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A Clinical Evaluation Report Of Professional Blood Pressure Monitor HBP-9020/HBP-9021.

Subject: Validation of the accuracy of the HBP-9020/HBP-9021 in adults and adolescents using the AAMI Protocol ANSI/AAMI/ISO 81060-2:2009 (1).

1. Background: Shared Care Research and Education Consulting has completed the collection of data in the US in 85 adults and adolescents.

2. Methods:

Human Subjects:

The research study was approved by the Integreview (2). Subjects were recruited and studied by Shared Care in the US. Subjects were mostly recruited from participants who had taken part in previous studies of home blood pressure devices. Written informed consent was obtained in all subjects.

Human observers: 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.

3. Devices:

Two HBP-9020 devices were supplied by Omron Healthcare Inc. One device was randomly selected and used for the entire testing. The selection of the cuff used for auscultatory readings was based on the mid-arm circumference to assure that the length of the cuff encircled at least 80% of the arm. Omron has certified that the HBP-9021 is the equivalent to the HBP-9020 that we tested. We did not perform a complete AAMI validation on the HBP-9021 as it is an equivalent device. However we did carry out an AAMI opposite arm simultaneous study in 10 subjects in which the 9020 and the 9021 were on opposite arms. We found that we could detect no significant difference in the device's readings for systolic or diastolic pressure ($p>0.05$). This further validates that the 9020 and 9021 are equivalent.

4. Data collection: The AAMI protocol (1) was followed. If paired 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 systolic or diastolic readings after several attempts or if subjects had arrhythmias, could not sit still for the study, coughed excessively, or complained of not feeling well during the study .
b. Studies were also rejected if the four averaged human systolic readings differed by more that 12 mmHg or the averaged human diastolic readings varied by more that 8 mmHg.

c. HBP-9020 being an arm-in blood pressure monitor with fixed cuff system, special attention was paid to ensure patient sitting position during the test with retest done on 8 subjects (3).

5. Data Management/Analysis: Data was recorded separately by each human observer. The printout from the HBP-9020 was recorded independently. 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 ≤ 5 ± 8.00 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)

$\bar{x}_e$	Maximum permissible standard deviation, s_e, as function of mean error, $\bar{x}_e$ 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 5.49.

6. Results: The demographic results are summarized below in Table 2 in the 85 subjects. There were 36 males (43%). AAMI requires at least 30% males and 30% females.

Table 2

Demographic	Average	SD	Minimum	Maximum
Age (years)	40	± 20	12	73
Arm Circumference (cm)	30	± 5	19	42

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

		AAMI Goal	This study
	Total	85	85
Gender	% Male	N ≥26	36
Cuff range			This study
R 17-22	Small	NA	10
M 22-32	Medium	NA	42
L 32-42	Large	NA	30
AAMI requires	Arm Circumference (cm)	Goal number	This study
20% in lower quartile	20% ≤ 23.3	17	17
40% in lower half	40% ≤ 29.5	34	47
40% in upper half	40% >29.5	34	38
20% in upper quartile	20% ≥ 35.8	17	18
Systolic BP	Calculation of Goal	Goal number	This study
5% ≤100	85 x 5% = 4.5 or ≥5	5	31
20% ≥140	85 x 20% = 17	17	19
5% ≥160	85 x 5 = 4.5 or ≥5	5	7
Diastolic BP	Calculation of Goal	Goal number	This study
5% ≤60	85 x 5% = 4.5 or ≥5	5	17
20% ≥85	85 x 20% = 4.5 or ≥5	17	20
5% ≥100	85 x 5% = 4.5 or ≥5	5	6

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

Blood Pressure results in mmHg are summarized in Table 4.

Table 4

			Method 1 n = 225						Method 2 n = 85					
Human Baseline			Systolic			Diastolic			Systolic			Diastolic		
	Systolic	Diastolic	Human	9020	Error	Human	9020	Error	Human	9020	Error	Human	9020	Error
Mean	120.86	71.96	121.04	124.05	3.01	71.69	71.20	-0.49	121.04	124.05	3.00	71.72	71.20	-0.52
SD	22.94	16.82	24.32	23.56	7.30	15.07	15.73	7.04	24.57	23.46	5.97	15.07	15.58	6.67
Min	85.0	27.0	80.5	86.0	-29.0	42.0	47.0	-15.0	81.0	88.7	-9.2	42.5	47.0	-12.1
Max	205.0	112.0	223.8	234.0	23.3	112.0	112.0	28.5	222.1	214.7	15.6	111.9	108.7	19.8

The Human baseline blood pressures in Table 4 were used to classify the subject's blood pressure group as required by AAMI for Table 3.

