Noninvasive Blood Pressure Measurement and Motion Artifact: A Comparative Study

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Abstract

Protocol Systems, Inc., a designer and manufacturer of patient monitoring instruments and systems, has introduced an advanced software filtering technology aimed at improving the performance of oscillometric noninvasive blood pressure (NIBP) measurement in the presence of motion artifact. Under the trade name of Smartcuf ™, Protocol Systems developed this technology to refine NIBP performance during vehicular transport or under conditions of shivering, tremors, or other sources of patient movement.

To assess the efficacy of the Smartcuf technology, Protocol Systems engineers created a new validation regimen and retained Revision Labs Inc.™ of Beaverton, Oregon to participate in a study of NIBP artifact tolerance and to confirm the scientific validity and objectivity of the data collection and analysis. The validation methods made possible performance comparisons between NIBP attempts with and without motion artifact repeatedly on the same patient profile and provided quantitative data on the disruptive effects of motion artifact on NIBP performance. This joint study lasted for approximately three months, required 1000 hours of labor, and documented NIBP performance data on accuracy, yield, measurement time, repumps, and false positive readings for a total of 6000 NIBP attempts. The experiment focused on side-by-side performance comparisons of a wide variety of patient monitors including the Propaq 200 with Smartcuf, the Propaq 200 without Smartcuf, the Hewlett Packard M3, the Datascope XG, the Dinamap Plus, and the MDE Escort. Monitor models included in this study represent medical devices commonly used in portable patient monitoring.

The results of this study clearly established the success of the Smartcuf technology in redefining performance expectations for NIBP under motion artifact conditions. The Propaq 200 monitor with Smartcuf had the best performance with 80% of its 900 NIBP attempts within +/-10% error. More significantly, the monitor returned < 1% of its readings in which errors exceeded 20%. In contrast the Propaq 200 without Smartcuf, generated 65% of its readings within a ± 10% error, but this configuration had errors greater than 20% 25 times more often than did the monitor with Smartcuf. The other four monitors struggled in the presence of artifact, with only 17 to 38% of their readings falling below a +/-10% error.

Introduction

Oscillometric blood pressure devices derive a patient's blood pressure by applying a cuff to an arm (or leg), inflating that cuff to an occlusive pressure, and then bleeding the pressure from the cuff in a controlled fashion. During the bleed-down phase, the device detects and measures the pressure oscillations in the cuff caused by the heart's pumping activity and then analyzes the pressure pulse data to determine the systolic (SYS), diastolic (DIA), and mean arterial (MAP) pressures. With quiet patients these noninvasive blood pressure (NIBP) devices provide clinically accurate readings in a wide variety of physiologic conditions. However, pressures oscillations impinging on the cuff from sources other than the heart (such as transport vibration, shivering, or tremors, to name a few), may seriously degrade NIBP performance. This degradation includes reduced accuracy, increased patient discomfort from prolonged measurement times and increased repumps, and readings ended before completion of a blood pressure determination. In addition, oscillometric NIBP devices regularly interpret pressure oscillations caused by motion artifact as patient pulses in cases where no patient pulses exists, such as misapplication of the cuff or cardiac arrest. That is to say, they can report blood pressures that do not reflect the patient's true condition. For these reasons most manufacturers warn clinicians not to use these devices in the presence of motion artifact.

Clinicians have generally failed to appreciate the extent of this problem for two primary reasons. First, NIBP displays no waveform. As a consequence, clinicians have no visualization of the magnitude of motion artifact as they would on the ECG or SpO_2 channels. Second, the very factors that produce motion artifact in the blood pressure cuff during transport also produce auditory noise and, thereby, prevent verification of NIBP accuracy through the traditional auscultatory measurement method with a stethoscope.

To minimize these disruptive effects of motion artifact on NIBP measurements, Protocol Systems has developed the Smartcuf technology. The technology synchronizes the ECG data and the NIBP data enabling the noncardiac pulses to be stripped from the artifact-contaminated cuff oscillations, leaving only the cardiac-derived pressure oscillations for analysis and blood pressure determination.

Methods

To assess and quantify the effectiveness of this ECG-dependent NIBP filter, Protocol Systems innovated a new analytical method. This method employed a commercially available NIBP simulator (Bio-Tek) with modifications to allow the injection of typical vehicular motion artifact signals from an Hewlett Packard Arbitrary Waveform Generator® onto the patient profile from the Bio-Tek simulator. The Bio-Tek NIBP simulator provided a mechanism to challenge an NIBP device with a repeatable patient blood pressure profile (e.g. 120/80 mmHg) and pulse rate (e.g. 150 BPM) that remained constant from one reading to the next. The new "method" consisted of comparing the NIBP pressure values obtained in the absence of artifact with those obtained in the presence of artifact. In addition to the pressure values, evaluators recorded measurement time, incidence of retries/repumps, and incidence of readings ending with no pressure values. By adjusting the size of the patient pulses to zero in the Bio-Tek simulator and continuing to inject artifact signals from the waveform generator, this methodology also provided quantification of the artifact-only performance. In the artifact-only tests, evaluators required no baseline readings because "no answer" constituted the correct response for these cases. All blood pressure readings in which pressure values were returned under artifact-only conditions fell into the category of "false-positive" readings.

Utilization of these analytical methods permitted comparisons of the Propaq 200 Smartcuf performance with the performance of the Propaq 200 without Smartcuf as well as with other monitor configurations including the Hewlett Packard M3, the Datascope XG, the MDE Escort, and the Dinamap Plus. Side-by-side comparisons of the tested NIBP devices encompassed accuracy, yield (incidence of values within specific error limits), measurement times, rates of retries/repumps, and frequency of false-positive readings under artifact-only conditions. Evaluators selected monitors for inclusion in this study on the basis of their potential importance in portable monitoring applications.

