

# Validation of the Microlife WatchBP Home device for self home blood pressure measurement according to the International Protocol

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**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.

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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