Performance Of The CAS Oscillometric Algorithm When Compared Against Various Commercially Available NIBP Simulators

Introduction

As the use of automated oscillometric non-invasive blood pressure (NIBP) monitors becomes more wide spread, so does the use of oscillometric NIBP simulators. The main function of an oscillometric NIBP simulator is to dynamically reproduce the pressure profile of a live subject during a blood pressure measurement cycle. A common question that arises when using an NIBP simulator is, "why are the results produced by my blood pressure monitor different than the settings on the NIBP simulator?"

This paper will explore the underlying factors that lead to the disagreement between the blood pressure measurement results acquired by an NIBP monitor using the oscillometric method and the settings on an oscillometric NIBP simulator. Specifically, this paper will address the blood pressure measurement differences between the CAS oscillometric blood pressure measurement algorithm and various commercially available NIBP simulators.

By comparing the results produced by the CAS oscillometric blood pressure measurement algorithm to settings on various simulators, an offset measurement table of expected results will be created for each NIBP simulator. This table can then be used to establish an expected range of performance between the CAS NIBP algorithm and the settings on a particular NIBP simulator.

Background

General Description of the Oscillometric Method

The oscillometric method measures blood pressure by monitoring the pulsatile changes in pressure that are caused by the flow of blood through an artery that is restricted by an occluding cuff. At the start of a measurement, the cuff around a subject's limb is inflated to a pressure that completely occludes the underlying artery. The cuff is then deflated in a controlled manner. As the pressure in the cuff decreases, blood begins to flow through the artery.

The increasing blood flow causes the amplitude of the pressure pulses detected by the cuff to increase; refer to figure 1. As the pressure in the cuff decreases further, the pulses reach a maximum amplitude ($\mathbf{A_m}$). The pressure in the cuff that corresponds to the point of maximum oscillation has been shown to correlate to a subject's mean arterial pressure (MAP) [1, 2]. As the pressure in the cuff is decreased further, the pulses begin to decrease in amplitude. The rising and falling amplitude of the pressure pulses creates an envelope that is used to determine the subject's systolic (P_s) and diastolic (P_d) pressures.

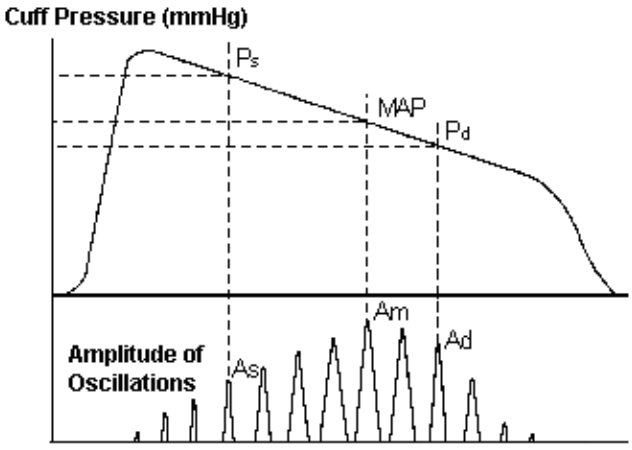

Figure 1 - Cuff pressure and oscillations in cuff pressure ($\mathbf{A_s}$, $\mathbf{A_m}$ and $\mathbf{A_d}$) used to identify a subject's Systolic (P_s), MAP and Diastolic (P_d) pressures.

The CAS oscillometric algorithm determines a subject's systolic and diastolic pressures by locating the points on the pulse pressure envelope that correspond to predetermined percentage of the maximum amplitude (A_m).

General Principles of an Oscillometric NIBP Simulator

The main function of an oscillometric NIBP simulator is to dynamically reproduce the pressure profile of a live subject during a blood pressure measurement cycle. An oscillometric NIBP simulator accomplishes this by creating a series of pulses that vary in amplitude as a function of cuff pressure. The relationship between cuff pressure

and the varying amplitude of each pressure pulse is made to match, as close as possible, the response that would occur from a live subject during a blood pressure measurement. The manufacturers of NIBP simulators use various means to create the pulsatile pressure changes that are detected by the NIBP monitor. Some simulator manufacturers use an audio transducer (speaker), some use a stepper motor to pulse a piston and some use a cam to push against an air bladder to create these pressure pulses. How these pressure pulses are created is less important than how well these pressure pulses and the corresponding pressure profile emulate the response of an actual subject. Ultimately it is how repeatable an NIBP simulator is that determines how useful it is as a test platform for evaluating the performance of an NIBP monitor.

