dabl®Educational Trust — Validation Study Registration Form

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

Study Ref. 1305 Do Not Fill

Study Investigator Details

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Test Device Details

Maker	**TaiDoc**	**Manufacturer**	**TaiDoc**
Brand	**U RIGHT**		
Model	**TD-3124**	**Internal Model Number**	TD-3124
Initiator	**Manufacturer**	*Details if "Other"*	
	If not initiated by the manufacturer, did the manufacturer agree to the study?		

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

Location	**Upper Arm**	*Details if "Other"*
Method	**Oscillometry**	*Details if "Other"*
Purpose	**Clinic Measurement**	*Details if "Other"*
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.

Cuff details including arm circumference ranges (as recommended by the device manufacturer).

Cuffs	*Small Adult:* *cm to* *cm*	*Standard Adult:* *cm to* *cm*
	Large Adult: *cm to* *cm*	*Other* Wide Ranged: 24 *cm to* 43 *cm*
Wrist Cuff	*cm to* *cm*	**Wrist Support Method**

Other features of the device (about 100 words).

The device of URIGHT TD-3124 blood pressure monitoring system automatically inflates the cuff and displays the readings. The device of URIGHT TD-3124 blood pressure monitoring system designs one button for easy to operate, and make sure patient can easily to understand the readings of blood pressure from the display of the monitor. Furthermore, the device offers the function of detection Irregular Heart Beat with our IHB technology.

Agreement

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

Signed Jim Jan **Company Stamp or Seal**

Name **Jim Jan**

Date **2013/09/24**

TaiDoc 泰博科技 TaiDoc Technology Corp.

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KRISHNA(陳軒振)

dabl®Educational Trust

Validation Study Result Form

Please complete Section 1 to Section 3 of this form and return it to dabl®Educational Trust with copies of the validation plots and a digital photograph of the device used for the study showing its front face. Please follow the instructions for each section. The requirements for each table entry are described, by box number, under the respective table.

Study Ref.
1305
Do Not Fill

Maker	**TaiDoc**	**Manufacturer**	**TaiDoc**
Brand	**U RIGHT**	**Model**	**TD-3124**
Investigator	**Dauyuan Ding**		
Signed		**Date**	**2013/10/08**

Section 1: Methodology

Familiarisation

A brief description of the familiarisation session should be provided. Any difficulties should be reported.

Several pre-test were performed in house before clinical test started. No problems were encountered.

Recruitment

The population should be outlined and the method of selecting the sample should be described. Difficulties in recruitment should be described and how they were overcome.

Population	**General**	*Details if "Other"*

Procedure

Two observers with an independent supervisor ☒

Observers blinded from each other's readings and from the device readings ☒

The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely. ☒

Enter protocol adjustments, as necessary, when the study population is not general with sex, age and blood pressure distribution stated in detail. These adjustments should be justified, with references where possible. Because children and adolescents have wide range of body size and blood pressure levels, the sample size for a validation study should depend on the study inclusion criteria. Thus, for example, a 33-subject study would be appropriate only if a narrow age range of children is included.

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Section 2: Results

Note 1: The data from *Form 2 – Subject Data* for each subject should be analysed so that the results on this form can be completed. All references to boxes 201-289 refer to values obtained from all of the Forms 2 from the relevant subjects.

Table 1: Screening and Recruitment Details

Screening and Recruitment

Total Screened		54 (301)
Total Excluded		21 (302)
Ranges Complete	0 (303)	
Range Adjustment	12 (304)	
Arrhythmias	3 (305)	
Device Failure	0 (306)	
Poor Quality Sounds	1 (307)	
Cuff Size Unavailable	0 (308)	
Observer Disagreement	5 (309)	
Distribution	0 (310)	
Other Reasons*	0 (311)	
Total Recruited		33 (312)

Recruitment Ranges

		mmHg	All	On Rx
SBP	Low	< 90	0 (314)	2 (324)
		90 – 129	11 (315)	
	Medium	130 – 160	11 (316)	4 (325)
	High	161 – 180	9 (317)	3 (326)
		> 180	2 (318)	
DBP	Low	< 40	0 (319)	3 (327)
		40 – 79	11 (320)	
	Medium	80 – 100	11 (321)	3 (328)
	High	101 – 130	11 (322)	3 (329)
		> 130	0 (323)	

***Explanation Summary**

None (313)

Box 301: The total number of subjects screened, regardless of whether or not they were included in the study.

