Pulse Oximetry: Comparative Technology Analysis

Successful Clinical Evaluation of Next Generation Pulse Oximeters

The key to accomplishing a successful clinical evaluation, and ultimately the selection of a clinically useful pulse oximetry technology, is having a logical, structured methodology. Logical methodology will lead to selecting the pulse oximeter, which will ultimately lead to improved clinical care and patient outcomes. However, before commiting to such an evaluation, consider the many ways that a clinical standard of care can be validated for its core measurement accuracy (SpO_2 and HR) by "stress-testing" across a wide spectrum of real clinical conditions. The premium next generation pulse oximeter should deliver improved clinical outcomes to your hospital.[1,2,3] In the evaluation and selection of the most useful clinical pulse oximeter, these few logical steps should be strongly considered.

1. Do side-by-side simultaneous evaluations on the same subjects using the pulse oximeters under consideration. Testing the oximeters on the same patient at the same time minimizes variability and increases the power of evaluation.
2. Use similar sensors (compare adhesive to adhesive or reusable clip to reusable clip). Comparing two different types of sensors would add one more variable to the evaluation, making interpretation of the results difficult.
3. Put the sensors on similar sites (digit vs. digit, ear vs. ear, forehead vs. forehead, and on babies, hand vs. hand or feet vs. feet). Using the same monitoring sites allows comparison of technology and not differences in physiology naturally inherent with different sites.
4. Switch the sensor sites halfway through the evaluation to minimize differences between the sites, sometimes referred to as site bias. Small but real differences in perfusion, noise and oxygen saturation can occur even between two digits on the same hand. By rotating the sensor sites, all sensors are exposed to the same physiologic and anatomic variations. Although these variations may be small they are quite real and can appear to cause small, albeit "statistically significant," differences between oximeters.
5. Devise the evaluation such that determination can be made as to which pulse oximeter will make a clinical difference. When the pulse oximeters' measurements differ substantially (e.g. 97% vs. 85%), identify which one is reading correctly, and which is not, in order to bring comparative meaning to the evaluation, as well as to guide clinical decision/intervention once the appropriate oximetry technology for the hospital has been determined. Thus, beyond the fundamental exchange of arterial oxygen saturation, the evaluation should be considerate of other measurements and parameters that improve the quality of care and reduce costly errors.
6. Continuously log SpO_2, pulse rate and other data from all the test units, (for e.g. the Low Signal IQ message for Masimo and the Motion and Pulse Search indicators for Nellcor) as well as perfusion index (PI), Pleth Variablity Index (PVI), and heart rate, if available.
7. Evaluate the pulse oximeters on the most clinically challenging patients in all departments (OR, PACU, NICU, ICU, Sleep Lab, ER) that are considering a switch to next generation pulse oximetry. It is the most difficult patients that cause pulse oximeters to fail, so to choose the best system for patients, it is imperative that difficult patients are included in any evaluation.

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Side-by-side evaluations to minimize variables

When designing pulse oximetry evaluations it is essential that every effort be made to decrease the amount of external confounding variables. Variables that can be controlled and minimized include such things as patient-to-patient variability, site-to-site physiologic differences and changes that occur within the patient during the course of treatment (changes in their clinical condition). Minimize the external variables to maximize the veracity of results, which also serves to decrease the necessary sample size for the evaluation.

Evaluations should thus be designed such that all of the oximeters being evaluated can be placed on the same patient at the same time; this is referred to as a side-by-side evaluation. When conducting side-by-side evaluations of the pulse oximeters, evaluate them on the same subjects, under the same changes in physiology and during the same clinical conditions, thereby minimizing the amount of variables in the evaluation. Exposing all evaluated oximeters to the same conditions at the same time enables a direct comparison of the performance of each device under identical conditions - the ultimate circumstances to drive a true comparison.

Compare similar sensors and sites to minimize variables

Another factor to consider to minimize variability is to use the same sensor type (compare adhesive to adhesive or reusable finger clip to reusable finger clip). Manufacturers construct different types of sensors for different conditions and each type has its own advantages and disadvantages. For example, adhesive sensors are made in wide variety of sizes. If the correct size sensor is used the best results will be obtained. If an incorrect size is used, suboptimal results will be obtained. Using one size (correctly) from one manufacturer and another size (incorrectly fitting) from another manufacturer will introduce an artificial and uncontrollable variable - effectively comparing apples to oranges.

