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.
Do Not Fill

Maker Guangdong Transtek Medical Electronics Co., Ltd. Manufacturer Guangdong Transtek Medical Electronics Co., Ltd.

Brand PIC solution Model helpRAPID

Investigator Zhonghua Liu

Signed Zhonghua Liu Date Oct 18th,2016

Section 1: Methodology

Familiarisation

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

The familiarisation session had been held before the study.

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.

dabl®Educational Trust Limited is a not-for-profit organisation.
Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland
Tel +353 1 278 0247 Email info@dableducational.org
Fax +353 1 278 0882 Web www.dableducational.org

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	43 (301)
Total Excluded	10 (302)
Ranges Complete	0 (303)
Range Adjustment	10 (304)
Arrhythmias	0 (305)
Device Failure	0 (306)
Poor Quality Sounds	0 (307)
Cuff Size Unavailable	0 (308)
Observer Disagreement	0 (309)
Distribution	0 (310)
Other Reasons*	0 (311)
Total Recruited	33 (312)

Recruitment Ranges

		mmHg	All	On Rx
SBP	Low	< 90	0 (314)	0 (324)
		90 – 129	10 (315)	
	Medium	130 – 160	11 (316)	1 (325)
	High	161 – 180	8 (317)	9 (326)
		> 180	4 (318)	
DBP	Low	< 40	0 (319)	0 (327)
		40 – 79	11 (320)	
	Medium	80 – 100	12 (321)	4 (328)
	High	101 – 130	10 (322)	6 (329)
		> 130	0 (323)	

***Explanation Summary**

(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**	19 : 14 (330)	
Age *(years)*	**Range** *(Low:High)*	25 : 73 (331)	
	Mean (SD)	50.5 (15.8) (332)	
Arm Circumference *(cm)*	**Range** *(Low:High)*	22.2 : 40.4 (333)	
	Mean (SD)	30.5 (4.7) (334)	
Cuff for Test Device	**Small**	(335)	– cm
	Standard	33 (336)	22 – 42 cm
	Large	(337)	– cm
	Other	(338)	– cm
Wrist Circumference *(cm)* (Wrist devices only)	**Range** *(Low:High)*	: (339)	
	Mean (SD)	( ) (340)	
		SBP	**DBP**
Recruitment BP *(mmHg)*	**Range** *(Low:High)*	90 : 199 (341)	48 : 118 (342)
	Mean (SD)	145.8 (27.2) (343)	87.5 (16.7) (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-*	89 : 194 345	**Overall Range** *(mmHg) Low:High*	50 : 120 350
Low *(< 130 mmHg)*	29 346	**Low** *(< 80 mmHg)*	35 351
Medium *(130 mmHg – 160 mmHg)*	43 347	**Medium** *(80 mmHg – 100 mmHg)*	35 352
High *(> 160 mmHg)*	27 348	**High** *(> 100 mmHg)*	29 353
Maximum Difference	16 349	**Maximum Difference**	6 354

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 (1.8) 357	0.2 (1.6) 358	3 359

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	85 (360)	96 (361)	99 (362)	Pass (363)	-0.4 (364)	3.9 (365)
	DBP	89 (366)	96 (367)	99 (368)	Pass (369)	-0.9 (370)	3.7 (371)

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade 2	Grade 3
Pass Requirement		≥ 24	≤ 3		
Achieved	SBP	30 (372)	0 (373)	Pass (374)	Pass (375)
	DBP	31 (376)	1 (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

The study was carried out strictly according to the ESH-IP 2010 and the results showed a good agreement between mercury sphygmomanometer and Artsana helpRAPID in systolic and diastolic blood pressures. The 33 subjects had a wide range in age, systolic and diastolic blood pressures and the cuff was used in this study for arm circumferences ranging of 22-42cm to meet the requirements of various population. The study results indicated that the hardware and algorithms of the tested device have the capacity to work properly in blood pressure measurements over a wide range.

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.

According to the results of this study on the basis of the ESH-IP 2010, Artsana helpRAPID upper-arm blood pressure monitor is suitable for self/home measurement in general adult population.

dabl® Educational Trust — Validation Study Registration Form

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

Study Ref.
Do Not Fill

Study Investigator Details

Name	Zhonghua Liu
Address	Zhongshan City People's Hospital,No.2Sunwen Dong Road,Zhongshan 528403,P.R.China.

