CASMED®
FOR WHAT'S VITAL

Non-Invasive Blood Pressure Technology (NIBP): Comparative Study

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BLOOD PRESSURE BASICS 1|ONE

WHAT IS BLOOD PRESSURE?

Blood pressure is defined as the pressure of the blood against the walls of the arteries. Blood pressure results from two forces. One is created by the heart as it pumps blood into the arteries and through the circulatory system. The other is the force of the arteries as they resist the blood flow.[1]

WHAT DO BLOOD PRESSURE NUMBERS INDICATE?

- The higher (systolic) number represents the pressure while the heart contracts to pump blood to the body.
- The lower (diastolic) number represents the pressure when the heart relaxes between beats.

The systolic pressure is always stated first. For example: 118/76 (118 over 76); systolic = 118, diastolic = 76.

Blood pressure below 120 over 80 mmHg (millimeters of mercury) is considered optimal for adults. A systolic pressure of 120 to 139 mmHg or a diastolic pressure of 80 to 89 mmHg is considered "prehypertension" and needs to be watched carefully. A blood pressure reading of 140 over 90 or higher is considered elevated (high).[1]

WHY IS BLOOD PRESSURE MEASUREMENT IMPORTANT?

Throughout the world, 1 in every 4 adults suffers from hypertension, a disease that contributes to 49% of ischemic heart disease and 62% of strokes worldwide. Inadequately controlled hypertension is currently the number one attributable risk for death across the globe.[2]

> *Inadequately controlled hypertension is currently the number one attributable risk for death across the globe.*

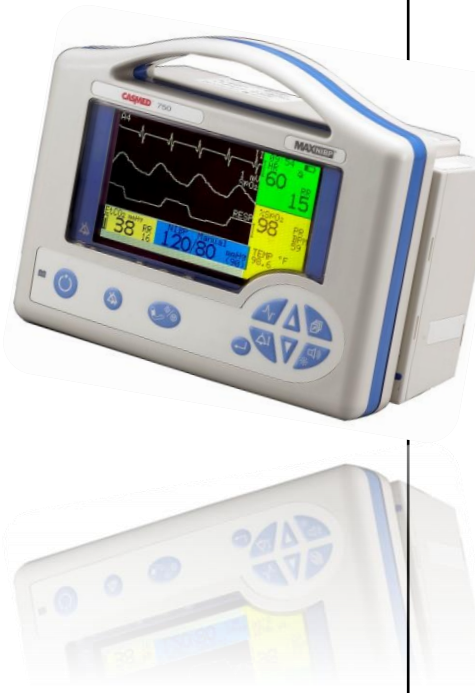
As noted in the American Heart Association (AHA) Scientific Abstract (2005), “blood pressure determination continues to be one of the most important measurements in all of clinical medicine and is still one of the most inaccurately performed. Hypertension is a major risk factor for coronary heart disease, stroke, and renal failure, and affects approximately one-third of the American population. The latest version of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood

Pressure (JNC) recommendations has drawn attention to the condition of "prehypertension," that is, people with blood pressures at the high end of the normal range, which applies to another one-quarter of the adult population. The target blood pressure for patients using antihypertensive treatment has recently been lowered for those with diabetes or renal disease. Thus, it is becoming increasingly important to be able detect small differences in blood pressure."[3]

COMMON BP MEASUREMENT TECHNIQUES 2|TWO

Blood pressure can be measured in a variety of ways. Common measurement techniques include auscultatory and oscillometric methods.

The ascultatory method works by sound. The detection and interpretation of the sounds can be accomplished by human examiners or by automated blood pressure devices.[5] The manual, or traditional auscultatory method is a technique in which a blood pressure cuff is used to occlude blood flow to the limb until flow is completely blocked. As air pressure in the cuff is released, systolic blood pressure can be determined, using a stethoscope, by the detection of first audible (Korotkoff) arterial wall sounds. Diastolic pressure is detected when audible sounds fade and disappear as air pressure in the cuff drops below the diastolic blood pressure and blood flow returns to normal.[4] The examiner records the values seen on a mercury column or gauge associated with the appearance and disappearance of Korotkoff sounds.[4] For the automated reading, manufacturers typically place a microphone in a little pocket at the edge of the cuff. Automated devices process the microphone signal using analog, digital or hybrid methods.[5]

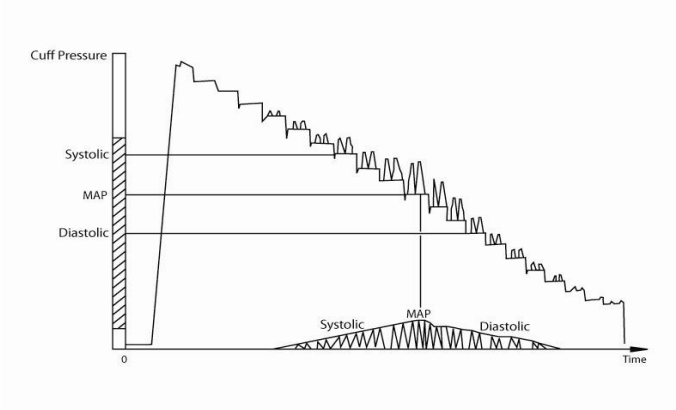


However, most automatic machines today do not use the auscultatory principle, but rather the oscillometric method, as do most automatic clinical instruments outside of special application areas like stress testing.[5]

Oscillometric instruments have neither a stethoscope nor a microphone and don't need the quiet environment necessary to detect the auscultatory sounds. They work on the principle that when the artery opens during a portion of the pressure cycle, an oscillation is superimposed on the pressure inside the cuff due to a tiny enlargement of the circumference of the limb caused by the surge of blood under the cuff.[5]