Compare similar sites to minimize variables

Likewise sensors should be placed on similar sites (digit to digit, ear to ear, forehead to forehead, and on babies, hand to hand or feet to feet). Compare the differences in technology and not differences in human physiology at different sites. Several critical conditions exist that can cause perfusion differences at different sites. Congenital heart disease is one example of a condition that can cause shunting of blood and unequal distribution of blood throughout the body. Shock is another condition that can cause the body to unevenly distribute the blood. In order to make certain that each oximeter is exposed to the same conditions in each patient, every effort should be made to monitor similar sites during the evaluation.

Rotate sensor sites to expose each oximeter to similar local conditions

Finally, switch the sensor sites midway through the study on each patient to minimize differences between the sites. Peripheral perfusion, the amount of noise at the sites, and even the true arterial oxygen saturation may vary from site to site, even on the same patient. Conditions may exist that cause side to side differences in arterial oxygenation. Usually these differences are small, within the range of 1 - 3% saturation. These typically small differences are often observed and may become extreme in certain critical conditions. The most common of these conditions is called Patent Ductus Arteriosus or PDA. In this condition, because of an open conduit between the pulmonary artery and the descending aorta, the lower portion of the body and the right arm will have significantly lower SpO_2 values than the left arm and the brain. Do not consistently and unfairly expose one sensor

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(and oximeter system) to conditions that are different from the other sensor and oximeter system being evaluated, even if these conditions are small. Without switching sites within the same subject, a low confidence level in results may follow because both sensors were not normalized to the same clinical conditions.

Devise the evaluation to detect clinical differences

In well perfused patients, with stable physiology, most modern pulse oximeters will provide accurate data. In patients who are critically ill, experiencing rapid and critical changes in physiology, the differences in pulse oximetry technology become apparent. The evaluation should be devised such that when the pulse oximeters are reporting information that lead to different clinical decisions about the patient (for example one is reporting 97% and one is reporting 82%), document the difference and determine which oximeter is correct. Or if one pulse oximeter is "working" and one isn't, you can tell if the one that is apparently working is reporting data that represents the patient's true physiology (clinically useful data) rather than "freezing" or holding old data.

In order to accomplish this type of comparison, determine the actual arterial oxygen saturation and pulse rate when there are clinically relevant differences between the values reported by the pulse oximeters under evaluation. Of course the "Gold Standard" method to determine oxygen saturation and pulse rate is an arterial blood gas analysis (with CO-Oximetry) together with an ECG monitor for heart rate. Recording the arterial line pulse rate or ECG heart rate continuously to a common data file also containing the pulse oximetry data will help determine the "correct" pulse rate during changing conditions and is relatively easy to do. However, there are many limitations to the use of blood gases for determining accuracy of SpO_2 in a clinical setting. A controlled laboratory environment is needed for quality accuracy studies for several reasons including, most importantly, the establishment and maintenance of a stable SaO_2 during the period of time the blood sample is obtained for comparison to the SpO_2 values from the pulse oximeters. Many problems exist when you try to use blood gas measurement to determine accuracy in the changing clinical situation, including:

1. The challenge of stable data (the patient's clinical condition is capable of changing quite rapidly); by the time you obtain a blood gas sample the SpO_2 is likely to have changed.
2. The intense clinician attention required to monitor patients for these potentially dynamic states.
3. The unpredictable nature of the disagreement between oximeters under evaluation; one can never know when the patient's condition will cause problems for one or more of the oximeters.
4. Lack of access to arterial blood sampling for all patients.
5. IRB approval and informed consent is typically needed to obtain arterial blood samples not necessary for routine clinical care.

