Technical Bulletin

May 2009

Oximeters with Next Generation Signal Processing Require Patient Simulator Improvement

Nonin Medical's advanced PureSAT® oximetry technology uses sophisticated algorithms to separate the true human pulse from artifact. Nonin recently tested a number of simulators and found that some simulators have not yet been upgraded to perform adequately with Nonin's latest PureSAT technology. This paper discusses the findings on one simulator in particular, the Fluke Biomedical Index 2, which was found to be incompatible with Nonin's PureSAT signal processing, as well as the unique, advanced design of Nonin's sensors. The Index 2 simulates the older, conventional oximeter method using maximum and minimum points of the pulse waveform; this technology does not accurately represent a true physiological pulse and therefore is not compatible with Nonin's PureSAT oximeters.

INTRODUCTION

Use of the Fluke Biomedical Index 2 Simulator with Nonin's next generation PureSAT oximetry results in oximeter readings that differ from the simulator settings. This technical bulletin explains the technology issues that cause the discrepancy in readings.

TECHNICAL ANALYSIS

1) Simulated Patient Signal

The Fluke Biomedical Index 2 Simulator simulates pulse oximeter signals using an artificial optical finger. The simulated signal from the Index 2 Simulator was evaluated by Nonin's engineering team and found to be incompatible with Nonin's PureSAT signal processing technology. The incompatibility is due to the fact that the simulated waveform produced by the Index 2 Simulator does not accurately represent a true physiological signal, which results in a discrepancy of +/-4 SpO_2 points between the reported oximeter SpO_2 value and the simulator SpO_2 set point.

The Index 2 Simulator accurately simulates the maximum and minimum points of the pulse waveform; however, the sample points between the maximum and minimum do not replicate the pulse signals produced by humans. Older or traditional oximetry signal processing technology only uses the maximum and minimum points for calculating SpO_2 — therefore this older technology will operate without discrepancy on the Index 2 Simulator. However, this older or traditional oximetry technology does not perform well in challenging situations such as motion, low perfusion and high patient absorption.

Nonin's advanced PureSAT signal processing technology looks beyond the pulse maximum and minimum. PureSAT evaluates the patient signal waveform and makes use of the entire signal without interference from motion artifact. Since the signal processing algorithm used in PureSAT analyzes the entire pulse waveform, the waveforms produced by simulators must also simulate points between the maximum and minimum in a manner that is physiologically accurate.

2) Test Method

Pulse tracings were collected over a 15-minute period while operating a Fluke Biomedical Index 2 Simulator set at 70% SpO_2. During the 15-minute period, pulse waveforms were extracted when the oximeter SpO_2 value was within +/-1 of the simulator setting, (Figure 1) and again when the oximeter SpO_2 value was four points higher than the simulated SpO_2 value (Figure 2).

Figure 1: Oximeter readings within +/-1 of simulator setting

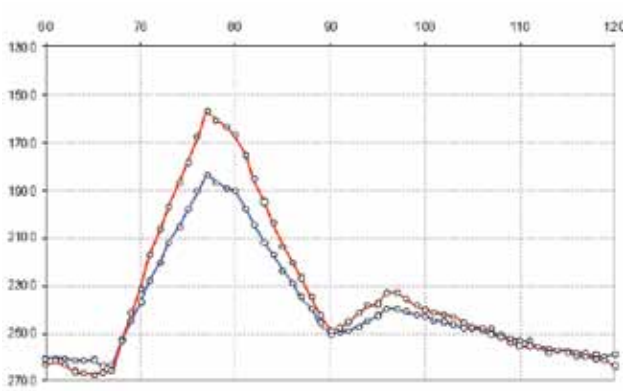
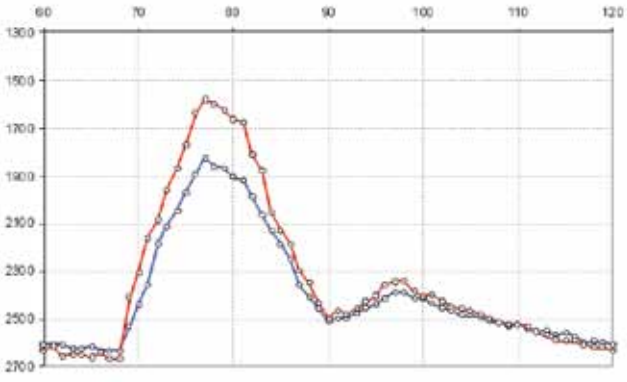


