Summary: Using data collected in the US in adults and in Japan in children the HBP-1300 device passes the AAMI validation protocol as accurate and reliable in adults and children.

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References Cited

i. American National Standard ANSI/AAMI/ISO 81060-2:2009 (Revision of SP10:2002 and Amendment 1:2003 and Amendment 2:2006) Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. Association for the Advancement of Medical Instrumentation, Arlington, VA. www.aami.org

ii. Although the newest AAMI protocol "recommends" (but does not mandate) using K4 as the diastolic pressure in children. As the standard in medical practice around the world is to use K5 as the diastolic pressure at age of ≥3 the Japanese team used K5 as the diastolic pressure in children.

iii. IntegReview. 3001 S. Lamar Blvd., Suite 210, Austin, Texas 78704. http://www.integreview.com/

Figure 4

Bland-Altman Plot for Diastolic Pressure Method 2 (n = 85)

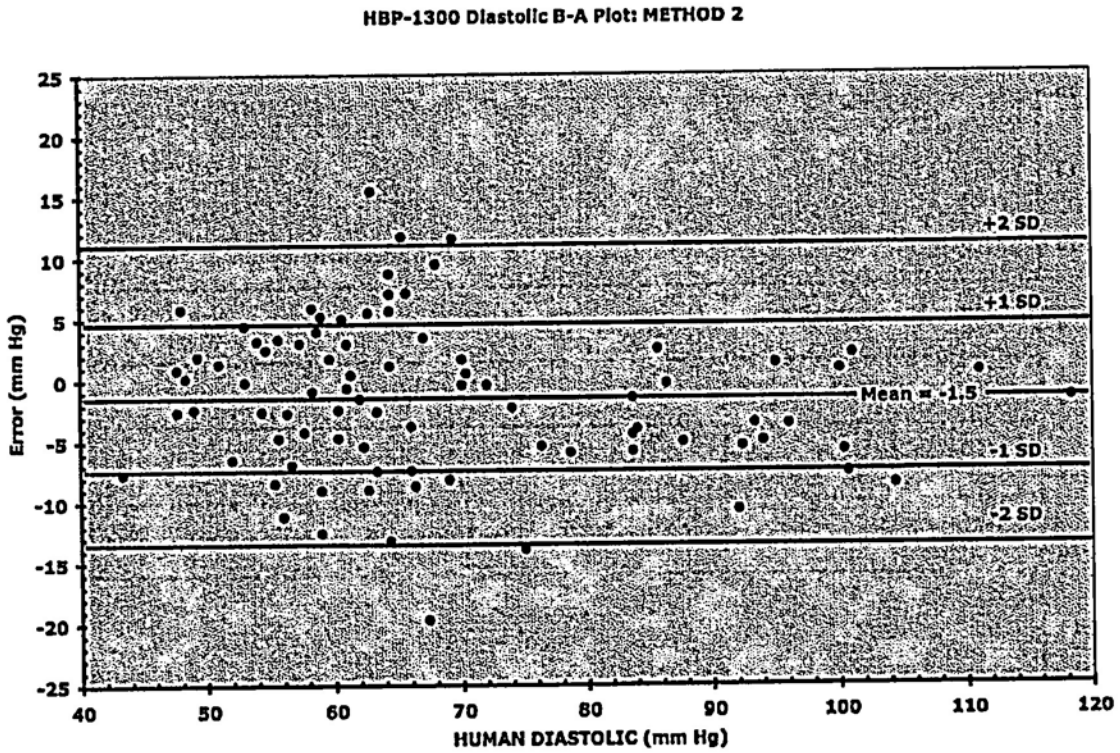


Figure 3

Bland-Altman Plot for Systolic Pressure Method 2 (n = 85)