Recording important clinical events

Continuous recording of the oximeter data to a computerized system allows the capture of events that might otherwise be missed, or which occur during times when attending caregivers are busy with other clinical responsibilities. Also, it is paramount that the data be collected to determine data availability and data integrity from each pulse oximeter. This involves logging SpO_2 and pulse rate data from all the test units, as well as an ECG monitor if available. Additionally, it is very helpful to log the other indicators that assess signal quality. For example, the Low Signal IQ message, and the perfusion index from Masimo devices, and the frequency of the Motion and Pulse Search indicators for Nellcor devices.

Logging the data with computer programs allows objective accurate review of the data following completion of the evaluation. Programs, such as PhysioLog (available from Masimo and discussed below) allow for simultaneous recording of all pulse oximeters and ECG heart rate. Comments, such as when an ABG was taken or important notes concerning the patient's condition, can be entered and time stamped while the data is being collected. In addition, PhysioLog allows for collection of raw Red and Infrared data.

Select challenging patients for the evaluation

As mentioned earlier, the real differences in next generation pulse oximetry technology become apparent when monitoring critically ill patients. As such, consider including patients in the evaluation that present problems for conventional pulse oximeters. Patients that are moving (seizures, shivering, kicking or crying), or patients who have poor perfusion are two examples of difficult patient types. The evaluation should include the toughest patients in all the departments (OR, PACU, NICU, ICU, Sleep Lab, ER) that are considering a switch to new generation pulse oximetry.

Once the evaluation has been correctly designed, with the goal of determining which pulse oximeter will improve patient care and outcomes, careful analysis of the data is important. Use of tools like PhysioLog (to collect the data) and the Automatic Data Collection (to know which oximeter is reading correctly), offer the best method for determining differences between test pulse oximeters

PhysioLog

Masimo has developed a data collection system for collecting physiological data from multiple monitors. This system includes a software program, PhysioLog, which can be installed on any Windows-based computer, such as a laptop computer. A USB to serial multiplexer (Edgeport) is then connected to the laptop computer. This Edgeport device allows simultaneous data collection from up to 8 separate monitors. This system allows for the collection of SpO_2 and pulse rate from pulse oximeters, as well as quality indicators provided by the pulse oximeters. In addition, other parameters such as ECG heart rate from multiparameter monitors can be collected. These physiological parameters can be viewed in real time and displayed as a trend when the PhysioLog program is running. Comments can be added and stored in the file at any time. Once data collection is complete, the stored data can be reviewed in trend format in one-second intervals. From all the collected data, the parameters of interest (for example, SpO_2 and pulse rate) can be chosen and added to the trend plot. In addition, to help with assessing data quality, the indicators from the pulse oximeters (such as motion lights, Pulse Search from the Nellcor device or Low Signal IQ message from the Masimo device, etc.) can be added to the plot. The comments that were stored in the file can be displayed to indicate where they occur in the trend. All comments can be printed in tabular format. The trend plots and comment tables can then be printed for permanent record.

Collect and Review the Data Objectively - Use of PhysioLog & the Automated Data Collection

Figure 1 is a snapshot of data collected by PhysioLog. It shows two pulse oximeters that are monitoring the same patient. There appears to be an event with a desaturation and an increase in pulse rate. Looking at the trend plot, it is difficult to ascertain which pulse oximeter is reading correctly. Is this desaturation real, should the patient receive treatment? This is where the Advanced Comparative Analysis methodology, a clinical comparison of pulse oximetry technologies during either static or dynamic conditions when arterial blood samples are not freely available, can be a big help in arriving at the truth. The Automated Data Collection Comparative Technology Analysis represents a powerful tool for clinicians to study pulse oximetry performance and physiology.