Box 302: The total number excluded. This equals the sum of Boxes 303 to 311

Box 303: The number of subjects excluded with *Ranges Complete* circled in *Box 287 (Form 2 for each excluded subject).*

Box 304: The number of subjects excluded with *Range Adjustment* circled in *Box 287.*

Box 305: The number of subjects excluded with *Arrhythmias* circled in *Box 287.*

Box 306: The number of subjects excluded with *Device Failure* circled in *Box 287.*

Box 307: The number of subjects excluded with *Poor Quality Sounds* circled in *Box 287.*

Box 308: The number of subjects excluded with *Cuff Size Availability* circled in *Box 287.*

Box 309: The number of subjects excluded with *Observer Disagreement* circled in *Box 287.*

Box 310: The number of subjects excluded with *Distribution* circled in *Box 287.*

Box 311: The number of subjects excluded with *Other Reasons* circled in *Box 287.* A summary of those reasons must be provided in Box 313.

Box 312: The total recruited equals the number screened (Box 301) less the number excluded (Box 302). This should equal 33 except in validations in some specific populations.

Box 313: A summary of why those counted in Box 311 were excluded. (*Box 288*)

Boxes 314-323: In a completed study in a general adult population, the sum of Boxes 314 & 315, Box 316, the sum of Boxes 317 & 318, the sum of Boxes 319 & 320, Box 321 and the sum of Boxes 322 & 323 must each be between 10 and 12. The sum of Boxes 314, 318, 319 & 323 must be at most 4. The sum of Boxes 314 to 318 and the sum of Boxes 319 to 323 must each be exactly 33. Studies in specific populations may have different restrictions and totals. (*Boxes 219* and *220 – Form 2 for each included subject*)

Boxes 324-329: The number of subjects in each range on antihypertensive medication. (*Boxes 207, 219* and *220)*

Table 2: Subject Details

Sex	**Male:Female**	**11 : 22** 330	
Age *(years)*	**Range** *(Low:High)*	**42 : 88** 331	
	Mean (SD)	**62.4 (11.2)** 332	
Arm Circumference *(cm)*	**Range** *(Low:High)*	**24.5 : 44** 333	
	Mean (SD)	**28.9 (3.5)** 334	
Cuff for Test Device	**Small**	335	– cm
	Standard	336	– cm
	Large	337	– cm
	Other	**33** 338	**24 – 43** cm
Wrist Circumference *(cm)* (Wrist devices only)	**Range** *(Low:High)*	: 339	
	Mean (SD)	( ) 340	
		SBP	**DBP**
Recruitment BP *(mmHg)*	**Range** *(Low:High)*	**91 : 185** 341	**42 : 127** 342
	Mean (SD)	**142.6 (28.1)** 343	**86.9 (20.4)** 344

Note 2: The values in Boxes 314–380 refer only to the final recruited subjects, each of whom contributes SBP and DBP measurements for analysis. Excluded subjects are not included in any of this analysis.

Box 330: Enter the number of males, a colon and the number of females. They should total 33 except in validations in some specific populations. If the minimum requirements (10 for a general population) are not met, subjects must be replaced as necessary. (*Box 206*)

Box 331: Enter the age of the youngest subject, a colon and the age of the oldest subject e.g. *31:74*. Subjects outside the required range (25 and over for a general population) are not permitted. (*Box 205*)

Box 332: Enter the mean and, in parentheses, the SD of the subject ages. Values should be rounded to one decimal place e.g. *52.3 (11.9)*. (*Box 205*)

Box 333: Enter the smallest arm circumference, a colon and the largest arm circumference e.g. *24:34*. (*Box 208*)

Box 334: Enter the mean and, in parentheses, the SD of the subject arm circumferences. Values should be rounded to one decimal place e.g. *29.0 (3.1)*. (*Box 208*)

Box 335: If a small cuff was supplied, enter the number of subjects on whom it was used. If it was not supplied, enter an "X". Enter the arm sizes for which it is recommended beside it. (*Box 209*)

Box 336: Enter the number of subjects on whom a standard (or medium) cuff was used. Enter the arm sizes for which it is recommended beside it. (*Box 209*)

Box 337: If a large cuff was supplied, enter the number of subjects on whom it was used. If it was not supplied, enter an "X". Enter the arm sizes for which it is recommended beside it. (*Box 209*)

