A Blood Pressure Study Demonstrating Equivalence of the ViSi Mobile® System and GE DINAMAP™ CARESCAPE™ V100

Prepared by Sotera Wireless, Inc.

Babs Soller, PhD - Vice President, Clinical Affairs
Devin McCombie, PhD - Vice President, Science and Research
Benjamin Kanter, M.D., FCCP

Sotera WIRELESS

A Blood Pressure Study Demonstrating Equivalance of the ViSi Mobile® System and GE DINAMAP™ CARESCAPE™ V100

Summary

The ViSi Mobile® and the GE DINAMAP™ CARESCAPE™ V100 both use a technique called automated cuff oscillometry to determine mean arterial pressure (MAP). Both monitors estimate systolic (SBP) and diastolic (DBP) blood pressure from MAP with proprietary algorithms. A study was conducted by an independent laboratory to compare non-invasive blood pressure (NIBP) determined by ViSi Mobile and the GE DINAMAP on the same person. Measurements were made on 79 separate individuals of varying ethnic origins, arm size and blood pressures. The average difference between ViSi Mobile and GE DINAMAP NIBP was 4 mmHg for both SBP and DBP. This difference is small and clinically insignificant; we can conclude that there is no difference in blood pressure determined with the ViSi Mobile and the GE DINAMAP.

Background

Blood pressure is typically measured every 4 hours in medical/surgical units. The spot check monitor, very often a model of the GE DINAMAP, is wheeled to the patient bedside, the cuff placed on the patient's arm and blood pressure determined. The GE DINAMAP uses a method called automated cuff oscillometry to noninvasively determine Mean Arterial Pressure (MAP); Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) are calculated from MAP using pre-determined algorithms in the monitor. Blood pressure measured this way is typically referred to as non-invasive blood pressure (NIBP) determination.

The ViSi Mobile also determines NIBP using automated cuff oscillometry. When ViSi Mobile is first placed on the patient, the Cuff Module is attached and a single NIBP measurement is made. The cuff can then be removed and cuffless continuous blood pressure (cNIBIP) can be continuously measured. The ViSi Mobile cNIBP measurement is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. As shown in Figure 1, Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected by the Chest Sensor to its arrival at the SpO_2 Thumb Sensor. The calibration of PAT for an individual patient occurs during the initial cuff measurement. During the inflation of the blood pressure cuff, the ViSi Mobile System establishes a calibration curve that depends on the patient's cardiovascular profile. As the blood pressure cuff inflates, the contractility of the brachial artery is predictably altered, causing a change in PAT. After cuff removal, PAT continues to be measured and blood pressure displayed on a beat-to-beat basis without the need for additional cuff inflations. cNIBP accuracy depends upon the initial NIBP oscillometric calibration, so agreement between GE DINAMAP and ViSi Mobile NIBP will also assure agreement for cNIBP measurements.

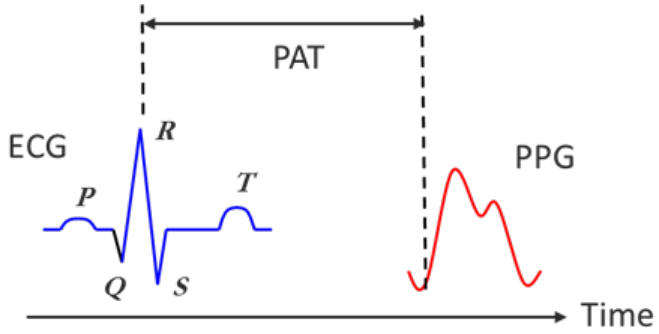

Figure 1: Pulse Arrival Time (PAT)

Study Methods

The study was performed by Clinimark Laboratories located in Avista Adventist Hospital Plaza in Louisville, CO. The primary purpose of the study was to review performance differences for the ViSi Mobile System NIBP system with the WelchAllyn® disposable cuff with the GE DINAMAP NIBP system with GE reusable cuff on the intended adult population.

The study population consisted of 85 qualified healthy adult subjects of any racial / ethnic background. The subject understood the study and provided consent for participation by signing the Informed Consent Form prior to start of the test. The subjects were healthy showing no evidence of significant medical problems, other than high blood pressure. Eligible subjects met all of the inclusion criteria and none of the exclusion criteria for participation.