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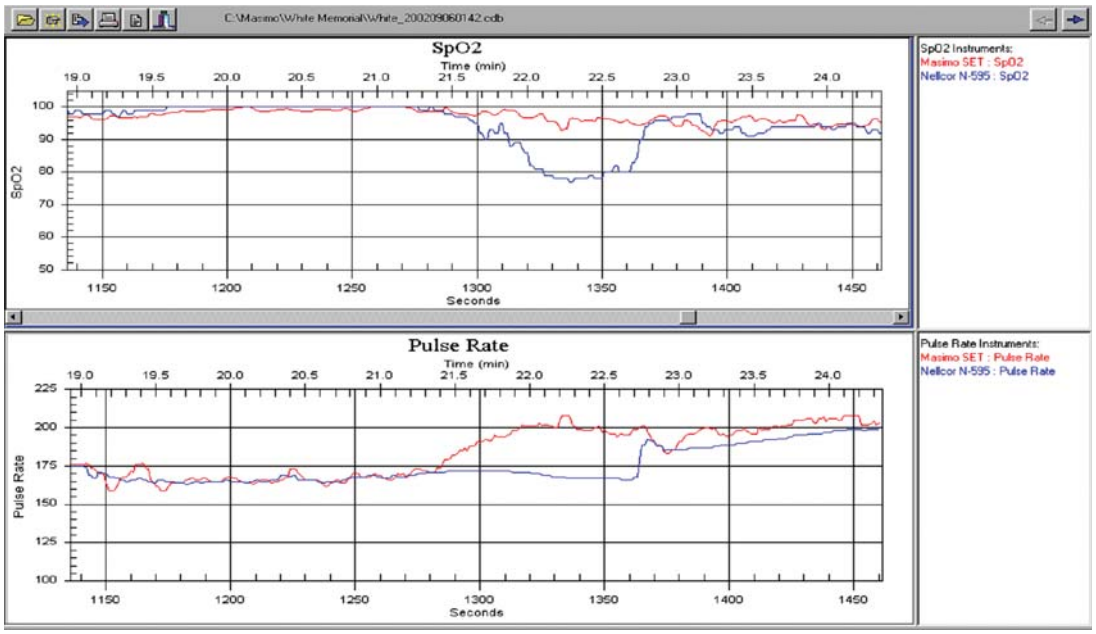

Figure 1 - This trend plot displays periods of agreement and disagreement between two pulse oximeters (Masimo SET Radical and the Nellcor N-595), for both SpO_2 and pulse rate. When they are disagreeing, which is correct? The Radical is reporting SpO_2 in the 90s between minutes 21.5 to 23, but the N-595 shows a desaturation to the 70s with pulse rate. Which is accurate?

Example of Automated Data Collection with PhysioLog

We will focus our example of the Automated Data Collection on the data collected in Figure 1 where measurement disparity between the two pulse oximeters is observed.

