

**CSI HEALTH STATION - BLOOD PRESSURE KIOSK VALIDATION STUDY
Comparison to Auscultatory method (4.4.5.1.B)**

Report Date: March 16, 2007

Study Dates: February 5th through the 15th, 2007

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RENO, NV, 89512 Reno, NV 89509

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Study Design: Pharmacy and clinic customers who were ambulatory and without cardiac or other health complaints were approached randomly and asked to have their blood pressure taken. CSI's commercial product described and company interest in verifying their product was described to prospective volunteers. After agreeing to assist in the study and after blood pressures were taken, volunteers were offered \$5 USD for their cooperation.

Volunteers were asked for their blood pressure history and drug therapy. Height, weight, arm circumference and smoking history were noted. Three separate measurement of blood pressure were taken simultaneously by the CSI Health Station and by an investigator using auscultation. Three consecutive readings were recorded. No difference in the accuracy of readings comparison was found between manual operators recording their readings simultaneously in 92% of all observations.

These data have been assembled, analyzed and checked for accuracy.


_____ Iain L. O. Buxton

Participant

Demographics: 157 (157 x 3 = 471 observations for each manual and machine determinations)
58 Males, 99 Females

33% of patients reported a diagnosis of HBP; 24.8% smoked cigarettes
72% of hypertensive patients were on medication for HBP at the time of testing
Average arm circumference 29.04 cm. (range 20-40 cm)
Average age, 45 years, 9.86 months.
Average height, 167.9 cm (5'6.116"); average weight 179 lbs.

Results and Interpretation:

Our study was conducted with the CSI Health Station technology as represented in the Model 6000 Health Station. The specific purpose of the study was to address the performance of the 6000 using the AAMI/ANSI standard 4.4.5.1.2.B. All of the inclusion criteria were met by the study and enrollment exceeded the standard. Data were collected and separated from participant ID at the time of inclusion of subjects. All subjects were ambulatory and denied current cardiac disease. Auscultatory gaps were normal as induced by the cuff method. No cardiac major rhythm disturbances were detected. Three patients experienced bigeminy during testing. All patients were in sinus rhythm. Heart rates collected ranged from a mean of 44 to 111. Mean heart rate was 72.85. Seventy-two percent of patients had a heart rate within one SD of the mean.

The conclusion from this study is clear; the CSI 6000 instrument measures blood pressure accurately based on the comparison to the auscultatory method. Moreover, the CSI 6000 is precise because we found measurements to be repeatable.