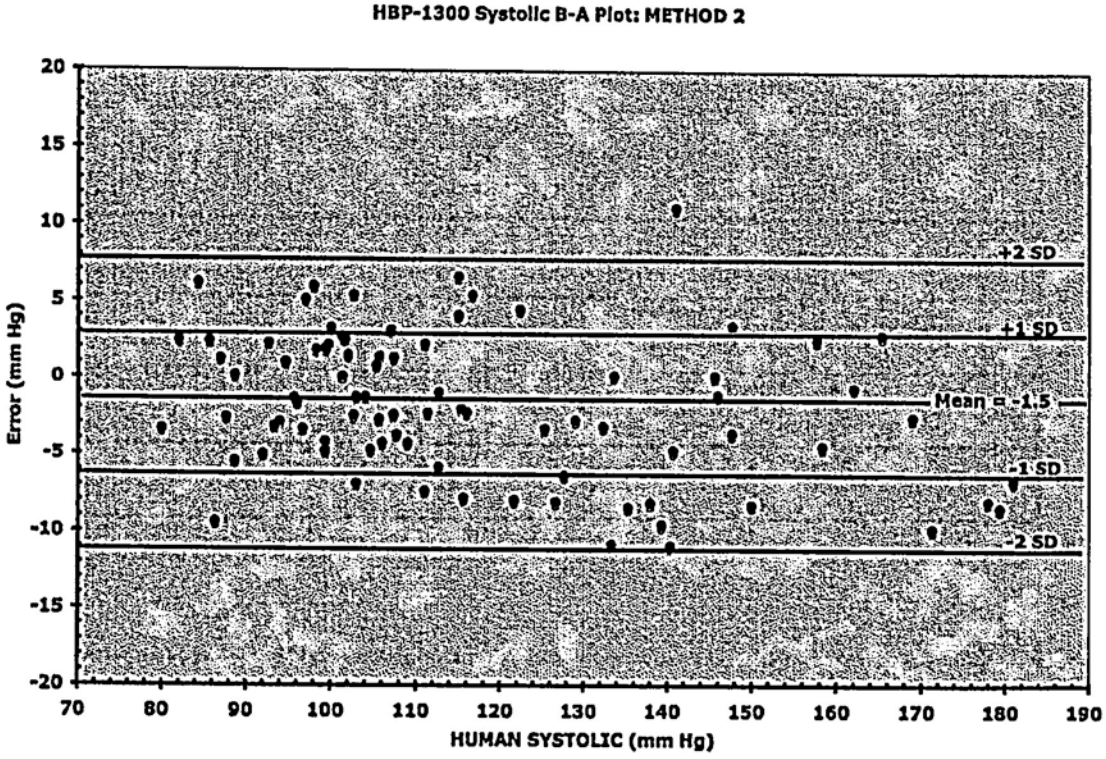


Figure 2

Bland-Altman Plot for Diastolic Pressure Method 1 (n = 255)

