SUPPLEMENTARY FILE

RECOMMENDATIONS AND PRACTICAL GUIDANCE FOR PERFORMING AND REPORTING VALIDATION STUDIES

ACCORDING TO THE UNIVERSAL STANDARD FOR THE VALIDATION OF BLOOD PRESSURE MEASURING DEVICES BY THE ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION/ EUROPEAN SOCIETY OF HYPERTENSION/ INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (AAMI/ESH/ISO)

(ISO 81060-2:2018)

SUPERVISOR

Date:___/___/20__

Time: __:___

Subject ID No

Supervisor's initials: _____

Subject's initials: _____ **DOB**:___/___/_____ **Sex:**___ **Arm circ:**_____cm

Test device: _____

Test device cuff: _____

Reference device cuff (*inflatable bladder dimensions*): _____X _____ cm

Test device SBP/DBP measurements (*mmHg*)

			Notes
T0	_____/_____		
	PR: _____		
	T1	_____/_____	
	T2	_____/_____	
	T3	_____/_____	
Repeat measurements (if necessary)	**T4**	Repeat _____/_____	
	T5	Repeat _____/_____	
	T6	Repeat _____/_____	
	T7	Repeat _____/_____	
	T8	Repeat _____/_____	

Comments

_____

_____

_____

_____

AAMI/ESH/ISO Universal Standard for the Validation of Blood Pressure Measuring Devices (ISO 81060-2:2018)
European Society of Hypertension Working Group on Blood Pressure Monitoring. J Hypertens 2019;37.

OBSERVER A

Date:___/___/20__

Time: __:___

Subject ID No

Observer's initials: _____

Subject's initials: _____

Test device: _____

Ausc. BP R0: _____ /_____ mmHg

PR: _____ bpm

		Auscultatory SBP/DBP (*mmHg*)	Notes
	R1	_____ / _____	
	R2	_____ / _____	
	R3	_____ / _____	
	R4	_____ / _____	
Repeat measurements (if necessary)	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	

AAMI/ESH/ISO Universal Standard for the Validation of BPM Devices (ISO 81060-2:2018) (ESH Working Group on BP Monitoring)

OBSERVER B

Date:___/___/20__

Time: __:___

Subject ID No

Observer's initials: _____

Subject's initials: _____

Test device: _____

Ausc. BP R0: _____ /_____ mmHg

		Auscultatory SBP/DBP (*mmHg*)	Notes
	R1	_____ / _____	
	R2	_____ / _____	
	R3	_____ / _____	
	R4	_____ / _____	
Repeat measurements (if necessary)	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	
	Repeat	_____ / _____	

AAMI/ESH/ISO Universal Standard for the Validation of BPM Devices (ISO 81060-2:2018) (ESH Working Group on BP Monitoring)

CHECKLIST FOR VALIDATION STUDIES USING THE AAMI/ESH/ISO UNIVERSAL STANDARD (ISO 81060-2:2018)

European Society of Hypertension Working Group on Blood Pressure Monitoring. J Hypertens 2019;37.

