Development of an accurate oscillometric blood pressure device for low resource settings

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Objective **To assess and develop an accurate blood pressure measurement device for use in low resource settings and by untrained staff, according to the World Health Organisation guidelines.**

Methods **Ninety-nine adults were recruited to validate the device according to the International Protocol of the European Society of Hypertension. All participants provided written informed consent. Patients with an arrhythmia or unclear Korotkoff sounds were excluded. Nine sequential same-arm measurements were taken from each participant alternating between the test device and mercury sphygmomanometry. Differences between the test device and observers were evaluated according to the criteria of the International Protocol and the Association for the Advancement of Medical Instrumentation.**

Results **The device failed the first assessment of the oscillometric function and required modification to both the deflation rate and the algorithm to fulfil the International Protocol criteria. It then achieved an acceptable mean difference of −0.7 (4.7) mmHg for systolic and −2.0 (4.6) mmHg for diastolic pressure (oscillometric function) and −1.9 (3.8) mmHg and −0.9 (3.3) mmHg for systolic and diastolic pressures, respectively (auscultatory function).**

Conclusion **The Microlife 3AS1-2 is a semi-automated upper arm device with features consistent with low resource requirements. We successfully developed this device for accurate blood pressure measurement in adults according to the International Protocol, through adjustment of the deflation rate and algorithm. The accuracy and user-friendly design of this low-cost device makes it a highly valuable monitor in clinical practice, particularly in low resource settings and for use by untrained staff.** ***Blood Press Monit*** **13:342–348 © 2008 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Keywords: adults, Association for the Advancement of Medical Instrumentation, blood pressure measurement, International protocol, low resource setting, oscillometric, validation, WHO

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Introduction

The health risk associated with hypertension is recognized worldwide. In the 2003 World Health Report, heart disease and stroke were the leading causes of adult mortality resulting in over 10 million deaths in developing countries [1]. Unfortunately, awareness and subsequent treatment of hypertension is poor in developing countries compared with their industrialized counterparts [2], thereby preventing the early detection and effective management of a modifiable risk factor [3].

Fundamental to this is the accurate, reliable, and consistent measurement of blood pressure; a procedure that is traditionally dependent in the developed world on trained staff using calibrated equipment i.e. facilities that are unavailable to a large proportion of the global population. The progressive transition toward automated blood pressure measurement further widens this gap. Although automated devices have several advantages, such as removing the white-coat effect [4] and being reliable when used by nonclinicians [5], cost and electrical energy requirements generally preclude their use in the low resource setting.

Development of a device suitable for use in the low resource/developing world setting is a technical challenge. In this report, we detail the development of the Microlife 3AS1-2 (Fig. 1): a hand-held, upper arm, semi-automated oscillometric blood pressure measuring device. The device features are consistent with the requirements for low resource settings [6] (Table 1) and allow for both auscultatory and oscillometric measurement of blood pressure. The automatic pump has been replaced by a manual inflation mechanism, thereby reducing both the cost and electrical power requirements

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Fig. 1

The Microlife 3AS1-2.

Table 1 Technical requirements for automated blood pressure measuring devices suitable for office/clinic use in low resource settings; adapted from Parati *et al.*

Requirement	Brief description
Accuracy	CE label; independent validation to a recognized protocol
Transducers and power	Function on low power; solar chargers; low power indicator
Cuff inflation and deflation	Manual inflation; deflation rate 2–3 mmHg/s
Cuff size	Range of cuff sizes or universal cuff
Digital display	Large and easily legible
Calibration	Easy calibration after intensive use; recommended frequency
Environmental requirements	Temperature-stabilizing system for extreme weather conditions
Memory function	Not required
Performance requirements	Durable; robust; well-sealed device
Cost	Cost of production should be less than €20
Additional requirements	Instructions for use; customer service contact

of the device. An accurate algorithm is, however, difficult to achieve with manual inflation. We have therefore, in conjunction with the device manufacturer, also developed an algorithm, which will provide an accurate reading with a manual/variable inflation rate and have ensured that the device conforms with the requirements [6] of devices intended for use in low resource settings. This study was performed in an adult population according to the guidelines of the International protocol [7] of the European Society of Hypertension.

