dabl® Educational Trust Validation Study Registration Form

This form should be completed by the manufacturer or on behalf of the manufacturer.

Study Ref.
1001
Do Not Fill

Study Details

Brand FORA

Model D 30

Initiator Manufacturer *Details if "Other"*

If not initiated by the manufacturer, did the manufacturer agree to the study?

Population General *Details if "Other"*

Study Investigator Details

Name Professor Palatini

Address UNIVERSITA' DEGLI STUI DI PADOVA

DIPARTIMENTO DI MEDICINA CLINICA E SPERIMENTALE

VIA GIUSTINIANI 2, 35128 PADOVA ITALIA

Device Details

Please select the correct option on each of the following or, if required, complete the explanation beside "*Other*".

Manufacturer	As Brand	*Details if "Other"*	
Location	Upper Arm	*Details if "Other"*	
Method	Auscultation	*Details if "Other"*	
Purpose	Other	*Details if "Other"*	CLINICAL/SELF EDUCATION AND
Operation	Automatic	*Details if "Other"*	

Automatic: Cuff inflation, deflation and blood pressure determination are fully performed by the device automatically; *Semi-automatic*: Blood pressure determination is performed automatically but cuff inflation and deflation need manual operation; *Manual*: Cuff pressure control and blood pressure determination are all performed by manual operation.

Please provide cuff details including arm circumference ranged.

Cuffs *Standard Adult:* 24 *cm to* 35 *cm* *Large Adult:* 32 *cm to* 44 *cm*

Other/Further Details

Please list (about 100 words) other features of the device.

Upper Arm Device performs BPM and BGM. BPM with 3 modes: auscultatory, triplicate measurements & single measurement. It has the intended use as an educational tool to help doctors educate patients on the correct method to perform home BPM & BGM. For home use, a voice guides patients on how to perform BPM and BGM at home. A Bluetooth and PC connectivity enhances the product for telemedicine purposes.

Agreement

I agree to the publication of the results regardless of whether or not they are favourable to the device.

Signed _____ **Company Stamp or Seal**

Name Jimmy Hsu

Date 03/ 18/ 2010

ForaCare Suisse AG
Neugasse 55
9000 St.Gallen

dabl®Educational Trust Limited is a not-for-profit organisation.

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland
Tel +353 1 278 0247
Fax +353 1 278 0882
Email info@dabl.ie
Web www.dableducational.com

dabl® Educational Trust

Validation Study Result Form

Please complete Section 1 to Section 5 of this form and return it to dabl® Educational Trust with copies of the validation plots. In Section 3 to Section 5, complete 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.

Study Ref.
1001
Do Not Fill

Brand FORA

Model D 30

Investigator P. Palatini

Signed _____ **Date** 08/07/2009

Section 1: Checklist

Observer Training Method used: observer assessment as from ESH protocol ☒

Familiarisation Session ☒

Validation Environment Suitable ☒

Analysis

All boxes in Section 3 to Section 5 completed ☒

Plots completed according to protocol

SBP X-axis: Range 80 mmHg to 190 mmHg, reference lines at 130 mmHg and 160 mmHg ☒

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 ☒

Y-axis: Range -30 mmHg to 30 mmHg; reference lines every 5 mmHg from -15 mmHg to 15 mmHg ☒

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.

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland
Tel +353 1 278 0247
Fax +353 1 278 0882
Email info@dabl.ie
Web www.dableducational.com

Section 3: Screening and Recruitment Details

Screening and Recruitment			Phase 2 Recruitment Ranges (mmHg)		
Total Screened		47 (1)		**Low** (90 – 129)	11 (11)
Why Eliminated	**Ranges Complete**	10 (2)	**SBP**	**Medium** (130 – 160)	11 (12)
	BP out of Range	1 (3)		**High** (161 – 180)	11 (13)
	Arrhythmias	2 (4)			
	Poor Quality Sounds	1 (5)		**Low** (40 –79)	11 (14)
	Other Reasons*	0 (6)	**DBP**	**Medium** (80 – 100)	11 (15)
	Total Eliminated	14 (7)		**High** (101 – 130)	11 (16)
Total Recruited		33 (8)			
Subjects with both SBP and DBP used		33 (9)			
Subjects with one of SBP or DBP used		0 (10)			

***Explanation** (17)

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	2 (18)
		SBP	DBP
Sex	**Male:Female**	17:16 (19)	(20)
Age *(years)*	**Range** *(Low:High)*	30:85 (21)	(22)
	Mean (SD)	55(16) (23)	(24)
Arm Circumference *(cm)*	**Range** *(Low:High)*	24:37 (25)	(26)
	Mean (SD)	30(3) (27)	(28)
Cuff	**Standard**	30 (29)	(30)
	Large (> 35 cm)	3 (31)	(32)
Recruitment BP *(mmHg)*	**Range** *(Low:High)*	92:180 (33)	58:116 (34)
	Mean (SD)	144(25) (35)	91(14) (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

