

(P-5)
Non-Invasive
Blood Pressure
Monitors:
Comparative
Study



NIBP MONITORS - COMPARATIVE STUDY

A study was designed to compare the performance of non-invasive blood pressure technologies found in a variety of commonly used vital signs monitors. This study compared the CASMED 750 (MAXNIBP® technology), against Brand P, Brand W, Brand G, and Brand O when motion artifact was introduced. To introduce artifact, 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 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 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 monitors under test. The results were compiled and the following metrics were calculated and compared to determine the overall performance of each unit tested.

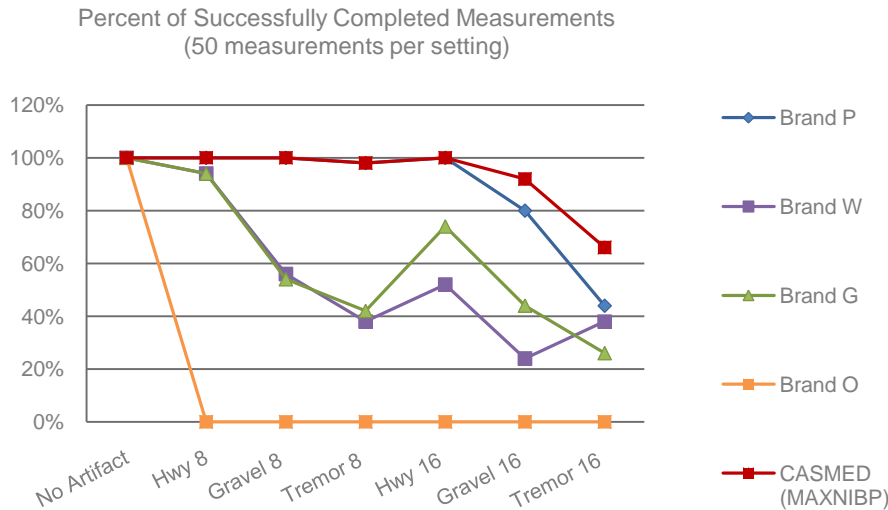
- *Number and percent of successful blood pressure measurements obtained*
- *Standard Deviation (SD) of the measured blood pressure results (SYS, DIA, MAP) from baseline for each of the artifact settings*



SUCCESSFULLY COMPLETED MEASUREMENTS

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 improved workflow, and earlier intervention and treatment. The figure and table below show the percentage and number of successful readings for each monitor tested under a variety of simulator settings.



SUMMARY OF MEASUREMENT SUCCESS FINDINGS

The CASMED MAXNIBP technology exhibited the greatest tolerance to motion artifact when compared to the other monitors tested, producing the highest percentage of successfully completed measurements at each artifact level.

CASMED with MAXNIBP technology was the only monitor that had a measurement success rate of greater than 50 percent.

Notably, at artifact level Tremor 16, CASMED with MAXNIBP technology was the only monitor that had a measurement success rate of greater than 50 percent. Brand O was unable to complete a single measurement at any of the tested artifact levels.

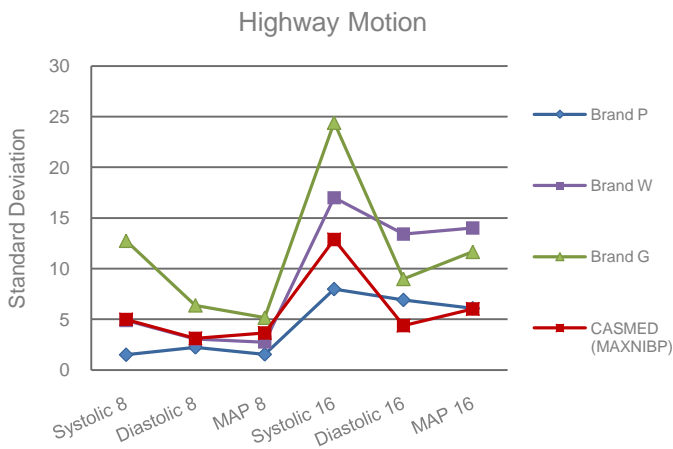
# Successfully Completed Measurements	Brand P	Brand W	Brand G	Brand O	CASMED (MAXNIBP)
No Artifact	50	50	50	50	50
Hwy 8	50	47	47	0	50
Gravel 8	50	28	27	0	50
Tremor 8	49	19	21	0	49
Hwy 16	50	26	37	0	50
Gravel 16	40	12	22	0	46
Tremor 16	22	19	13	0	33
TOTAL	311	201	217	50	328