		✓	NA	No
TITLE	Validation of the *"manufacturer" "model" "measuring method" "type"* blood pressure monitor for *"use"* in *"population"* according to the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018)			1
ABSTRACT				
Objective	• Device (*manufacturer, model*)			2
	• Device measuring method (*oscillometric, auscultatory, aneroid, hybrid, other*)			3
	• Device type (*upper-arm, wrist, other*)			4
	• Device use (*home, office, ambulatory, other*)			5
	• Population (*general or special*)			6
Methods	• Protocol *AAMI/ESH/ISO (ISO 81060-2:2018*)			7
	• Cuffs used for test device measurements (*number, arm circumferences*)			8
Results	• Recruited subjects (*number*)			9
	• Included subjects (*number*)			10
	• Validation Criterion 1 for systolic and diastolic BP			11
	• Validation Criterion 2 for systolic and diastolic BP			12
Conclusion	• Pass or fail			13
	• Recommendation for specific clinical use			14
INTRODUCTION ***(avoid unnecessary general comments on BP, devices and hypertension)***				
• Device (*manufacturer, model*)				15
• Device type (*oscillometric, auscultatory, aneroid, intra-arterial, other*)				16
• Device use (*home, office, ambulatory, other*)				17
• Device type (*upper-arm, wrist, other*)				18
• Population (*general or special*)				19
• Protocol *AAMI/ESH/ISO (ISO 81060-2:2018*)				20
METHODS ***(avoid detailed presentation of validation protocol)***				
• Test device (*description, cuff sizes and recommended use*)				21
• Participants (*sources of recruitment*)				22
• Validation team				23
• Reference BP (*devices, cuffs with bladder dimensions*)				24
• Procedure (*brief*)				25
• Analysis (*brief*)				26
• Study approval - Participants' consent				27
RESULTS				
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• Included subjects (*number*) and excluded subjects (*number*, reasons for exclusion)				29
• Participants' age, gender, arm (or wrist) circumference, entry BP R0 (separately in children) (*mean, SD, range*)				30
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• Validation Criterion 2 (*SD*) for systolic and diastolic BP				34
• Validation Criterion 1 (*mean±SD*) separately for each cuff *(not a pass/fail criterion)*				35
• Validation Criterion 1 (*mean*±SD) separately for 35 children or 15 preeclamptic women *(not a pass/fail criterion)*				36
• Standardized Bland-Altman scatterplots of BP differences against their average value (systolic and diastolic)				37
DISCUSSION ***(avoid unnecessary comments on BP measurement, devices, and hypertension)***				
• Pass or Fail				38
• Recommendation for specific clinical use				39
CONFLICT OF INTEREST				
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REFERENCES ***(avoid unnecessary references on general issues)***				
• Protocol used: *AAMI/ESH/ISO (ISO 81060-2:2018) reference*				41
• Previous validation studies of the test device. Study limitations. Other relevant comments				42

EXAMPLE OF FULL PAPER REPORTING AN 85-SUBJECT GENERAL POPULATION VALIDATION STUDY OF A BLOOD PRESSURE MONITOR ACCORDING TO THE AAMI/ESH/ISO UNIVERSAL STANDARD (ISO 81060-2:2018)

TITLE: Validation of the NovelBP-99HT oscillometric blood pressure monitor for professional office use in general population according to the AAMI/ESH/ISO Universal Standard.

ABSTRACT

Objective: To evaluate the accuracy of the NovelBP-99HT oscillometric upper-arm professional office blood pressure (BP) monitor in general population according to the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018).
Methods: Subjects were recruited to fulfil the age, gender, BP and cuff distribution criteria of the AAMI/ESH/ISO Universal Standard in general population using the same arm sequential BP measurement method. Two cuffs of the test device were used for arm circumference 22-32 (medium) and 32-42 cm (large).
Results: Ninety-one subjects were recruited and 85 were analyzed. For validation Criterion 1, the mean±SD of the differences between the test device and reference BP readings was -2.3±6.2/0.6±4.8 mmHg (systolic/diastolic). For validation Criterion 2, the SD of the averaged BP differences between the test device and reference BP per subject was 4.62/4.01 mmHg (systolic/diastolic).
Conclusions: The NovelBP-99HT professional office BP monitor fulfilled the requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018) in general population and can be recommended for clinical use.

Keywords: accuracy, blood pressure measurement, validation, automated, oscillometric, office.

Conflict of interest: None for all authors.
Funding: The study was funded by NovelBP, London, UK.

INTRODUCTION

This study assessed the blood pressure (BP) measurement accuracy of the professional oscillometric upper-arm cuff device NovelBP-99HT (*NovelBP, London, UK*) developed for office BP measurement using the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018) in general population [1].