Box 338: If a different size cuff was supplied, enter the number of subjects in whom it was used. If no such cuff was supplied, enter an "X". Enter the arm sizes for which it is recommended beside it. (*Box 209*)

Box 339: Enter the smallest wrist circumference, a colon and the largest wrist circumference e.g. *15:22*. (Applicable only for wrist devices) (*Box 210*)

Box 340: Enter the mean and, in parentheses, the SD of the subject wrist circumferences. Values should be rounded to one decimal place e.g. *18.1 (2.3)*. (Applicable only for wrist devices) (*Box 210*)

Boxes 341-342: Enter the lowest pressure, a colon and the highest pressure from BPA measurements only e.g. *104:180*. (*Boxes 217* and *218*)

Boxes 343-344: Enter the mean and, in parentheses, the SD of the subject pressures from BPA measurements only. Values should be rounded to one decimal place e.g. *140.4 (20.3)*. (*Boxes 217* and *218*)

Table 3: Distribution

This section analyses the distribution of comparative measurements.

SBP		DBP	
Overall Range *(mmHg) Low:High*	**87 : 186** 345	**Overall Range** *(mmHg) Low:High*	**45 : 127** 350
Low *(< 130 mmHg)*	**33** 346	**Low** *(< 80 mmHg)*	**33** 351
Medium *(130 mmHg – 160 mmHg)*	**33** 347	**Medium** *(80 mmHg – 100 mmHg)*	**33** 352
High *(> 160 mmHg)*	**33** 348	**High** *(> 100 mmHg)*	**33** 353
Maximum Difference	**0** 349	**Maximum Difference**	**0** 354

Box 345: Enter the lowest pressure, a colon and the highest SBP from the observer measurements. (*Boxes 281, 283* and *285*)

Boxes 346-348: The observer measurements (three per subject) for SBP are categorised similarly to the recruitment ranges. Enter the counts of measurements falling into each range. These must total 99. (*Boxes 281, 283* and *285*)

Box 349 Subtract the smallest value from Boxes 346 to 348 from the largest one and enter the result.

Box 350: Enter the lowest pressure, a colon and the highest DBP from the observer measurements. (*Boxes 282, 284* and *286*)

Boxes 351-353: The observer measurements (three per subject) for DBP are categorised similarly to the recruitment ranges. Enter the counts of measurements falling into each range. These must total 99. (*Boxes 282, 284* and *286*)

Box 354: Subtract the smallest value from Boxes 351 to 353 from the largest one and enter the result.

Note 3: In order to ensure a uniform distribution, there must be at least 22 measurements and at most 44 measurements (Boxes 346 to 348 and 351 to 353) in each of the low, medium and high ranges and the maximum differences (Boxes 349 and 354) must be at most 19. If not, further recruitment will be necessary. Subjects to be excluded will be those whose pressures drifted from recruitment pressures.

Note 4: The overall SBP range must be from ≤ 100 mmHg to ≥ 170 mmHg and the overall DBP range must be from ≤ 50 mmHg to ≥ 120 mmHg. If not, further recruitment will be necessary. Subjects to be excluded will be the last recruited within the relevant ranges.

Note 5: The minimum number of replacements should take place. If a subject is replaced for either of these reasons, circle *Distribution* in *Box 287 of Form 2* for that subject.

Note 6: In validations carried out in specific populations requiring more than 33 subjects but with similar blood pressure distributions, similar proportions should be used. If the blood pressure distribution in the specific population differs from the standard distribution, ignore this table but comment on the distribution in the discussion.

Table 4: Observer Differences

This section is for the differences in pressures between the two observers.

		SBP *(mmHg)*	DBP *(mmHg)*	
Observer 2 – Observer 1	**Range** *Low:High*	**-4 : 4** 355	**-4 : 4** 356	**Repeated Measurements**
	Mean (SD)	**0.1 (2.0)** 357	**0.3 (1.6)** 358	**0** 359

Boxes 355-356 Enter the lowest difference, a colon and the highest difference between the observers. Include the signs e.g. -3:+4. (*Boxes 247, 249, 251* and *253* and *Boxes 248, 250, 252* and *254*). If the range is outside -4:+4, then this is a violation. Relevant subjects should be excluded, by reason of *Observer Disagreement*, and replaced.