Test Device Details

Maker	Guangdong Transtek Medical Electronics Co., Ltd.	Manufacturer	Guangdong Transtek Medical Electronics Co., Ltd.
Brand	PIC solution		
Model	helpRAPID	Internal Model Number	TMB-1586-A
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	Self/Home 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:* 22 *cm to* 42 *cm*	
	Large Adult:	*cm to cm*	*Other : cm to cm*	
Wrist Cuff	*cm to cm*		Wrist Support Method	

Other features of the device (about 100 words).

Agreement

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

Signed	Kevin Tan	Company Stamp or Seal	GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD. 广东乐心医疗电子股份有限公司
Name	Kevin Tan		
Date	Oct 18th,2016		

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

dabl®Educational Trust

Validation Study Evaluation Form

Study Details

Assessment Recommended

Protocol ESH 2010

Special Group No

Investigator Zhonghua Liu

Reference

Device Details

Maker Guangdong Transtek Medical Electronics Co., Ltd.

Manufacturer Guangdong Transtek Medical Electronics Co., Ltd.

Brand PIC solution

Model helpRAPID

Screening and Recruitment Details

Fully Completed Yes

Ranges Correct Yes

Included/Screened 33 / 43

Exclusions Explained All

Subject Details

Fully Completed Yes

Ages Correct Yes

Sexes Correct Yes

Procedure

Methods Good

Procedure Description Good

Protocol Adaptation None

Problems None

Problem Areas

BP Detection	☐	*Device Failure*	☐	*Recruitment*	☐
Software	☐	*Environmental*	☐	*Patient Discomfort*	☐
Other (add details)	☐				

Validation Results

Result Well Demonstrated Pass

Description Good

Fully Completed Yes

Properly Interpreted Yes

Plots Omitted

Weaknesses

Size	☐	*Points*	☐	*Labels*	☐
Ranges	☐	*Horizontal Ref. Lines*	☐	*Vertical Ref. Lines*	☐
Other (add details)	☐				

Notes

Overall Assessment

Comments The range of DBP in Table3 is exactly equal to the two limit values.

The study is well conducted and the final result is "pass".

I have no conflict of interest in this study.

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247

Signed Gloria Cirpri Date 17/11/16

Validation of Artsana helpRAPID according to European Society of Hypertension International Protocol revision 2010 in adults

Zhonghua Liu, Xianyue Liu, Hengyi Zhou

Abstract

The purpose of this study was to determine the accuracy of Artsana helpRAPID upper-arm blood pressure monitor in adult subjects by comparison to a non-invasive (auscultatory) reference mercury sphygmomanometer according to the European Society of Hypertension International Protocol revision 2010 (ESH-IP 2010). The results was that all the validation requirement were fulfilled. 85, 96, 99 of SBP measurements and 89, 96, 99 of DBP measurements were within 5, 10, 15mmHg of absolute difference. The mean ± SD device-observer difference was -0.4 ± 3.9mmHg for SBP and -0.9 ± 3.7mmHg for DBP. For SBP and DBP respectively, 30 and 31 of subjects had at least two of their three difference within 5mmHg and there are zero and one subject who didn't have any difference within 5mmHg. In conclusions, Artsana helpRAPID has passed all phases of ESH-IP 2010 and is suitable for self/home measurement in adults.

Keywords: Artsana helpRAPID; ESH-IP 2010; Blood pressure monitor; Validation; Accuracy

Introduction

Blood pressure, it refers to the pressure of the blood for the unit area of the vessel wall. Hypertension is one of the most readily preventable causes of stroke, some cardiovascular complications and other chronic disease[1-3]. If blood pressure is higher than normal level, it's necessary to monitor blood pressure at home which is recommended by The American Society of Hypertension[4], American Heart Association and other organizations[5,6]. Home monitoring can help to quantify blood pressure variability to obtain a more stable and consistent estimation of participant's actual blood pressure level and to assess the degree of coverage offered by anti-hypertensive drugs [7].

Along with the advancement of society, people began to pay attention to physical health and the sphygmomanometer began to enter ordinary families. Thus the the accuracy and reliability of self/home measurement blood pressure monitor used by patients has been focus of attention [8,9]. The purpose of this study was to assesses the accuracy and reliability of Artsana helpRAPID upper-arm blood pressure monitor for home blood pressure monitoring according to ESH-IP 2010 in adults[10].

According to a different principle, the blood pressure monitor can be divided into three types: a mercury sphygmomanometer, pressure sphygmomanometer and electronic blood pressure monitor. With the electronic technology continues to progress, blood pressure monitors currently on the market mostly are electronic blood pressure monitor. Artsana helpRAPID uses the Oscillometric Measuring Method to detect blood pressure during inflation and the blood pressure displayed on a liquid crystal digital display. Even more, Artsana helpRAPID has additional functions, such as detection of body movement and irregular heartbeat to ensure the accuracy of self/home measurement.