This report summarizes data collected for the blood pressure variables listed below in Table 1. These variables represent the ranges of conditions commonly present in patient transport.

Normotensive Profile 120/80 mmHg (93)	Hypertensive Profile 170/100 mmHg (123)	Hypotensive Profile 70/40 mmHg (50)
50 BPM	50 BPM	50 BPM
80 BPM	80 BPM	80 BPM
150 BPM	150 BPM	150 BPM

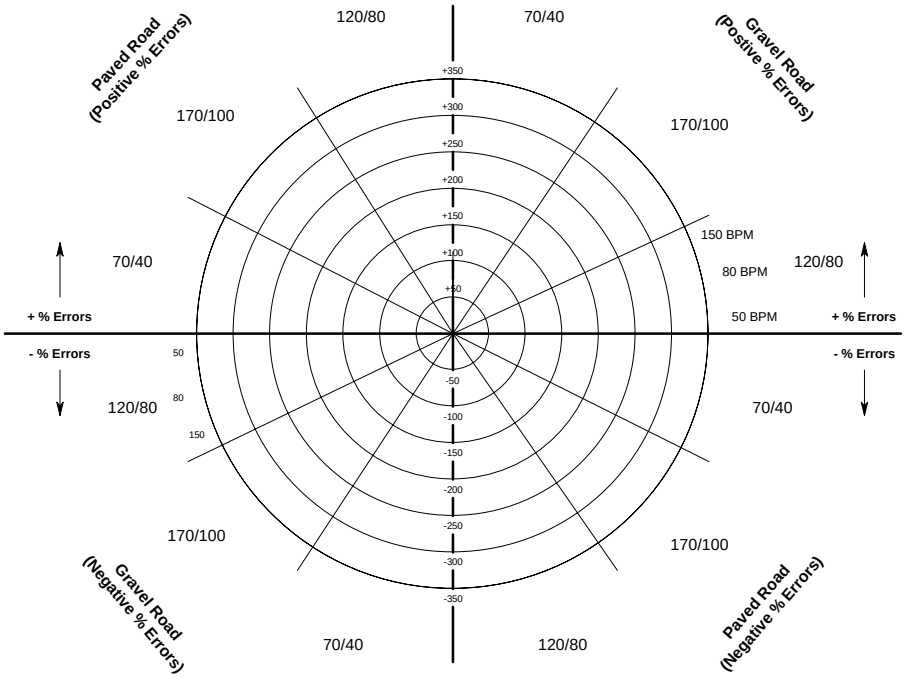
Table 1 Blood pressure profiles and heart rates tested for this report.

In addition to the pressure profile and heart rate variables in Table 1, the experimental design also varied the amplitude of artifact profiles over 5 levels. Expressed in terms of the Hewlett Packard Arbitrary Waveform Generator® settings, these amplitudes included 200, 400, 600, 800, and 1000 mV. These voltage levels simulated light to moderate motion artifact under typical transport conditions. The artifact tests also included two distinct road artifact profiles (a gravel road and a paved road) for all combinations of pressure profile, heart rate, and artifact amplitude level. Developers created the two road profiles by collecting vibration data to a lap-top computer from a Propaq monitor over the monitor's communications port during vehicular transport on a gravel road or on a paved road. Artifact data contained no patient pulses. Analysis of the artifact data in MatLab® documented the spectral content of the two artifact profiles. Reformatting of the artifact data allowed importing of the two artifact profiles into the arbitrary waveform generator's nonvolatile memory for superimposition on patient profiles or for artifact-only trials.

The following formula summarizes the experimental cases: 3 pressure profiles x 3 heart rates x 5 artifact levels x 2 artifact profiles x 10 readings for each combination of the preceding = 900 NIBP attempts for each NIBP monitor type. With three values possible for each attempt (SYS, DIA, MAP), each monitor had the potential to deliver 2700 blood pressure values in response to the combined patient/artifact profiles. In addition, artifact-only performance data were collected for 100 NIBP attempts in all models without an ECG-dependent filter and 300 NIBP attempts for the Propaq with Smartcuf (100 attempts for each heart rate).

Evaluators collected performance data to an Excel® spreadsheet. The data made possible calculation of the artifact-induced error by subtracting the artifact-free values from the pressure values for the combined artifact/patient profiles. These error values, expressed in mmHg were then converted to a percent value. For example, if an expected or artifact-free systolic value of 120 resulted in a reading of 90 due to artifact, the formula (90-120/120) x 100 expresses the percent error. In this example the calculation yields an error of - 25 percent. Artifact-only data recorded the incidence off attempts ending with blood pressure values.

The study's analysis plotted the error data for the combined artifact/patient profiles on a polar axis in which the readings for each experimental case (each combination of pressure profile, heart rate, artifact profile, and noise level) were plotted along a single diameter. Figure 1 portrays the mapping scheme for these error plots. Positive error data for the gravel road and for the paved road appear in the upper right and left quadrants of the plots, respectively. The negative error data for the gravel and paved roads appear in the lower left and right quadrants, respectively. The plots reveal both the central tendency of the errors and the variability of the data about that central tendency for the various monitor types. In the hypothetically perfect monitor, all 2700 values would lie exactly at the center of the polar plot. If a particular monitor always missed the expected value by 100 percent all data points would lie on the upper half of the second percent error ring.