Boxes 357-358 Enter the mean and, in parentheses, the SD of the observer differences. Values should be rounded to one decimal place e.g. *0.3 (1.2)*. (*Boxes 247, 249, 251* and *253* and *Boxes 248, 250, 252* and *254*)

Boxes 359 Enter the number of measurements that were repeated in the included subjects because observers were more than 4 mmHg apart.

Table 5: Validation Results

Part 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean *(mmHg)*	SD *(mmHg)*
Pass Requirement	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	73 (360)	94 (361)	99 (362)	Pass (363)	-0.4 (364)	4.9 (365)
	DBP	77 (366)	97 (367)	99 (368)	Pass (369)	-1.8 (370)	4.0 (371)

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade 2	Grade 3
Pass Requirement		≥ 24	≤ 3		
Achieved	SBP	28 (372)	0 (373)	Pass (374)	Pass (375)
	DBP	25 (376)	0 (377)	Pass (378)	Pass (379)

Part 3	Result
	Pass (380)

Note 7: In order for the device to pass, all requirements must be fulfilled. A fail in any part will result in an overall fail.

Box 360: Enter the number of SBP differences (at most 99) between observer and device measurements falling within 5 mmHg. (The total number of *Boxes 273, 275* and *277* circled A in the 33 subjects)

Box 361: Enter the number of SBP differences (at most 99) between observer and device measurements falling within 10 mmHg. (The total number of *Boxes 273, 275* and *277* circled A or B in the 33 subjects)

Box 362: Enter the number of SBP differences (at most 99) between observer and device measurements falling within 15 mmHg. (The total number of *Boxes 273, 275* and *277* circled A, B or C in the 33 subjects)

Box 363: If Boxes 360, 361 and 362 fulfil the Pass requirements, then this is "Pass"; otherwise, it is "Fail".

Boxes 364-365: Enter the mean and standard deviation respectively of the 99 SBP differences between observer and device measurements. (Use data from circled *Boxes 261* or *267, 263* or *269* and *265* or *271*)

Box 366: Enter the number of DBP differences (at most 99) between observer and device measurements falling within 5 mmHg. (The total number of *Boxes 274, 276* and *278* circled A in the 33 subjects)

Box 367: Enter the number of DBP differences (at most 99) between observer and device measurements falling within 10 mmHg. (The total number of *Boxes 274, 276* and *278* circled A or B in the 33 subjects)

Box 368: Enter the number of DBP differences (at most 99) between observer and device measurements falling within 15 mmHg. (The total number of *Boxes 274, 276* and *278* circled A, B or C in the 33 subjects)

Box 369: If Boxes 366, 367 and 368 fulfil the Pass requirements, then this is "Pass"; otherwise, it is "Fail".

Boxes 370-371: Enter the mean and standard deviation respectively of the 99 DBP differences between observer and device measurements. (Use data from circled *Boxes 262* or *268, 264* or *270* and *266* or *272*)

Box 372: Enter the number of subjects (at most 33) with two or three of the absolute differences between observer and device SBP measurements within 5 mmHg. (*Box 279* is 2 or 3)

Box 373: Enter the number of subjects (at most 33) with none of the absolute differences between observer and device SBP measurements within 5 mmHg. (*Box 279* is 0)

Box 374: If Boxes 372 and 373 fulfil the Pass requirements, then this is "Pass"; otherwise, it is "Fail".

Box 375: If Boxes 363 and 374 are both "Pass", then this is "Pass"; otherwise, it is "Fail".

Box 376: Enter the number of subjects (at most 33) with two or three of the absolute differences between observer and device DBP measurements within 5 mmHg. (*Box 280* is 2 or 3)

Box 377: Enter the number of subjects (at most 33) with none of the absolute differences between observer and device DBP measurements within 5 mmHg. (*Box 280* is 0)

Box 378: If Boxes 376 and 377 fulfil the Pass requirements, then this is "Pass"; otherwise, it is "Fail".

Box 379: If Boxes 369 and 378 are both "Pass", then this is "Pass"; otherwise, it is "Fail".

Box 380 If Boxes 375 and 379 are both "Pass", then this is "Pass"; otherwise, it is "Fail".

Note 8: In validations carried out in specific populations requiring more than 33 subjects, proportionally equivalent passing criteria should be used.

Section 3: Closeout

Plots

Include the plots with this document. Confirm that they comply with the requirements

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	☒

Image

Include a digital photograph, of the device used in the study, with this document. The photograph should show the front face of the device. Use a plain background.

