

# Validation of the Microlife WatchBP O3 device for clinic, home, and ambulatory blood pressure measurement, according to the International Protocol

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To determine the accuracy of the Microlife WatchBP O3 blood pressure measuring device tested according to the requirements of the International Protocol of the European Society of Hypertension. The WatchBP O3 is designed to provide clinic, ambulatory, and self blood pressure (BP) measurements. Device evaluation was performed in 33 participants with a mean  $\pm$  standard deviation age of  $56.1 \pm 20.7$  years (range 30–95 years). Their systolic BP (SBP) was  $144.7 \pm 24.1$  mmHg (range 90–180 mmHg), diastolic BP (DBP) was  $86.8 \pm 18.3$  mmHg (range 50–120 mmHg), and arm circumference was  $28.1 \pm 2.9$  cm (range 22.0–34.0 cm). Blood pressure measurements were performed in the sitting position. The WatchBP O3 passed all three phases of the European Society of Hypertension protocol for SBP and DBP. Mean blood pressure differences for the WatchBP O3 (device observer) were

$-1.7 \pm 6.9$  mmHg for SBP and  $-1.1 \pm 4.3$  mmHg for DBP. In conclusion, these results indicate that the Microlife WatchBP O3 monitor can be recommended for clinical use in the adult population. *Blood Press Monit* 15:59–62 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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## Introduction

To obtain a careful assessment of an individual blood pressure (BP) profile, current international guidelines recommend repeated measurements of BP using the traditional sphygmomanometric technique, self-measurement of BP at home, and the use of ambulatory BP monitoring for some clinical conditions [1,2]. This implies the use of a specific device in each setting and the production of several clinical reports. Mercury is progressively being banned in several European countries [3,4] and a modern approach is to abandon the auscultatory technique and use electronic devices for clinical BP assessment as well. Recently, the Microlife Company (Microlife AG, Widnau, Switzerland) produced the WatchBP O3, a device provided with three different function modes for clinic, home, and ambulatory BP measurement. The aim of this study was to verify the accuracy and reliability of this device according to the recommendations of the International Protocol of the European Society of Hypertension (ESH) [5].

## Methods

### Participants

We evaluated the WatchBP O3 in 33 adult participants (18 women) with a mean  $\pm$  standard deviation (SD) age of  $56.1 \pm 20.7$  years (range 30–95 years). Their systolic BP (SBP) was  $144.7 \pm 24.1$  mmHg (range 90–180 mmHg), diastolic BP (DBP) was  $86.8 \pm 18.3$  mmHg (range 50–120 mmHg), and arm circumference was  $28.1 \pm 2.9$  cm (range 22.0–34.0 cm). Blood pressure measurements were

performed in the sitting position. Twenty-five participants were excluded because BP ranges were complete ( $n = 23$ ), Korotkoff sounds were of poor quality ( $n = 1$ ), or there was atrial fibrillation ( $n = 1$ ). The study was approved by the Ethics Committee of the University of Padua, and written informed consent was given by the participants.

### Device

The WatchBP O3 is a fully automated monitor that measures BP at the upper arm using the oscillometric technique. The device offers three measurement modes for clinic, home, or ambulatory BP. The proper operational mode can be selected using a switch on the side of the device. In the 'ambulatory' mode, the device takes measurement at fixed intervals of 15, 20, 30, or 60 min, as programmed by the physician. In the 'home' mode, the patient is assumed to take measurements in accordance with the recommendations of the ESH [6], collecting a double measurement in the morning and the evening for 7 consecutive working days. When measurements have been carried out for the full 7-day period, a symbol will flash on the screen and the patient is invited to return to the clinic. In the 'casual' mode, the device functions as a regular automatic monitor and the stored readings can be reviewed by the physician at a later date.

The cuffs provided by the manufacturer are suitable for arm circumferences ranging from 22 to 42 cm. Other characteristics of the device are reported in the Appendix.