Data Mapping Key for Polar Scatter Plots
NIBP Comparative Study

Figure 1 Polar Plot Data Map (Blood pressure measurement e.g. 170/100 is expressed in mmHg)

Results

Figures 2 to 7 compare the distribution patterns of percent errors in response to motion artifact for the six monitor types tested in this study. The data plots include all three pressure values (SYS, DIA, and MAP) for a total of 2700 potential values. The actual number of values returned by the NIBP devices appears in the description of the plot at the top of each graph. For example, Figure 2 for the HP M3 documents that this monitor achieved a yield of 2080 pressure values out of a total of 2700 possible values. Comparing Figure 7 with the Figures 2 through 6 establishes the superiority of the Smartcuf technology in producing a high yield of accurate blood pressure values in the presence of motion artifact. The four outliers in the Smartcuf data (the Propaq 200 with ECG) represent two circumstances. First, the three data points lying between 200 and 250 percent error rings resulted from a single NIBP attempt in which the heart rate and noise frequency aligned in a way that allowed the artifact to breach the Smartcuf filter. The Smartcuf filter has to permit waveform data at the heart rate to pass through the filter in order to ascertain the blood pressure reading. If the artifact has the same frequency as the heart rate or a multiple of the heart rate, the Smartcuf could fail to strip the artifact data from the incoming data. In the present study the heart rate did not vary throughout an NIBP attempt. In a human patient this invariability of the heart rate would not exist, reducing the likelihood that the heart rate and artifact would remain aligned at a problematical relationship long enough to breach the filter. The remaining outlier near the 100 percent ring represents an NIBP attempt in which the artifact failed to trigger the use of the Smartcuf. Consequently, this mean-only reading reflects the same type of errors made by the other monitor types.