Subject Inclusion to the study:

- Subjects must be able to provide an informed consent or have legally authorized representative consent to participate.
- Subject must be willing and able to comply with the study procedures.
- Subject must be ≥18 years of age.
- Subject must be able to read or write in English.
- Subjects with an arm circumference in the range of 20-43cm.

Subject exclusion to the study:

- Lack of Informed consent.
- Subjects with deformities or abnormalities that may prevent proper application of the device under test.
- Subject is evaluated by the investigator or clinician and found to be medically unsuitable for particpation in this study.
- Subjects with known heart dysrhythmias
- Subjects with compromised circulation or peripheral vascular disease.
- Subjects with clotting disorders or taking blood thinners.
- Subjects that cannot tolerate sitting for up to 1 hour.
- Subject with a blood pressure demographic that has already been filled.

The goal for Systolic and diastolic blood pressure distributions:

- At least 5% of subjects with systolic pressure ≤100 mmHg.
- At least 20% of subjects with systolic pressure ≥ 140 mmHg.
- At least 5% of subjects with systolic pressure ≥ 160 mmHg.
- At least 5% of subjects with diastolic pressure ≤ 60 mmHg.
- At least 20% of subjects with diastolic pressure ≥ 85 mmHg.
- At least 5% of subjects with diastolic pressure ≥ 100 mmHg.

Data collection methods and analysis followed the International Standards Organization protocol ISO 81060-2:2013 Non-invasive Sphygomomanometers – Part 2: Clinical investigation of automated measurement type. Subjects underwent the following procedures:

1. Informed consent was obtained.
2. Subject was seated in a chair with arm at heart level, rested for 5 minutes.
3. ViSi Mobile with Welch-Allyn disposable cuff was attached and a single NIBP measurement was made.
4. After a resting period of 60 seconds the GE DINAMAP with the reusable DuraCuff® was applied and NIBP was determined.
5. The order of the 2 devices was alternated between subjections.
6. The mean difference and the standard deviation of the differences was calculated.

Study Results

A total of 90 subjects were enrolled for the study. Data from the first six subjects were not used in the analysis due to finding an incorrect algorithm setting on the GE DINAMAP monitor; this was corrected for subsequent subjects. An additional 5 subjects were not analyzed because of excessive coughing or irregular heartbeat. Data from 79 subjects were included for analysis in this study; all had normal heart rhythms.

The ISO 81060-2 has requirements for subject distribution. The subject demographics are illustrated in Tables 1 – 4 and all requirements were met.

Table 1: Gender, Age, & Ethnicity Distribution

Requirements	Result
Gender Distribution: At least 30% of the subjects shall be made and at least 30% of the subjects shall be female	30 (38%) Male 49 (62%) Female (meets requirement)
Age Distribution: The age of every subject shall be >12 years of age	20-83 years (meets requirements)
Race / Ethnicity: No requirement	**Race:** 63 White, 11 Black/African-American, 1 Asian, 3 American Indian / Alaskan Native, 1 Native Hawaiian / Other Pacific Islander **Ethnicity:** 11 Hispanic 68 Non-Hispanic

Table 2: Limb Size Distribution			
Distribution of Test Subject Arm Circumference in the Specified Cuff Size Range of the Test Device Requirement: A minimum of 14 subjects (16%) is needed for each cuff = (1/2(2*3)*85)			
Specified Range 20 - 43 cm	**# of Test Subjects with Arm Circumference in Range**	**% of Subjects**	**Meets Requirements**
Small Adult (20-26 cm)	17	22%	Yes
Adult (25-34 cm)	44	56%	Yes
Large Adult (32-43 cm)	18	23%	Yes

Table 3: Systolic Reference Blood Pressure Distribution Requirements			
255 Total Points Collected	**≤ 100mmHg 5% of the Data Points**	**≥ 140mmHG 20% of the Data Points**	**≥ 160mmHg 5% of the Data Points**
# of Points Collected	18 pts	19 pts	4 pts
% of the Data Points	23%	24%	5%
Meets Requirement	Yes	Yes	Yes

Table 4: Diastolic Reference Blood Pressure Distribution Requirements			
255 Total Points Collected	**≤60mmHg 5% of the Data Points**	**≥ 85mmHG 20% of the Data Points**	**≥ 100mmHg 5% of the Data Points**
# of Points Collected	11 pts	24 pts	7 pts
% of the Data Points	14%	30%	9%
Meets Requirement	Yes	Yes	Yes

A summary of the comparison data is shown in Table 5.