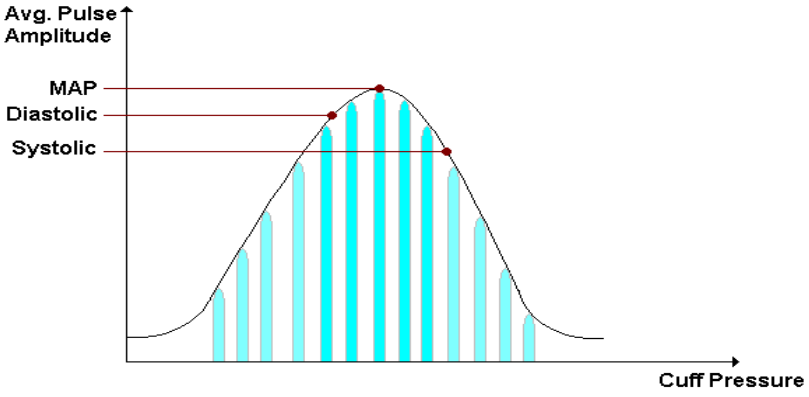
The amplitude of the oscillometric signals change over the course of the deflation of the cuff. Oscillometric devices look for oscillation amplitude of certain percentages of the maximum amplitude at mean arterial pressure (MAP), defining one percentage as the systolic point and another as the diastolic point. Alternatively, a combination of the amplitude, the slope of the increase or decrease, and some other complex factors are used to find these points. Further, several methods may be used and the results selected from the method that best meets the integrity checks established by the manufacturer.[5]

The CASMED MAXNIBP® device utilizes an oscillometric step deflation method. Unlike continuous deflation or linear bleed methods, step deflation qualifies each stage of the pressure envelope for accuracy. In the stepped deflation method, as the pressure in the cuff is released, pulsatile changes in the arterial walls are detected at decreasing cuff pressures and an oscillometric envelope is formed (see figure below).



The inflation pressure is held at each stepped decrease in pressure while the monitor matches the pulses to qualify the pulse amplitude. After the pulse amplitude is determined at the current pressure step, the monitor releases additional pressure and steps down to the next level, repeating the process of qualifying the pulse amplitude and timing. Non-matching pulses are rejected. When pulse amplitude data has been captured over a range of cuff pressures sufficient for the measurement of a subject's blood pressure, the cuff is fully deflated.

MAP is determined by measuring the point at which the matching pulse amplitude is largest. Systolic and diastolic are calculated based upon MAP and specific points on the pulse amplitude envelope.



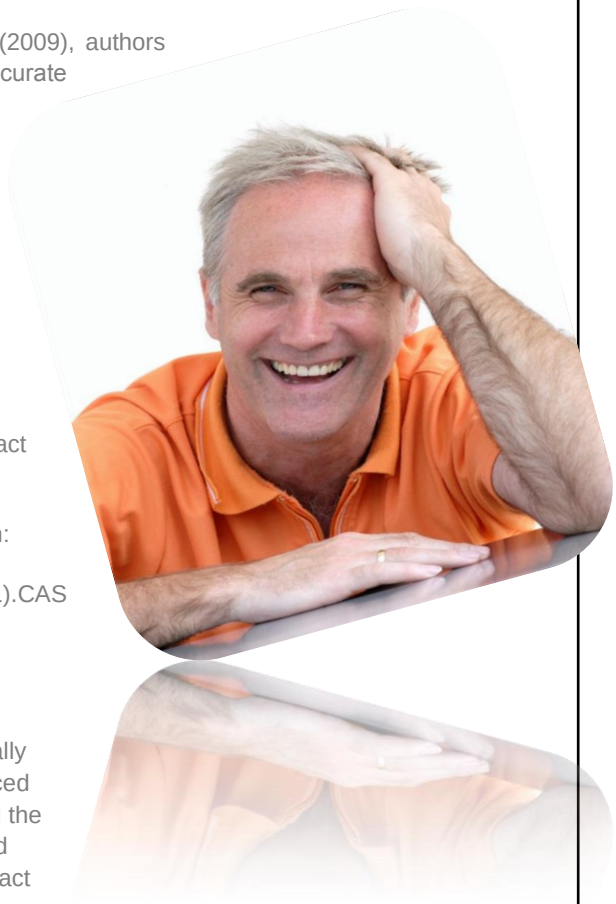
BP STUDY – MOTION TOLERANCE 3|THREE

INTRODUCTION

Non-invasive blood pressure (NIBP) monitors approved for clinical use must be tested to demonstrate compliance to one of the standards that exist for this purpose. Typically, these devices are tested against an auscultatory reference following the established protocols of either the Association for the Advancement of Medical Instrumentation (AAMI) or the British Hypertension Society (BHS).

Whichever protocol is used to clinically validate an NIBP monitor, the movements of all subjects that participate in the study are kept to an absolute minimum.

In a recent scientific statement from the American Heart Association (2009), authors suggested that “careful selection of equipment” “is essential for accurate recording.” Authors also noted that “monitors should be able to tolerate some subject movement without giving excessive error readings.” [2]



In order to evaluate non-invasive blood pressure technology for motion tolerance, a comparative study was conducted among several commonly used blood pressure monitor manufacturers.

For clinically validated NIBP monitors that are used in a transport environment, the testing performed to clinically validate the device may not accurately represent the performance of the device when operated in the presence of motion artifact. To date, a standard for validating the performance of an NIBP monitor when used in the presence of motion artifact does not exist.

