



### Section 3: Screening and Recruitment Details

Screening and Recruitment		Phase 2 Recruitment Ranges (mmHg)	
<b>Total Screened</b>	41 <small>1</small>	<b>Low</b> (90 – 129)	11 <small>11</small>
<b>Why Eliminated</b>	<b>Ranges Complete</b>	<b>SBP</b>	<b>Medium</b> (130 – 160)
	<b>BP out of Range</b>		<b>High</b> (161 – 180)
	<b>Arrhythmias</b>		
	<b>Poor Quality Sounds</b>	<b>DBP</b>	<b>Low</b> (40 – 79)
	<b>Other Reasons*</b>		<b>Medium</b> (80 – 100)
	<b>Total Eliminated</b>		<b>High</b> (101 – 130)
	<b>Total Recruited</b>	85 <small>8</small>	
<b>Subjects with both SBP and DBP used</b>	27 <small>9</small>		
<b>Subjects with one of SBP or DBP used</b>	14 <small>10</small>		
<b>*Explanation</b>	Arm circumference out of Range (4), Body motion (3)		<small>17</small>

- Legend:
- Box 1      The total number of subjects screened, regardless of whether or not they were included in the *study*.
  - Box 2      The number eliminated because both SBP and DBP fell into ranges for which there were already 11 subjects included.
  - Box 3      The number eliminated because (a) SBP was out of range (< 90 mmHg or > 180 mmHg) and DBP fell into a range for which there were already 11 subjects included. (b) DBP was out of range (< 40 mmHg or > 130 mmHg) and SBP fell into a range for which there were already 11 subjects included (c) both SBP and DBP were out of range.
  - Box 4      The number eliminated due to arrhythmias.
  - Box 5      The number eliminated due to an inability to auscultate their BP accurately due to poor quality sounds regardless of the reason for the lack of quality.
  - Box 6      The number eliminated for reasons not covered in boxes 2 to 5. An explanation must be provided in Box 17.
  - Box 7      The total number eliminated. This equals the sum of boxes 2 to 6
  - Box 8      The total recruited equals the number screened (Box 1) less the number eliminated (Box 7). Box 8 also equals Box 9 plus Box 10.
  - Box 9      The number of subjects where both SBP and DBP fell into recruitment ranges with less than 11 subjects already included
  - Box 10     The number of subjects where only one of SBP or DBP fell into recruitment ranges with less than 11 subjects already included but where the other pressure either fell into a range for which there were already 11 subjects included or where it was out of range. Box 9 plus half Box 10 must equal 33.
  - Boxes 11-16   These must each equal 11 in a completed study. They may be less if a device is eliminated at Phase 1.
  - Box 17     An explanation of those listed as excluded in Box 6.

## Section 4: Subject Details

		Phase	
		SBP	DBP
<b>Sex</b>	<b>Male:Female</b>	18:15 19	19:14 20
	<b>Age (years)</b>		
	<b>Range (Low:High)</b>	35-89 21	35-89 22
	<b>Mean (SD)</b>	68 (11) 23	65 (13) 24
<b>Arm Circumference (cm)</b>	<b>Range (Low:High)</b>	19:30 25	19:31 26
	<b>Mean (SD)</b>	26 (3) 27	26 (3) 28
<b>Cuff</b>	<b>Standard</b>	33 29	33 30
	<b>Large (&gt; 35 cm)</b>	0 31	0 32
<b>Recruitment BP (mmHg)</b>	<b>Range (Low:High)</b>	94:179 33	57:115 34
	<b>Mean (SD)</b>	140 (25) 35	87 (17) 36

If the study was terminated at Phase 1, please complete this table for those 15 subjects only; otherwise complete it for all included subjects. If the same subjects are used for both SBP and DBP in all cases, then the DBP and SBP columns will be the same for boxes 19 to 32. The values in this table refer only to the 15 (Phase 1) or 33 (Phase 2) subjects analysed for the respective pressure. Eliminated subjects are not included. Subjects in whom only one pressure is analysed are included only for that pressure.

