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Validation in the General Population of the iHealth Track Blood Pressure Monitor for Self-Measurement According to the European Society of Hypertension International Protocol Revision 2010: Descriptive Investigation.

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BACKGROUND: High blood pressure is one of the most common reasons why patients seek assistance in daily clinical practice. Screening for hypertension is fundamental and, because hypertension is identified only when blood pressure is measured, accurate measurements are key to the diagnosis and management of this disease. The European Society of Hypertension International Protocol revision 2010 (ESH-IP2) was developed to assess the validity of automatic blood pressure measuring devices that are increasingly being used to replace mercury sphygmomanometers.

OBJECTIVE: We sought to determine whether the iHealth Track blood pressure monitor meets ESH-IP2 requirements for self-measurement of blood pressure and heart rate at the brachial level and is appropriate for use in the general population.

METHODS: This study was a descriptive investigation. ESH-IP2 requires a total number of 33 participants. For each measure, the difference between observer and device blood pressure and heart rate values is calculated. In all, 99 pairs of blood pressure differences are classified into 3 categories (≤ 5 , ≤ 10 , and ≤ 15 mm Hg), and 99 pairs of heart rate differences are classified into 3 categories (≤ 3 , ≤ 5 , and ≤ 8 beats/min). We followed these protocol procedures in a convenience sample of 33 participants.

RESULTS: iHealth Track fulfilled ESH-IP2 requirements and passed the validation process successfully. We observed an absolute difference within 5 mm Hg in 75 of 99 comparisons for systolic blood pressure, 78 of 99 comparisons for diastolic blood pressure, and 89 of 99 comparisons for heart rate. The mean differences between the test and standard readings were 4.19 (SD 4.48) mm Hg for systolic blood pressure, 3.74 (SD 4.55) mm Hg for diastolic blood pressure, and 1.95 (SD 3.27) beats/min for heart rate. With regard to part 2 of ESH-IP2, we observed a minimum of 2 of 3 measurements within a 5-mm Hg difference in 29 of 33 participants for systolic blood pressure and 26 of 33 for diastolic blood pressure, and a minimum of 2 of 3 measurements within a 3-beat/min difference in 30 of 33 participants for heart rate.

CONCLUSIONS: iHealth Track readings differed from the standard by less than 5, 10, and 15 mm Hg, fulfilling ESH-IP2 requirements. Consequently, this device is suitable for use in the general population.

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