Figure 2: Oximeter readings outside +/-2 of simulator setting



3) Physiological Analysis

A comparison of the tracings indicates that the simulator was adjusting the light measurements to provide precise maximum and minimum points as required by older, conventional oximetry. The adjustments made by the simulator between the maximum and minimum points of the pulse introduce changes in light measurements that are not physiologically possible. (See pulse traces in Figures 1 and 2 where the red tracing correlates to the infrared sensor diode sample and the blue tracing correlates to the red sensor diode sample).

In humans, the heart pumps blood through the body. As blood rushes in and out of the finger, the red and blue tracings track each other because the source of the blood circulation is from a single source — the heart. In Figure 2, the red and blue tracings do not track each other — indicating that the simulated blood rushing in and out of the finger is not from a single source, but rather from two independent circulatory systems which is not physiologically possible. Due to the poor control of the simulated pulse shape, we conclude that the waveform generator used in the Index 2 Simulator is not an appropriate solution for testing the next generation technology.

4) Simulated Sensor Light Levels

Unlike other pulse oximeter technologies, Nonin's PureSAT technology is designed for high performance and low power. To achieve low power, PureSAT uses hardware that quickly responds to changes for a rapid measure of the analog-to-digital sample — conserving power by only turning the sensor emitters on for short periods. The Index 2 Simulator does not simulate Nonin's typical DC light levels when applied to a human finger. The simulated IR and RED DC levels are lower than DC levels typical of subjects having low DC light (e.g. thick fingers or dark skin pigmentation).

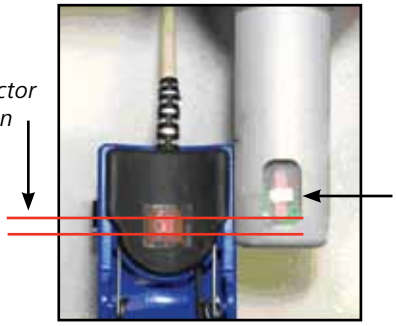
5) Simulator Optical Finger to Sensor Connection

The Fluke Biomedical Index 2 Simulator uses an optical finger probe that passes a simulated light to an oximeter's sensor photodetector. To ensure optimal performance, the simulator's optical finger must allow proper alignment and spacing of the oximeter's photodetector.

Because the simulator's optical finger does not represent the true oval shape of a human finger, proper alignment from the simulator to the Nonin sensor is not possible (see Figures 3a and 3b). As a result, performance is greatly distorted when simulating low perfusion.

Figure 3a: View of optical finger probe on Index 2. The optical finger on the simulator does not accurately reflect the shape of a human finger.

Figure 3b: Misalignment of the light path. The Index 2 optical finger misrepresents the operation with a true finger.



CONCLUSION

The Fluke Biomedical Index 2 Simulator's poor control of the waveform generator, incompatibility of the DC light levels, and the shape of the optical finger are incompatible with Nonin's PureSAT signal processing and the advanced design of Nonin's sensors. The method using maximum and minimum points of the pulse waveform used by the Index 2 Simulator is acceptable for older or traditional pulse oximetry technology but, due to its inability to accurately represent a true physiological pulse, is not compatible with the next generation motion-tolerant technology used in Nonin's PureSAT oximeters. Because of Nonin's unique oximetry hardware and signal processing, the Index 2 Simulator should not be used for functional testing of Nonin oximeters.

RECOMMENDED SIMULATOR SOLUTIONS

Nonin recommends these alternative simulator solutions for use with our PureSAT oximeters:

Manufacturer	Simulator ID/Name	Type of Simulation	Simulator Setup
Datrend	Oxitest Plus 7	Optical	Nonin #63 and 65 *(do not use non-OEM)*
Clinical Dynamics	SmartSat	Non-optical	Name = PureSAT
Nonin	8000S	Non-optical	N/A
Nonin	OEM Bench Simulator	Non-optical	N/A

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