

Validation of the CSI Health Station 6K Blood Pressure Kiosk®

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ABSTRACT

Established in 1978, Computerized Screening Inc. (CSI) is the manufacturer of medical kiosks that combine non-invasive & invasive preventive health-screening technology and services in the U.S. The centerpiece of CSI's health complement is the CSI Health Station, one-stop health information and screening using patented technology. The CSI Health Station (Model 6K) represents the corporation's evolution from its self-administered automated blood pressure monitors (Model 3K). CSI Health Stations also offer touch screen activated heart rate testing, patented, seated weight measurement and fitness evaluations plus other non-invasive features like BMI, resting metabolic rate, spirometry, pulse oximetry and customized health risk assessments or triage guidelines. Invasive testing such as urine analysis, cholesterol, and glucose is also accommodated in an attended setting. In addition, CSI Health Stations feature comprehensive, one-stop availability of health information, with access to a drug encyclopedia and an extensive library of health education videos, and information on local health providers and services. It also is web enabled and supports secure website access direct from the kiosk. The purpose of this study was to determine, using current standards from the Association for the Advancement of Medical Instrumentation (AAMI), whether or not the CSI 6K could accurately and reproducibly measure blood pressure in an ambulatory population in comparison to manual auscultation.

INTRODUCTION

The management of chronic disease and the dissemination of medical information in order to improve access, and follow-through to medical care are essential goals for the improvement of public health [1-3]. Empowering individuals is an essential objective if this goal is to be realized. The benefits of technology-based methods to achieve these and the associated goals of developing a portable health record that can be accessed by both providers and consumers of health care cannot be over-stated [4,5]. Computerized Screening Incorporated (CSI) has been innovating, manufacturing and installing interactive patient kiosks for a decade. The company holds four patents for its' Health Station screening applications, including one for the automated non-

invasive methodology for taking blood pressure with unparalleled accuracy. CSI Health Stations also offer touch screen activated heart rate testing, patented, seated weight measurement and fitness evaluations plus other non-invasive features like BMI, resting metabolic rate, spirometry, pulse oximetry and customized health risk assessments or triage guidelines. In addition, CSI Health Stations feature comprehensive, one-stop shopping for health information, with access to a drug encyclopedia and an extensive library of health education videos, and information on local health providers and services. It also is web enabled and supports secure website access direct from the kiosk. Community based health stations allow for a continuity of care that extends into the daily life of each user and not only provides an access point but also provides the healthcare professional an ongoing record [6-8]. Partnership between academia and industry to validate technology such as the CSI 6K is essential for the benefit of the public health. Validation studies such as the one reported here, offer unbiased validation of the usefulness and reliability of instrumentation that serves industry, the healthcare community and the public.

MATERIALS AND METHODS

Study Locations: Our study was conducted from February 5th through the 15th, 2007 in Reno Nevada at the following public locations: Sak N' Save Pharmacy, 2375 Oddie Blvd, Reno, NV, 89512. HAWC Clinic, (Health Access Washoe County) 6490 S McCarran Blvd # A9, Reno, NV 89509.



Figure 1. Illustration of the CSI 6K health Station.

Instrumentation: The CSI Health Station 6K holds the following certifications. FDA Medical Device Class 2a; UL Medical Device IEC 60601; RoHS compliant (lead free); ANSI/AAMI SP10 accuracy validated (*herein*); certified ISO 13485:2003 - "Medical device - Quality Management Systems" compliant - certified by Det Norske Veritas; HIPAA compliant; CE MDD 93/42/EEC; BS EN 1041; BS EN 980. Our study was conducted with the CSI Health Station technology as represented in the Model 6K Health Station; the purpose was to address the performance of the CSI 6K using the AAMI/ANSI SP-10 standard (4.4.5.1.2.B). Available from the American National Standards Institute.

Patented Technology: CSI holds four patents for its equipment and has three patents pending. CSI's patented technology for blood pressure monitoring uses "multiple measurement techniques" that incorporate sound, pressure and Pattern Identification to produce a single blood pressure result. Using the most powerful DSP processor available, CSI technology analyzes up to 60,000 heart sound impressions to determine the Pattern Identification result.

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 the CSI 6K Health Station (Fig. 1) was 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. 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. Three separate measurements 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.

One-hundred and fifty-seven subjects (58 males, and 99 females) completed the study (157x3=471 observations for each manual and machine determinations). Thirty-three % 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.

