Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension

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Background: Four electronic devices for self-measurement of brachial blood pressure (BP): the Omron M1 Plus, the Omron M6 Comfort, the Spengler KP7500 D, and the Microlife BP A100 Plus, were evaluated in four separate studies according to the International Protocol of the European Society of Hypertension (ESH).

Design: The International Validation Protocol is divided into 2 phases: the first phase is performed on 15 selected subjects (45 pairs of BP measurements); if the device passes this phase, 18 supplementary subjects are included (54 pairs of BP measurements) making a total number of 33 subjects (99 pairs of BP measurements) on which the final validation is performed.

Methods: The same methodology recommended by the ESH protocol was applied for the 4 studies. In each study and for each subject, 4 BP measurements were performed simultaneously by 2 trained observers using mercury sphygmomanometers alternately with 3 measurements by the tested device. The difference between the BP value given by the device and that obtained by the two observers (mean of the two observers) was calculated for each measure. The 99 pairs of BP differences were classified into 3 categories (≤5, ≤10, ≤15 mmHg). The number of differences in each category was compared with the number required by the International Protocol. An individual analysis was then done to determine for each subject the number of comparisons ≤5 mmHg. At least 22 of the 33 subjects should have 2 of their 3 comparisons ≤5 mmHg.

Results: All 4 tested devices passed the first and the second phase of the validation process. The average differences between the device and mercury sphygmomanometer readings were –1.4 ± 5.5 and –0.4 ± 4.8 mmHg for SBP and DBP respectively for the Omron M1 Plus device, –2.1 ± 7.4 and 0.1 ± 4.9 mmHg for SBP and DBP respectively for the Omron M6 Comfort device, –1.4 ± 8.6 and –0.1 ± 3.5 mmHg for SBP and DBP respectively for the Spengler KP7500 D device, and 1.6 ± 4.2 mmHg and 0.54 ± 2.8 mmHg for SBP and DBP respectively for the Microlife BP A100 Plus device. For all devices, readings differing by less than 5, 10, and 15 mmHg for SBP and DBP values fulfill the recommendation criteria of the International Protocol as well as the individual analysis.

Conclusions: Omron M1 Plus (HEM-4011C-E), Omron M6 Comfort (HEM 7000-E), Spengler KP7500 D, and Microlife BP A100 Plus devices fulfilled the validation recommendations of the International Protocol.

Keywords: Omron M1 Plus (HEM-4011C-E), Omron M6 Comfort (HEM-7000-E), Spengler KP7500 D and Microlife BP A100 Plus, validation, International Protocol, self-blood pressure measurement

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Introduction

Advantages of blood pressure (BP) self-measurement have been well documented (Pickering et al 1996; White 1998; O'Brien et al 2005). Indeed, self-BP measurement