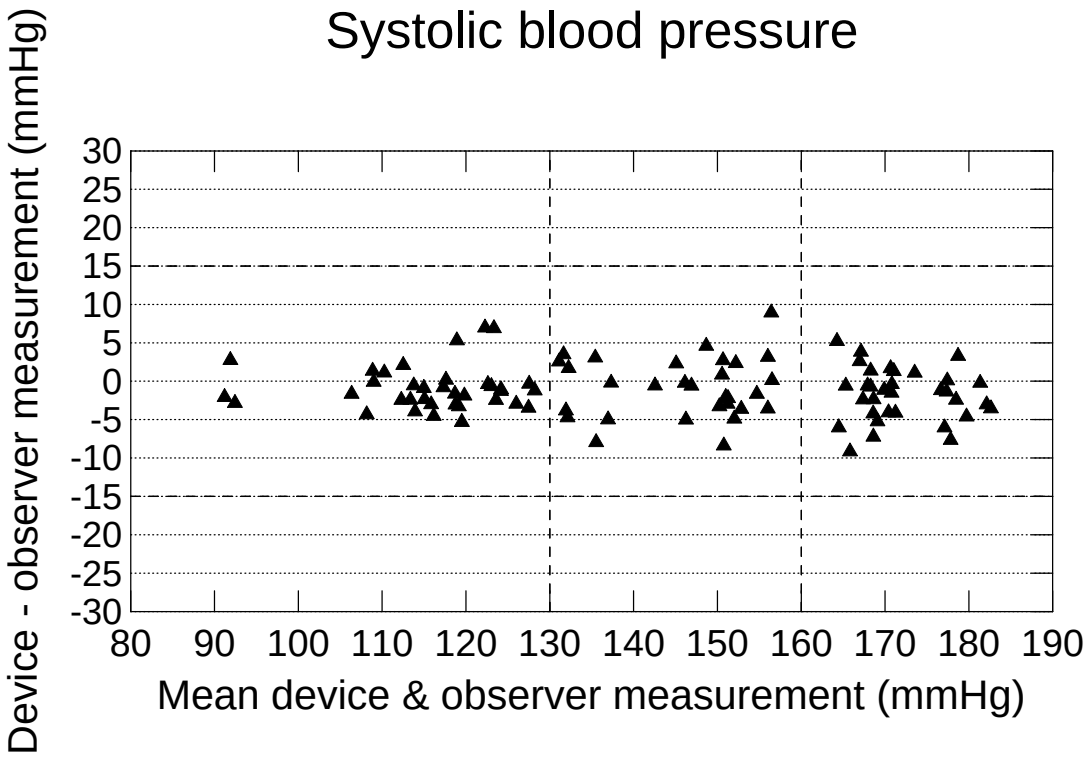
Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Phase 1 Result
Required	One of	25	35	40	
Achieved	SBP	35 (37)	45 (39)	45 (41)	Continue (43)
	DBP	42 (38)	45 (40)	45 (42)	Continue (44)

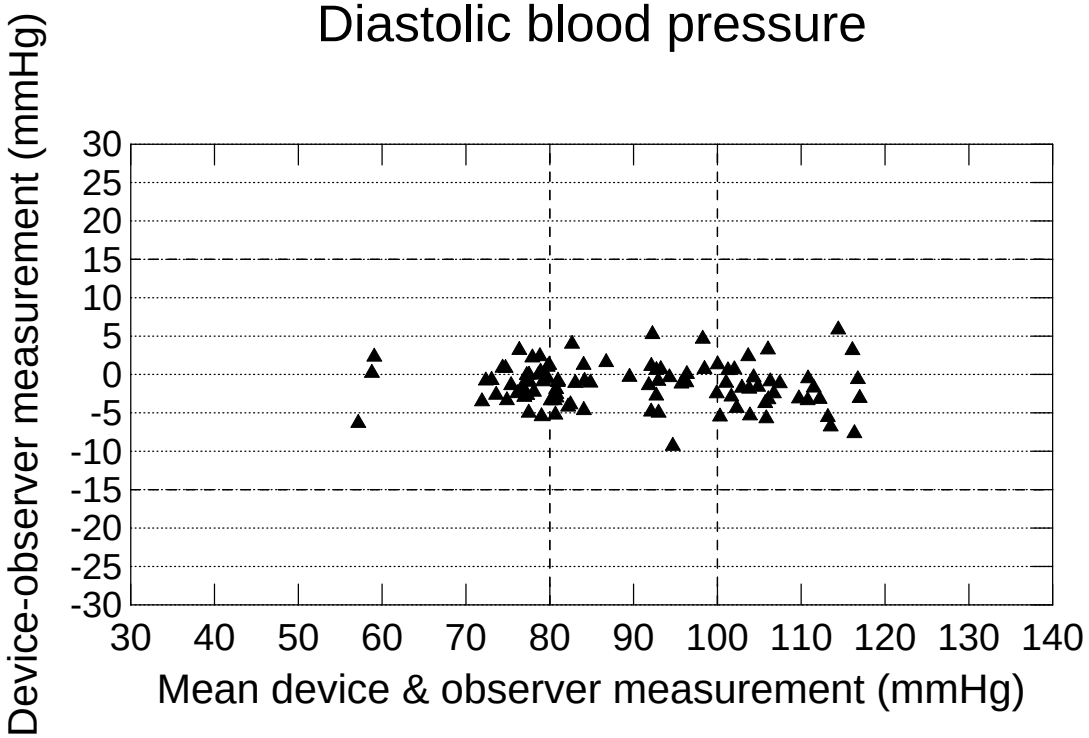
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Phase 2.1 Result	Mean	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	87 (45)	99 (47)	99 (49)	Pass (51)	-1.2 (53)	3.3 (55)
	DBP	95 (46)	99 (48)	99 (50)	Pass (52)	-1.5 (54)	2.6 (56)

Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Phase 2.2 Result	Overall Result
Required		≥ 22	≤ 3		
Achieved	SBP	31 (57)	1 (59)	Pass (61)	Pass (63)
	DBP	32 (58)	0 (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”.


Systolic blood pressure
Device - observer measurement (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
-25
-30
80
90
100
110
120
130
140
150
160
170
180
190
Mean device & observer measurement (mmHg)


Diastolic blood pressure
Device-observer measurement (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
-25
-30
30
40
50
60
70
80
90
100
110
120
130
140
Mean device & observer measurement (mmHg)