Method 1: It can be seen that the device passes AAMI Method 1 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 3.00 mmHg the SD must be ≤6.25 mmHg. In this data set is 3.00± 5.97 mmHg. Thus the device passes Method 2 for systolic pressure.
2. **Diastolic Pressure**: For a diastolic pressure error of -0.52 mmHg the SD must be ≤ 6.92 mmHg. The SD in this data set is ± 6.67 mmHg. Thus the device passes Method 2 for diastolic pressure.

Bland-Altman Plots of HBP-9020/HBP-9021 AAMI data.

The Bland-Altman Plots for the HBP-9020/HBP-9021 study are shown on the next 4 pages. In each plot horizontal dashed lines show the mean error and ± 1 and ± 2 standard deviations (SD) from this error.

Figure 1

Bland-Altman Plot for the HBP-9020/HBP-9021 Systolic Pressure: Method 1 (n = 255)

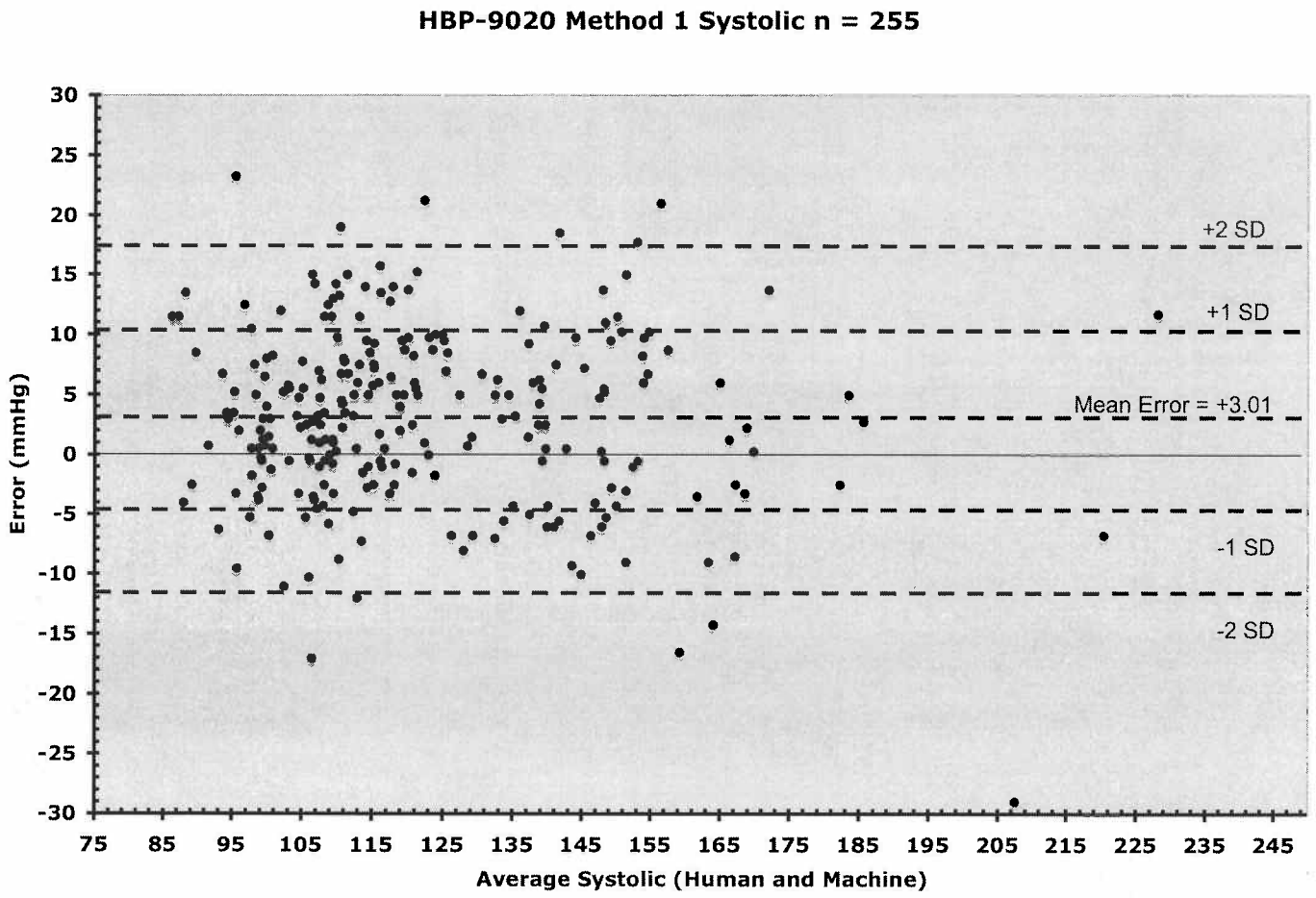


Figure 2

Bland-Altman Plot for the HBP-9020/HBP-9021 Diastolic Pressure: Method 1 (n = 255)

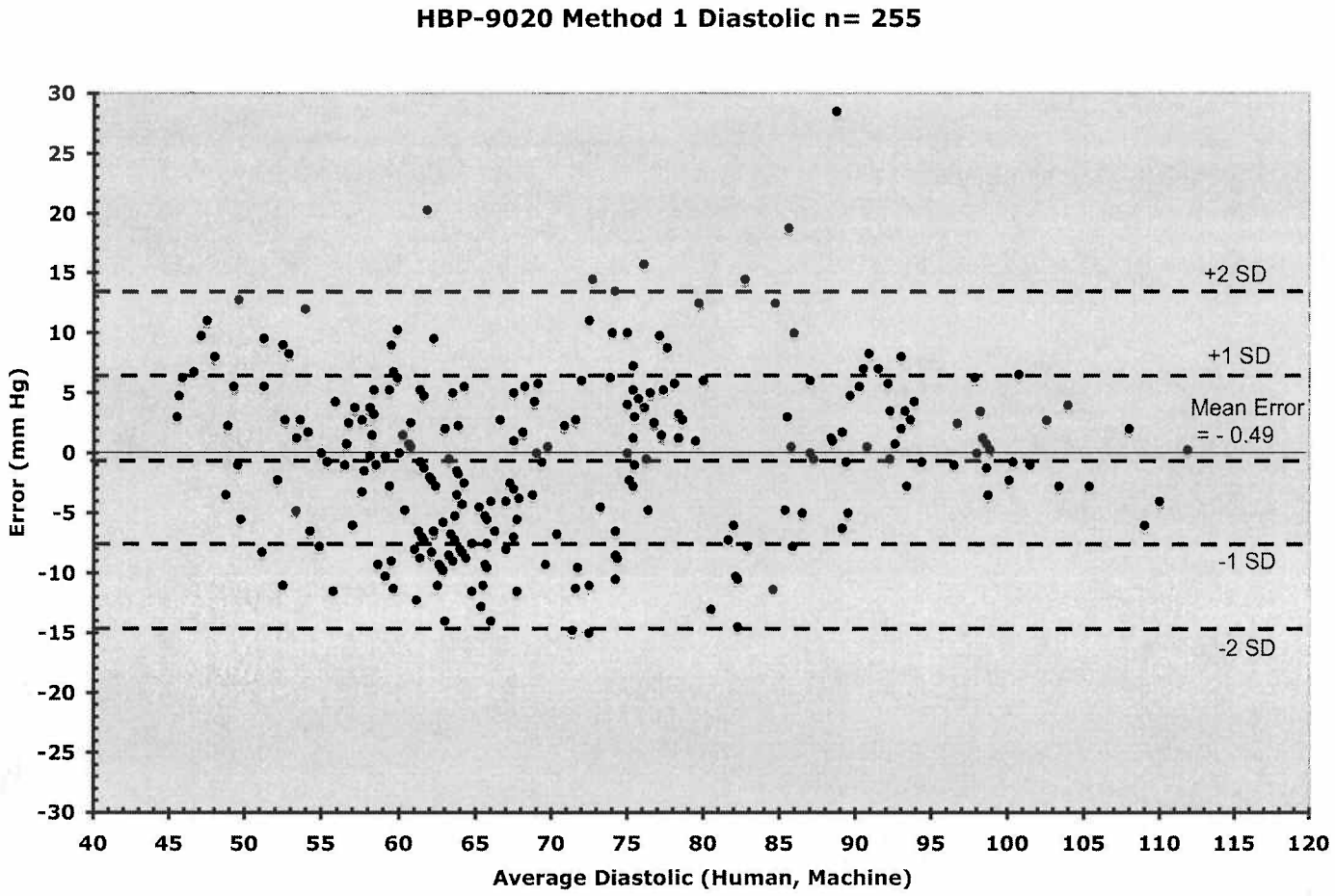


Figure 3

Bland-Altman Plot for the HBP-9020/HBP-9021 Systolic Pressure: Method 2 (n = 85)