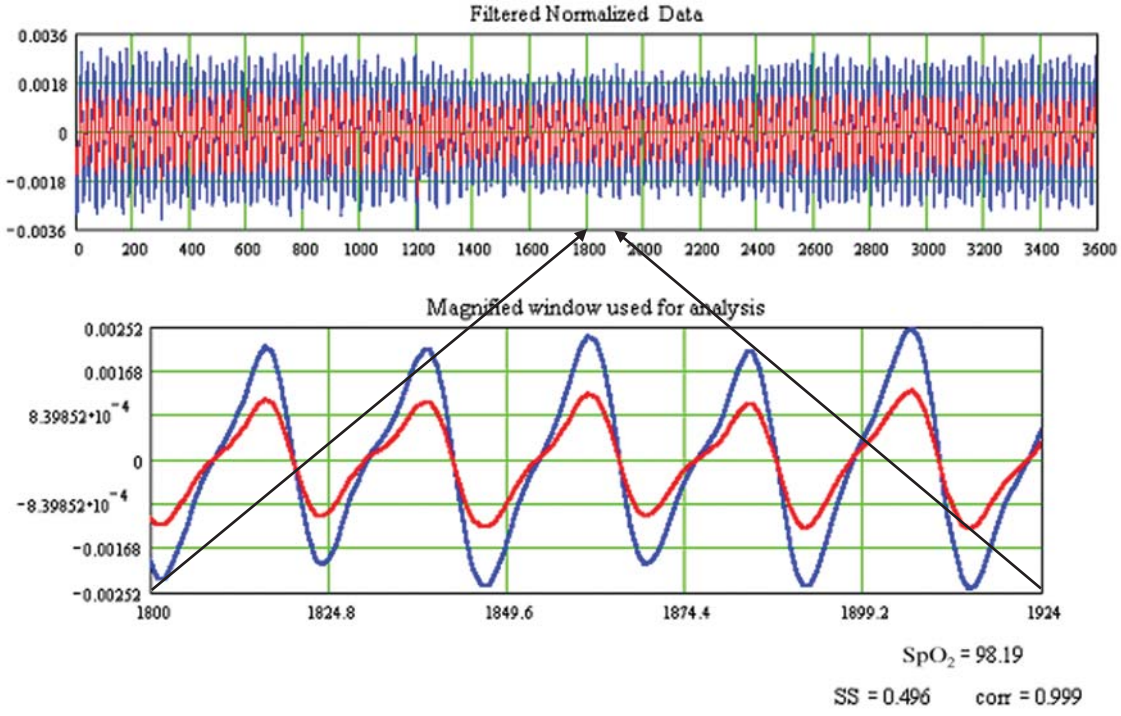

Figure 2 - Raw wave form data collected during minutes 20 to 21 from Figure 1. Lower panel shows data collected at minute 20.5.

Starting at minute 20 (Figure 1), Figure 2 (top panel) displays 60 seconds of raw data. At this point, the data is very clean, i.e., it is not perturbed by motion or other artifact. During the time between minutes 20 to 21, there is very close agreement between the two pulse oximeters. The SpO_2 found in the lower panel 2-second window (approximately minute 20.5 in Figure 1) is 98.2% with a pulse rate of ~165 bpm (~5.5 x30).

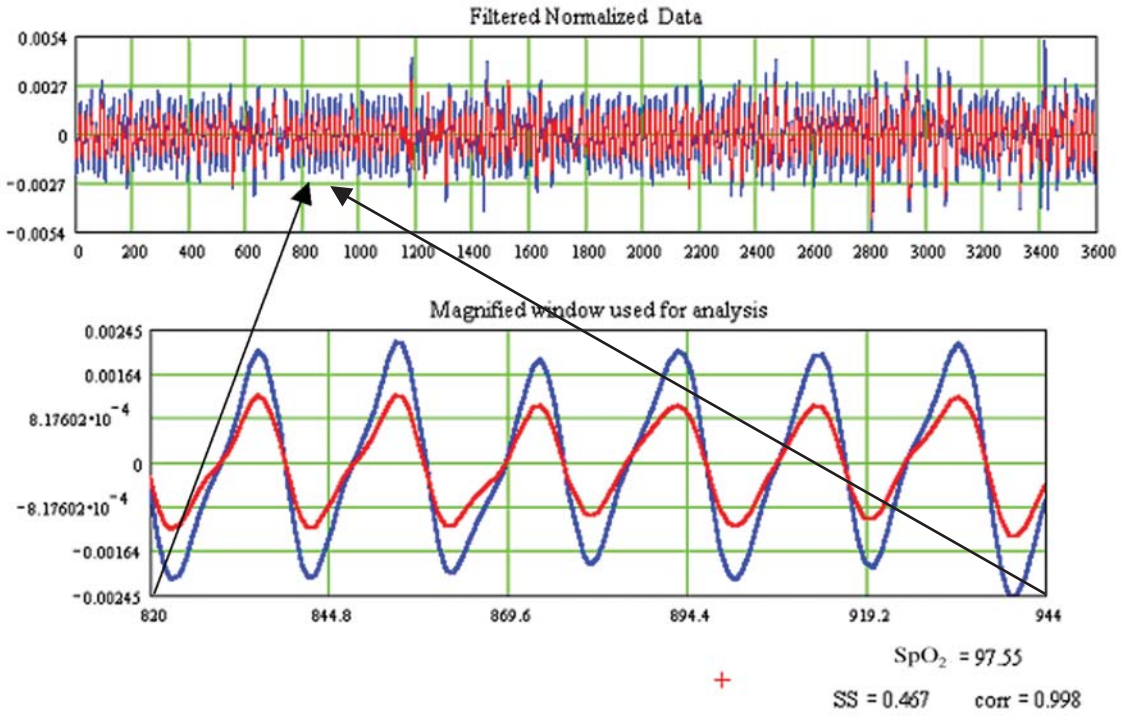

Figure 3 - Raw waveform data collected during minute 21.5 to 22.5 from figure 1. Lower panel shows data collected at minute 21.7.