This report describes the results of a comparison study conducted between:

- CASMED® Model 750 E-3MS (MAXNIBP® technology- ND+ V3.1).CAS Medical Systems, Inc., USA.
- Brand P
- Brand W

All three of the NIBP technologies used in these monitors have been clinically validated. All monitors were tested without artifact, and with simulator induced artifact. This study compares the degree to which motion artifact influenced the blood pressure measurements reported by each NIBP unit when a standard patient blood pressure profile was used and varying degrees of motion artifact were superimposed on the blood pressure signal.

METHODS

To compare the performance of the CASMED 750 (MAXNIBP technology), Brand P and Brand W when motion artifact is present, a commercially available BioTek NIBP simulator (BioTek Instruments Inc., Vermont, USA) was used. The BioTek simulator allows motion and tremor artifact to be superimposed onto the oscillometric blood pressure signal in a controlled, repeatable manner. The motion artifact injected by the BioTek simulator replicates the vibration that would result from patient transport on a smooth highway or a gravel road. The tremor artifact simulates muscular activity associated with Parkinson’s disease or shivering.

During testing, the BioTek simulator was set to a fixed blood pressure setting of 120 / 80 (93 MAP) 80 BPM, 100 % Gain, at the following artifact levels:

- No Artifact
- Motion, Highway levels 8 and 16
- Motion, Gravel Road levels 8 and 16
- Tremor, levels 8 and 16

Artifact level choices on the simulator ranged from 0-16 (0, 2, 4, 8, 16) with 16 representing the greatest amount of interference and 0 representing no interference.

Fifty (50) measurements were taken at artifact settings of 0, 8 and 16 for each of the NIBP technologies under test. The results were compiled and the following metrics were calculated and compared to determine the overall performance of each of the NIBP units under test.

- Number and percent of successful blood pressure measurements obtained
- Average time to complete each successful blood pressure measurement
- Standard Deviation of the measured blood pressure results (SYS, DIA, MAP) from baseline at no interference, and for each of the artifact settings

The figure below shows the equipment setup used to test the performance of each NIBP unit under test.

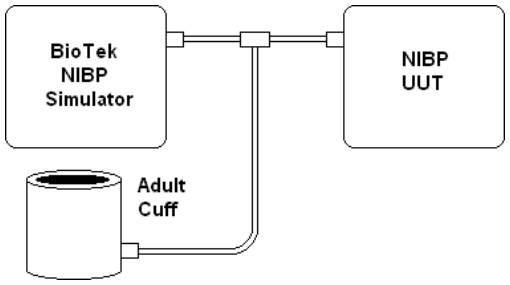


Fig. 1 – Motion Artifact Comparison Testing Equipment Setup

RESULTS

When analyzing the data in the comparative motion tolerance study, a number of factors were considered to assess each monitor's capacity to provide accurate, reliable measurements under varied levels of induced artifact.

First, the quantity and percent of each completed measurement was assessed at each artifact level. Second, the length of time required to successfully complete each blood pressure measurement at each artifact level was recorded. Last, the accuracy of the subject monitors was analyzed by measuring the standard deviation from baseline reading at each artifact level.

Fifty (50) blood pressure measurements at each motion artifact level were taken. The standard deviation (SD) was recorded from baseline for each blood pressure technology assessed. Systolic, Diastolic and Mean Arterial Pressure (SYS, DIA, MAP) were recorded. The baseline reading for each monitor was taken at the simulator setting for 120/80 (93), 80 BPM, 100% gain.

MEASUREMENT SUCCESS

Often, motion artifact will cause an error when using automated NIBP monitors, resulting in the inability to obtain a reading. This may create a problem clinically, as retaking a blood pressure may add to patient discomfort and stress. Therefore, limiting the number of times that a blood pressure cuff needs to re-inflate is beneficial.

The ability to obtain a successful reading in difficult conditions may also be of great benefit to care providers, as it allows for quick assessment, leading to earlier intervention and treatment. The figure below shows the percentage and number of successful readings (out of 350 total readings) for each monitor tested under a variety of simulator settings.

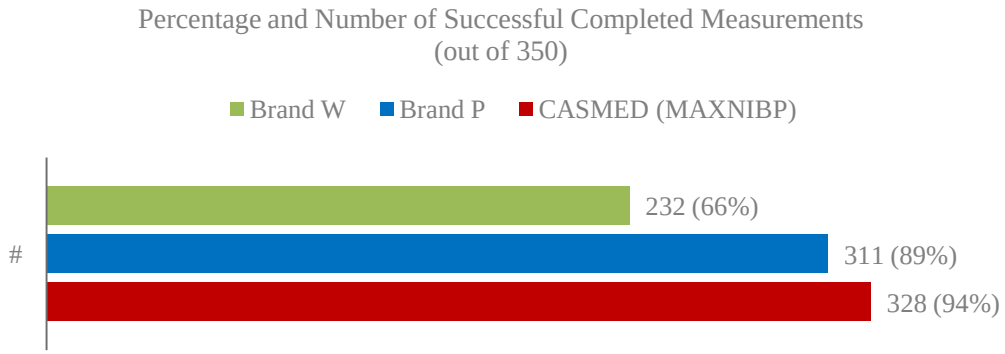


Fig. 2 – Overall Percentage and Number of Successfully Completed Measurements Out of a Total of 350 Measurements Taken