A photograph, of the device used in the study, is included ☒

Discussion

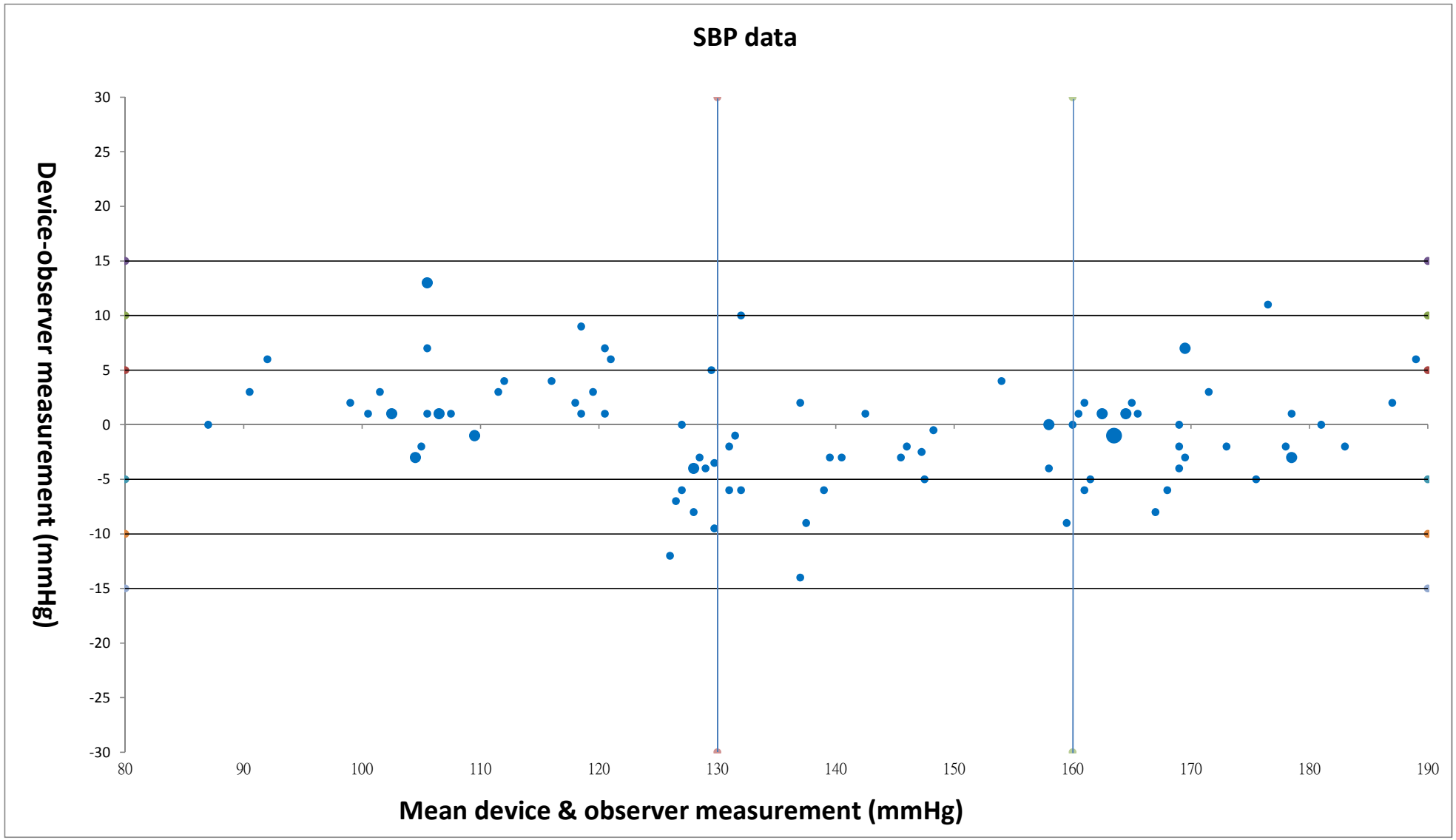
For tight blood pressure control, people with high blood pressure choose a convenient device provides the reliable measurement is important. The device of URIGHT TD-3124 automatically inflates the cuff and displays the readings. The display on the monitor is easy to read and understand. The clinically outcomes show an accurate and consistent results of URIGHT TD-3124 blood pressure monitoring system to detect hypertension.