In Figure 3, the upper panel shows 60 seconds of raw waveform data from minute 21.5 to 22.5 (from Figure 1). Notice that this data shows intermittent motion is present for most of this interval (shown by the distorted, non-uniform plethysmographic waveforms). Within this period of motion, a 2-second segment of clean data occurs starting at point 820 and shows the SpO_2 to be 97.6%. The calculated pulse rate from this small segment of data would be approximately 6.3 x 30, or 189 bpm.

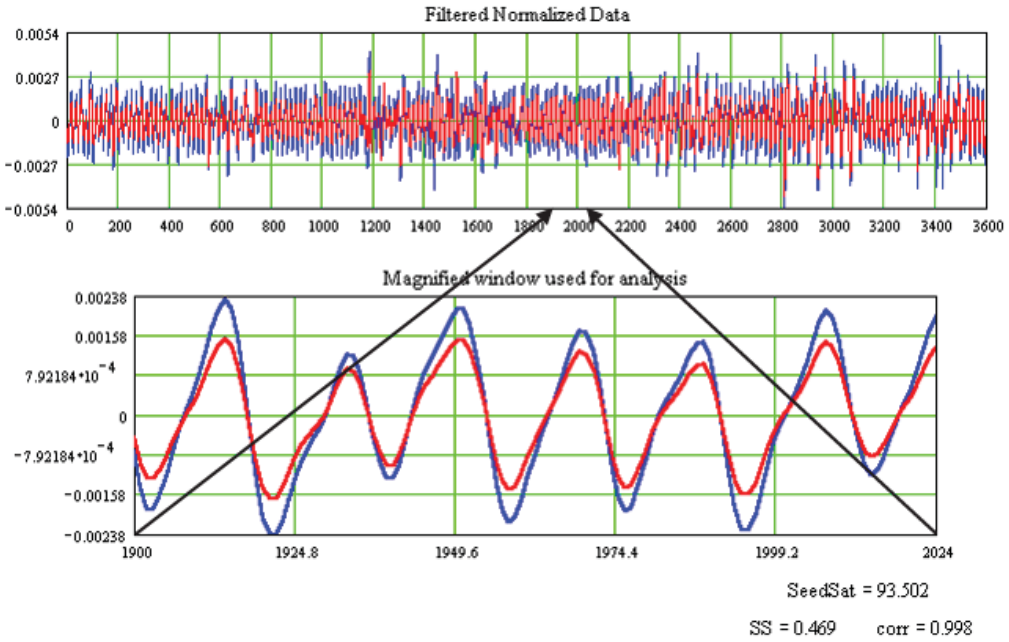

Figure 4 - Raw waveform data collected during minute 21.5 to 22.5 from figure 1. Lower panel shows data collected at minute 22.0.

This small segment of data (lower panel) in Figure 4 above occurs approximately 15 seconds later than the data shown in the lower panel of Figure 3. By using the Advanced Comparative Analysis, it reveals an SpO_2 of 93.5% and a pulse rate of approximately 200 bpm (6.7 x 30).