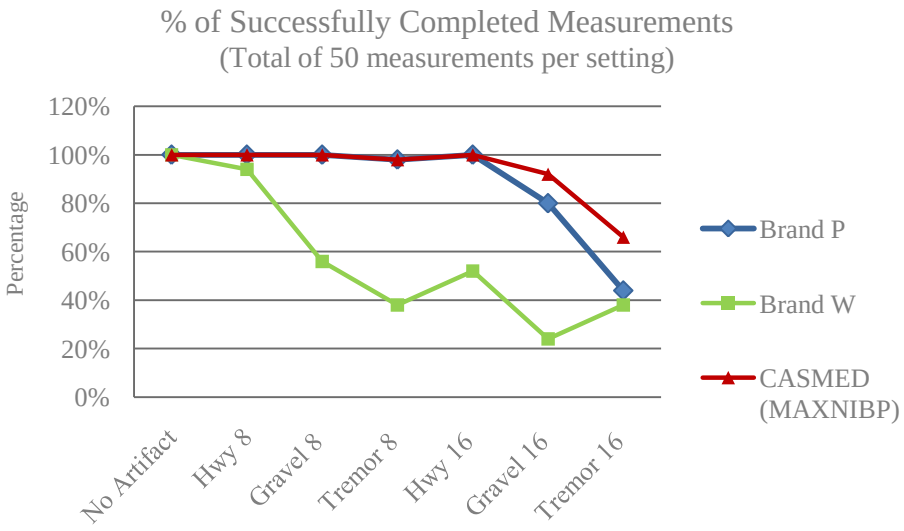


Fig. 3 – Percent of Successfully Completed Measurements at each Setting for All NIBP Units Tested

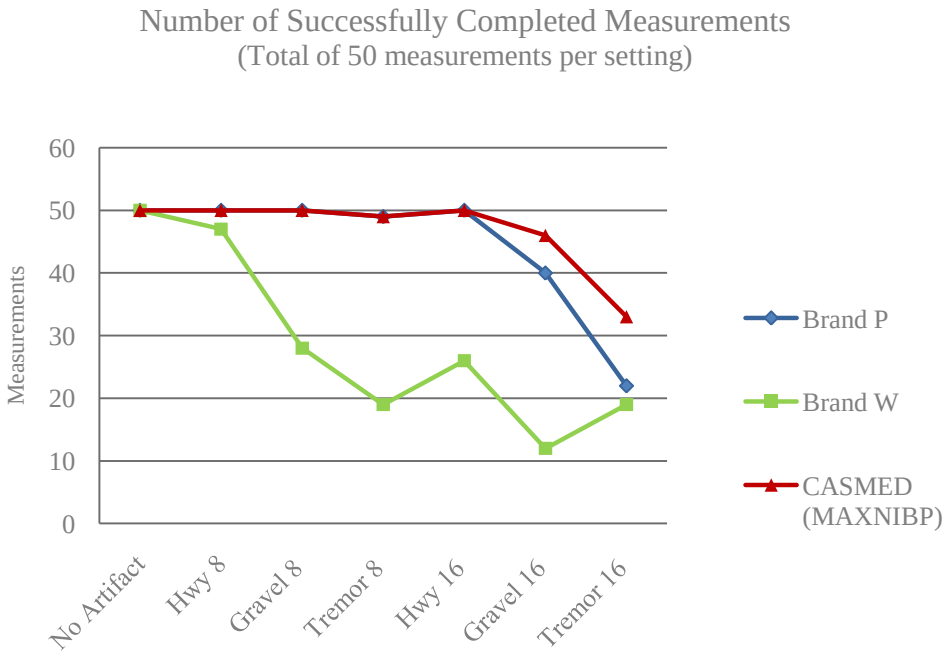


Fig. 4 – Number of Successfully Completed Measurements at each Setting for All NIBP Units Tested

Figures 2, 3 and 4 demonstrate that the CASMED MAXNIBP technology exhibited a greater tolerance to motion artifact, producing the highest number and percentage of successfully completed measurements at each artifact level, and in total over all artifact levels.

Notably, at artifact level Tremor 16, both Brand P and the Brand W fell below the 50 percent success rate for successful measurement completion (see figure 3).

MEASUREMENT TIME

As expected, as the induced artifact level increases, the time required to complete each blood pressure measurement also increases. The figure below shows the average blood pressure measurement time in seconds for each NIBP unit under test at the various motion artifact settings on the BioTek NIBP simulator. If the unit was unable to complete a measurement, the time recorded was standardized at 120 seconds.

