

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

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

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

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

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

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

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Introduction

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

Methods

Subjects

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