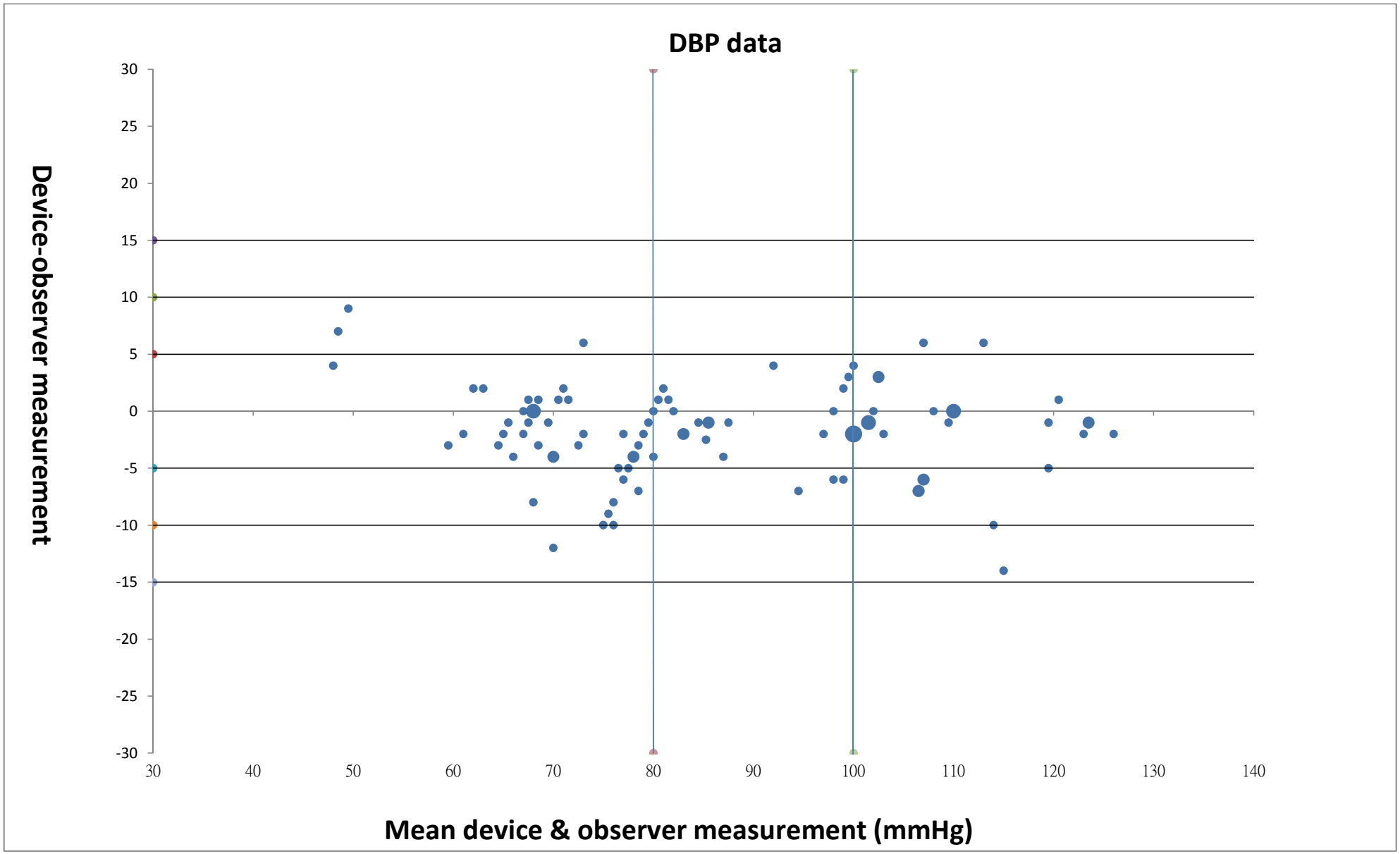
Recruitment of subjects with high DBP range was difficult and accounted more screened subjects. However, the distribution conditions from 45 mmHg to 127 mmHg of DBP ranges were fulfilled the requirement of EHS protocol.