A typical test setup between an NIBP monitor and an NIBP simulator can be seen in figure 2.

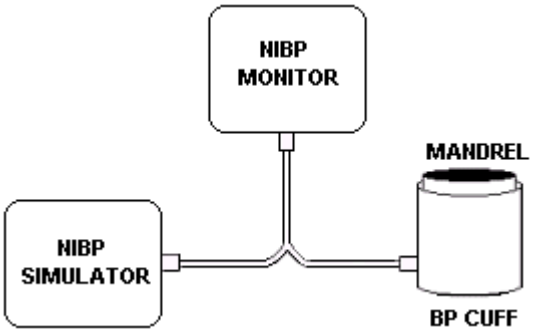

Figure 2 – Typical Setup For An NIBP Monitor Test Using An NIBP Simulator

The NIBP monitor in figure 2 is connected directly to the simulator through a pneumatic hose. The blood pressure cuff wrapped around a mandrel is there strictly to provide an appropriate sized air volume. Some NIBP simulators have an internal air volume and the use of an external blood pressure cuff is not required.

Discussion

Before an NIBP monitor is approved by the Food and Drug Administration (FDA) for clinical use, evidence must be supplied to the FDA that clinical trials have been performed on the blood pressure monitor. The current accepted standard used to establish clinical accuracy is the AAMI SP10:2002. When using an auscultatory reference the SP10 standard requires that 3 blood pressure measurements be taken on 85 subjects and that these measurements be compared against the averaged results acquired by 2 trained observers. To pass the more stringent requirements of the SP10 standard (Method 2), 68 percent of the measurements reported by the NIBP monitor must be within less than 10 mmHg as compared to the results obtained by the trained observers.

So what causes the discrepancy between a blood pressure monitor that has been cleared by the FDA for clinical use and an NIBP simulator?

Some variation in blood pressure measurement results can be expected. This variation is mainly caused by the sampling error that can be attributed to the way the oscillometric method is implemented.

Ideally, the oscillometric algorithm would be allowed to sample the pulse amplitude at every cuff pressure along the measurement profile; however, in practice this is not practical. There are limits to how long the blood flow in a limb can be restricted by an occluding cuff. So compromises are made to acquire as many pressure pulses as possible to achieve an accurate blood pressure measurement and still maintain the safety and comfort of the subject.

An example of a typical pulse pressure envelope acquired from a normotensive adult subject during an oscillometric blood pressure measurement can be seen in figure 3.

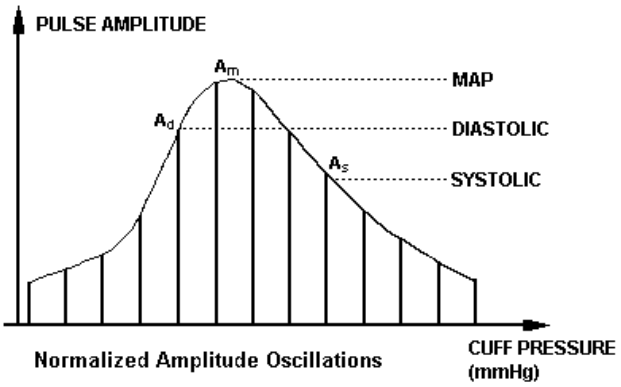

Figure 3 – Pulse Pressure Envelope Produced By a Normotensive Adult Subject During An Oscillometric Blood Pressure Measurement

Let us see how the stepped down implementation of the oscillometric method affects the accuracy of an oscillometric blood pressure reading. What stepped down means is that discrete cuff pressures are held while pressure pulses are qualified; then the pressure in the cuff is reduced to the next pressure step. While this does increase the noise immunity of the

oscillometric algorithm, it does add a slight bit of uncertainty to the developing pulse pressure envelope. Since it cannot be guaranteed that a sample will be acquired precisely at the cuff pressure corresponding to the peak amplitude, an estimate of the peak amplitude and the corresponding cuff pressure must be made. This approximation adds a slight degree of error to the determination of the mean arterial pressure (MAP). Since the mean arterial pressure is used to derive both the systolic and diastolic pressures, any error in the approximation of the MAP is carried through to the derivation of the systolic and diastolic pressures as well.