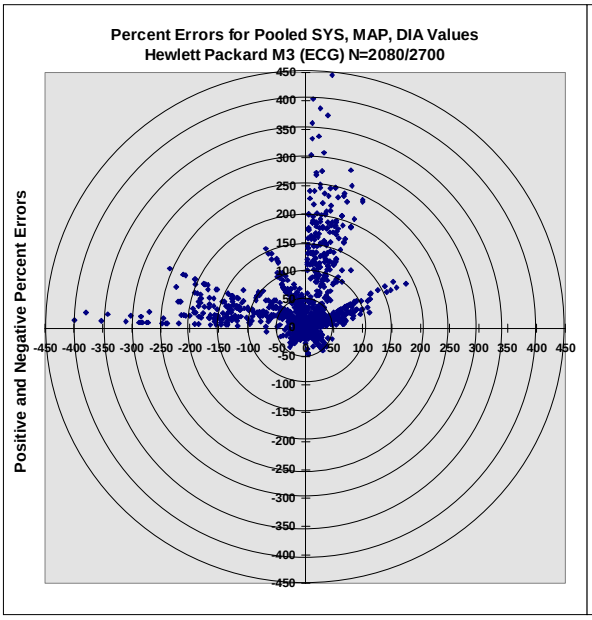


Figure 2 Hewlett Packard M3 data

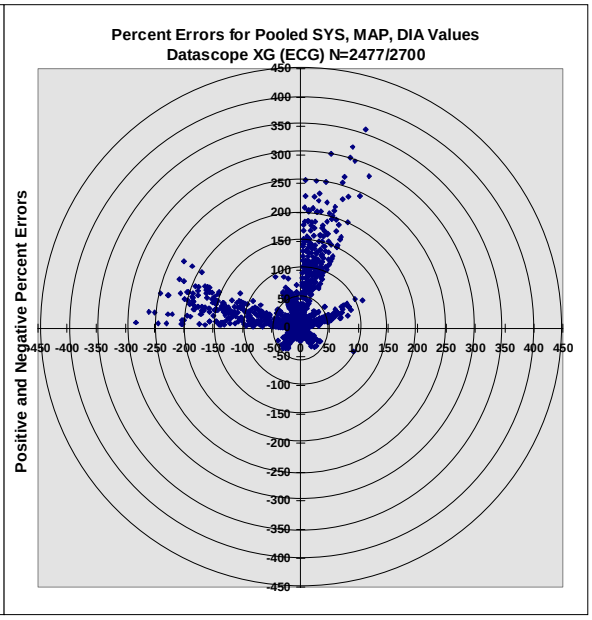


Figure 3 Datascope XG data

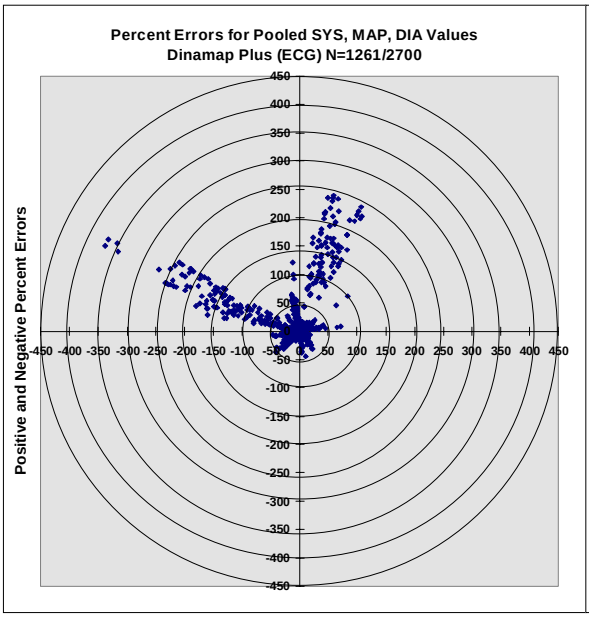


Figure 4 Dinamap Plus data

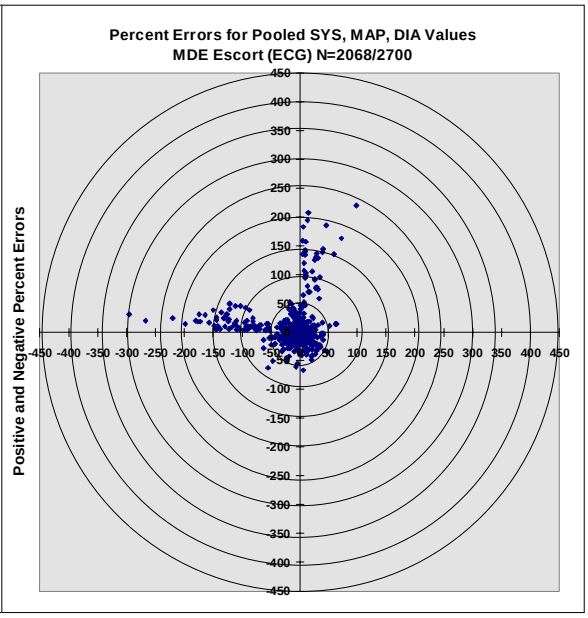


Figure 5 MDE Escort data

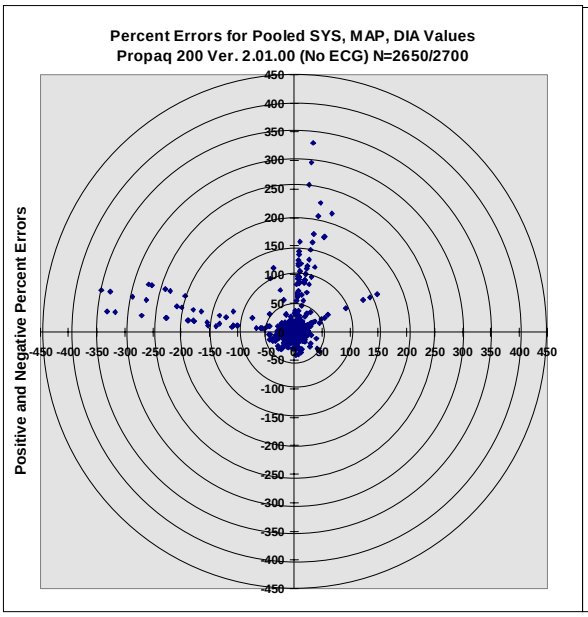


Figure 6 Propaq 200 without *Smartcuf*

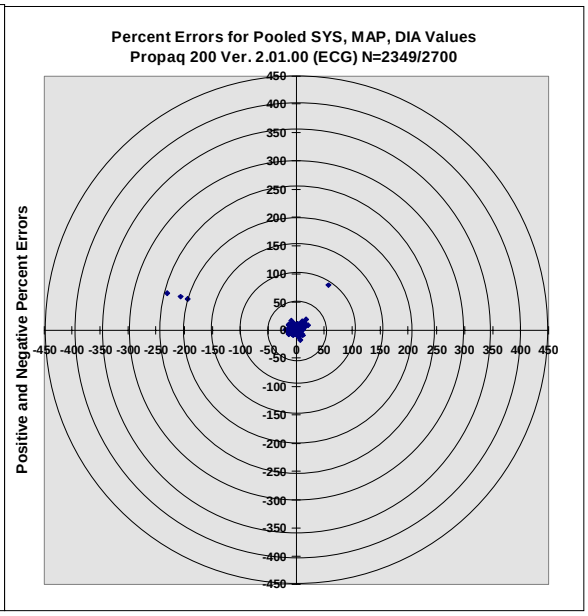


Figure 7 Propaq 200 with *Smartcuf*

Figure 8 summarizes the scatter plot data previously presented in Figures 2 through 7. This bar graph portrays the average percent errors over all pressure values (SYS, DIA, and MAP) ± the standard deviation for each monitor. The graph clarifies the relative accuracy and variability of the six monitors. The MDE Escort and the Propaq 200 without Smartcuf both had smaller average errors and standard deviations than did the Hewlett Packard M3, the Datascope XG, and the Dinamap Plus. The Propaq 200 with Smartcuf derived blood pressures with the lowest average error and contained the variability of the readings better than the other five monitor configurations.