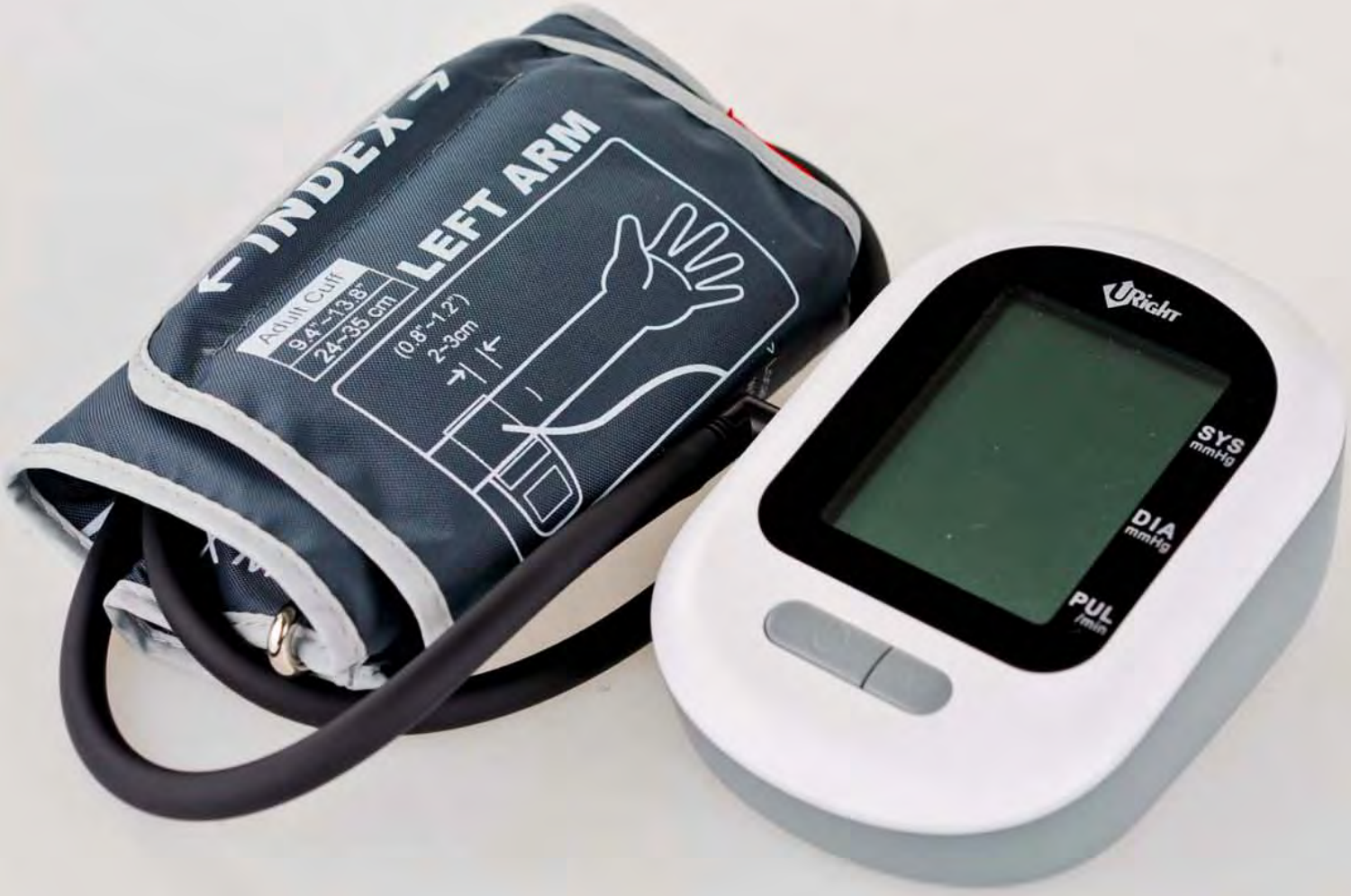
Conclusion

The conclusion as to whether the device is accurate for use in the population should be stated. If the results are particularly sensitive to correct use (e.g. most wrist devices) then this caution must be stated.

The device has passed to the criteria of ESH 2010 protocol, it is recommended for clinical and home use. The device of URIGHT TD-3124 blood pressure monitoring system provides an accurate and consistent results for most patients can more easily to detect hypertension.


SBP data
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)


DBP data
Device-observer measurement
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)


INDEX
LEFT ARM
Adult Cuff
9.4"-13.8"
24-35 cm
(0.8"-1.2")
2-3cm
URight
SYS
mmHg
DIA
mmHg
PUL
/min


← INDEX →
Wide Range Cuff
9.4"~16.9"
24~43 cm
LEFT ARM
(0.8"~1.2")
2~3cm