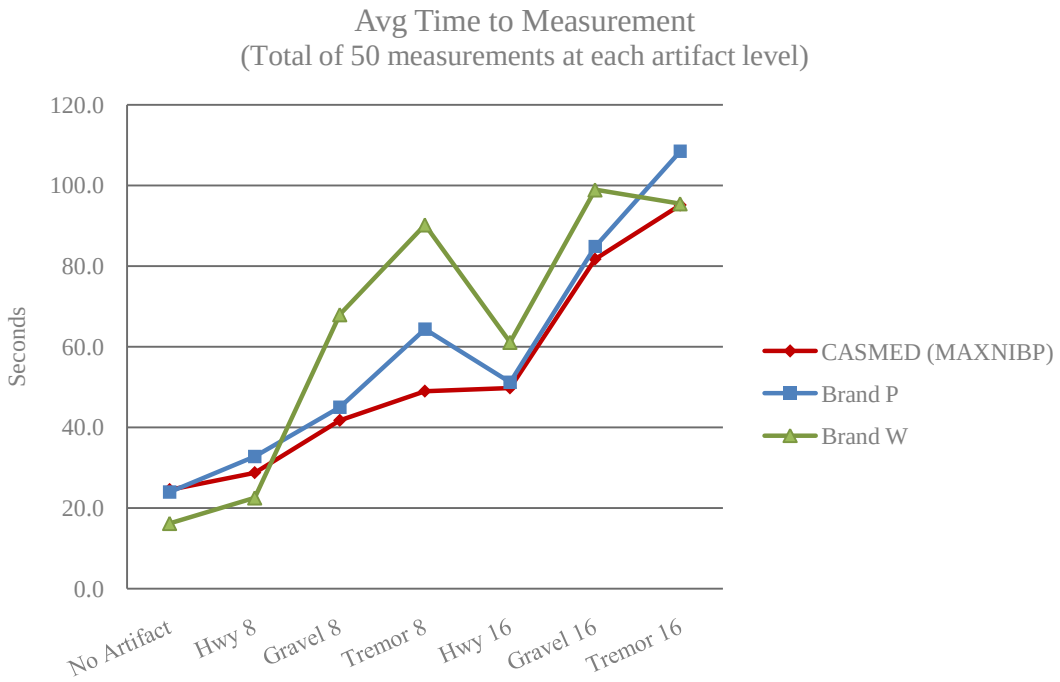


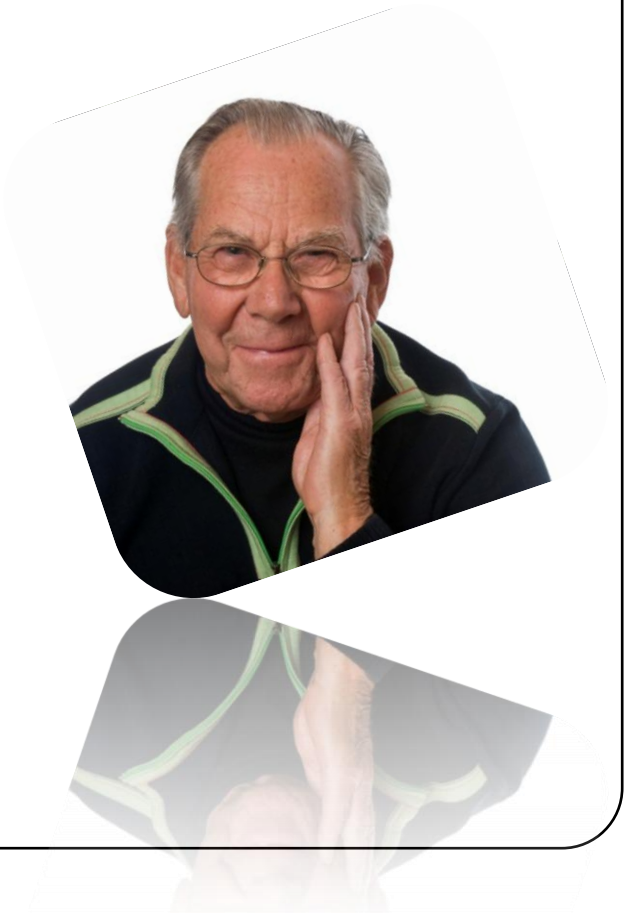
Fig. 5 – Average Time to Measurement at Each Artifact Level for All NIBP Units Tested

As demonstrated in Figure 5 above, the CASMED monitor with MAXNIBP technology outperformed the other monitors tested, having the lowest time to complete a measurement in the comparative series.

STANDARD DEVIATION

The graphs below show the standard deviation from baseline of measured blood pressure results for all three monitors under simulated conditions corresponding to one of three types of artifact (highway, gravel or tremor) and two levels (8,16) of motion artifact.

In an ideal situation with no artifact present, the standard deviation (variation) of each measured blood pressure parameter (SYS, DIA, MAP) is zero when a fixed blood pressure profile is used. As noise influences the measurement, however, the standard deviation of the measured blood pressure value begins to increase. By comparing the standard deviations of each NIBP monitor at various artifact settings, it is possible to see how well each device handles the interference caused by the introduced artifact.



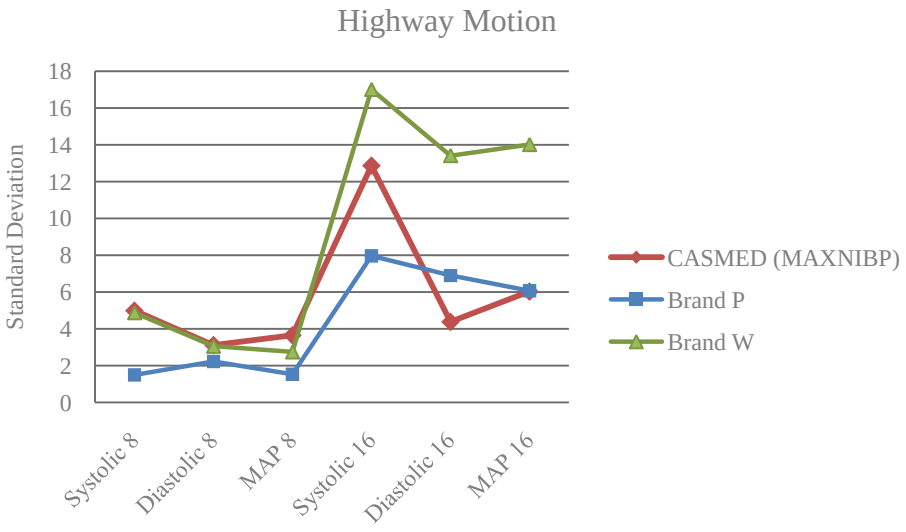


Fig. 6 – Standard Deviation of Systolic, Diastolic and MAP at Highway Simulator Levels 8 & 16 for all Monitors Measured

As seen in figure 6, with Highway motion at level 8, all monitors appeared to produce similar results, with the Brand P monitor producing more favorable results for systolic SD (1.5) versus CASMED MAXNIBP (4.99) and Brand W (4.88).