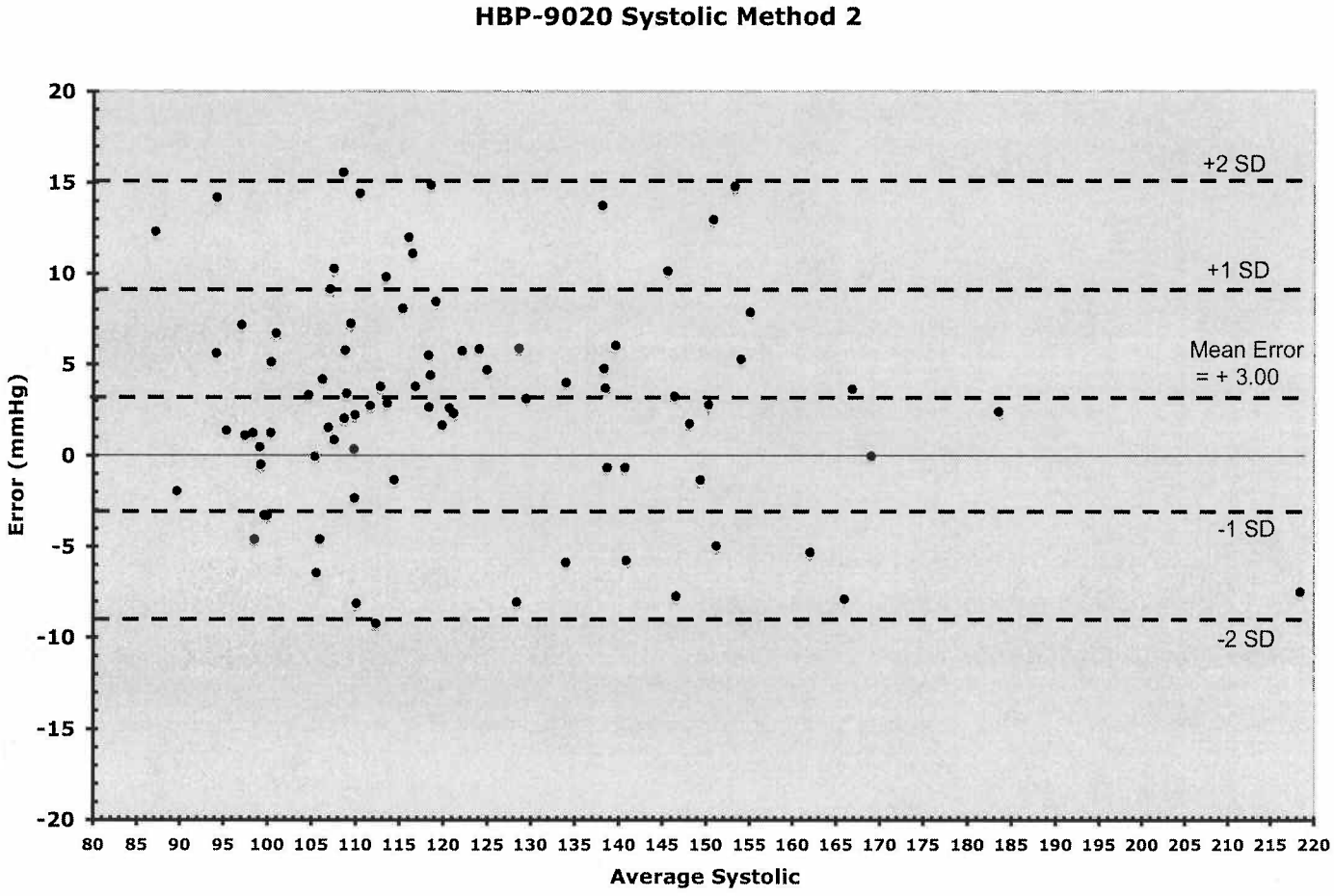
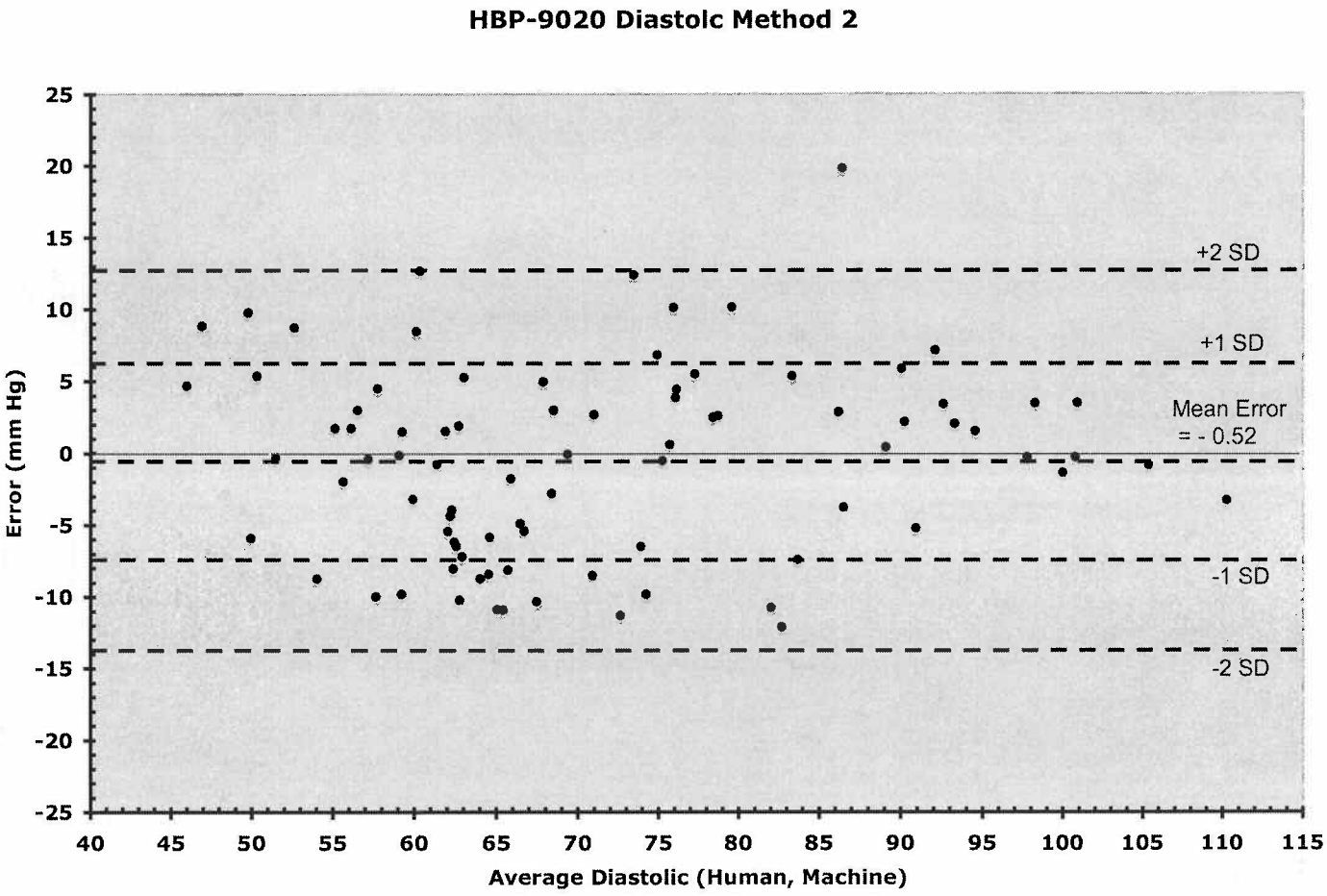


Figure 4

Bland-Altman Plot for the HBP-9020/HBP-9021 Diastolic Pressure: Method 2 (n = 85)



Summary: Using data collected in US HBP-9020/HBP-9021 device passes the AAMI validation protocol Methods 1 and 2 as accurate and reliable in adults and adolescents.

Signed by the Shared Care Team:

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References & Comments:

1. 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
2. IntegReview. 3001 S. Lamar Blvd., Suite 210, Austin, Texas 78704. http://www.integreview.com/
3. During the course of testing, larger diastolic errors were noted on 10 patients. Retests were done on 8 patients who can be reached, paying particular attention to the positioning. As the average difference between the first and second test were not significantly different, we elected to use the second testing numbers on the retested subjects.