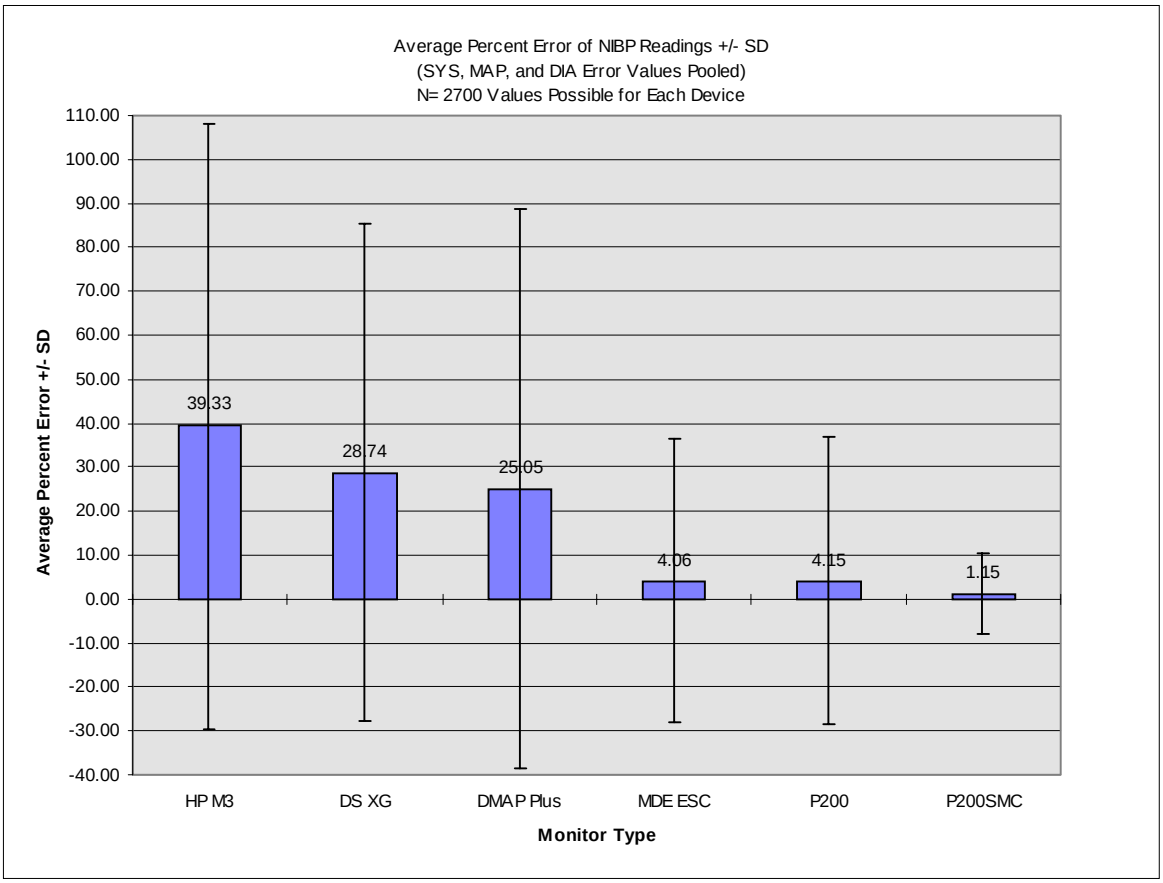


Figure 8 Summary of the average percent error data for the 6 monitor configurations tested (SMC = Smartcuf)

Figure 9 depicts the accuracy from another point of view. This stacked bar graph plots the relative incidences of errors in various categories; errors ≤ 10 percent, errors > 10 percent and ≤ 20 percent, errors > 20 percent, and readings ending with no values. In this analysis, a reading had to have no single value exceeding the category limit to qualify for inclusion in that category. Both Propaqs (with and without Smartcuf) outperformed the other monitors in the ≤ 10 percent category. For example, the Propaq 200 with Smartcuf attained 717 readings in the ≤ 10 percent. This meant that of these 717 readings, no single pressure value for SYS, DIA or MAP exceeded the 10 percent error limit. The Propaq 200 without Smartcuf attained the second highest incidence of readings ≤ 10 percent with 586 readings in that category. However, the Propaq 200 without Smartcuf also experienced twice as many values in the > 10 ≤ 20 percent category and 25 times as many values in the > 20 percent category as did the Propaq 200 with Smartcuf. The Smartcuf technology accomplished this increased reliability at the cost of a higher incidence of NIBP attempts ending with no answers. In other words, the Smartcuf succeeded more often than the Propaq without Smartcuf at detecting conditions of risk and disqualifying a reading for display. For monitors other than the Propaq 200 (both with and without Smartcuf), performance limitations resulted in greater than half of the NIBP attempts ending with errors > 20 percent.