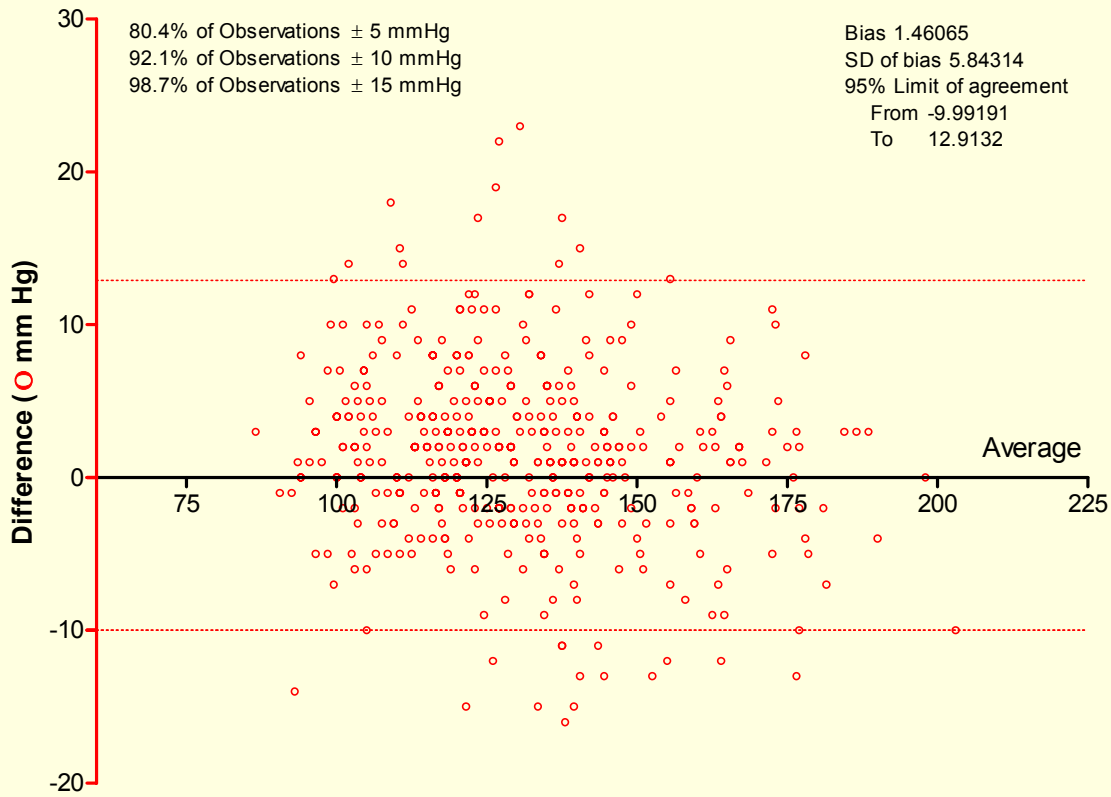
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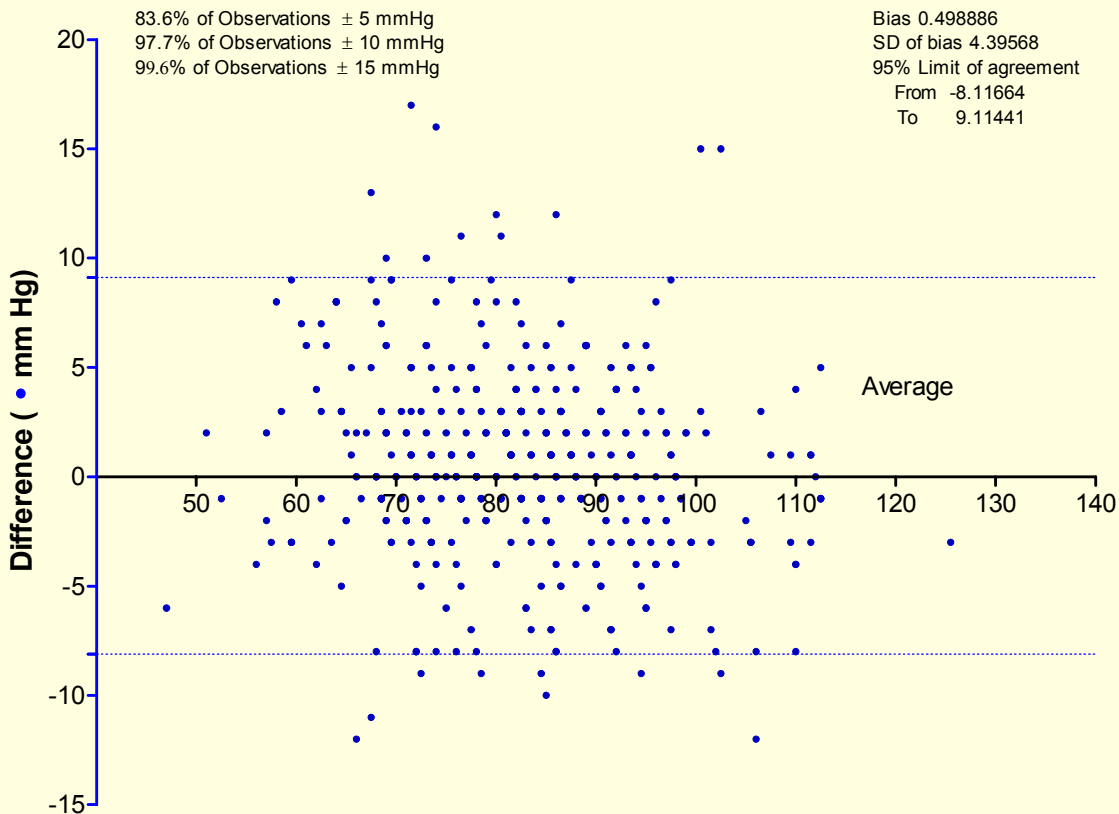
Iain L. O. Buxton

CSI Health Station: BP Comparison

Bland-Altman of Systolic Pressures: Difference vs Average



Bland-Altman of Diastolic Pressures: Difference vs Average



Heart Rate Data: Mean \pm SD