Equipment and methods

Tested device

- Name of device: Artsana upper-arm Blood Pressure Monitor.
- Model of device: helpRAPID.
- Manufacturer: Guangdong Transtek Medical Electronics Co.,Ltd.
- Manufacturer Address: Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, Guangdong.
- Dimensions: 100x 186 x 40 mm.
- Weight: 388g(Without batteries and cuff).
- Cuff size: 22-42 cm.
- Cuff type: Hard cuff.
- Memory: 100*2 (For two users).
- Range of measurement: pressure range of 0-300mmHg and heart rate of 40-199 beats/min.

Reference equipment

- Name of equipment: Yuyue medical BP meter, mercury sphygmomanometer and double stethoscope.
- Accuracy: ±1mmHg.
- Range of measurement: 0-300mmHg.

Subjects

These subjects were recruited from the hypertension, outpatients and normal volunteers in Zhongshan City People's Hospital in zhongshan, Guangdong, China. The Ethics Committee of Zhongshan City People's Hospital approved this study and informed consent was obtained from all subjects who agreed to participate this investigation. Record the age, gender, height, weight, arm circumference and on antihypertensive or not before the validation.

Validation procedure

Completely following the ESH-IP 2010, the procedure was performed by two observers and an independent supervisor experienced in blood pressure measurement.This study choose auscultatory method and same-limb sequential measurement. Two observers auscultated simultaneously and were blinded to each other's readings and tested device reading. Sequential measurements reference mercury sphymomanometer and tested device were performed on the left upper arm supported at the heart level. Subjects had to rest in sitting position for at least 10 min quietly before test. No motion and speaking were allowed during the measurement. If happen any problems during the test, record them. BP1, BP3, BP5, BP7 measured by reference mercury sphymomanometer and BP2, BP4, BP6 measured by tested device for every subject were used for data analysis.

Data analysis

The measurements were analyzed in Microsoft Excel according to the the European Society of Hypertension International Protocol revision 2010.

Results

Study results included screening and recruitment information, recruitment ranges of blood pressure, subject details, distribution of overall pressure, observer differences and validation results. All of these contents would be expressed list form, as below Table 1 - Table 5.

Table 1 Screening and recruitment details and recruitment ranges

Screening and recruitment			Recruitment range				
Total screened		43			mmHg	All	On Rx
Total excluded		10	SBP	Low	<90	0	0
The reasons and count of exclusion	Ranges complete	0			90-129	10	
	Range adjustment	10		Medium	130-160	11	1
	Arrhythmias	0		High	161-180	8	9
	Device failure	0			>180	4	
	Poor quality sounds	0					
	Cuff size unavailable	0	DBP	Low	<40	0	0
	Observer disagreement	0			40-79	11	
	Distribution	0		Medium	80-100	12	4
	Other reasons	0		High	101-130	10	6
Total recruited		33			>130	0	

The number of total recruited subjects was 33 and the number of subjects in each of SBP ranges (Low, Medium and High) was 10, 11, 12 and 11,12,10 in each of the three DBP ranges (Low, Medium and High), respectively, which had be fulfilled from 10 to 12 completely.

Table 2 Subjects details

Sex	Male:Female	19:14	
Age (years)	Range (Low : High)	25 : 73	
	Mean (SD)	50.5 (15.8)	
Arm circumference (cm)	Range (Low : High)	22.2 : 40.4	
	Mean (SD)	30.5 (4.7)	
Cuff for tested device	22 - 42 cm(arm)	33	
Recruitment blood pressure(mmHg)		SBP	DBP
	Range (Low : High)	90:199	48:118
	Mean (SD)	145.8(27.2)	87.5(16.7)

33 subjects included 19 male and 14 female with mean±SD age 50.5±15.8 years. The arm circumference of all subjects was 30.5±4.7cm with all subjects using the hard cuff (22-42cm) for the tested device. The SBP and DBP of the 33 subjects was 145.8±27.2 and 87.5±16.7mmHg, respectively.

Table 3 Distribution of overall pressure

SBP (mmHg)		DBP (mmHg)	
Overall range (Low:High)	89 : 194	Overall range (Low:High)	50 : 120
Low (< 130)	29	Low (< 80)	35
Medium (130–160)	43	Medium (80–100)	35
High (>160)	27	High (> 100)	29
Maximum difference	16	Maximum difference	6

The overall range of observer measurements was 89-194mmHg for SBP and 50-120mmHg for DBP. SBP and DBP respectively had 99 comparison measurements which located in each recruitment range (Low, Medium and High) were 29, 43 and 27 for SBP and 35, 35 and 29 for DBP, respectively. The maximum difference was 16 for SBP and 6 for DBP which were not both more than 19.