Table 5: Blood Pressure Comparison of ViSi Mobile to GE DINAMAP System		
	Mean Error[1] mmHg	**Standard Deviation[2] mmHg**
Systolic Pressure	-4.2	8.7
Diastolic Pressure	-3.8	5.8

[1]*Mean error is the mean difference between the 2 measurements.*
[2]*Standard deviation is a measure of the variability of the error (difference) across all 79 subjects.*

Figure 2 illustrates the comparison of the ViSi Mobile and GE DINAMAP measurements for systolic blood pressure.

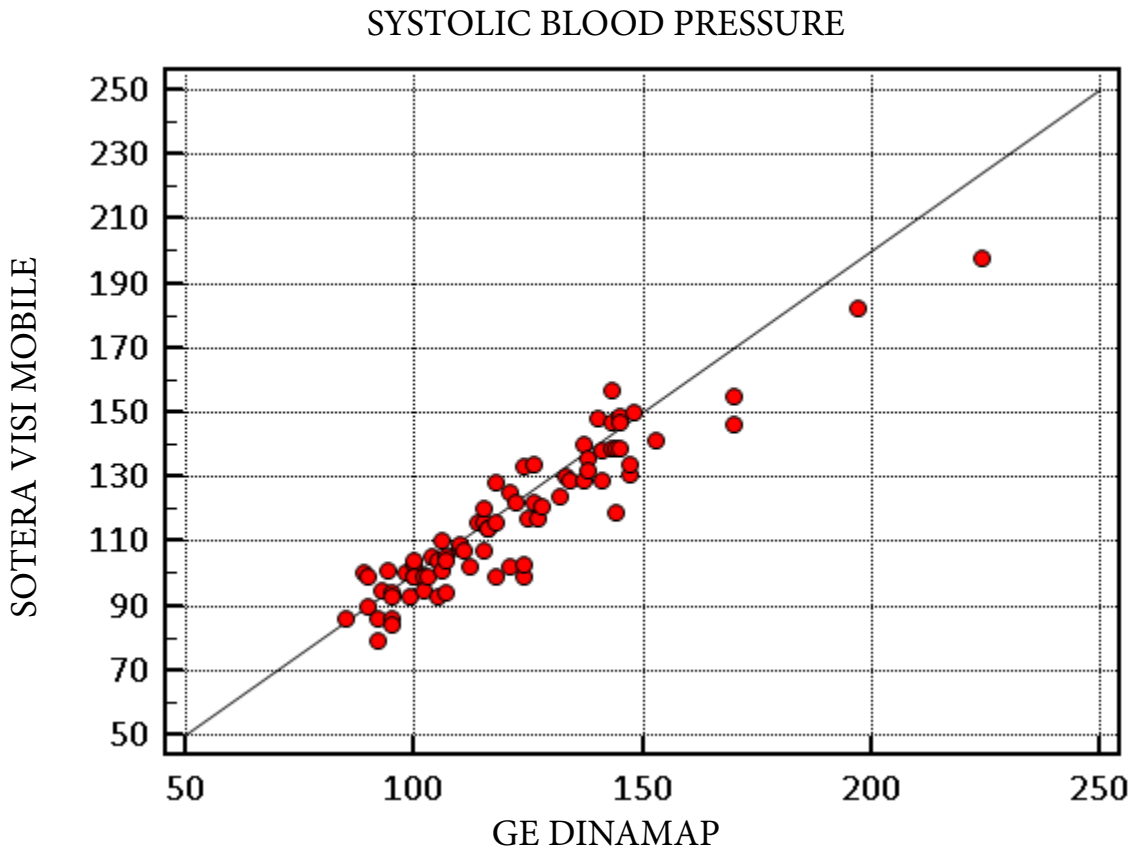

Figure 2: Comparison of the ViSi Mobile and GE DINAMAP for systolic blood pressure for 79 subjects.