METHODS

Test device
The NovelBP-99HT is an automated oscillometric upper-arm BP monitor developed for professional use in the office. The device has a medium size cuff for arm circumference 22-32 cm and a large cuff for arm 32-42 cm, which were used in the validation study according to the manufacturers' instructions. Two identical devices were provided by the manufacturer for the validation study together with a written declaration that they were standard production models. One of them was randomly selected for the validation procedure.

Participants
According to the AAMI/ESH/ISO Universal Standard, for a general population validation study of a BP monitor at least 85 subjects aged >12 years are required [1]. Subjects were recruited from patients attending the outpatient hypertension clinic and from hospital staff.

Validation team

The study was conducted by a supervisor and 2 trained observers who were experienced in BP measurement research and were standardized for their agreement in BP measurement before the study initiation [1].

Reference BP

Two connected (Y-tube) standard mercury sphygmomanometers (*Supermeter, Meditools, Chicago, USA*), which had been calibrated before the study initiation were used for simultaneous reference auscultatory BP measurements by two observers using a dual-head teaching stethoscope (*Doctor Educ-3, Cardiocare, Berlin, Germany*). Three cuffs with inflatable bladder dimensions 12X23, 14X28, 16X33 cm respectively were used so that the length would be at 75-100% of the individual participant's midarm circumference and the width at 37-50% [1].

Procedure

The same arm sequential method was applied [1], which includes 2 entry BP measurements (reference R0 and test device T0) followed by 4 reference measurements (R1, R2, R3, R4) taken alternately with 3 test device measurements (T1, T2, T3). All measurements were taken on the left arm. The observers were blinded to each other's readings and the test device results. The supervisor recorded the test device measurements and checked the observers' measurements. In case of disagreement between the observers, additional pairs of measurements were performed. A maximum of 8 pairs of BP determinations was allowed after which the subject was excluded.

Analysis

The AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018) requirements were strictly followed [1].

Study approval

The study protocol was approved by the hospital scientific committee. All participants signed informed consent for study participation.

RESULTS

Ninety-one individuals were recruited and 85 were analyzed. Reasons for exclusion are presented in **Table 1**. The participants' characteristics are presented in **Table 2**. The requirements for age, gender, BP and cuff distribution were fulfilled [1]. The mean BP difference between the simultaneous observers' measurements was 0.3±1.6[SD]/-0.2±1.7 mmHg (systolic/diastolic, range -4 to 4 mmHg). There were 18 BP readings with inter-observer disagreement >4 mmHg.

The distribution of the reference BP measurements R1-R4 is presented in **Table 3**. The medium cuff of the test device was used in 43 subjects and the large in 42. Participants with arm circumference within the upper/lower half of the specified range of use of the medium cuff were 24/19 respectively (56/44%) and of the large cuff 17/25 (40/60%). The validation analysis is shown in **Table 4**. Both the validation Criteria 1 and 2 suggested 'pass' for systolic and diastolic BP. Validation Criterion 1 results per cuff size are presented in **Table 5**. Standardized Bland-Altman scatterplots of the test-reference BP differences against their average are shown in **Figure**.

Table 1. Participants recruited and excluded from the analysis.

	Subjects
Recruited	91
Excluded	6
Reasons for exclusion	
- Reference BP variability (>12/8 mmHg for systolic/diastolic)	4
- K sounds not audible	1
- Talking during BP measurements	1
Analyzed	85

Table 2. Participants' characteristics (n=85).

	Mean ± SD	**Range**
Age (years)	54.8±12.1	22-75
Gender (male/female)	45/40	-
Arm circumference (cm)	32.1±4.1	23.0-39.8
Entry SBP *R0* (mmHg)	129.7±18	82-174
Entry DBP *R0* (mmHg)	79.8±11.7	48-112

Table 3. Distribution of reference BP measurements (*R1-R4*).

SBP	≤100 mmHg	≥160 mmHg	≥140 mmHg
	9.8%	6.7%	28.2%
DBP	≤60 mmHg	≥100 mmHg	≥85 mmHg
	5.1%	5.9%	34.9%

Table 4. Validation study results.