AAMI Standards: The purpose of the AAMI standards program is to assist the health care professions and industry in the U.S. and abroad with the use, acceptance, and advancement of medical technology. This is accomplished by AAMI technical committees, which develop consensus recommendations on medical device safety, performance, and use. As adjuncts to these recommendations, AAMI also establishes referee test methods, conducts technical conferences and educational programs, and issues expert opinion statements on technical issues of concern to the AAMI membership and the health care community. The end result of these activities is publication of voluntary standards, recommended practices, technical information reports, and conference reports, all of which contribute toward advancing medical technology and the quality of patient care.

A medical device standard recommends to the manufacturer the information that should be included with the product, basic safety

and performance criteria, and measurement techniques that can be used to determine whether the product meets the safety and performance criteria [6]. While a standard is primarily directed towards the device manufacturer, it may also be of value to the potential user of the device as a reference for device evaluation.

RESULTS AND DISCUSSION

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 major cardiac rhythm disturbances were detected. Three patients experienced bigeminy during testing. All patients were in sinus rhythm. Heart rates collected ranged from a low of 44 to 111 beats per minute. Mean heart rate was 72.85 beats per min. Seventy-two percent of patients had a heart rate within one SD of the mean.

The results of the study show a mean error (average of the pressure differences between methods) of 1.46 mmHg for systolic pressures with a standard deviation of 5.84 mmHg. For diastolic pressures, the mean error is 0.49 mmHg and the standard deviation for diastolic pressure data between the methods is 4.39 mmHg.

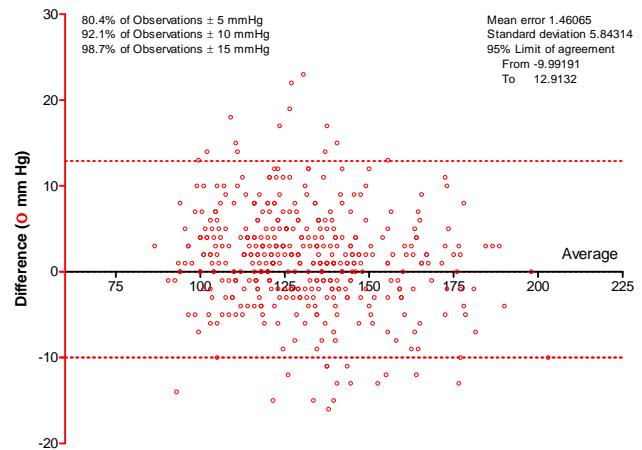


Figure 2. Bland-Altman of Systolic Pressures: Difference vs. Average. Individual determinations are plotted as the difference versus the average of systolic pressures. Statistical determinations are shown in the graph.

The mean error is computed as the value determined by one method minus the value determined by the other method [9-10]. This number is small if the methods agree. The standard deviation (SD) value is used to calculate the limits of agreement, computed as the mean error plus or minus 1.96 times its SD. Thus, for any future sample, the difference between measurements using these two methods should lie within the limits of agreement 95% of the time.

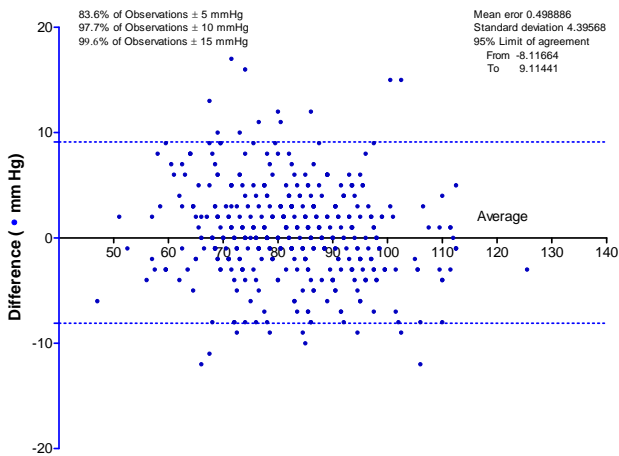


Figure 3. Bland-Altman of Diastolic Pressures: Difference vs. Average. Individual determinations are plotted as the difference versus the average of systolic pressures. Statistical determinations are shown in the graph.

Data for both systolic and diastolic pressure presented in here for the CSI 6K fall within the AAMI/ANSI SP-10 standard. The maximum allowed values are ± 5 mm Hg for the mean error and a standard deviation of 8 mm Hg. Therefore the results of this study demonstrate that the CSI 6K Health Station is in compliance with the standard.

CONCLUSIONS

The conclusion from this study is clear; the CSI 6K instrument measures blood pressure accurately based on the comparison to the auscultatory method. Moreover, the CSI 6K is precise because we found measurements to be repeatable.

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