Methods and results

International protocol

Observers were trained to accurately measure blood pressure using mercury sphygmomanometry and the test device. Each observer successfully completed the training exercises on the British Hypertension Society website (*http://www.bhsoc.org/how_to_measure_blood_pressure.stm*) and was tested against an expert observer. Ethical approval was obtained and participants were asked to give written informed consent. Volunteers were recruited from the staff and outpatient clinics at Guy's and St Thomas' Hospitals and were at least 30 years of age [7].

The International Protocol [7] is divided into two phases and the protocol advises the investigator to abandon further assessment if the device fails to achieve the criteria of phase 1. It was, however, decided that a full protocol would be completed regardless of the phase 1 results to enable the investigators to better define any error and make appropriate changes. Phase 2 of the International Protocol assessed both intersubject accuracy (phase 2.1) and intrasubject accuracy (phase 2.2).

Fifteen participants were recruited for phase 1, five in each of the three specified blood pressure ranges (Table 2) and with a minimum of five male and five female participants. After analysis of the phase 1 results, a further 18 participants were recruited in phase 2, resulting in a total of 33 participants with at least 10 male and 10 female participants.

Blood pressure measurements were taken in a designated quiet consultation room. Demographic information was obtained and each participant was asked to relax for 5 min without talking. The arm was supported at the estimated heart level by resting the arm on a desk or the armchair and an appropriately sized cuff was placed according to the manufacturer's instructions. A normal adult cuff was used in participants with an arm circumference of 22–32 cm and a large adult cuff for those with an arm circumference of 32–42 cm.

Two mercury sphygmomanometers were connected with a Y-connector and placed at the observers' eye level. A double-headed stethoscope (ADC Adscope; Hauppauge, New York, USA) enabled observers to listen to the

Table 2 Distribution of adult blood pressures according to the International protocol

Group	SBP/DBP (mmHg)	Number of participants recruited for phase1	Number of participants recruited for phase2	Total number of participants
Low	<130/80	5	6	11
Medium	130–160/80–100	5	6	11
High	>160/100	5	6	11

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

Korotkoff sounds simultaneously, interpreting Korotkoff I as systolic blood pressure and Korotkoff V as diastolic blood pressure. Nine sequential same-arm measurements, alternating between the test device and the mercury sphygmomanometer, were recorded to assess the oscillometric accuracy of the device. In addition, an auscultatory reading was taken at the same time of the test device reading, by listening to Korotkoff sounds and using the LCD (liquid crystal display) of the test device as a pressure scale during cuff deflation. The aim of the auscultatory assessment was to determine whether the device could also be used in this capacity, as the deflation rate of the device varied between 2 and 6 mmHg (depending on the cuff pressure). In addition, the ability of the observers to read a falling digital display under these circumstances had to be evaluated.

Participants were excluded from the study if after three attempts the device failed to produce an oscillometric reading or if the participant had any arrhythmia or if Korotkoff sounds were too weak to be accurately interpreted by either of the observers.

Data analysis

The last seven sequential measurements taken from each participant were analyzed according to the International Protocol guidelines. First, the mean of each pair of observer measurements was calculated. The first mean value was used to classify the patient into one of the three specified blood pressure categories for systolic and diastolic pressures, respectively (Table 2). Neither this reading nor the first device reading was used in the analysis. Each subsequent test device reading was then compared with the mean of the observers' readings taken immediately before and immediately after that device reading, resulting in six calculable differences: three 'before' and three 'after'. For each device reading either the difference 'before' or the difference 'after' was chosen to result in a set of three final differences for each participant for systolic and diastolic pressure values, respectively.

The number of absolute differences was calculated for phase 1 of the protocol and had to meet at least one of the following criteria: 25 differences (out of a possible 45) within 5 mmHg; 35 differences within 10 mmHg; 40 differences within 15 mmHg.

In phase 2.1, the device had to achieve any two of the following three criteria: 65 differences (out of a possible 99) within 5 mmHg; 80 differences within 10 mmHg; 95 differences within 15 mmHg. In addition, the device had to achieve a minimum of 60 differences within 5 mmHg and 75 differences within 10 mmHg and 90 differences within 15 mmHg. These results reflected intersubject accuracy.

