

Validation of the FREESCAN pulse transit time-based blood pressure monitor

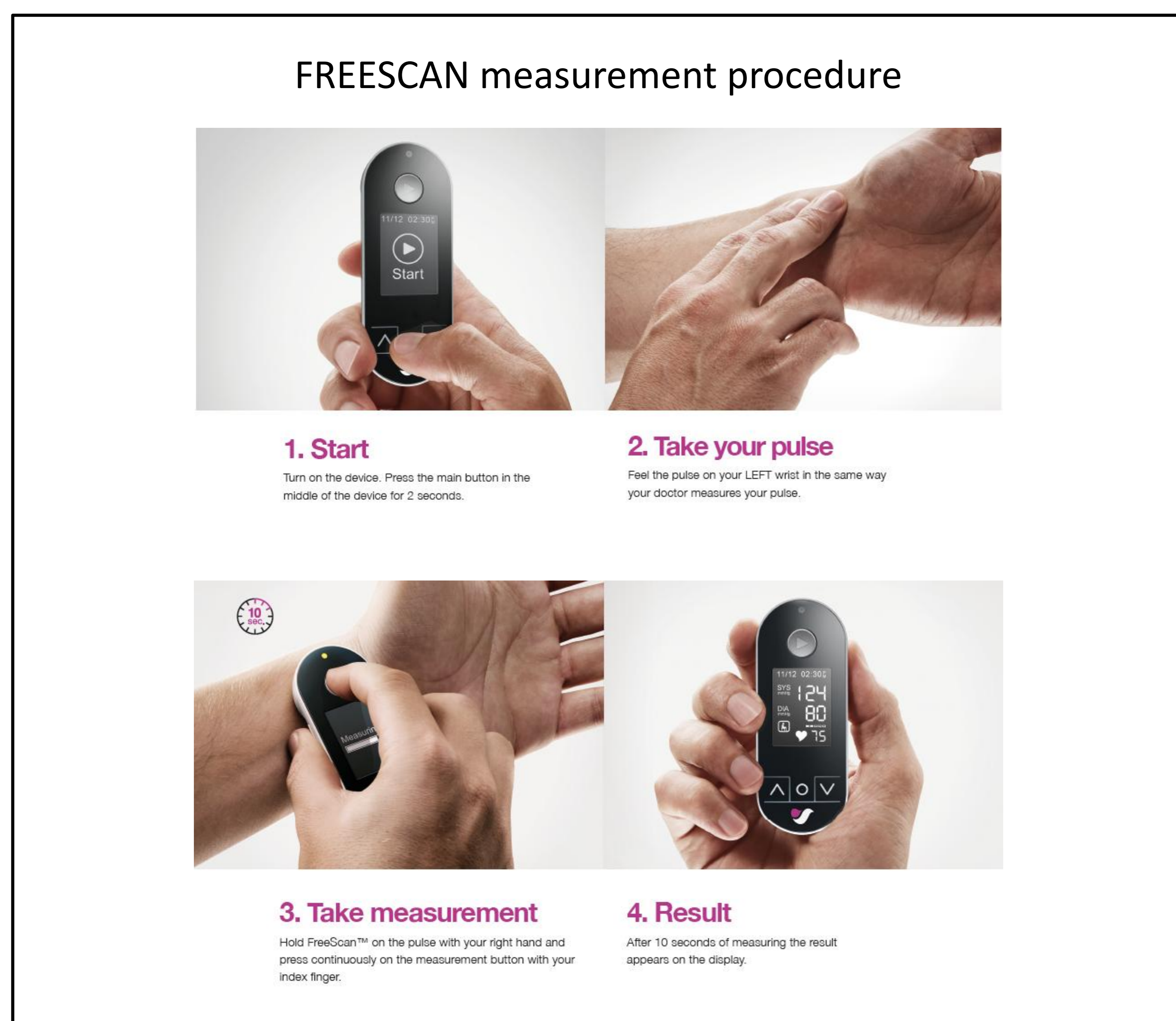
