Blood Pressure Device Validation Checklist

General Submission Information	
Manufacturer Name	
Device Model Number	
Is device listed with STRIDE BP? (www.stridebp.org)	☐Yes ☐No
Is device listed with VALIDATE BP? (www.validatebp.org/)	☐Yes ☐No
Device type/indication (home, office, ambulatory*, kiosk, exercise/stress testing*)	
Population (general or special*, e.g. pregnancy, children) *If no special mode, children 3-12 years are not considered a "special population" and can be included in the general population study.*	
Cuff sizes and corresponding arm circumference ranges **for use** with device	
Cuff sizes and corresponding arm circumferences **tested with** the device	
Was an auscultatory or invasive* reference device used?	☐ auscultatory ☐ invasive*
If auscultatory: Was an appropriate reference device used? *-Mercury or Aneroid that Complies with the requirements of ISO 81060-1, except that the maximum permissible error shall be ± 1 mmHg (0. 13 kPa).* *Bladder length: 75-100 % of the upper arm circumference* *Bladder width: 37-50 % of the upper arm circumference*	☐Yes ☐No ☐Unknown
For non-peer reviewed submissions only: Was the validation study conducted by an independent organization?	☐Yes ☐No ☐Not applicable

**these devices have additional/separate testing requirements*

Blood Pressure Device Validation Checklist

Review Checklist					
Submission Information	**Notes**	**Yes**	**No**	**N/A**	**Page number**
Number of Subjects included in validation study *Minimum of 85 for general population*		☐	☐	☐	
Number of participants tested per cuff sold with the device *- Each CUFF size shall be tested on at least 1/(2n) of the subjects, where n is the number of CUFF sizes.*		☐	☐	☐	
Distribution of subjects tested across cuffs: *For multiple cuff sizes:* *1) At least 40 % of the subjects shall have a limb circumference which lies within the upper half of the specified range of use of the cuff; and 2) at least 40 % of the subjects shall have a limb circumference within the lower half of the specified range of use of the cuff.*		☐	☐	☐	
Requirements for participant distribution (age/gender) *Age range: All participants must be 13 years or older if intended for adult or adolescent patients; if intended for use in children (without a special mode), there must be 35 children aged 3-12 years and 50 participants aged 13 years or older included*		☐	☐	☐	
Sex: *At least 30 % of the subjects shall be male and at least 30 % of the subjects shall be female.*		☐	☐	☐	
Requirements for SBP: *-At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SBP≤ 100 mmHg (13.33 kPa).*		☐	☐	☐	
-At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SBP ≥ 160 mmHg (21.33 kPa).		☐	☐	☐	
-At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a SBP ≥ 140 mmHg (18.66 kPa).		☐	☐	☐	
Requirements for DBP: *-At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DBP ≤ 60 mmHg (8.0 kPa)*		☐	☐	☐	
-At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DB P≥ 100 mmHg (13.33 kPa).		☐	☐	☐	
-At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a DBP ≥ 85 mmHg (11.33 kPa).		☐	☐	☐	
BP readings (SBP and DBP) **-***There shall be a minimum of 255 valid paired BP determinations*		☐	☐	☐	
-The 5th Korotkoff sound was used for determination of DBP		☐	☐	☐	
- Any pair of observers' determinations with a difference greater than 4 mmHg (0.53 kPa) was excluded.		☐	☐	☐	

Blood Pressure Device Validation Checklist

For Reviewer Use only

Validation Criterion 1 for systolic and diastolic BP

1. Average differences overall no more than ± 5 mm Hg
2. Average standard deviation overall no more than 8 mmHg

Validation Criterion 2 for systolic and diastolic BP

1. The averaged difference between each participant's measurements obtained from the reference sphygmomanometer and the measurements obtained by the device under test are in the allowable difference +/- standard deviation range as detailed below:

Table 1 — Averaged subject data acceptance (criterion 2) in mmHg

$\bar{x}_n$	Maximum permissible standard deviation, s_m, as function of, $\bar{x}_n$ mmHg									
	0,0	**0,1**	**0,2**	**0,3**	**0,4**	**0,5**	**0,6**	**0,7**	**0,8**	**0,9**
±0,	6,95	6,95	6,95	6,95	6,93	6,92	6,91	6,90	6,89	6,88
±1,	6,87	6,86	6,84	6,82	6,80	6,78	6,76	6,73	6,71	6,68
±2,	6,65	6,62	6,58	6,55	6,51	6,47	6,43	6,39	6,34	6,30
±3,	6,25	6,20	6,14	6,09	6,03	5,97	5,89	5,83	5,77	5,70
±4,	5,64	5,56	5,49	5,41	5,33	5,25	5,16	5,08	5,01	4,90
±5,	4,79	—	—	—	—	—	—	—	—	—
EXAMPLE For mean of ±4,2 mmHg, the maximum permissible standard deviation is 5,49 mmHg.										

Device meets Criterion 1?	☐Yes ☐No
Device meets Criterion 2?	☐Yes ☐No
Device passes?	☐Yes ☐No

FINAL RECOMMENDATION			
☐Pass ☐Fail ☐Need More Information			
If more information needed, specify what is needed here:			
ADDITIONAL COMMENTS:			
Reviewer Name		**Reviewer Signature**	
Date			

We acknowledge the checklist developed by Validate BP team, which has been modified for HT Canada purposes