Phase 2.2 of the protocol assessed intrasubject accuracy. In at least 22 participants, a minimum of two out of the three differences had to be within 5 mmHg and differences greater than 5 mmHg in all three device comparisons were not allowed in more than three participants.

This procedure was followed to compare both the oscillometric and the auscultatory device readings to the observers' readings using mercury sphygmomanometry. The mean difference and standard deviation of the difference was calculated to ascertain whether the device passed the criteria of the Association for the Advancement of Medical Instrumentation (AAMI), that is, mean difference (SD) less than or equal to $\pm 5(8)$ mmHg. As a graphical illustration of the results, mean-against-difference plots [8] were used to plot the mean pressure of the observers and the device against their difference.

Three separate studies were completed during the assessment and development of the Microlife 3AS1-2: baseline validation to assess accuracy; revalidation after modifications to the deflation rate and a final validation following algorithm modifications to improve accuracy.

Baseline validation: first prototype

The first prototype device successfully passed phase 1 of the International Protocol, but failed phase 2 (Table 3) for the oscillometric assessment. In contrast, the auscultatory comparison achieved the criteria of both the International protocol (Table 4) and the AAMI with a mean difference (SD) of -1.8 (4.7) mmHg and -0.9 (3.9) mmHg for systolic and diastolic pressures respectively. It was noted that once the device had obtained a diastolic reading through its oscillometric function, it commenced a rapid deflation rate, whereas on occasions Korotkoff sounds were still apparent to the observers taking an auscultatory reading from the falling pressures displayed on the device's LCD. For this reason the controlled deflation action was extended to a lower pressure. In addition, the deflation speed at the start of cuff deflation was slowed down to reduce the variability experienced in systolic comparisons with the oscillometric function.

Revalidation: second prototype

The second prototype device was revalidated and failed phase 2.2 of the International Protocol for systolic pressure as determined by the oscillometric function (Table 3), suggesting that a fundamental algorithm change was required. For the auscultatory comparison, the device achieved all the criteria of the International protocol (Table 4) and the AAMI with a similar mean difference, but improved standard deviation of -1.9 (3.8) mmHg for systolic pressure and -0.9 (3.3) mmHg for diastolic pressure when compared with the first

Table 3 Criteria of International protocol and device results for the oscillometric function

	Phase 1				Phase 2.1				Phase 2.2					
Categories (mmHg)	≤ 5	≤ 10	≤ 15	Result	≤ 5	≤ 10	≤ 15	Result	2 of 3 ≤ 5	0 of 3 ≤ 5	Result	Mean difference	SD	Final result
Requirements														
One of	25	35	40		–	–	–							
Two of	–	–	–		65	80	95							
All of	–	–	–		60	75	90							
Min of (participants)	–	–	–		–	–	–		22					
Max of (participants)	–	–	–		–	–	–		–	3				
First validation														
SBP	28	36	42	Pass	61	76	89	Fail	21	6	Fail	−1.9	8.3	Fail
DBP	32	42	43	Pass	75	92	96	Pass	26	1	Pass	−2.9	4.8	
Revalidation[a]														
SBP	28	40	42	Pass	60	81	95	Pass	24	5	Fail	−4.6	6.8	Fail
DBP	32	39	43	Pass	65	88	94	Pass	23	1	Pass	−3.0	5.5	
Final validation[b]														
SBP	36	43	44	Pass	82	94	98	Pass	30	0	Pass	−0.7	4.7	Pass
DBP	35	43	44	Pass	75	94	98	Pass	27	3	Pass	−2.0	4.6	

[a]Following modification to the deflation rate.
[b]Following modification to the algorithm.
DBP, diastolic blood pressure; max, maximum; min, minimum; SBP, systolic blood pressure; SD, standard deviation of the mean.
$n=33$ in all three studies.