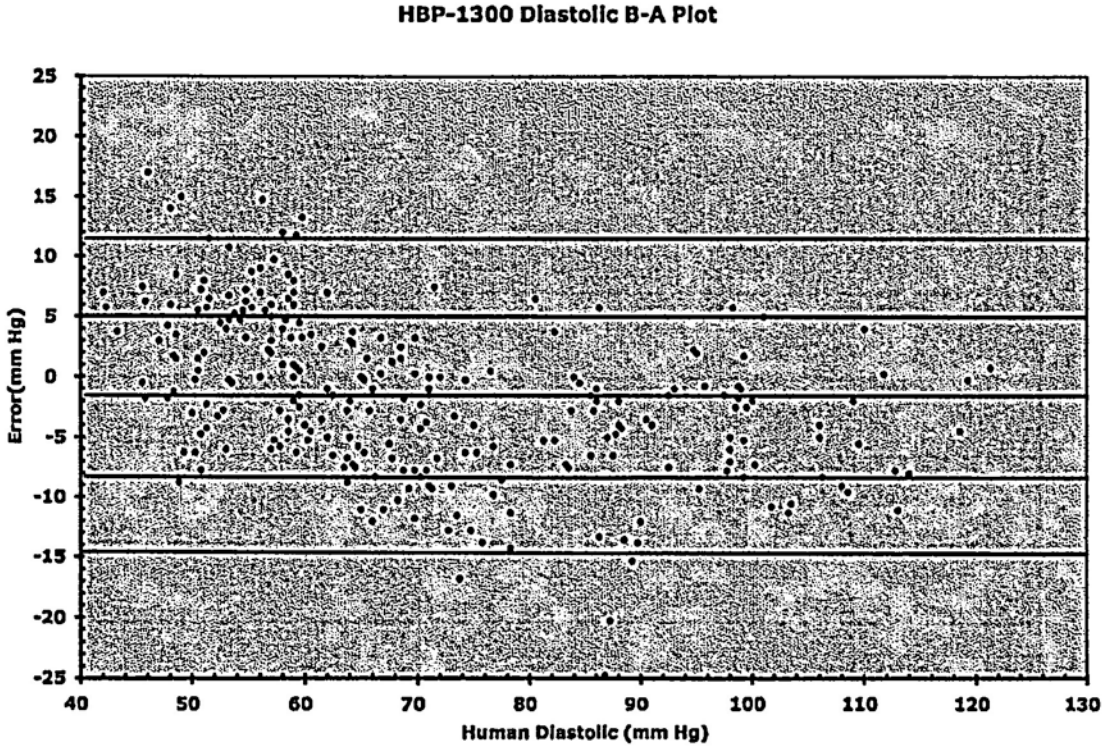
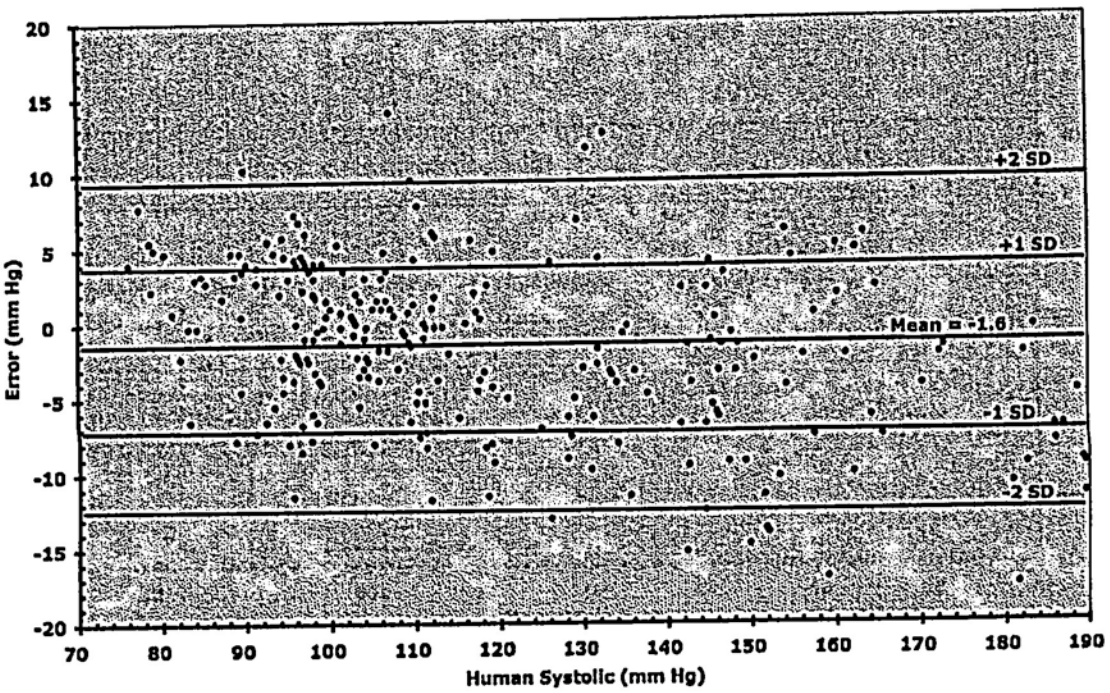


Figure 1

Bland-Altman Plot for Systolic Pressure Method 1 (n = 255)



Blood Pressure results in mmHg are summarized in Table 4.