Table 4 Observer differences

Observer2-Observer 1	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Range (Low:High)	–4 : +4	–4 : +4	3
Mean (SD)	0.1(1.8)	0.2(1.6)	

The range of observer differences was -4 to 4mmHg with mean±SD values 0.1±1.8mmHg for SBP and 0.2±1.6mmHg for SBP.

Table 5 Validation result

Part 1		≤5mmHg	≤10mmHg	≤15mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass requirement	Two of	73	87	96	/	/	/
	All of	65	81	93	/	/	/
Achieved	SBP	85	96	99	Pass	-0.4	3.9
	DBP	89	96	99	Pass	-0.9	3.7
Part 2		2/3≤5mmHg		0/3≤5mmHg		Grade 2	Grade 3
Pass requirements		≥24		≤3		/	/
Achieved	SBP	30		0		Pass	Pass
	DBP	31		1		Pass	Pass
Part 3	Result	Pass					

The differences of tested device-observer measurements produced 85, 96, and 99 measurements within 5, 10, and 15mmHg for SBP and 89, 96, and 99 for DBP, respectively. The mean ± SD of device-observer was -0.4 ± 3.9mmHg for SBP and -0.9 ±

3.7mmHg for DBP. The number of subjects with two or three of the device-observer differences within 5mmHg was 30 for SBP and 31 for DBP. In addition, none of subjects had no device-observer difference within 5mmHg for SBP and one subjects had the same for DBP.

Plots: these were mean-difference plots which represented all 99 point of the device and observer measurements. The plots indicated BP uniform distribution rather than being clustered with in a range(Fig.1).