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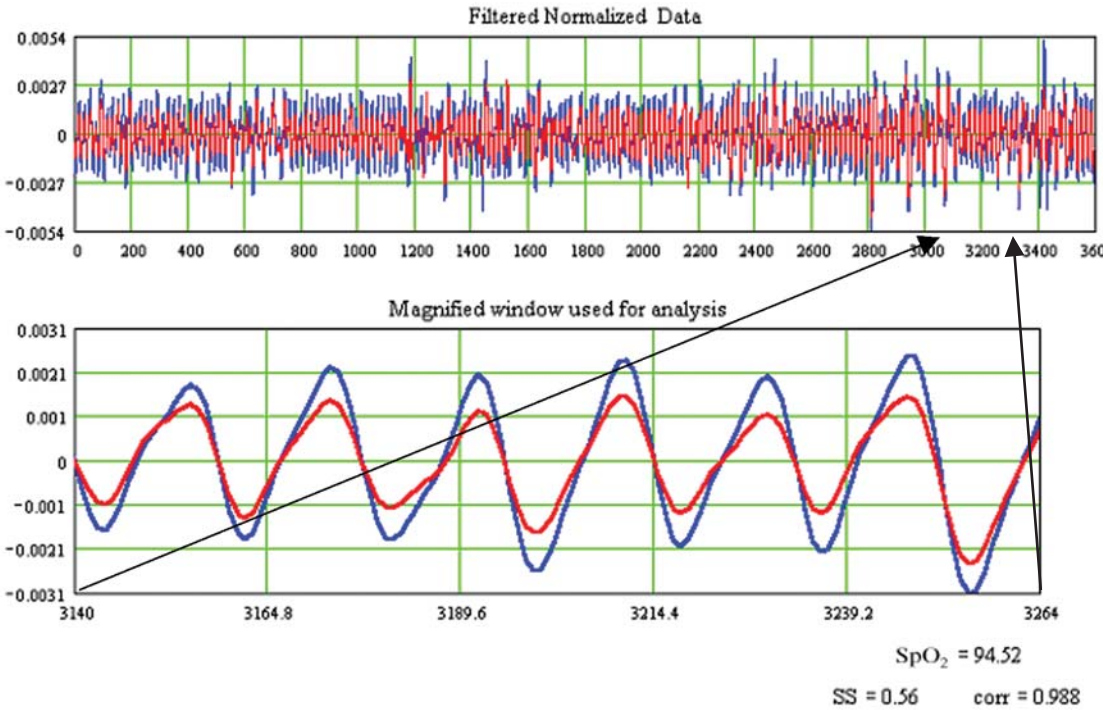

Figure 5 - Raw waveform data collected during minute 21.5 to 22.5 from figure 1. These values correspond to the displayed numbers that occurred approximately at minute 22.3.

The upper panel again displays the same 60 seconds of raw waveform data from minute 21.5 to 22.5. The lower panel shows 2 seconds of fairly clean data with SpO_2 of 94.5% and pulse rate of ~195 bpm (~ 6.5 x 30).