The same problem arises when using the linear bleed method. The blood pressure monitor cannot allow the air pressure in the cuff to decrease so slowly that there is a pressure pulse at every cuff pressure. Once again an estimate of the maximum pressure pulse amplitude must be made. As with the stepped down method, the process of estimating the peak amplitude of the pressure profile induces some degree of error into the measurement.

Even if an NIBP simulator was capable of producing the same pressure profile every time a simulation was performed, the process of approximating the MAP would add some degree of variation in the final measured results.

In practice this variation is not a significant source of error. Table 1 shows the results from 100 measurements taken using the CAS oscillometric algorithm and a DNI Nevada NIBP simulator. The NIBP simulator was set to adult mode with a blood pressure setting of 120 mmHg systolic, 80 mmHg diastolic and a pulse rate of 80 beats per minute (BPM).

Adult Mode - 120/80 (93) 80 BPM

	Systolic	Diastolic	MAP
Average	117.62	80.96	91.68
Mean Difference	-2.38	0.96	1.68
Standard Deviation	1.05	0.49	0.77
Max Error One STD	3.43	1.45	2.45

Table 1 – Results from 100 measurements taken using the CAS oscillometric algorithm and the DNI Nevada simulator (all values are in mmHg)

What is important to note from Table 1, is the standard deviation of the measured results. The standard deviation represents the true measurement error between the oscillometric algorithm and the NIBP simulator. The mean difference is a constant offset that can be accounted for if the performance between the NIBP monitor and the simulator has been previously established.

So what contributes to the major source of error when using an NIBP simulator?

The major source of error between an NIBP simulator and an oscillometric blood pressure monitor is caused by the way the two devices create and interpret the pulse pressure envelope. This difference translates directly into the mean difference error between the monitor's results and the setting on the NIBP simulator.

Manufacturers of oscillometric blood pressure monitors all use proprietary methods to determine the systolic and diastolic pressure values. The same applies to manufacturers of NIBP simulators, but with simulators the difference is in the way the pulse pressure envelopes are created.

The most common criteria used to determine a subject's systolic and diastolic pressures when using the oscillometric method is to identify these pressure values as a percentage of the maximum pressure oscillation (A_m); refer to figure 3. Typically, the systolic blood pressure is identified as the cuff pressure that is greater than MAP where the amplitude of the pulse pressure envelope is equal to 50 percent of the maximum oscillation (A_m). The diastolic blood pressure is identified as the cuff pressure that is less than MAP where the amplitude of the pulse pressure envelope is equal to 80 percent of the maximum oscillation.

A study was conducted in 1982 on 23 adult subjects[3] in an attempt to determine the precise ratios that correspond to the oscillometric, systolic and diastolic pressures. This study used the auscultatory method as a reference to determine the subject's actual blood pressure. When the blood pressure measurement results were compared to the amplitude of the oscillometric pulse pressure envelope, the ratios of the maximum pressure oscillation that corresponded to the systolic and diastolic pressure points were found to range from 57 to 45 percent and from 82 to 74 percent respectively. This study demonstrates the wide range of ratios that can be used to accurately calculate the systolic and diastolic pressures.

When an oscillometric algorithm is in the process of being fine-tuned, the ratios used to determine the systolic and diastolic pressures are based on data acquired from a particular group of subjects. As no two groups of subjects will yield the same results, each manufacturer will arrive at a slightly different value for the ratios that are used to determine the systolic and diastolic pressures.

If the algorithm used by a particular blood pressure monitor agrees with the pulse pressure envelope generated by the simulator, then the measured results reported by the monitor and the settings on the simulator will be within a clinically acceptable margin of error and should have a mean difference of no more than 5 mmHg. If the pulse pressure envelope generated by the simulator does not agree with the selection criteria used by the monitor to determine the systolic and diastolic pressure values, the results reported by the monitor can easily have a mean difference error that is greater than 10 mmHg.

There can be a disagreement between the NIBP monitor and the simulator even if the simulator is using actual recorded data to create the pulse pressure envelope. To be approved for clinical use, the AAMI SP10 standard requires 68 percent of the measurements reported by the NIBP monitor to be within 10 mmHg as compared with the measurement taken by the auscultatory reference. This means that 32 percent of the measurements taken by the monitor can fall outside of the 10 mmHg window. If the recorded subject data used by the simulator was recorded from a subject that is outside the monitor's 10 mmHg window, then the results produced by the monitor will reflect this. The simulator may be using actual recorded data, but that data will produce the same measurement error every time it is run through the monitor's implementation of the oscillometric algorithm. This is why the AAMI SP10 standard requires a wide variety of subjects be used in the clinical validation process.