	Pass requirement	**Achieved**	
		SBP	**DBP**
Criterion 1 *(255 BP pairs)*			
Mean BP difference (mmHg)	≤5	-2.3	0.6
SD (mmHg)	≤8	6.2	4.8
		Pass	Pass
Criterion 2 *(85 Subjects)*			
SD (mmHg, SBP/DBP)	≤6.55/6.91	4.62	4.01
		Pass	Pass
Result		Pass	

Table 5. Test device cuff size distribution and results (criterion 1).

Test device cuff size	Participants (%)	Mean SBP difference ±SD (mmHg)	Mean DBP difference ±SD (mmHg)
Medium	43 (51)	-2.2±6.0	1.6±4.6
Large	42 (49)	-2.3±6.4	-0.4±4.9

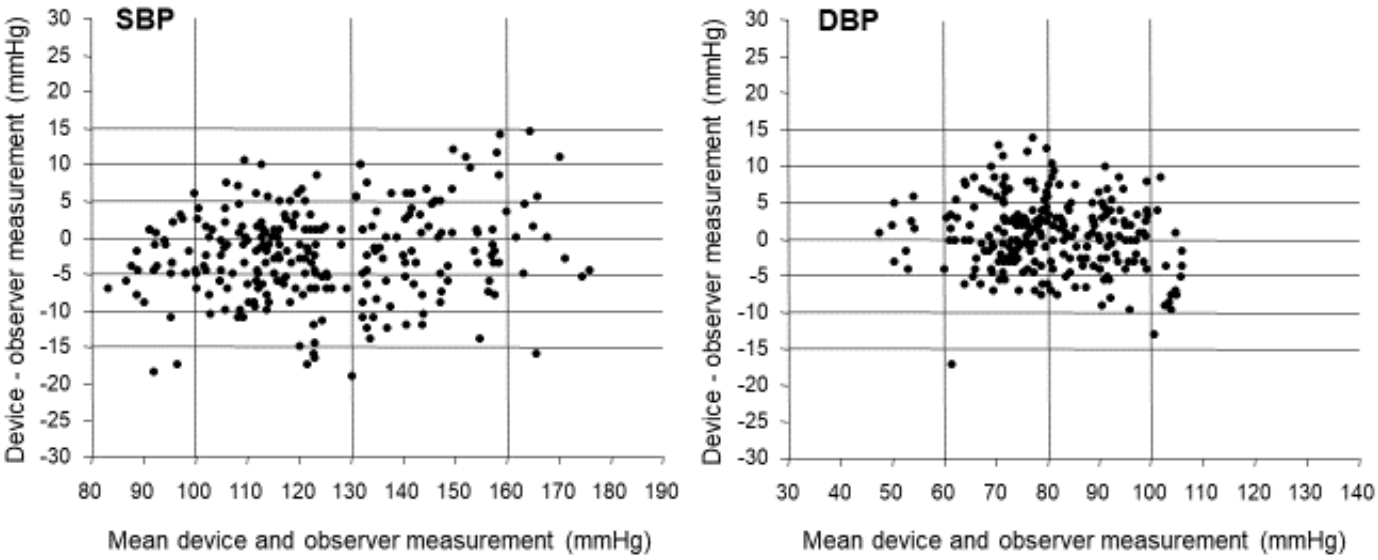

Figure. Standardized Bland-Altman scatterplots of the Test-Reference BP differences against their average [1].

DISCUSSION

This study shows that NovelBP-99HT office BP monitor fulfils the accuracy criteria of the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018) in a general population and can be recommended for clinical use.

REFERENCES

1. Stergiou G, Palatini P, Asmar R, Ioannidis JP, Kollias A, Lacy P, McManus R, Myers M, Parati G, Shennan A, Wang J, O'Brien E, on behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring. Recommendations and Practical Guidance for Performing and Reporting Validation Studies according to the Universal Standard for the Validation of Blood Pressure Measuring Devices by the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO). *J Hypertens* 2019;37.