Table 4 Criteria of International protocol and device results for the auscultatory function

	Phase 1				Phase 2.1				Phase 2.2					
Categories (mmHg)	≤ 5	≤ 10	≤ 15	Result	≤ 5	≤ 10	≤ 15	Result	2 of 3 ≤ 5	0 of 3 ≤ 5	Result	Mean difference	SD	Final result
Requirements														
One of	25	35	40		–	–	–							
Two of	–	–	–		65	80	95							
All of	–	–	–		60	75	90							
Min of (participants)	–	–	–		–	–	–		22					
Max of (participants)	–	–	–		–	–	–		–	3				
First validation														
SBP	40	45	45	Pass	92	99	99	Pass	31	1	Pass	−1.8	4.7	Pass
DBP	41	45	45	Pass	92	99	99	Pass	33	0	Pass	−0.9	3.9	
Revalidation[a]														
SBP	35	44	45	Pass	82	98	99	Pass	30	0	Pass	−1.9	3.8	Pass
DBP	42	44	45	Pass	86	95	96	Pass	30	0	Pass	−0.9	3.3	
Final validation[b]														
SBP	38	43	45	Pass	87	97	99	Pass	32	0	Pass	−1.2	3.5	Pass
DBP	41	44	45	Pass	90	98	99	Pass	32	0	Pass	−0.7	3.1	

[a]Following modification to the deflation rate.
[b]Following modification to the algorithm.
DBP, diastolic blood pressure; max, maximum; min, minimum; SBP systolic blood pressure; SD standard deviation of the mean.
$n=33$ in all three studies.

prototype device. As the oscillometric results showed a systematic underrecording of blood pressure, but a good standard deviation, it was decided to modify the algorithm by introducing a systematic shift to improve the overall device accuracy. We repeated the validation, including the auscultatory mode, to ensure that our changes did not influence its accuracy.

Final validation: the Microlife 3AS1-2

The final study included 12 male and 21 female participants with a mean age of 53 years. The mean systolic and diastolic pressures were 141 and 86 mmHg, respectively, and the mean arm circumference 29 cm. The mean height and weight of participants were 169 cm and 76 kg, respectively. Only one participant was excluded because of the device giving three consecutive error readings and the reasons for this could not be explained.

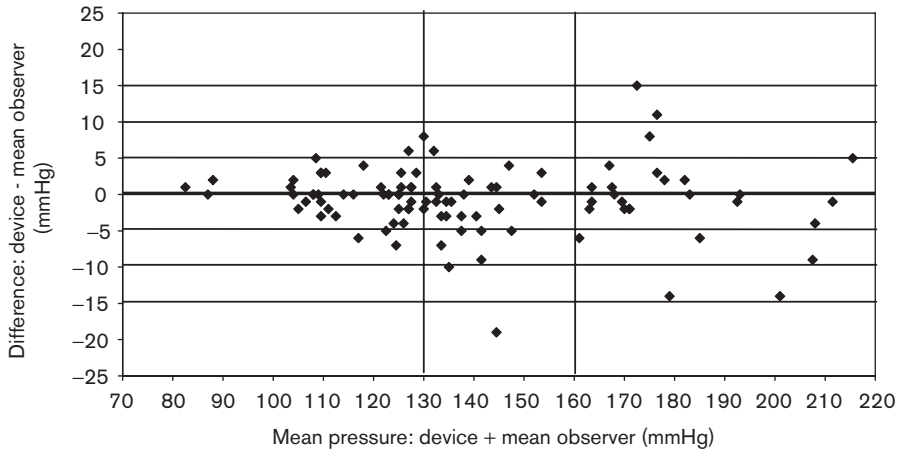
In the final assessment, the Microlife 3AS1-2 successfully achieved all of the requirements for phases 1, 2.1 and 2.2 of the International Protocol for the oscillometric function (Table 3). Out of 99 differences, 82/94/98 (systolic blood pressure), and 75/94/98 (diastolic blood pressure) differences were within the categories less than or equal to 5/10/15 mmHg, respectively. In 30 participants, at least two of the three differences were within 5 mmHg for systolic pressure and the same was true

for the diastolic pressure comparisons in 27 participants. All of the participants had at least one of three differences within 5 mmHg for systolic pressure and three participants had all three differences greater than 5 mmHg for diastolic pressure. The mean difference (SD) for both systolic and diastolic pressures was well within the AAMI requirements, being −0.7 (4.7) and −2.0 (4.6) mmHg for systolic and diastolic pressures, respectively.