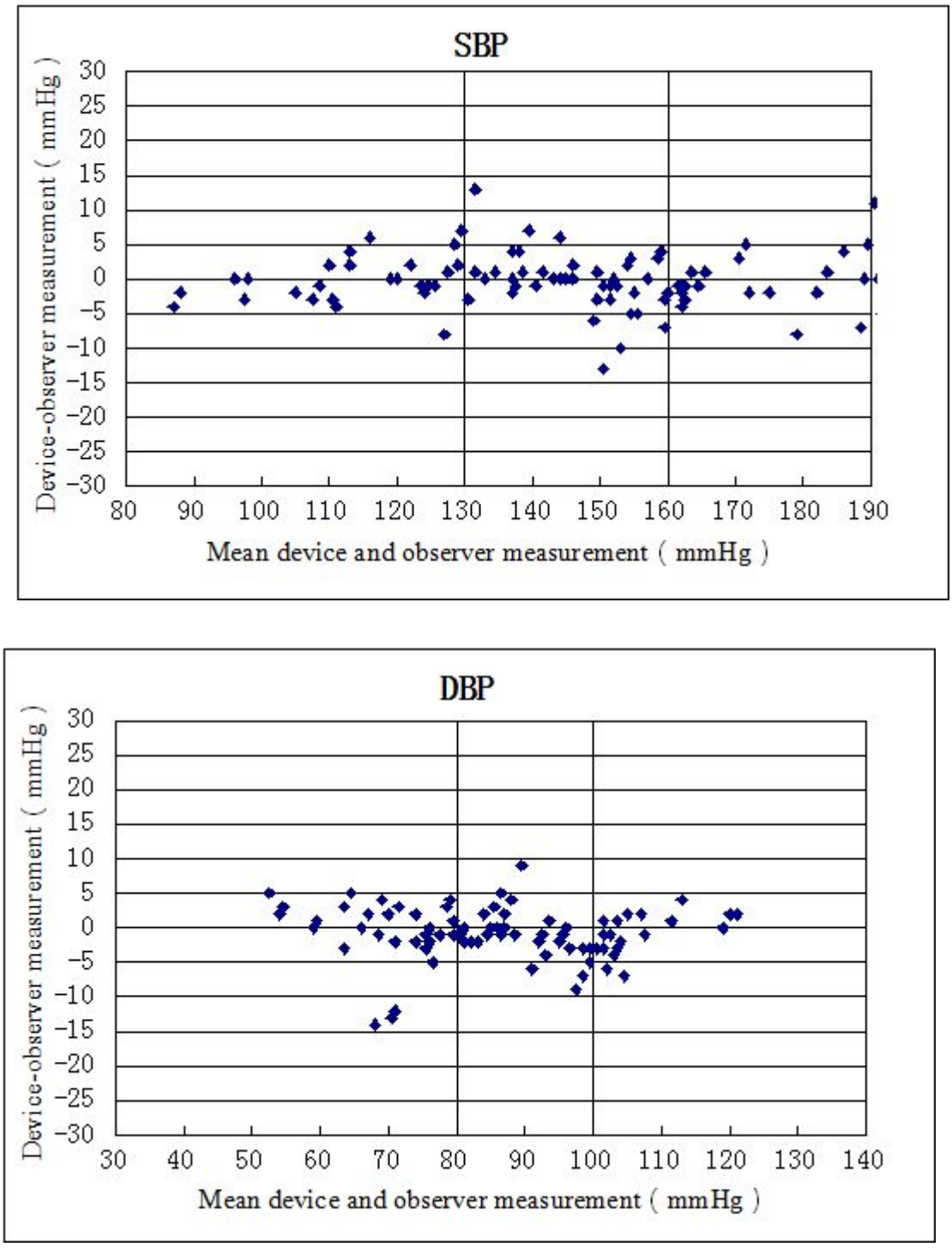

Fig.1 Differences versus the mean pressure between the tested device and the observer values

Discussion

The study was carried out strictly according to the ESH-IP 2010 and the results showed a good agreement between mercury sphygmomanometer and Artsana helpRAPID in systolic and diastolic blood pressures. The 33 subjects had a wide range in age, systolic and diastolic blood pressures and the cuff was used in this study for arm circumferences ranging of 22-42cm to meet the requirements of various population. The study results indicated that the hardware and algorithms of the tested device have the capacity to work properly in blood pressure measurements over a wide range.

Conclusion

According to the results of this study on the basis of the ESH-IP 2010, Artsana helpRAPID upper-arm blood pressure monitor is suitable for self/home measurement in general adult population.

Acknowledgements

Guangdong Transtek Medical Electronics Co.,Ltd. provided funding for this validation study and chosen the tested device randomly. There are no conflicts of interest.

References

1 Lewis JB. Blood pressure control in chronic kidney disease: is less really more? J Am Soc Nephrol. 2010 July; 21(7):1086–1092.

2 Eleni Rapsomaniki, Adam Timmis, Julie George, Mar Pujades-Rodriguez, Anoop D Shah, Spiros Denaxas, Ian R White, Mark J Caulfield, John E Deanfield, Liam Smeeth, Bryan Williams, Aroon Hingorani and Harry Hemingway. Blood pressure and incidence of twelve cardiovascular diseases: lifetime risks, healthy life-years lost, and age-specific associations in 1·25 million people. Lancet. 2014 May 31; 383(9932): 1899–1911.

3 Eastern Stroke and Coronary Heart Disease Collaborative Research Group. Blood pressure, cholesterol, and stroke in eastern Asia. Lancet 1998; 352:1801–1807.

4 White JR, PA-C, Schick J. Home blood pressure monitoring and diabetes. Clinical Diabetes 2004; 22:28–31.

5 American Heart Association. High blood pressure patients advised to use home monitors. http://americanheart.mediaroom.com. [Accessed 10 February 2010].

6 Aylett M, Marples G, Jones K. Home blood pressure monitoring: its effect on the management of hypertension in general practice. Br J Gen Pract 1999; 49:725–728.

7 Omboni S, Riva I, Giglio I, Caldara G, Groppelli A, Parati G. Validation of the Omron M5-I, R5-I and HEM-907 automated blood pressure monitors in elderly individuals according to the International Protocol of the European Society of Hypertension. Blood Press Monit 2007; 12:233–242.

8 O'Brien E, Mee F, Atkins N, O'Malley K. Inaccuracy of seven popular sphygmomanometers for home measurement of blood pressure. J Hypertens 1990; 8:621–634.

9 Gretchen M. Ray, James J. Nawarskas and Joe R. Anderson. Blood Pressure Monitoring Technique Impacts Hypertension Treatment. J Gen Intern Med. 2012 Jun; 27(6): 623–629.
10 O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, et al., on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. International protocol revision 2010 for the validation of blood pressure measuring devices in adults. Blood Press Monit 2010; 15:23–38.

刘中华 2016.9.22　　刘俊新 2016.9.22　　周恒高 2016.9.22


M-L
22~42cm
8¾"~16½"
PIC solution
2~3cm
LATEX
SYS mmHg
DIA mmHg
Pul/min
128
83
68
10:38
ok
MEM
START
STOP
SET