Conclusion

Non-invasive blood pressure simulators are excellent tools for verifying a host of safety and performance requirements that NIBP monitors approved for clinical use must meet. In the area of blood pressure simulation, it is not the absolute agreement between the oscillometric blood pressure monitor and an NIBP simulator that matters, but how repeatable the results produced by the monitor under test are when using the simulator.

With each manufacturer using a different criteria to calculate the systolic and diastolic pressure values, it is unreasonable to expect a single NIBP simulator to achieve universal agreement with all clinically approved oscillometric blood pressure monitors.

To establish the absolute performance between an NIBP monitor and a particular NIBP simulator, an offset table must be employed. The offset tables at the end of this paper establish the expected performance of the CAS oscillometric algorithm as compared with various commercially available NIBP simulators.

Literature Cited

[1] Posey JA, Geddes LA, Williams H, and Moore AG. 1969. The meaning of the point of maximum oscillations in cuff pressure in the indirect measurement of blood pressure. Part 1. *Cardiovasc. Res. Cent. Bull.* 8:15-25.

[2] Ramsey III M. 1979. Noninvasive blood pressure determination of mean arterial pressure. *Med. Biol. Engng. Comp.*, 17:11-18

[3] Geddes, L.A., Voelz, M., Combs, C., Reiner, D., and Babbs, C. F. 1982, Characterization of the oscillometric method for measuring indirect blood pressure. *Ann. Biomed. Eng.*, 10:271-280

Measurement Tables

An NIBP simulator can be used to gauge the absolute performance of an NIBP monitor if the expected results produced are known beforehand.

The following tables represent the expected results from various commercially available simulators at various settings when using an NIBP monitor implementing the CAS oscillometric algorithm.

The NIBP monitor and the NIBP simulator were set up as shown in Figure 2 during these tests. Ten measurements were taken at each simulator setting and the average result, mean difference and standard deviation were calculated and recorded for the data set.

Measurement Tables for the Fluke DNI CuffLink and the CAS oscillometric algorithm

Adult Mode (hypotensive) - 80/50 (62) 80 BPM

	Systolic	Diastolic	MAP
Average Result	83.70	52.62	63.94
Mean Difference	3.70	2.62	1.94
Standard Deviation	0.61	0.67	0.55

Table 2 [1]

Adult Mode (normotensive) - 120/80 (90) 80 BPM

	Systolic	Diastolic	MAP
Average Result	121.32	83.62	94.96
Mean Difference	1.32	3.62	4.96
Standard Deviation	0.74	0.53	0.60

Table 3 [1]

Adult Mode (hypertensive) - 200/150 (165) 80 BPM

	Systolic	Diastolic	MAP
Average Result	204.14	151.38	172.66
Mean Difference	4.14	1.38	7.66
Standard Deviation	0.88	1.37	1.12

Table 4 [1]

Measurement Tables for the Fluke DNI CuffLink and the CAS oscillometric algorithm cont.

Neo Mode (normotensive) - 80/50 (62) 120 BPM

	Systolic	Diastolic	MAP
Average Result	81.62	50.26	63.53
Mean Difference	1.62	0.26	1.53
Standard Deviation	0.64	0.56	0.50

Table 5 [1]

Neo Mode (hypertensive) - 120/80 (90) 120 BPM

	Systolic	Diastolic	MAP
Average Result	118.52	81.00	94.00
Mean Difference	-1.48	1.00	4.00
Standard Deviation	0.71	0.29	0.64

Table 6 [1]

[1] Results from 10 measurements on each of 5 different modules taken using the CAS oscillometric algorithm and the **DNI Nevada** simulator (all values are in mmHg).