The final auscultatory assessment was comparable with previous results and the device successfully achieved all the criteria of the International Protocol with 87/97/99 (systolic blood pressure) differences and 90/98/99 (diastolic blood pressure) differences out of 99 within 5/10/15 mmHg of the mercury standard (Table 4). The mean difference (SD) for systolic pressure was −1.2 (3.5) mmHg and for diastolic pressure −0.7 (3.1) mmHg, conforming to AAMI requirements.

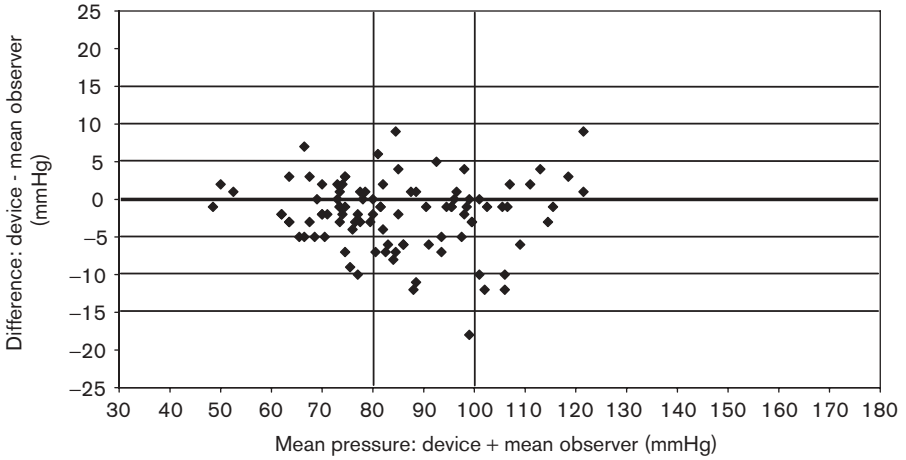
Mean-against-difference plots of the oscillometric function are presented in Figs 2 and 3 and of the auscultatory function in Figs 4 and 5 for systolic and diastolic pressures, respectively.

Fig. 2



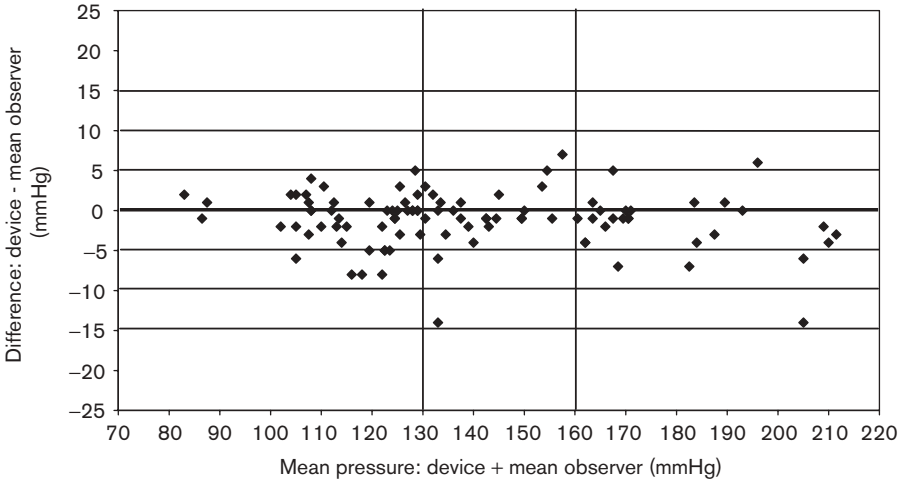
Plot showing the difference and mean pressure between the observers' and device readings for systolic pressure for the final validation of the Microlife 3AS1-2 (oscillometric mode).