Figure 3 illustrates the comparison of the ViSi Mobile and GE DINAMAP for diastolic blood pressure.

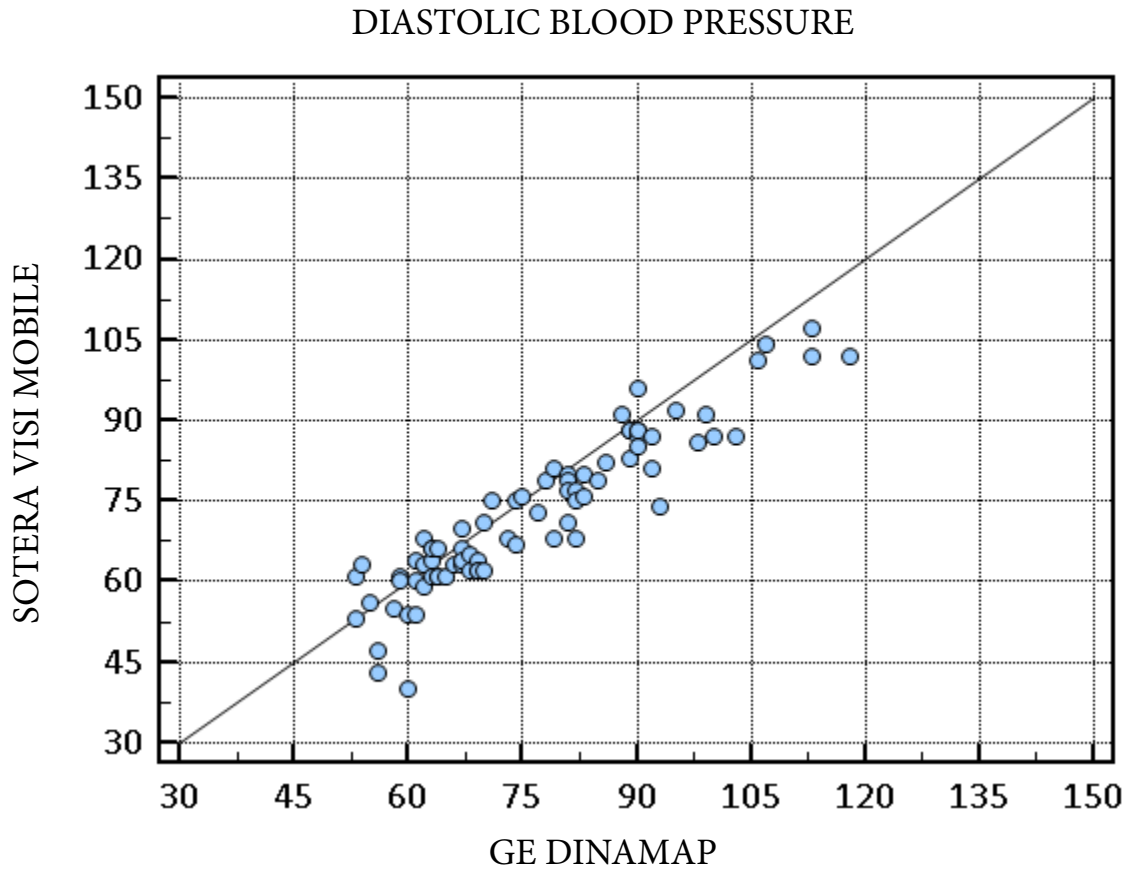

Figure 3: Comparison of the ViSi Mobile and GE DINAMAP for diastolic blood pressure for 79 subjects.

Conclusions

The mean difference between ViSi Mobile and the GE DINAMAP NIBP was 4 mmHg for both SBP and DBP. This difference, or estimated error, would not effect a clinical decision on how to treat the patient. This study demonstrates equivalence between blood pressures taken with the ViSi Mobile System and GE DINAMAP.

10200 Huennekens Street
San Diego, CA 92121
(858) 427-4620
www.soterawireless.com

PN: 6-000559-00_CO: 02806 13 AUG 15