Table 4

	Human Baseline		Method 1 n = 225						Method 2 n = 85					
			Systolic			Diastolic			Systolic			Diastolic		
	Sys	Dia	Human	1300	Error	Human	1300	Error	Human	1300	Error	Human	1300	Error
Mean	119.9	70.6	118.1	116.2	-1.6	70.4	68.7	-1.7	118.2	116.5	-1.7	70.4	68.7	-1.5
SD	26.2	18.2	26.9	25.8	5.5	18.5	16.7	6.6	26.9	25.1	4.7	18.4	16.5	6.2
Min	62.5	42.0	76.0	77.0	-17.5	42.0	40.0	-24.8	78.1	80.0	-10.9	42.1	43.3	-19.7
Max	188.0	113.5	189.5	184.0	14.0	121.3	122.0	17.0	187.8	181.0	11.1	119.9	118.3	15.5

The Human Baseline blood pressures in Table 4 were used to classify the subjects blood pressure group as required by AAMI in Table 3.

Method 1: It can be seen that the device passes AAMI Method 2 for systolic and diastolic pressure.

Method 2: In order for a device to pass AAMI Method 2 the mean error must be within the limits noted in Table 1 above.

1. **Systolic Pressure:** From Table 1 a systolic pressure error of -1.7 mmHg the SD must be ≤6.30 mmHg. The SD in this data set is ± 4.7 mmHg. Thus the device passes Method 2 for systolic pressure.
2. **Diastolic Pressure:** For a diastolic pressure error of -1.5 mmHg the SD must be ≤ 6.78 mmHg. The SD in this data set is ± 6.2 mmHg. Thus the device passes Method 2 for diastolic pressure.

Bland-Altman Plots of HBP-1300 AAMI data.

The Bland-Altman Plots for the HBP-1300 study are shown on the next 4 pages. In each plot horizontal lines show the mean error and ± 1 and ± 2 standard deviations (SD) from this error.

6. Results: The demographic results are summarized below in Table 2 in the 85 subjects. There were 43 males (51%). AAMI requires at least 30% males and 30% females.

Table 2

Demographic	Average	SD	Minimum	Maximum
Age (years)	30.7	±23	3	71
Arm Circumference (cm)	27.1	±9.8	14	48.7

The ethnicity breakdown of subjects was Caucasian 29 (34%), African Americans 21 (25%) and Japanese 35 (41%).

Table 3 lists the number of subjects required by AAMI in various categories and the number of subjects in our data set in each category.

Table 3. AAMI definitions and our numbers in each group

		Goal	This study
	Total	85	85
Gender	% Male	≥26	43%
Children	Age 3-11	At least 35 for approval for children	35
Cuff range	Cuff size label	Need 85/2*(number of Cuffs) or 85/10 = 9	This study
R 12-18	SS	9	22
R 17-22	S	9	13
M 22-32	M	9	25
L 32-42	L	9	16
XL 42-50	XL	9	9

Systolic BP	Calculation	Goal number	This study
5% ≤100	85 x 5% = 4.5 or ≥5	5	31
20% ≥140	85 x 20% = 17	17	20
5% ≥160	85 x 5 = 4.5 or ≥5	5	8
Diastolic BP	Calculation	Goal	This study
5% ≤60	85 x 5% = 4.5 or ≥5	5	14
20% ≥85	85 x 20% = 4.5 or ≥5	17	25
5% ≥100	85 x 5% = 4.5 or ≥5	5	8

It can be seen that all requirements were met as outlined by AAMI.

the length of the cuff encircled at least 80% of the arm.

