Masimo SET SpO_2 Technology is More Sensitive than an Arterial Line in Detecting Arterial Pulsations During Conditions of Low Perfusion

Summary

Recently it was brought to our attention that one of our competitors is showing a video which attempts to demonstrate that Masimo pulse oximeters continue to display oxygen saturation and pulse rate measurements, even when there is no pulse present. The assertion that a Masimo pulse oximeter will read without blood pulsation is simply false. Masimo's breakthrough ability to accurately measure during motion and low perfusion does not change the basic physics of pulse oximetry, which requires a "pulse" by definition.

However, rather than simply ignore these false assertions, Masimo elected to thoroughly evaluate our competitor's experiment and their associated claims. The competitor's video was shot in the office of a company near their corporate headquarters—not in a hospital or other independent and objective clinical setting. Human volunteers were brought in to the office, and a tourniquet was used to alter the blood flow in the arm, where Masimo and competing pulse oximeters were placed. In an apparent effort to prove that there was no pulse at the digits when the tourniquet was inflated, an arterial line was also used. The supposition was that if the arterial line cannot measure a pulse rate, then any measurement from a pulse oximeter is an error.

After a thorough evaluation of our competitor's experiment, we discovered two key facts which proved this tourniquet cuff test does not ensure a "no pulse" condition:

- On many occasions, a pulse can still be detected, even when the tourniquet pressure is applied to greater than 100 mm Hg above systolic pressure; and,
- An arterial line is less sensitive than Masimo SET pulse oximeters in reporting flow and pulse rate.

A tourniquet cannot fully occlude blood flow to the digits in all cases because pressures required to fully occlude brachial arterial blood flow vary between individuals. In addition, collateral flow through bone and other secondary channels—such as the profunda artery and deep arterioles—may continue to provide minimal levels of perfusion. It has been shown that pressure transmission from a pneumatic tourniquet to various tissue depths is incomplete and highly individually variable.[1,2] Tuncali showed that a tourniquet cuff pressure of 200 mm Hg is reduced to between 142 and 185 mm Hg in the forearm varying from individual to individual.[1]

The variability of these basic physiological issues, combined with the uniqueness of each subject, creates very unpredictable results from cuff inflation. To study the physiologic issues involved, we have conducted over 100 cuff inflations using a similar tourniquet, on multiple subjects, and found significant variability in the results. Sometimes the competitor's pulse oximeter (CPO) zeroed out first, sometimes Masimo's did. Sometimes both Masimo and CPO zeroed out evenly, and sometimes both Masimo and CPO continued to read a pulse after cuff inflation.

Experiment and Results:

To eliminate the variability caused by physiological differences of test subjects and the inherent limitations of a tourniquet to completely occlude flow to the digits, we pursued a test setup that could provide the same precise pulse signal to an arterial line and the digit used for pulse oximetry. To accomplish this, we utilized a Biotek Model 601 pressure simulator which permits precise adjustments in pulse rate and pulse pressure, and provides the same pulse signal to an arterial channel and a test digit simultaneously. We used a setup with one test digit for comparison of competing pulse oximeters in order to eliminate the potential variability of differences of multiple test digits.

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This testing showed that competitive oximeters and an invasive arterial line would stop measuring pulse rate at low perfusion levels, despite the fact that the simulator was still generating a pulse. However, when the Masimo oximeter was attached to the same test digit with no changes to the Biotek settings, the Masimo oximeter quickly and accurately measured the pulse rate and also displayed a small but clearly discernible pleth waveform which accurately represented the Biotek's settings. We then adjusted the Biotek's pulse rate without any change in the pulse pressure and the Masimo oximeter tracked this change immediately, further demonstrating Masimo was accurately measuring the same signal that the arterial line and competitive pulse oximeters were not able to measure.

As a final step in this demonstration, we turned the Biotek Simulator off and the pulse tone on the Masimo Radical immediately ceased, followed by a zeroing out of the pulse rate value on the oximeter.

Conclusion:

These experiments demonstrated that Masimo oximeters can accurately measure pulsatile flow at perfusion levels four or more times below that of an arterial line, something even we were not aware of prior to the need to conduct these experiments to address our competitor's assertions. This experiment also validates what has been reported for years since the advent of Masimo SET: that Masimo SET accurately measures at a perfusion level lower than other pulse oximeters, in clinical situations such as during resuscitation and cardiopulmonary bypass.[3-6]

We are disappointed that a competitor has elected to use poorly designed experiments to make false claims about our technology. In contrast, we believe that Masimo's performance in over 100 independent and objective studies, as well as over 400,000 Masimo oximetry sockets in use around the world, has clearly proven that Masimo SET represents the "gold standard" in performance and patient safety. And with Masimo's continued expansion of noninvasive Pulse CO-Oximetry including Carboxyhemoglobin (SpCO), Methemoglobin (SpMet), Pleth Variability Index (PVI), and more innovative noninvasive parameters to come, Masimo has demonstrated its commitment to provide innovative solutions that enhance patient safety and reduce the cost of care.

References:

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7617-4793A-1107

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