

CLINICAL VALIDATION OF A NOVEL CUFFLESS BLOOD PRESSURE MONITOR

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OBJECTIVE

- ❖ A pocket-size cuffless device for self-measurement of blood pressure (BP) has been developed (Freescan, Maisense, Taiwan ROC).
- ❖ The device requires individualized initial calibration based on a standard arm BP measurement performed using a validated arm BP monitor and calculates systolic (SBP) and diastolic BP (DBP) through the radial pulse using three electrodes and one force-sensor.
- ❖ An interim analysis of a clinical validation study was performed.



METHODS

- ❖ Three BP measurements were taken simultaneously by 2 observers (Y-tube connected mercury sphygmomanometers) and the last 2 were averaged for test device calibration in each individual.
- ❖ According to the validation protocol, 5 same arm sequential BP measurements were taken by the observers (mercury sphygmomanometers) alternately with 4 test device measurements.
- ❖ Validation criteria of the American National Standards Institute / Association for the Advancement of Medical Instrumentation / International Organization for Standardization (ANSI/AAMI/ISO) 2013 and the European Society of Hypertension International Protocol (ESH-IP) 2010 protocols were applied.

RESULTS

- ❖ 64 subjects were recruited.
- ❖ 43 subjects with complete BP data were analysed.
- ❖ Men: 31 (72.1%)
- ❖ Age: mean 48.4±10.9 (±SD)
- ❖ Entry BP (mmHg)
SBP: 134.0±15.8 (105-174)
DBP: 88.6±12.5 (54-126)

ESH-IP PROTOCOL CRITERIA

<i>PART 1</i>	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade
Pass requirements (%)				
Two of	≥74	≥88	≥97	
All of	≥66	≥82	≥94	
Achieved (%)				
SBP	67	94	99	Pass
DBP	89	99%	100	Pass
<i>PART 2</i>	2/3 ≤5 mmHg	0/3 ≤5 mmHg		
Pass requirements (subjects)				
	≥31	≤4		
Achieved (subjects)				
SBP	31	2		Pass
DBP	43	1		Pass

ANSI/AAMI/ISO PROTOCOL CRITERIA

CRITERION 1 <i>Mean±SD device-observers difference (allowable mean±SD: 5.0±8.0 mmHg)</i>		
SBP	2.3±6.7 mmHg	Pass
DBP	1.1±4.0 mmHg	Pass
CRITERION 2 <i>Inter-subject variability (SDs) (allowable SD: SBP 6.55; DBP 6.86)</i>		
SBP	5.93 mmHg	Pass
DBP	3.68 mmHg	Pass

CONCLUSION

- These preliminary results suggest that the Freescan cuffless BP monitor seems to achieve a pass grade after calibration according to both the ANSI/AAMI/ISO 2013 and ESH-IP 2010 validation protocols.
- This novel technology has challenging potential for portable self-monitoring of BP by patients with hypertension.