4. Data collection:

1. The AAMI protocol was followed. Shared Care provided observers for the US data collection and the Kyoto Perfecture Hospital Department of Pediatric Cardiology provided the observers for the measurements in children. If observer readings differed by more than 4 mmHg they were repeated.
   a. Studies were stopped or rejected if the readers could not agree on the diastolic readings after several attempts or if subjects had arrythmias, could not sit still for the study, or coughed excessively.
   b. Studies were also rejected if the 4 averaged human systolic readings differed by more that 12 mmHg or the diastolic readings varied by more that 8 mmHg.

5. Data Management/Analysis:

1. Data analysis was done by Shared Care using AAMI Methods One and Two.
   a. Method 1: The device reading was tested by comparing it to the average of the preceding and following human reading. For 85 subjects this results in 225 data sets. The average absolute device error and its standard deviation (SD) must be $\leq 5 \pm 8$ mmHg.
   b. Method 2: The average of the 3 devices readings is compared to the average of the 4 human readings. For 85 subjects this results in 85 data sets. The average device error in the 85 subjects must fit within the range of SDs in Table 1 from AAMI.

Table 1 — Averaged subject data acceptance (criterion 2)

$\bar{x}_n$	Maximum permissible standard deviation, s_{up}, as function of mean error, $\bar{x}_n$ mmHg									
	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
± 0.	6.95	6.95	6.95	6.95	6.93	6.92	6.91	6.90	6.89	6.88
± 1.	6.87	6.86	6.84	6.82	6.80	6.78	6.76	6.73	6.71	6.68
± 2.	6.65	6.62	6.58	6.55	6.51	6.47	6.43	6.39	6.34	6.30
± 3.	6.25	6.20	6.14	6.09	6.03	5.97	5.89	5.83	5.77	5.70
± 4.	5.64	5.56	5.49	5.41	5.33	5.25	5.16	5.08	5.01	4.90
± 5.	4.79	—	—	—	—	—	—	—	—	—
EXAMPLE For mean error of ± 4.2, the maximum permissible standard deviation is 5.40.										

A Clinical Evaluation Report Of Professional Blood Pressure Monitor HBP-1300, Based On Auscultation

Subject: Validation of the accuracy of the HBP-1300 in children and adults using the AAMI Protocol ANSI/AAMI/ISO 81060-2:2009.

1. Background: Shared Care Research and Education Consulting has now completed the collection of data in the US in 50 adults and adolescents and merged this with data provided by the Japanese investigators in 35 children. The combined data analysis documents that the device passes the AAMI ANSI/AAMI/ISO 81060-2:2009(i) validation using K1 as the systolic pressure and K5 (ii) as the diastolic pressure in adults and children.

2. Methods:

Human Subjects:

USA: The research study was approved by the Integreview(iii). Subjects were recruited and studied by Shared Care in the US. Subjects were mostly recruited from participants who had taken part in previous studies. Written informed consent was obtained in all subjects.

Japan: The research study was approved by the Kyoto Hospital/University research committee. Subjects were recruited and studied during an outpatient visit (or inpatient) to the Hospital.

Human observers:

USA Adults: The human observers (Dr. CE Grim, Carlene M. Grim, SpDN and Dr. Jing LI, MD) have been doing such studies together for over 15 years. Their ability to read blood pressure accurately is tested at every 6 months using standardized video testing methods and by comparing double stethoscope results before formally conducting an AAMI validation. Hearing is formally tested annually.

Japanese Children: The human observers in Japan were Pediatric Cardiologists whose accuracy and reliability in blood pressure measurement in children was according to the standards of the Kyoto Perfecture University(see attached).

3. Devices:

Devices were supplied by Omron Healthcare Inc to each testing group. The cuffs used with the 1300 were also provided by Omron. The selection of the cuff used was based on the arm to assure that