As motion artifact increased to level 16, Brand P produced the lowest standard deviation for systolic BP (7.97) followed by CASMED (12.87) and Brand W (17). For diastolic BP at level 16 highway, CASMED showed the lowest standard deviation (4.38) followed by Brand P (6.9) and Brand W (13.41). MAP standard deviations at level 16 highway showed CASMED and Brand P at similar levels (6.03, 6.07) respectively, with Brand W standard deviation significantly higher at 14.01.

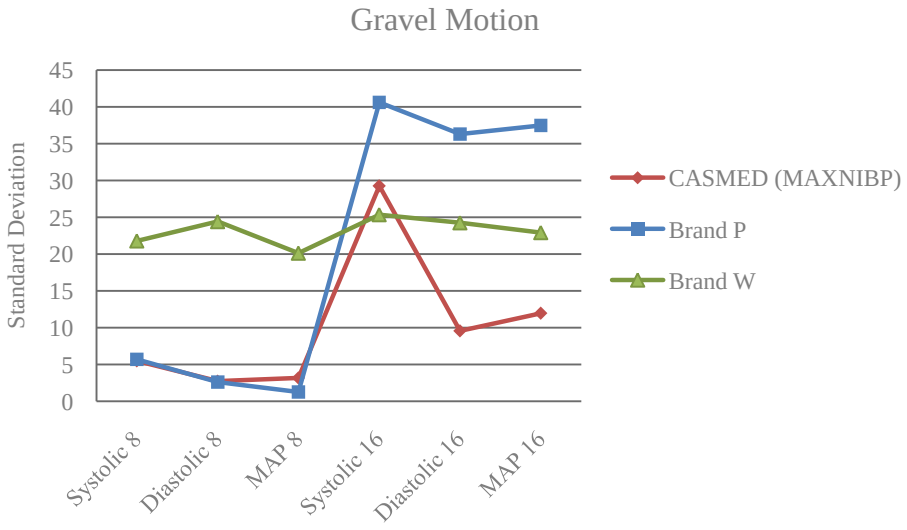


Fig. 7 – Standard Deviation of Systolic, Diastolic and MAP at Gravel Simulator Levels 8 & 16 for all Monitors Measured

In the (figure 7) Gravel motion standard deviation comparison, CASMED had the lowest overall standard deviation results signifying the greatest level of accuracy. Level 8 CASMED results for SYS, DIA and MAP (5.5, 2.74, 3.18) respectively, were similar to Brand P results of (5.72, 2.62, 1.28) respectively. Brand W returned significantly higher standard deviations of (21.8, 24.42, 20.14). At artifact levels of 16, CASMED and Brand W had similar Systolic SD (29.25, 25.36) respectively, but CASMED demonstrated significantly lower SD for DIA (9.57) than Brand P (36.31) and Brand W (24.26). MAP measurements followed a similar pattern with CASMED (11.97) demonstrating significantly lower SD readings than Brand P (37.47) and Brand W (22.93).

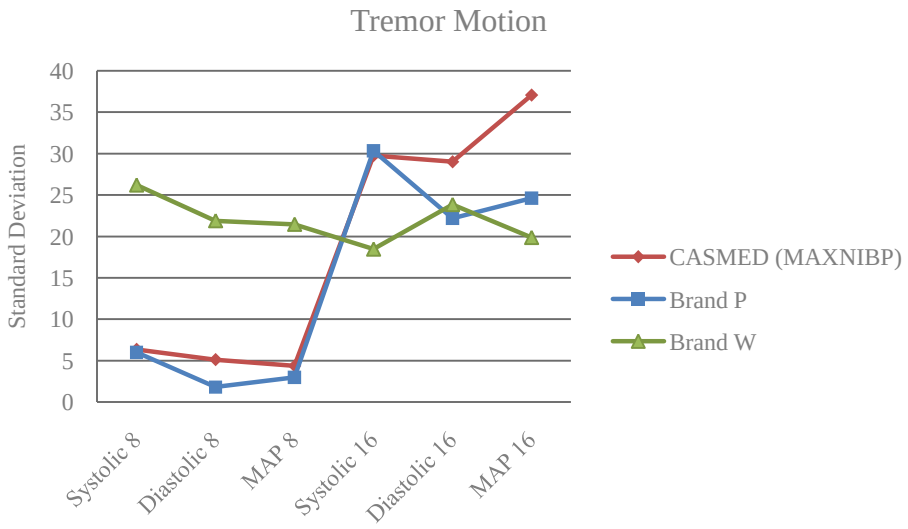


Fig. 8 – Standard Deviation of Systolic, Diastolic and MAP at Tremor Simulator Levels 8 & 16 for all Monitors Measured

Figure 8 demonstrates Tremor motion comparisons between the subject technologies. At level 8, CASMED and Brand P demonstrated similar SD for all measurements (ranging from 1.8 – 6.6 for all measurements), with Brand W SD ranging from 21.46 – 26.19. At level 16, Brand W maintained a similar level of SD as with level 8 (18.47 – 23.84) while CASMED and Brand P SD ranged from 22.17 – 37.07.

Interestingly, figures 7 and 8 demonstrate that the Brand W SD remains consistently high across all levels of motion artifact measured for Gravel and Tremor, while CASMED and Brand P have consistently lower SD at lower levels of artifact, with SD increasing, as expected, with higher levels of artifact.

The figures below present a graphical comparison of the total standard deviation for the SYS, DIA and MAP readings as measured by the subject monitors at each of the motion artifact settings.