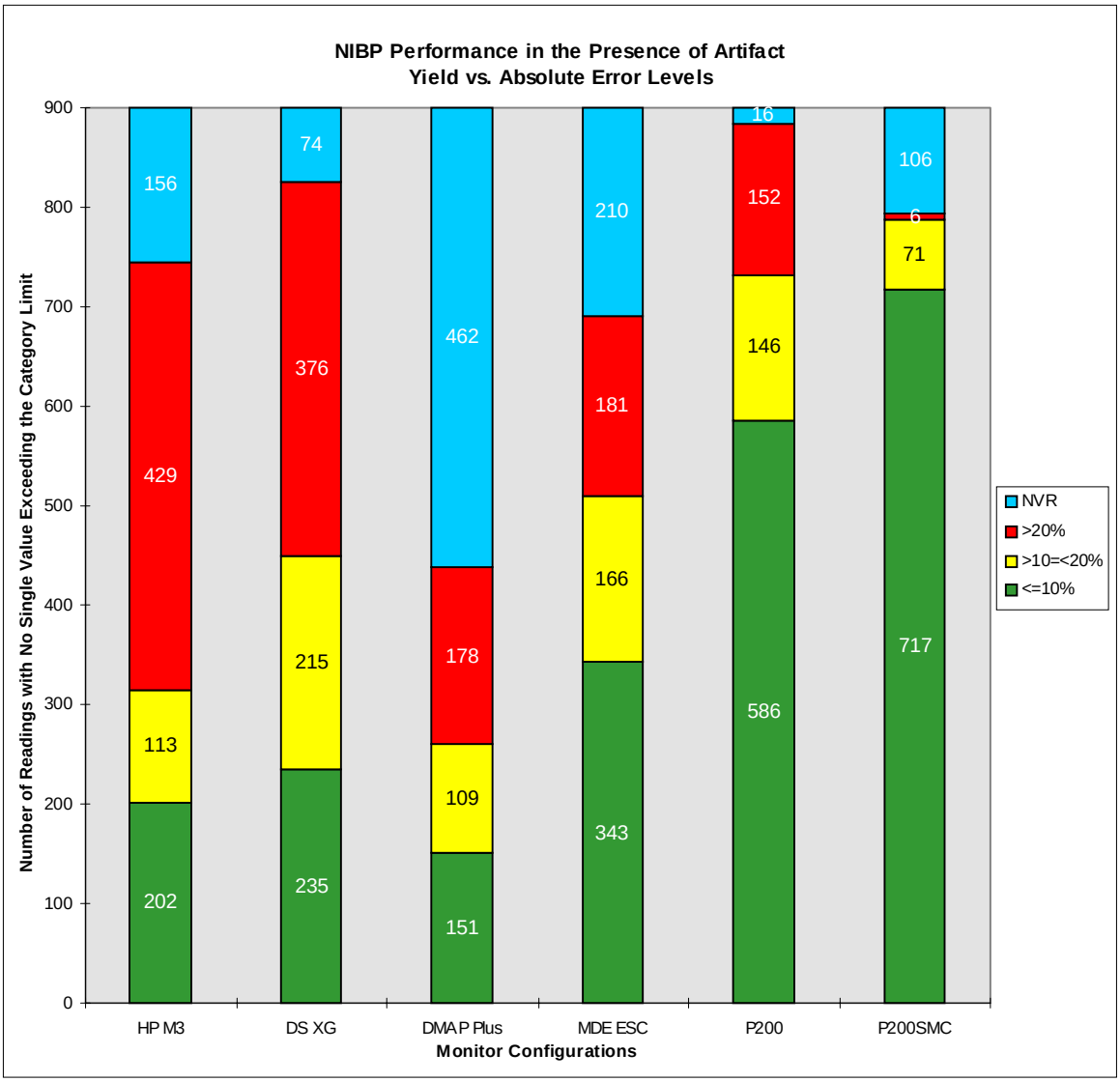


Figure 9 Yield data for error categories in the 6 monitor types tested (SMC = Smartcuf)

Figure 10 compares the average measurement times of the 6 monitor configurations (± standard deviation). Measurement time represents an important variable in NIBP performance for clinicians who must often make critical medical decisions promptly. Recognition of this fact raised concerns that the heavier filtering performed by the Smartcuf technology might prolong measurement times to unacceptable levels. The data in Figure 10 verify that the Smartcuf took about 15 to 20 seconds longer, on average, to complete readings than did the Propaq 200 without Smartcuf. This demonstrates the cost of attaining greater accuracy and reliability of blood pressure values in the Smartcuf system under artifact conditions. Despite the increased measurement time of the Smartcuf relative to the Propaq 200 without Smartcuf, the times for the Smartcuf are comparable to or faster than the other monitor configurations in this study. The analysis supports the conclusion that the modestly increased measurement times required to improve accuracy and reliability have not put the Smartcuf at a performance disadvantage relative to these other monitor configurations.

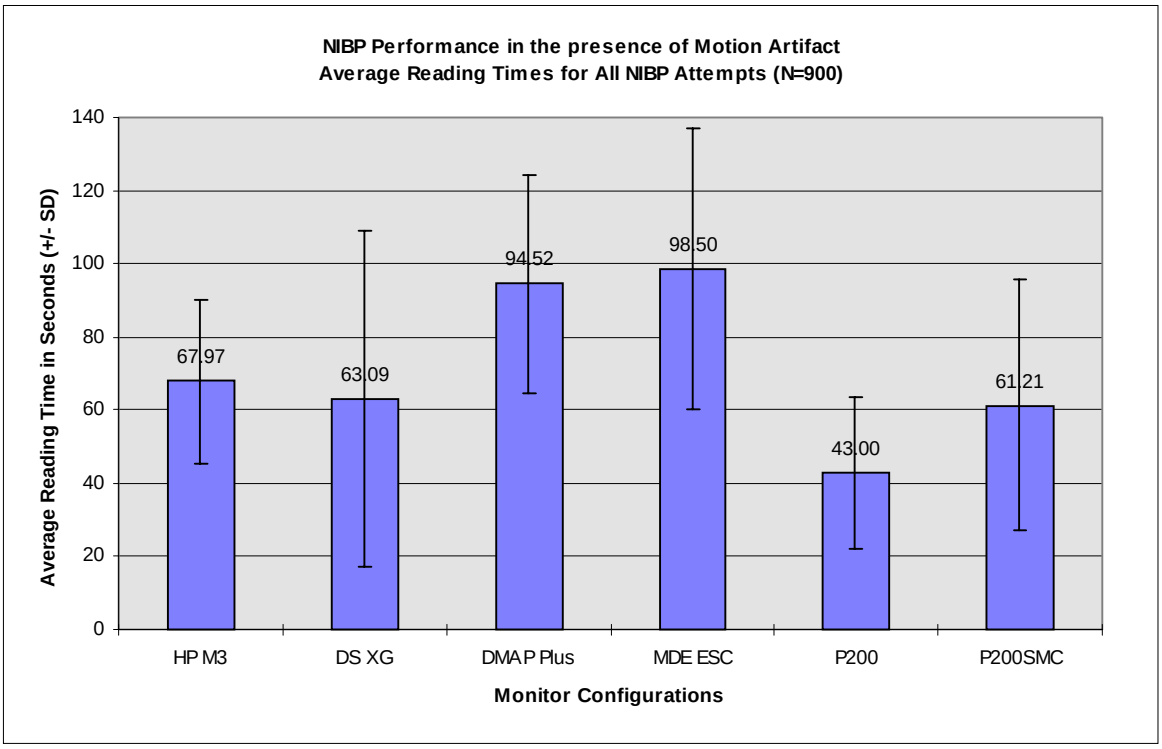


Figure 10 Comparison of the average reading times in the presence of motion artifact (SMC = Smartcuf)