Fig. 3



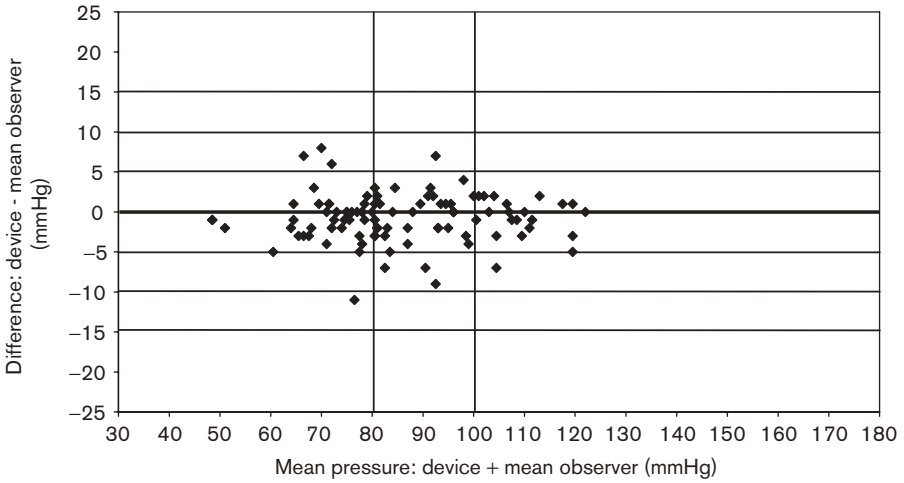
Plot showing the difference and mean pressure between the observers' and device readings for diastolic pressure for the final validation of the Microlife 3AS1-2 (oscillometric mode).

Fig. 4



Plot showing the difference and mean pressure between the observers' and device readings for systolic pressure for the final validation of the Microlife 3AS1-2 (auscultatory mode).

Fig. 5



Plot showing the difference and mean pressure between the observers' and device readings for diastolic pressure for the final validation of the Microlife 3AS1-2 (auscultatory mode).

Discussion

The Microlife 3AS1-2 is an accurate semi-automated device for measuring blood pressure in an adult population (including hypertensive patients) according to the criteria of the International protocol.

The first and second accuracy assessments of this device resulted in either failing the International Protocol or the AAMI or both. In collaboration with the device engineers and manufacturer, changes to the deflation speed, timing, and algorithm vastly improved the accuracy. The low values achieved by the device for both mean difference and standard deviation confirms a consistent accuracy when compared with mercury sphygmomanometry, both as an oscillometric and an auscultatory device.

In addition to its demonstrated accuracy, the Microlife 3AS1-2 encompasses all of the requirements stipulated by the WHO for an automated monitor suitable for low resource settings. The oscillometric function provides an

accurate measurement option for untrained staff, whereas the LCD display (which is large and easily legible) and the moderate deflation rate of 2–6 mmHg/s allows for accurate auscultatory measurement by a trained observer. This deflation rate is slightly higher than the recommended rate of 2–3 mmHg for auscultatory measurement, albeit slower then the device originally had. This did not affect its accuracy.

The device weighs 300 g (including batteries and medium cuff) with dimensions of $68 \times 186 \times 45.8$ mm ($W \times L \times H$). Features such as manual inflation and an automatic switch-off function reduce energy requirements, and therefore extend the lifetime of the four AAA batteries powering the device. Power is only required for the digital display, and therefore one charge or set of batteries will last for thousands of measurements. The Microlife 3AS1-2 functions at temperatures between + 10 and + 40°C and a humidity of 15–90% and it passed both the 1 m drop test and the vibration test (personal correspondence with manufacturer). The device is available with rechargeable batteries and a docking station that can be connected to a commercially available solar charger. The unit cost will be less than 20 euro for distribution by the WHO to low resource settings if required.

The Microlife 3AS1-2 is a lightweight, user friendly, durable, and reliable alternative to the mercury sphygmomanometer and fulfils the WHO criteria for use in low resource settings. Its accuracy in a normal adult population warrants further investigation into accuracy in pregnancy and preeclampsia. We are currently investigating the implementation of this device in a low resource setting to assess feasibility of use and impact on practice.

Acknowledgements

This study was approved by the Local Research Ethics Committee of Guy's and St Thomas' Hospital NHS Foundation Trust (Ref. EC99/016). All participants provided written informed consent. Individuals performing the study were employed by King's College London. No additional external funding was obtained. Microlife Corporation supplied test devices for this study and made the required software changes to the device. Microlife Co. has funded previous commissioned research.

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