In figures 9 through 12 the CASMED MAX NIBP technology demonstrated overall lower SD across the sum of all artifact levels (no artifact, Hwy 8, Hwy16, Gravel 8, Gravel16, Tremor 8, Tremor 16) for each of the SYS, DIA and MAP readings.

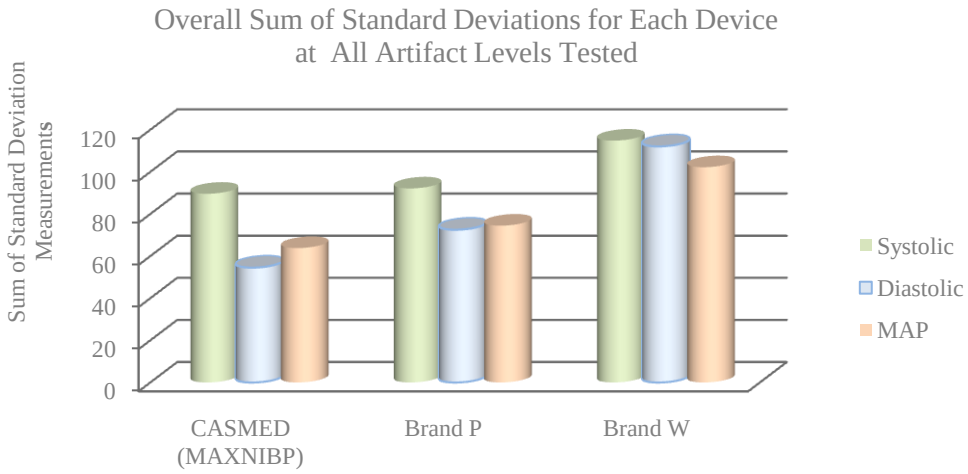
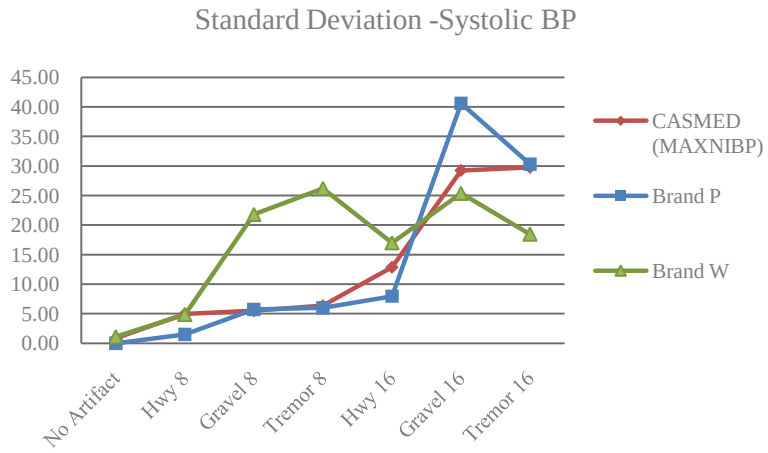
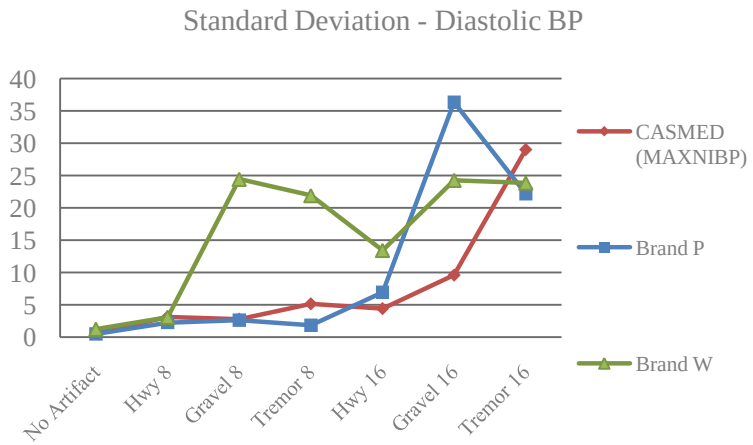


Figure 9 – Comparison of Total Systolic Standard Deviations for all Artifact Levels



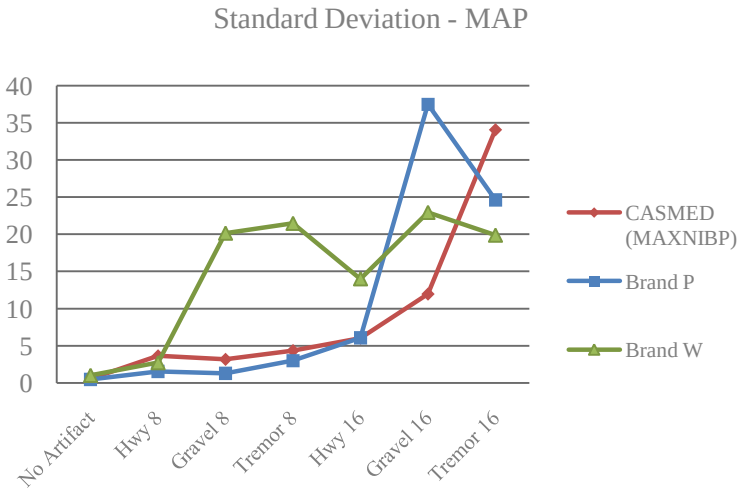
Systolic - SD			
	CASMED (MAXNIBP)	Brand P	Brand W
No Artifact	0.86	0	1.13
Hwy 8	4.99	1.5	4.88
Gravel 8	5.5	5.72	21.8
Tremor 8	6.36	6.01	26.19
Hwy 16	12.87	7.97	17
Gravel 16	29.25	40.6	25.36
Tremor 16	29.77	30.33	18.47
Total	**89.6**	**92.13**	**114.83**