Figure 11 compares the incidence of retries and repumps in the 6 monitor configurations tested. In this context, the term *retries* refers to cases in which the NIBP monitor bleeds the pressure to zero before reinflating the cuff during a single NIBP attempt. The term *repump* refers to cases in which the NIBP monitor need not bleed the cuff pressure to zero before reinflating to a higher pressure. Different monitors tend to employ one or the other and sometimes both schemes for gathering additional pulse data. These cuff reinflations tend to extend reading times and to increase patient discomfort. Therefore, the most efficient designs limit these reinflations to an absolute minimum. In some NIBP readings, reinflations of the cuff must occur even with no motion artifact in order to find the systolic pressure. For example, all of the tested monitors had default cuff inflation targets lower than the systolic pressure in the 170/100 mmHG patient profile. Consequently, all monitors should have performed cuff reinflations in at least 33 percent of the attempts in order to correctly identify the systolic pressure. Figure 11 demonstrates that the Dinamap Plus failed to perform correctly on the hypertensive profile with only 17 percent of reinflations over all NIBP attempts. All other monitors had repumps or retries in 33 percent or more of the attempts. Artifact also can cause reinflations if the NIBP attempt has, for example, found the MAP and the DIA but has been unable to determine the SYS because of the disruptive effects of motion artifact. Therefore, reinflation rates greater than 33 percent in this data did not necessarily represent improper performance.

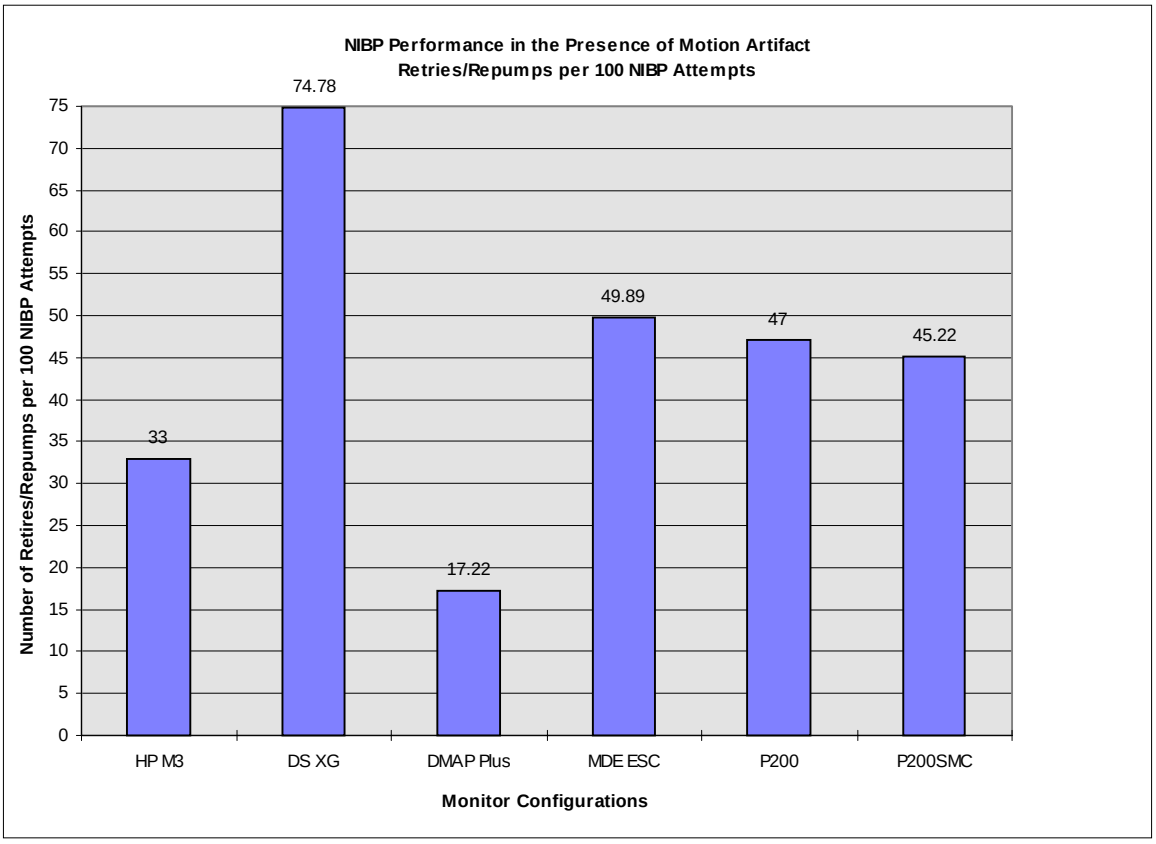


Figure 11 Comparison of the numbers of retries or repumps per 100 NIBP attempts in the presence of motion artifact (SMC = Smartcuf). (Note: Because one third of the NIBP attempts involved the 170/100 pressure profile, all monitors should have had at least a 33 percent incidence of retries)

Figure 12 compares the performance of the six monitors when exposed to motion artifact with no patient pulses. The Smartcuf technology surpassed all other monitor configurations in its ability to discern artifact-only pulses and displayed false positive readings in only 8 percent of attempts. The MDE Escort most closely approached this performance with a 31 percent incidence of false positive readings. The Datascope XG and the Dinamap Plus both returned false positives in 50 percent of the trials and the Hewlett Packard and the Propaq 200 without Smartcuf both experienced false positive readings in 80 percent of the trials.

