93%	99%	A
DBP ($n=96$)	86%	99%	99%	A
Medium pressure range (130/80–160/100 mmHg)				
Achieved				
SBP ($n=63$)	67%	88%	94%	B
DBP ($n=72$)	71%	93%	100%	A
High pressure range (>160/100 mmHg)				
Achieved				
SBP ($n=93$)	70%	85%	95%	A
DBP ($n=87$)	64%	90%	96%	A

Subjects, $n=85$.
BHS, British hypertension society; DBP, diastolic blood pressure; SBP, systolic blood pressure.

device with another [4]. As many devices have shown poorer accuracy for the high or very low BP levels, the BHS protocol also recommends to analyze BP differences in those ranges. This data show that the WatchBP Office ABI monitor was accurate in both the high and the low BP ranges achieving grade A/A for both. However, concern was raised that the BHS validation criteria may be inadequate to ensure that individuals receive accurate BP measurements, as it is possible that more than half of the patients will have an average error greater than 5 mmHg, and more than 1 in 4 will have an average error greater than 10 mmHg [9]. In 2002, the Working Group on BP Monitoring of the ESH published a protocol that had different passing criteria [3] and phase 2.2 also provided an assessment of individual patient accuracy. Thus, a device that satisfies the criteria of both protocols may provide greater assurance about its reliability.

We conclude that the Microlife WatchBP Office ABI monitor is an accurate device for BP measurement at the upper arm. It achieved BHS A grade for both SBP and DBP and can thus be recommended for clinical use in the adult population.

Acknowledgements

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Conflicts of interest

There are no conflicts of interest.

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Appendix

In this appendix, the basic information of the device under test, WatchBP Office ABI, is reported, following the suggestions of the ESH protocol.

Device identification

Microlife WatchBP Office ABI

Microlife Corporation, 9F, 431, RuiGang Road, NeiHu, Taipei, 114, Taiwan, R.O.C.

This device is a fully automatic, upper-arm type, BP monitor. Its measuring range spreads over 20–280 mmHg for BP.

The applied cuffs are suitable for arm circumferences ranging from 22 to 31.5 cm for the M-cuff and 32–42 cm for the L-cuff. Optionally, the manufacturer offers a validated L-XL cuff for arm size 32–52 cm (not tested in this study).

Optionally, the device is offered with an USB interface and PC-SW. For details see *http://www.watchBP.com*

Dimensions

D: 200 mm × W: 125 mm × H: 90 mm.

Weight: 1100 g including rechargeable battery pack.

List of components

Device including five cuffs (2 × M-size arm cuff, 2 × L-size arm cuff, 1 × M-size cuff for ankle) rechargeable battery pack, mains electricity adapter, and instruction manual.

Costs: retail price around €890, in Europe.

Compliance with standard

The device meets the Essential Requirements of the Medical Device Directive 93/42 EEC, Annex 1 and bears the conformity mark CE 0044.

Validation studies

EN 1060–4, ANSI /AAMI SP10, 2002 ESH Protocol (IP1).

Instructions for use, care, and maintenance

These are reported in detail in the instruction manual.

Power supply: Rechargeable battery pack 4.8 V 4000 mAh. Mains adapter DC 7.5 V 2 A.

Service facilities

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

Method of BP measurement

Oscillometric, corresponding to Korotkoff method: phase 1 systolic, phase 5 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.