Measurement Tables for the BioTek BP Pump and the CAS oscillometric algorithm

Adult Mode (hypotensive) - 80/50 (60) 80 BPM

	Systolic	Diastolic	MAP
Average Result	85.64	55.22	65.18
Mean Difference	5.64	5.22	5.18
Standard Deviation	0.95	0.82	1.02

Table 7 [2]

Adult Mode (normotensive) - 120/80 (93) 80 BPM

	Systolic	Diastolic	MAP
Average Result	125.72	87.34	99.50
Mean Difference	5.72	7.34	6.50
Standard Deviation	1.31	1.14	1.31

Table 8 [2]

Adult Mode (hypertensive) - 200/150 (166) 80 BPM

	Systolic	Diastolic	MAP
Average Result	205.30	156.86	171.96
Mean Difference	5.30	6.84	5.96
Standard Deviation	1.40	1.22	1.17

Table 9 [2]

Measurement Tables for the BioTek BP Pump and the CAS oscillometric algorithm cont.

Neo Mode (normotensive) - 80/50 (60) 120 BPM

	Systolic	Diastolic	MAP
Average Result	83.66	52.50	64.78
Mean Difference	3.66	2.50	4.78
Standard Deviation	1.24	0.61	0.62

Table 10 [2]

Neo Mode (hypertensive) - 120/80 (93) 120 BPM

	Systolic	Diastolic	MAP
Average Result	122.58	83.62	98.46
Mean Difference	2.58	3.62	5.46
Standard Deviation	1.33	0.90	1.05

Table 11 [2]

[2] Results from 10 measurements on each of 5 different modules taken using the CAS oscillometric algorithm and the **BioTek BP Pump** simulator (all values are in mmHg).

Measurement Tables for the Fluke BP Pump 2 and the CAS oscillometric algorithm

Adult Mode (hypotensive) - 80/50 (60) 80 BPM

	Systolic	Diastolic	MAP
Average Result	82.10	51.98	61.98
Mean Difference	2.10	1.98	1.98
Standard Deviation	0.46	0.47	0.43

Table 12 [3]

Adult Mode (normotensive) - 120/80 (93) 80 BPM

	Systolic	Diastolic	MAP
Average Result	121.08	83.08	95.76
Mean Difference	1.08	3.08	2.76
Standard Deviation	0.70	0.49	0.48

Table 13 [3]

Adult Mode (hypertensive) - 200/150 (166) 80 BPM

	Systolic	Diastolic	MAP
Average Result	201.62	153.56	169.40
Mean Difference	1.62	3.56	3.40
Standard Deviation	1.05	0.61	0.53

Table 14 [3]

Measurement Tables for the Fluke BP Pump 2 and the CAS oscillometric algorithm

Neo Mode (normotensive) - 80/50 (60) 120 BPM

	Systolic	Diastolic	MAP
Average Result	80.76	50.94	62.76
Mean Difference	0.76	0.94	2.76
Standard Deviation	1.30	0.79	1.02

Table 15 [3]

Neo Mode (hypertensive) - 120/80 (93) 120 BPM

	Systolic	Diastolic	MAP
Average Result	119.06	82.52	96.96
Mean Difference	-0.94	2.52	3.96
Standard Deviation	0.87	1.31	0.78

Table 16 [3]

[3] Results from 10 measurements on each of 5 different modules taken using the CAS oscillometric algorithm and the **Fluke BP Pump 2** simulator (all values are in mmHg).

Measurement Tables for the AccuPulse and the CAS oscillometric algorithm

Adult Mode (hypotensive) - 80/50 (60) 80 BPM
CalTable: CAS Medical

	Systolic	Diastolic	MAP
Average Result	79.54	50.60	60.08
Mean Difference	-0.46	0.60	0.08
Standard Deviation	0.58	0.49	0.49

Table 17 [4]

Adult Mode (normotensive) - 120/80 (93) 80 BPM
CalTable: CAS Medical

	Systolic	Diastolic	MAP
Average Result	119.28	80.30	92.52
Mean Difference	-0.72	0.30	-0.48
Standard Deviation	0.64	0.74	0.95

Table 18 [4]

Adult Mode (hypertensive) - 200/150 (166) 80 BPM
CalTable: CAS Medical

	Systolic	Diastolic	MAP
Average Result	199.54	148.98	164.96
Mean Difference	-0.46	-1.02	-1.04
Standard Deviation	0.97	1.04	1.28

Table 19 [4]

Measurement Tables for the AccuPulse and the CAS oscillometric algorithm

Neo Mode (hypotensive) - 60/30 (42) 120 BPM
CalTable: CAS Medical

	Systolic	Diastolic	MAP
Average Result	59.76	29.86	41.34
Mean Difference	-0.24	-0.14	-0.66
Standard Deviation	0.92	0.83	0.59