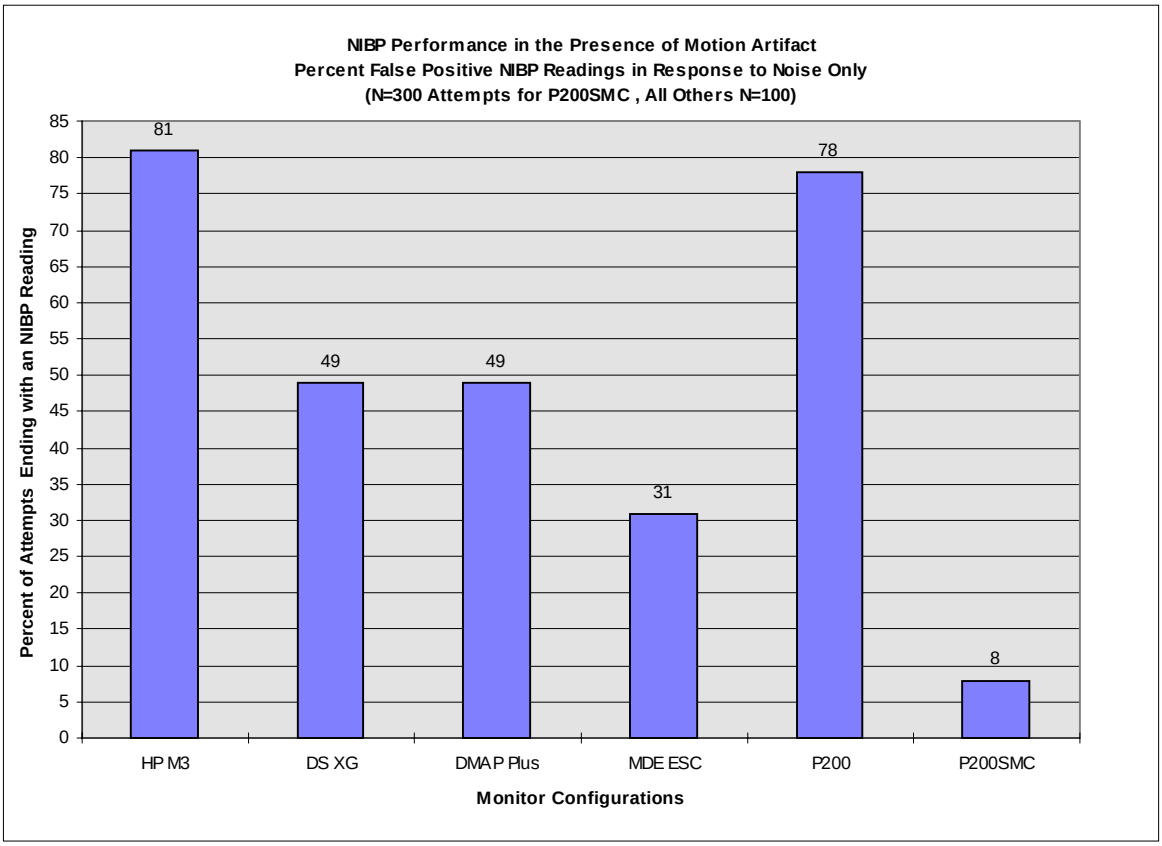


Figure 12 Comparison of the incidence of false positive NIBP readings on artifact-only NIBP attempts (SMC = Smartcuf)

Summary

The use of ECG synchronization to filter motion artifact from NIBP data in the Smartcuf technology produced a dramatic improvement in measurement accuracy/variability and in yield under artifact conditions. This increased accuracy did not produce a clinically unacceptable increase in times for the Smartcuf monitor compared to the measurement times of other monitor configurations included in this study. The Smartcuf technology had no adverse effects on the incidence of retries/repumps either when compared to the Propaq 200 without Smartcuf or when compared to the other four monitors. Furthermore, the Smartcuf technology surpassed all other monitor configurations in the ability to detect the absence of patient pulses in an artifact profile. This configuration had the lowest incidence of false-positive readings when patient pulses were not present in an artifact profiles.

NIBP Performance: Artifact Tolerance Comparison Summary						
Model	P200 (Smartcuf)	Propaq 200 (sans Smartcuf)	Hewlett Packard M3	Datascope XG	Dinamap Plus	MDE Escort
Average % Error	1.15	4.15	39.33	28.74	25.05	4.06
Standard Deviation	9.07	32.71	68.73	56.56	63.60	32.30
Average Measurement Time	61.21	43.00	67.97	63.09	94.52	98.50
Yield ≤10 %	717	586	202	235	151	343
Yield >10 ≤20 %	71	146	113	215	109	166
Yield > 20%	6	152	429	376	178	181
No Values Returned	106	16	156	74	462	210
Retries/100 Attempts	45.22	47	33	74.78	17.22	49.89
% False Positives	8.33	78	81	49	49	31

Table 2 NIBP Performance: Summary of numerical data for motion artifact tolerance