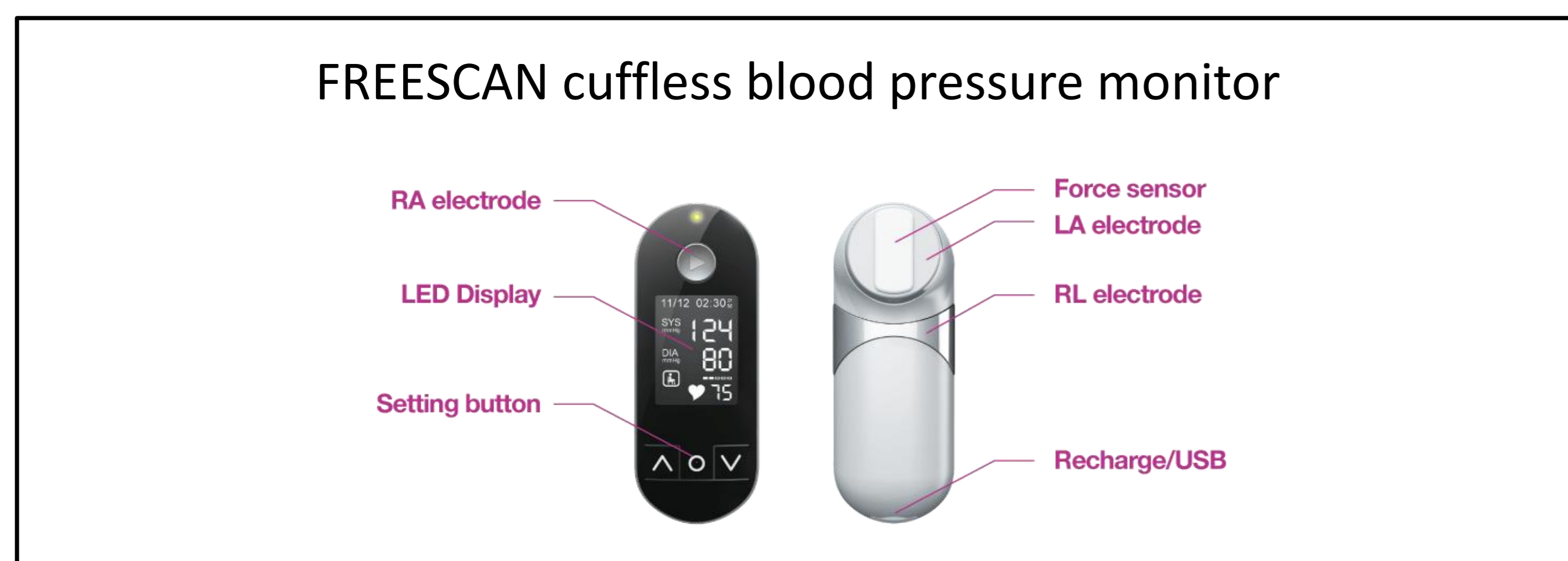
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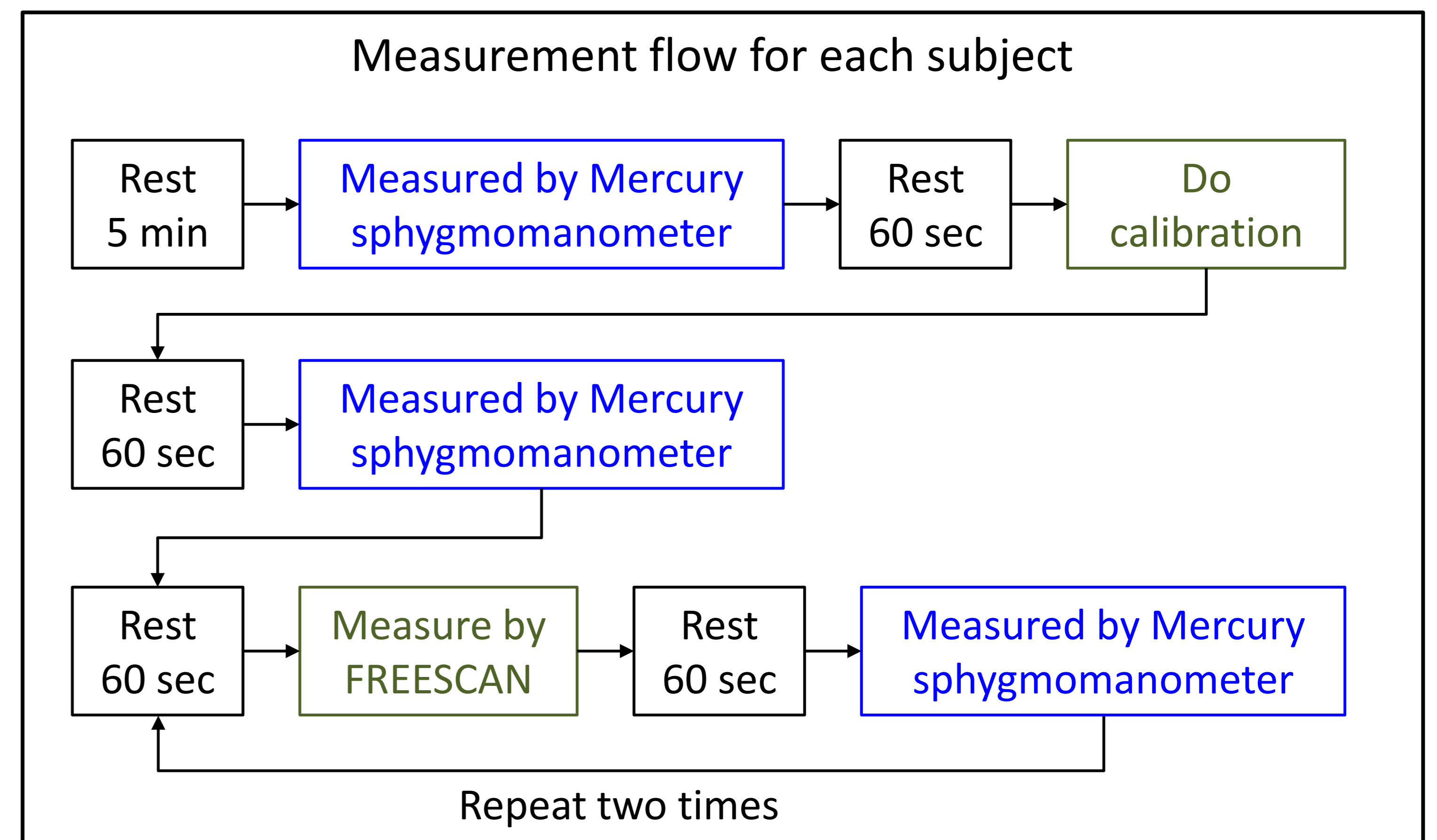
Objective:

A novel portable cuffless blood pressure (BP) monitor, FREESCAN, has been developed by Maisense Inc. Blood pressure was calculated by the information including body height, gender and pulse wave velocity (PWV), measured by electrodes and a force sensor on the radial pulse. The accuracy of the BP measuring devices is of prime importance and should be validated before devices are used clinically.



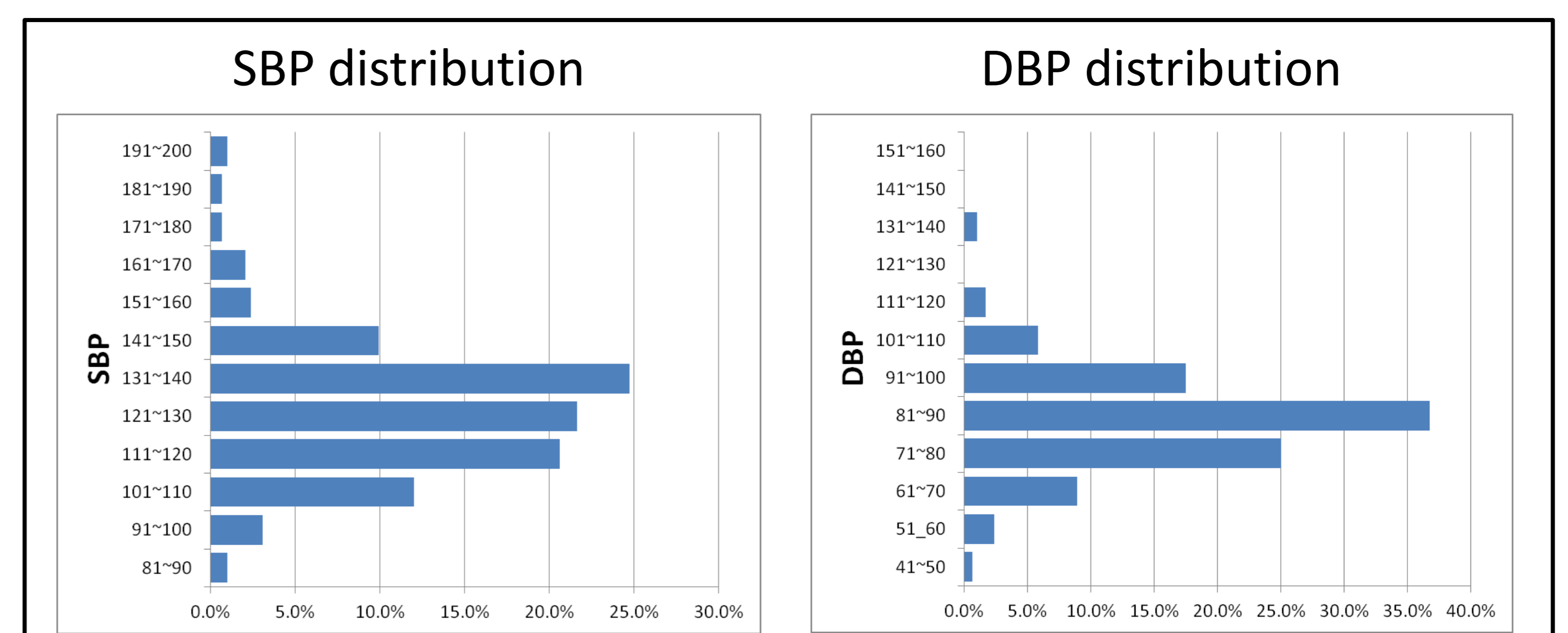
Design and Method:

This validation study followed the procedure of section 5.2.4.2, same arm sequential method, in ISO 81060-2:2013. This device is intended for use on adults only. Number of subjects, age distribution and BP distribution complied with the ISO recommendations. Two trained observers made simultaneous BP determinations on each participant using a mercury sphygmomanometer with a double stethoscope. Device calibration for each subject is done initially. After waiting for at least 60 seconds, the observers determine the subject's blood pressure by FREESCAN blood pressure monitor. According to the protocol, three valid BP determinations have been taken for each subject.