Table 20 [4]

Neo Mode (normotensive) - 80/50 (62) 120 BPM
CalTable: CAS Medical

	Systolic	Diastolic	MAP
Average Result	79.82	49.80	61.72
Mean Difference	-0.18	-0.20	-0.28
Standard Deviation	0.83	0.49	0.54

Table 21 [4]

Neo Mode (hypertensive) - 120/80 (103) 120 BPM
CalTable: CAS Medical

	Systolic	Diastolic	MAP
Average Result	120.30	90.32	102.64
Mean Difference	0.30	0.32	-0.36
Standard Deviation	0.65	0.47	0.60

Table 22 [4]

[4] Results from 10 measurements on each of 5 different modules taken using the CAS oscillometric algorithm and the **AccuPulse** simulator (all values are in mmHg).

Measurement Tables for the Fluke ProSim 8 and the CAS oscillometric algorithm

Adult Mode (hypotensive) - 80/50 (60) 80 BPM
Pulse Volume 0.50 mL, Envelope Shift -10%

	Systolic	Diastolic	MAP
Average Result	79.40	51.60	60.30
Mean Difference	-0.60	1.60	0.30
Standard Deviation	0.57	0.57	1.07

Table 17 [5]

Adult Mode (normotensive) - 120/80 (93) 80 BPM
Pulse Volume 0.50 mL, Envelope Shift -9%

	Systolic	Diastolic	MAP
Average Result	116.88	81.20	91.08
Mean Difference	-3.12	1.20	-1.92
Standard Deviation	0.82	0.78	0.80

Table 18 [5]

Adult Mode (hypertensive) - 200/150 (167) 80 BPM
Pulse Volume 0.50 mL, Envelope Shift -4%

	Systolic	Diastolic	MAP
Average Result	200.04	152.80	166.64
Mean Difference	0.04	2.80	-0.36
Standard Deviation	1.70	1.11	1.90

Table 19 [5]

Measurement Tables for the Fluke ProSim 8 and the CAS oscillometric algorithm

Neo Mode (hypotensive) - 60/30 (40) 120 BPM
Pulse Volume 0.15 mL, Envelope Shift -10%

	Systolic	Diastolic	MAP
Average Result	56.56	34.38	43.14
Mean Difference	-3.44	4.38	3.14
Standard Deviation	0.54	0.53	0.50

Table 20 [5]

Neo Mode (normotensive) - 80/50 (60) 120 BPM
Pulse Volume: 0.20 mL, Envelope Shift: -9%

	Systolic	Diastolic	MAP
Average Result	77.72	53.38	62.92
Mean Difference	-2.28	3.38	2.92
Standard Deviation	0.97	0.85	0.92

Table 21 [5]

Neo Mode (hypertensive) - 120/80 (93) 120 BPM
Pulse Volume 0.20 mL, Envelope Shift -7%

	Systolic	Diastolic	MAP
Average Result	116.60	84.18	95.96
Mean Difference	-3.40	4.18	2.96
Standard Deviation	0.93	0.66	1.07

Table 22 [5]

[5] Results from 10 measurements on each of 5 different modules taken using the CAS oscillometric algorithm and the **Fluke ProSim 8** simulator (all values are in mmHg).

Measurement Tables for the SimCube and the CAS oscillometric algorithm

Adult Mode (normotensive) - 120/80 (100) 70 BPM

	Systolic	Diastolic	MAP
Average Result	117.08	85.26	94.80
Mean Difference	-2.92	5.26	-5.20
Standard Deviation	1.21	0.69	1.12

Table 23 [6]

Adult Mode (hypertensive) - 190/120 (150) 70 BPM

	Systolic	Diastolic	MAP
Average Result	182.58	125.04	141.60
Mean Difference	-7.42	5.04	-8.40
Standard Deviation	1.20	0.75	1.93

Table 24 [6]

Neo Mode (normotensive) - 70/40 (55) 94 BPM

	Systolic	Diastolic	MAP
Average Result	70.22	42.86	52.20
Mean Difference	0.22	2.86	-2.80
Standard Deviation	0.84	0.93	1.65

Table 25 [6]

[6] Results from 10 measurements on each of 5 different modules taken using the CAS oscillometric algorithm and the **SimCube** simulator (all values are in mmHg).