% Successfully Completed Measurements	Brand P	Brand W	Brand G	Brand O	CASMED (MAXNIBP)
No Artifact	100%	100%	100%	100%	100%
Hwy 8	100%	94%	94%	0%	100%
Gravel 8	100%	56%	54%	0%	100%
Tremor 8	98%	38%	42%	0%	98%
Hwy 16	100%	52%	74%	0%	100%
Gravel 16	80%	24%	44%	0%	92%
Tremor 16	44%	38%	26%	0%	66%
AVG %	89%	57%	62%	14%	94%

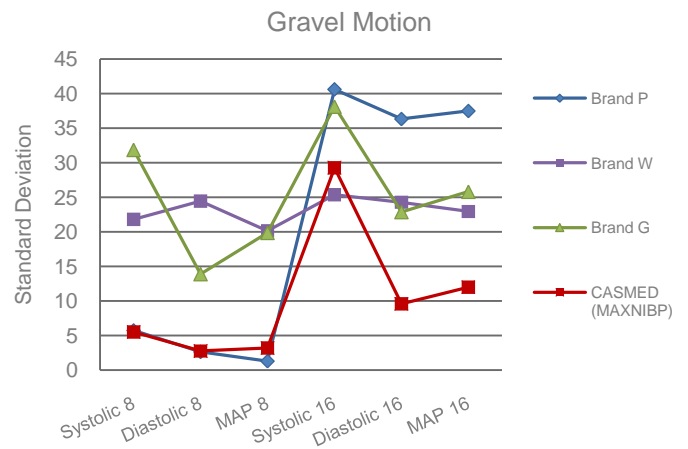
STANDARD DEVIATION

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

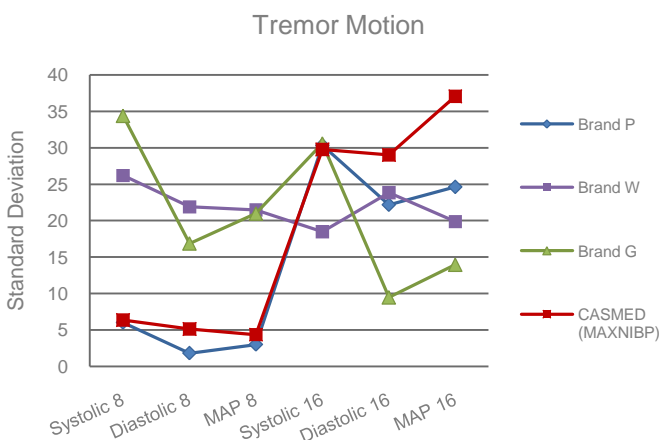
In an ideal situation with no artifact present, the standard deviation (variation) of each measured blood pressure parameter (SYS, DIA, MAP) is zero when a fixed blood pressure profile is used. As noise influences the measurement, however, the standard deviation of the measured blood pressure value begins 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.



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



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



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

SUMMARY OF STANDARD DEVIATION ACCURACY FINDINGS

The CASMED Monitor with MAXNIBP technology exhibited a very high degree of accuracy, as noted by low SD from baseline, for all levels and types of artifact tested.

CONCLUSION

A number of factors were analyzed to determine accuracy and reliability of NIBP used in several vital signs monitors. Monitor measurements were recorded under varied levels of simulator induced artifact. Comparison data included successful completion of measurements, and accuracy by comparing the standard deviation from baseline reading for each monitor with the introduction of induced motion artifact.

Summary of Results - (completed measurements are out of 350 total measurements – 50 per setting, SD measurements are total of Avg. SD for all artifact settings). NR = No Readings Successfully Completed. CBPM = Total of Combined Blood Pressure Measurements for all Artifact Settings (SYS, DIA & MAP, Levels 8 &16)

	CASMED MAXNIBP	Brand P	Brand W	Brand G	Brand O
# Completed Measurements	328	311	201	217	50
% Completed Measurements	94%	89%	57%	62%	14%
Highway SD - CBPM	35.04	26.21	55.11	69.35	NR
Gravel SD - CBPM	62.21	124	138.91	152.34	NR
Tremor SD - CBPM	111.69	87.94	131.72	126.29	NR

Summary of Results – (1-Best, 5-Worst in each category)

	CASMED MAXNIBP	Brand P	Brand W	Brand G	Brand O
# Completed Measurements	1	2	4	3	5
% Completed Measurements	1	2	4	3	5
Highway SD – CBPM	2	1	4	3	5
Gravel SD - CBPM	1	2	3	4	5
Tremor SD - CBPM	2	1	4	3	5
Sum of results	7	8	19	16	25

The results of our comparative study suggest that the CASMED MAXNIBP demonstrated the best overall rating for the sum of the performance metrics analyzed. Brand O was unable to successfully complete a measurement when any levels of artifact used in the test were introduced.

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

Test Data on file 4-15-2010.