Validation of the TRANSTEK TMB-988 wrist blood pressure monitor for home blood pressure monitoring according to the International Protocol

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Objective To evaluate the accuracy of the TRANSTEK TMB-988 for home blood pressure monitoring according to the International Protocol of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension.

Method Device evaluation was done in 33 participants (16 men and 17 women) with a mean ±SD age of 58.2±11.8 years (range 32-80 years). Blood pressures [systolic blood pressure (SBP) and diastolic blood pressure (DBP)] were sequentially measured using mercury sphygmomanometer (by two trained observers) and alternately measured by the test device (by one supervisor).

Results In phase 1, a total of 33, 42, and 44 of SBP differences and 40, 43 and 45 of DBP differences were within 5, 10 and 15 mmHg, respectively. In phase 2.1, 68, 93, and 97 of SBP differences and 75, 92 and 98 of DBP differences were within 5, 10 and 15 mmHg. The difference between the device and the mean of two observers was -0.6 ±5.0 mmHg for SBP and 0.2 ±5.8 mmHg for DBP, respectively. In phase 2.2, for SBP and DBP, respectively,

27 and 26 participants had at least two of their three differences with 5 mmHg, and there were two participants who did not have any difference within 5 mmHg for both SBP and DBP.

Conclusion The TRANSTEK TMB-988 successfully passed all the phases and is recommended for home use in adults. Blood Press Monit 15:326-328 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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Introduction

Hypertension is one of the primary risk factors for heart disease and stroke, the leading causes of death worldwide [1]. It is important to control the blood pressure (BP). Measuring BP is the only way to identify patients suffering from hypertension [2]. High BP can be easily detected, and most cases have no underlying detectable cause. The most effective way to reduce the associated risk is to reduce the BP [3]. Home BP monitoring has been shown to improve patient BP control, inform treatment decisions and provide diagnostic and prognostic information [4]. Furthermore, it eliminates the whitecoat effect, detects patients with resistant hypertension and patients with the so-called out-of-office hypertension [5]. The majority of patients probably should be encouraged to choose a digital monitor. Automated monitors offer both simplicity and ease of use for patients who lack the technical skills required to properly use the more sophisticated monitors [6]. The growing popularity of oscillometric devices worn at the wrist among hypertensive patients is mainly because of their light weight and ease of use. The main objective of this study is to assess the accuracy of the TRANSTEK TMB-988 wrist blood pressure monitor according to the International Protocol

of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH-IP) [7] in adults.

Methods

The TRANSTEK TMB-988 device

The TRANSTEK TMB-988 device (Transtek Electronics Co. Ltd, ZhongShan, GuangDong, China) is an automated electronic digital wrist blood pressure monitor. The device operates through the oscillometric technique and is designed for home BP monitoring. The applied cuff is suitable for wrist circumferences ranging from 13.5 to 19.5 cm. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) (ranging from 30 to 280 mmHg), and pulse rate (ranging from 40 to 199 bpm) are displayed on a liquid crystal digital display. The size is about 73 (length) × 70 (width) × 65 (height) mm and the weight is 120 g (without batteries). The device is powered by two batteries (1.5 V, type AAA).

Participants

Thirty-seven consecutive participants were recruited for the validation. Only two participants opted out of the study before a complete measurement. With regard to sex