### dabl\*Educational Trust Validation Study Result Form

Please complete Section 1 to Section 5 of this form and return it to dable Educational Trust with copies of the validation plots. In Section 3 to Section 5, complete  $\underline{all}$  boxes except where a study is stopped after Phase 1 – in that case, leave Phase 2 boxes empty. The requirements for each of these sections are detailed below the respective table.

Do Not Fill Brand Omron Model I-0132 (HEM-1010-E) Investigator Takahashi H, Yoshika M, Yokoi T Date/ 1, 7, 2012 Signed **Observer Training** Method used: BHS  $\boxtimes$ **Familiarisation Session**  $\times$ Validation Environment Suitable  $\times$ **Analysis** All boxes in Section 3 to Section 5 completed  $\boxtimes$ Plots completed according to protocol  $\boxtimes$ X-axis: Range 80 mmHg to 190 mmHg, reference lines at 130 mmHg and 160 mmHg  $\times$ Y-axis: Range -30 mmHg to 30 mmHg; reference lines every 5 mmHg from -15 mmHg to 15 mmHg DBP X-axis: Range 30 mmHg to 140 mmHg, reference lines at 80 mmHg and 100 mmHg  $\boxtimes$ Y-axis: Range -30 mmHg to 30 mmHg; reference lines every 5 mmHg from -15 mmHg to 15 mmHg  $\bowtie$ 

#### **Section 2: Procedure**

Please outline any adjustment to the protocol due to validation in a non-general population or any other exceptional issues relating to the study. If the protocol was followed as written, this section should be left blank.

This form is intended for use only in connection with blood pressure monitor validation studies carried out in accordance with the protocol of the European Society of Hypertension: O'Brien E et al. International protocol for validation of blood pressure measuring devices in adults. Blood Press Monit 2002;7:3-17 © 2010 dabl Educational Trust Limited - No reproduction of this document is permitted without the written authorisation of dabl Educational Trust Limited dabl<sup>®</sup>Educational Trust Limited is a not-for-profit organisation. Email info@dableducational.org

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Box 10

Boxes 11-16 Box 17

# **Section 3: Screening and Recruitment Details**

	ening and Recruitment	Phase 2 Recruitment Ranges (mmHg)				
Total Screened		41		<b>Low</b> (90 – 129)	11	
Why Eliminated	Ranges Complete	s Complete 17 SBP		<b>Medium</b> (130 – 160)	12	
	BP out of Range	10		<b>High</b> (161 – 180)	13	
	Arrhythmias	0 4				
	Poor Quality Sounds	10 5		<b>Low</b> (40 –79)	11 14	
	Other Reasons*	7 6	DBP	<b>Medium</b> (80 – 100)	11 15	
	Total Eliminated	7		<b>High</b> (101 – 130)	16	
Total Recruited		85				
Subjects with bot	h SBP and DBP used	27				
Subjects with one	of SBP or DBP used	14				
*Explanation	Arm circumference out	t of Range (4), Body	motion (3)		17	
gend: Box 1	The total number of	of subjects screened	, regardless of w	hether or not they were inc	luded in the st	
Box 2	The number elimi subjects included.		SBP and DBP fe	ll into ranges for which the	re were alread	
Box 3	into a range for	which there were	e already 11 su	nge (< 90 mmHg or > 180 m bjects included. (b) DBP ige for which there were a	was out of ra	
		SBP and DBP were o				
Box 4	included (c) both	SBP and DBP were o nated due to arrhyt	ut of range.			
Box 4 Box 5	included (c) both s The number elimi The number elim	nated due to arrhyt	ut of range. nmias. nability to auscu	ltate their BP accurately d		
	included (c) both s The number elimi The number elim sounds regardless	nated due to arrhyt inated due to an it of the reason for th	ut of range. nmias. nability to auscu le lack of quality.		ue to poor qu	
Box 5	included (c) both some final the number eliming the number eliming sounds regardless. The number eliming box 17.	nated due to arrhyt inated due to an it of the reason for th	ut of range.  nmias.  nability to auscu  le lack of quality.  ot covered in bo	xes 2 to 5. An explanation m	ue to poor qu	
Box 5	included (c) both some final sounds regardless The number elimi Box 17.  The total number	nated due to arrhyti inated due to an in of the reason for the nated for reasons n eliminated. This equals the number	ut of range.  nmias.  nability to auscuse lack of quality.  ot covered in bounds  uals the sum of b	xes 2 to 5. An explanation m	ue to poor qu nust be provide	

An explanation of those listed as excluded in Box 6.

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. These must each equal 11 in a completed study. They may be less if a device is eliminated at Phase 1.

## **Section 4: Subject Details**

		Phase	2 18	
		SBP	DBP	
Sex	Male:Female	18:15 19	19:14	
	Range (Low:High)	35-89 21	35-89 22	
Age (years)	Mean (SD)	68 (11)	65 (13)	
		25		
	Range (Low:High)	19:30 25	19:31	
Arm Circumference (cm)	Mean (SD)	26 (3)	26 (3)	
		27	28	
	Standard	33	33	
Cuff		0	0	
	<b>Large</b> (> 35 cm)	31	32	
	Panga (Lauretish)	94:179	57:115	
Recruitment BP (mmHg)	Range (Low:High)	33	34	
, , , ,	Mean (SD)	140 (25)	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)

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## Section 5: Validation Results

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Phase 1 Resu	ılt	
Required	One of	25	35	40			
Achieved	SBP	31	44	45	Continue	43	
	DBP	37	44 40	45	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	Pass 51	-2.1	4.9 55
	DBP	71 46	91 48	98 50	Pass 52	-0.2 54	5.5 56
Phase 2.2		2/3 <u>&lt;</u> 5 mm	Hg 0/	3 <u>&lt;</u> 5 mmHg	Phase 2.2 Result		Overall
Required		≥ 22		≤3			Result
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.g2.3
	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".

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