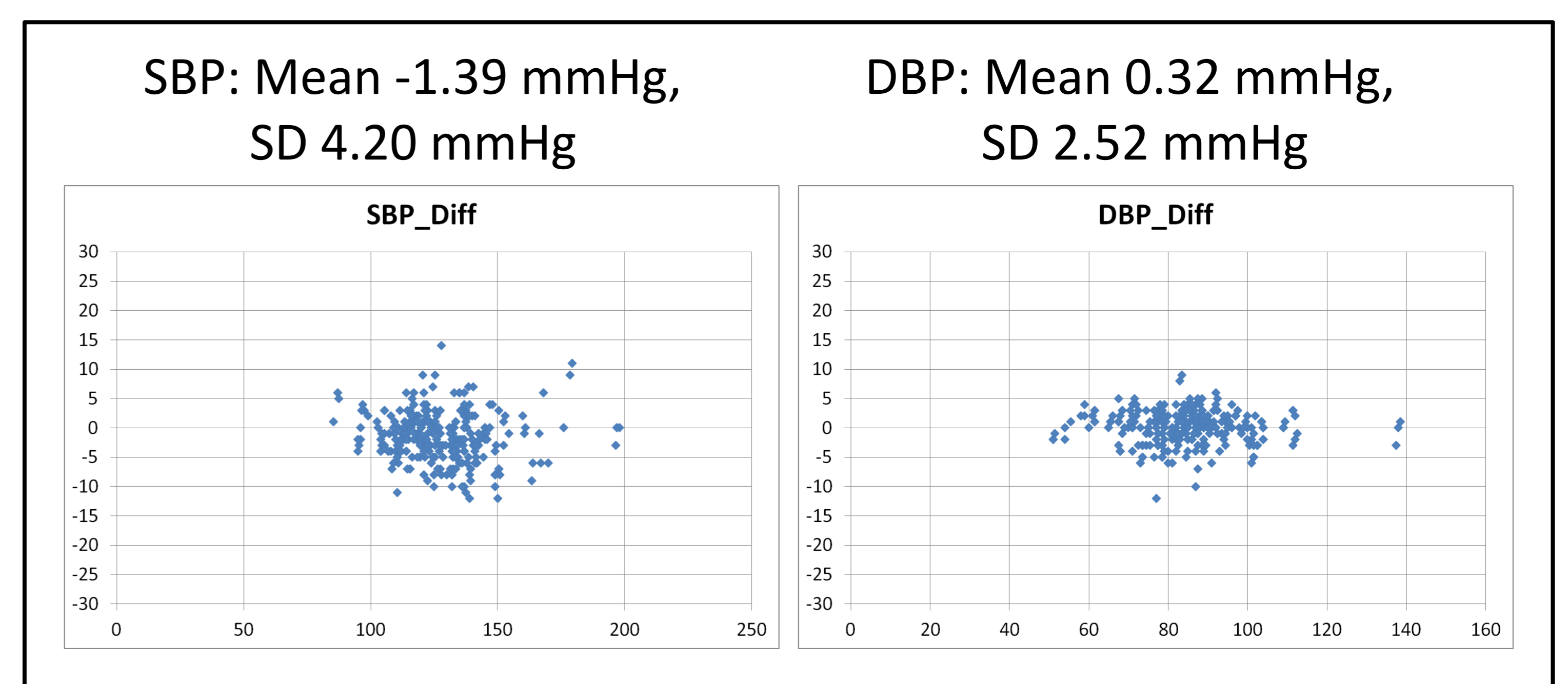


Results:

The main validation test was performed in 100 subjects (66 males and 34 females) for a total of 300 measurements. Systolic BP ranged from 86 to 198 mmHg and diastolic BP ranged from 50 to 139 mmHg. After calibration, the average difference and standard deviation of systolic BP are -1.39 and 4.20 mmHg, respectively. The average difference and standard deviation of diastolic BP are 0.32 and 2.52 mmHg, respectively.



Bland-Altman plot: The X-axis represents the average of FREESCAN and acoustic measurement, and the Y-axis represents the difference between FREESCAN and acoustic measurement.



Conclusions:

Our study results revealed that the cuffless BP monitor achieves the criterion of ISO 81060-2:2013. This novel device is suitable for portable and home BP monitoring by patients themselves.