GENERAL INFORMATION OF THE CLINICAL TRIAL

RPCEC code	RPCEC00000400
Public title	VALIDATION OF AUTOMATIC DEVICES IN THE CLINIC: VALIDAC-1
Scientific title	Validation study for the clinical use of the Hipermax BF automatic blood pressure measurement device in the general population.
Intervention description	Participants enrolled in the study will have their blood pressure measured eigth times with both the auscultatory method as the gold standard for the reference measurement and the oscillometer with the sphygmomanometer to be validated (Hipermax FB device). This process will be carried out 8 times to complete the three pairs of valid measurements established by the standard. The estimated duration for each patient is 1 hour.

PARTICIPANT FLOW

Evaluated	92
Excluded	7
Reasons for exclusion:	
1. Non-agreement between examiners (any two reference systolic blood pressure values differ by more than 12 mmHg (1.60 kPa); or any two reference diastolic blood pressure values differ by more than 8 mmHg (1.07 kPa))	2
2. Anxiety	1
3. Variability with respect to mercury	4
Recruited	85
Not Completed	0
Completed	85
Analyzed	85

BASELINE CHARACTERISTICS

Characteristic	Total (n=85)
Age (years)	
Media ± SD	44.8 ± 14.68
Minimum	13
Maximum	71
Gender	
Female	48 (56.5%)
Male	37 (43.5%)
Arm circumference (cm)	
Media ± SD	32.29 ± 6.23
Minimum	22
Maximum	44
Initial Systolic Blood Pressure (SBP) R0 (mmHg)	
Media ± SD	120.9 ± 19.2
Minimum	90
Maximum	173
Initial Diastolic Blood Pressure (DBP) R0 (mmHg)	
Media ± SD	78.1 ± 11.5
Minimum	58
Maximum	110
Heart Rate (HR) (l/m)	
Media ± SD	75.6 ± 11.2
Minimum	44
Maximum	115

Reference Pressures according to ISO 81060-2:2018 Standard (Steps 1-3 y 5, n=255)

Requirement to compliance	%	Evaluation
At least the 5 % of the SBP ≤100 mmHg	13.7	Compliance
At least the 5 % of the SBP ≥160 mmHg	5.1	Compliance
At least the 20 % of the SBP ≥140 mmHg	20	Compliance
At least the 5 % of the DBP ≤60 mmHg	5.1	Compliance
At least the 5 % of the DBP ≥100 mmHg	5.5	Compliance
At least the 20 % of the DBP ≥85 mmHg	25.1	Compliant

Compliance with the amendment of the standard on the distribution of arm diameters

Arm Diameter (Standard Amendment)						
Lower Octile	10%	22-24.75	14.1 %	Compliance	1/4 Overall Range 20% 22-27.5	29,4 % Compliance
	10%	24.76-27.5	15.3 %	Compliance		
	20%	27.6-32.9	24.7 %	Compliance	1/4 Overall Range	
	20%	33-38.4	21.2 %	Compliance	1/4 Rango Tot.	
	10%	38.5-41.24	12.9 %	Compliance	1/4 Overall Range 20% 38.5-44	24.7 % Compliance
Lower Octile	10%	41.25-44	11.8 %	Compliance		

OUTCOME MEASURES

a) Primary outcomes

Blood pressure value measured with the HIPERMAX BF (equipment under test) and the Mercury Column (reference equipment). Measurement time: A maximum of eight pairs of readings will be taken per subject, with intervals of 1 min. The evaluation criteria will be the relationship between the measurement of the HIPERMAX BF with that carried out by two certified experts using the reference device. The HIPERMAX BF must fulfil the following two criteria (ISO 81060-2:2018 Standard):

Criteria 1:

1) The differences of the n individual paired determinations of the sphygmomanometer under test and of the observers' readings with the reference sphygmomanometer for all subjects, calculated separately for systolic blood pressure and diastolic blood pressure, shall:

- Have the mean value of the differences ($\bar{x}n$) less than or equal to ±5.0 mmHg (±0.67 kPa), calculated according to formula (2) that appears in section a) of section 5.2.4.1.2 of the standard. and,
- Have a standard deviation (sn) no greater than 8.0 mmHg (1.07 kPa), calculated according to formula (3) that appears in section a) of section 5.2.4.1.2 of the of the standard.
- $\bar{x}n$ and sn must be calculated and expressed at least in 0.1 mmHg (0.01 kPa)

2) The reference blood pressure value PREF-sq will be the average of the observers' readings with the reference sphygmomanometer before and after the determination of the sphygmomanometer under test. The PREF-sq value will be calculated according to formula (4) that appears in subsection a) of section 5.2.4.1.2 of the standard.

Criteria 2:

1) For the systolic blood pressure and diastolic blood pressure of each of the m subjects, the standard deviation s_m of the subject-averaged paired determinations of the sphygmomanometer under test and of the observers' readings with the reference sphygmomanometer, must meet with the criteria listed in:

- Table 1: maximum permissible standard deviation (sm) as a function of $\bar{x}n$, expressed in mmHg (subsection b) of section 5.2.4.1.2 of the previous standard); either
- Table 2: maximum permissible standard deviation (sm) as a function of $\bar{x}n$, expressed in kPa (section b) of section 5.2.4.1.2 of the previous standard) Being sm calculated according to formula (5) that appears in section b) of section 5.2.4.1.2 of the previous standard.

Validation criteria's	Value	Evaluation
Criteria 1 (n=255 measurements)		
Mean value of SBP differences (mmHg) ≤±5	1.23	Compliance
Mean value of DBP differences (mmHg) ≤±5	0.84	Compliance
Standard Deviation SBP (mmHg) ≤8	4.95	Compliance
Standard Deviation DBP (mmHg) ≤8	4.88	Compliance
Criteria 2 (n=85 subjects)		
Standard Deviation SBP (mmHg) ≤6.84	4.19	Compliance
Standard Deviation DBP (mmHg) ≤ 6.89	4.18	Compliance

b) Secondary outcomes

The study doesn't have Secondary outcomes

ADVERSE EVENTS

No adverse events were reported in the study