Figure 10 – Comparison of Systolic Standard Deviations



Diastolic - SD			
	CASMED (MAXNIBP)	Brand P	Brand W
No Artifact	0.6	0.48	1.22
Hwy 8	3.12	2.23	3.06
Gravel 8	2.74	2.62	24.42
Tremor 8	5.12	1.81	21.89
Hwy 16	4.38	6.9	13.41
Gravel 16	9.57	36.31	24.26
Tremor 16	29.01	22.17	23.84
Total	**54.54**	**72.52**	**112.1**

Figure 11 – Comparison of Diastolic Standard Deviations



MAP- SD			
	CASMED (MAXNIBP)	Brand P	Brand W
No Artifact	0.56	0.48	1.05
Hwy 8	3.65	1.54	2.75
Gravel 8	3.18	1.28	20.14
Tremor 8	4.36	3	21.46
Hwy 16	6.03	6.07	14.01
Gravel 16	11.97	37.47	22.93
Tremor 16	34.07	24.62	19.87
Total	**66.82**	**74.46**	**102.21**

Figure 12 – Comparison of MAP Standard Deviations

CONCLUSION

A blood pressure artifact tolerance study was conducted, comparing non-invasive blood pressure technologies from CAS Medical Systems, Inc. [CASMED 750 monitor (MAXNIBP technology)], Brand P, and Brand W. All monitors were tested without artifact, and with simulator (BioTek Instruments) induced artifact.

A number of factors were analyzed to assess each monitor's capacity for providing accurate, reliable measurements under varied levels of motion artifact. Comparisons included successful completion of measurements, length of time required to complete each blood pressure measurement, and accuracy of the subject monitors by comparing the standard deviation from baseline reading for each monitor with the introduction of induced motion artifact.

The results of our comparative study suggest that the CASMED MAXNIBP demonstrated the best overall rating for the sum of the performance metrics analyzed.

Overall, the CASMED technology outperformed Brand P and Brand W in total accuracy (SD from baseline) for SYS, DIA and MAP measurements when analyzed separately for all artifact conditions. When SYS, DIA and MAP were combined and analyzed for each category of artifact (Highway, Gravel and Tremor), Brand P exhibited the lowest total SD for Tremor and Highway, and CASMED exhibited the lowest SD for Gravel artifact.

CASMED had the highest overall number and percentage (94%) of completed measurements (see figure 2), and produced overall measurements more quickly than either the Brand P or Brand W monitors (see figure 5).

Interestingly, the SD for the Brand W monitor with highway artifact tracked in a similar fashion to both CASMED and Brand P (performing better at lower artifact levels and worse at higher artifact levels), but for both the Gravel and Tremor artifact, exhibited an almost straight line standard deviation across all artifact levels regardless of intensity of simulated artifact (see figures 6,7 & 8).

Summary - Ratings in Each Category (Best 1, Worst 3)			
	CASMED (MAXNIBP)	Brand P	Brand W
Completed Readings #	1	2	3
Completed Readings %	1	2	3
Time to Reading	1	2	3
Systolic SD -AAL	1	2	3
Diastolic SD - AAL	1	2	3
MAP SD - AAL	1	2	3
Highway SD - CBPM	2	1	3
Gravel SD - CBPM	1	2	3
Tremor SD - CBPM	2	1	3
Total	**11**	**16**	**27**
AAL = All artifact levels (No artifact, Highway, Gravel, Tremor)			
CBPM = Combined Blood Pressure Measurements (SYS, DIA & MAP)			

When assessing a monitor for performance in a clinical setting, a number of variables should be considered prior to purchasing. When deciding upon non-invasive blood pressure technologies, accuracy, the ability to obtain an accurate measurement and the length of time required for a measurement are important starting points for evaluation.

ABOUT THE AUTHORS 4|FOUR

Contributors to this white paper included Wayne Hooper, MSEE; Suzanne Carroll BS, CG, MBA; and Ray Banas, RRT.

- Wayne has over 24 years of experience in the field of electrical engineering, with 10 of those years specializing in algorithm and hardware development focused on non-invasive blood pressure.
- Suzanne has over 15 years of medical device product marketing experience as well as clinical experience in cytogenetics.
- Ray has over 10 years of clinical experience, in addition to 8 years of experience in product marketing in the medical device industry.

BIBLIOGRAPHY 5|FIVE

1. **American Heart Association.** *American Heart Association.* [Online] [Cited: January 26, 2010.] http://www.americanheart.org/presenter.jhtml?identifier=4473.

2. *Ambulatory Blood Pressure Monitoring in Children and Adolescents: Recommendations for Standard Assessment. A Scientific Statement From the American Heart Association.* **Elaine Urbina, MD et al.** Dallas, TX : Hypertension: Journal of the American Heart Association, August 4, 2008, 52 Vol. 2008. 433-451.

3. *Recommendations for Blood Pressure Measurement in Humans and Experimental Animals. A Scientific Statement From the American Heart Association.* **Thomas G. Pickering, MD et al.** Dallas, TX : Hypertension: Journal of the American Heart Association, 2005, 45:45:142.

4. *Auscultatory Method - Methods of Blood Pressure Measurement.* SevereHypertension.net [Online] [Cited February 19, 2010] http://www.severehypertension.net/hbp/more/auscultatory-method/

5. *Guest Commentary: How blood-pressure devices work.* EDN.com [Online] [Cited: February 19, 2010] http://www.edn.com/article/CA511468.html