- Legend:
- Box 18 Enter the phase at which the study was completed.
  - Boxes 19-20 Enter the number of males, a colon and the number of females e.g. 16:17. They should total 15, if the final phase is Phase 1, or 33, if it is Phase 2.
  - Boxes 21-22 Enter the age of the youngest subject, a colon and the age of the oldest subject e.g. 31:74.
  - Boxes 23-24 Enter the mean and, in parentheses, the SD of the subject ages. Values should be rounded to the nearest integer. e.g. 52 (12).
  - Boxes 25-26 Enter the smallest arm circumference, a colon and the largest arm circumference e.g. 24:34.
  - Boxes 27-28 Enter the mean and, in parentheses, the SD of the subject arm circumferences. Values should be rounded to the nearest integer. e.g. 29 (3).
  - Boxes 29-30 Enter the number of subjects on whom a standard cuff was used.
  - Boxes 31-32 Enter the number of subjects on whom a large cuff was used. If no large cuff was supplied these boxes should contain an "X". If a large cuff was supplied but not used, these boxes should contain a zero.
  - Boxes 33-34 Enter the lowest pressure, a colon and the highest pressure from Observer A measurements only e.g. 104:180.
  - Boxes 35-36 Enter the mean and, in parentheses, the SD of the subject pressures from Observer A measurements only. Values should be rounded to the nearest integer. e.g. 140 (20)

### Section 5: Validation Results

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Phase 1 Result		
Required	One of	25	35	40			
Achieved	SBP	31 37	44 39	45 41	Continue 43		
	DBP	37 38	44 40	45 42	Continue 44		
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Phase 2.1 Result	Mean	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	64 45	95 47	99 49	Pass 51	-2.1 53	4.9 55
	DBP	71 46	91 48	98 50	Pass 52	-0.2 54	5.5 56
Phase 2.2		2/3 ≤ 5 mmHg		0/3 ≤ 5 mmHg	Phase 2.2 Result		Overall Result
Required		≥ 22		≤ 3			
Achieved	SBP	23 57		2 59	Pass 61		Pass 63
	DBP	25 58		3 60	Pass 62		Pass 64

- Legend: Boxes 37-42 Enter the number of absolute differences between observer and device measurements from Phase 1 falling within 5 mmHg, 10 mmHg and 15 mmHg respectively. Each is at most 45.
- Box 43 If boxes 37, 39 and 41 fulfil the requirements, then this is "Continue"; otherwise it is "Stop".
- Box 44 If boxes 38, 40 and 42 fulfil the requirements, then this is "Continue"; otherwise it is "Stop".
- Boxes 45-50 Enter the number of absolute differences between observer and device measurements from Phase 2 falling within 5 mmHg, 10 mmHg and 15 mmHg respectively. Each is at most 99
- Box 51 If boxes 45, 47 and 49 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
- Box 52 If boxes 46, 48 and 50 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
- Boxes 53-54 Enter the mean of the 99 differences between observer and device measurements. (Observer measurements are subtracted from device measurements.) Values should be rounded to one decimal place. e.g. -2.3
- Boxes 55-56 Enter the standard deviation of 99 differences between observer and device measurements. Values should be rounded to one decimal place. e.g. 4.5
- Boxes 57-58 Enter the number of subjects with two or three of the absolute differences between observer and device measurements within 5 mmHg. Each is at most 33.
- Boxes 59-60 Enter the number of subjects with none of the absolute differences between observer and device measurements within 5 mmHg. Each is at most 33.
- Box 61 If boxes 57 and 59 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
- Box 62 If boxes 58 and 60 fulfil the requirements, then this is "Pass"; otherwise it is "Fail".
- Box 63 If boxes 51 and 61 are both "Pass", then this is "Pass"; otherwise it is "Fail".
- Box 64 If boxes 52 and 62 are both "Pass", then this is "Pass"; otherwise it is "Fail".