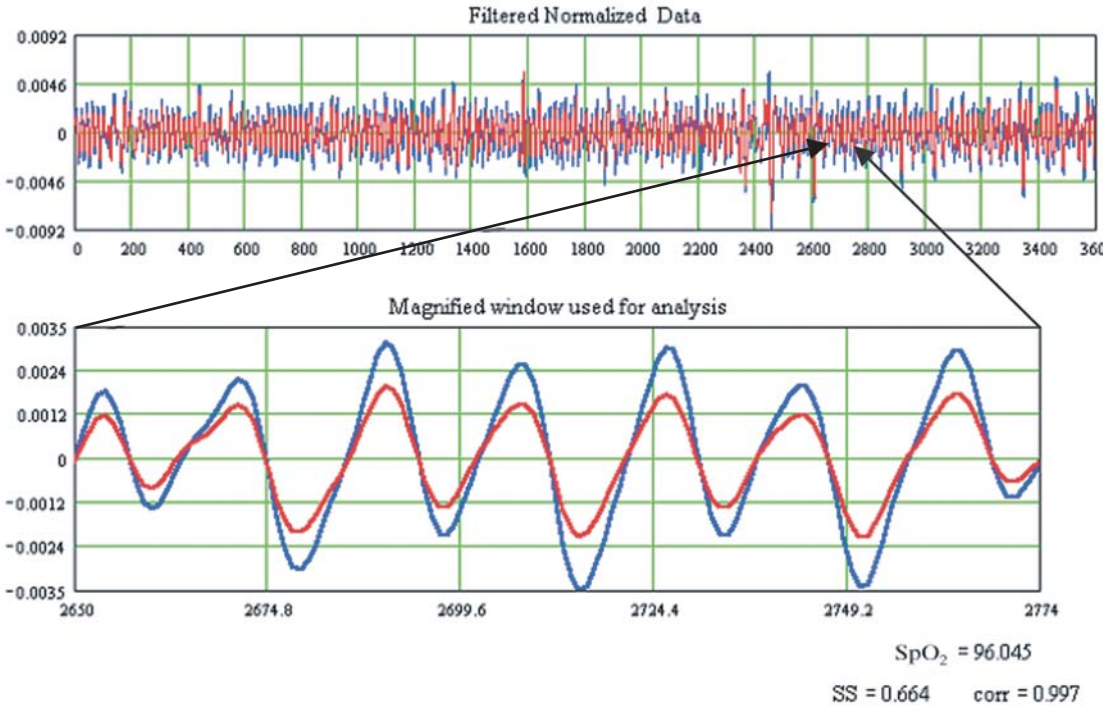

Figure 6 - Raw waveform data collected during minutes 23 - 24 from figure 1. Lower panel shows data collected at minute 23.7.

The lower panel displays 2 seconds of fairly clean data and, therefore, the SpO_2 of 96.0% and pulse rate of ~ 207 bpm (6.9 x 30) can be calculated.

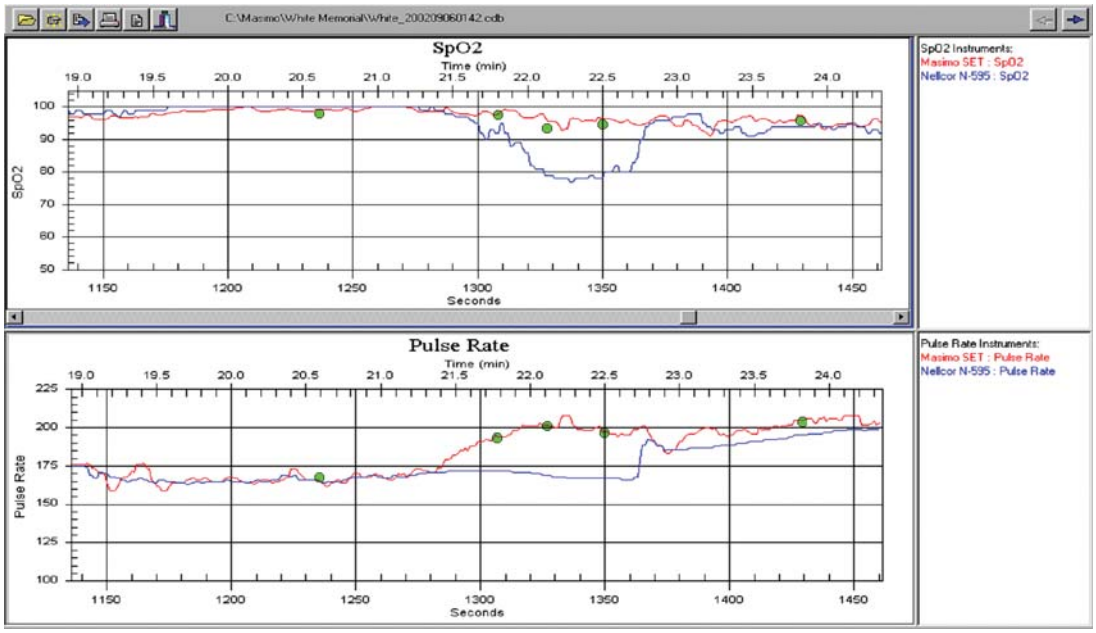

Figure 7 - Results of Comparitive Technology Analysis

In Figure 7 above, the inserted green dots show the values obtained by Advanced Comparative Analysis from normalized red and infrared raw data described in figures 2-6. These data points correspond well with the displayed SpO_2 values from the Masimo SET Radical, and thus suggest the Masimo SET pulse oximeter was able to process through the artifact during this data collection period and correctly track the patient's SpO_2 and pulse rate. The drop in SpO_2 and apparently "frozen" pulse rate values from the Nellcor N-595 may be the result of their oximeter failing to process through the artifact correctly.

It has been shown through the above screen captures and plots that the Advanced Comparative Analysis can be used in determining the correct values for SpO_2 and pulse rate when two pulse oximeters are displaying different results for the same patient. It is also extremely valuable when analyzing rapid changes in SpO_2 and/or pulse rate.

References

1. Durbin CG, Rostow SK. More reliable oximetry reduces the frequency of arterial blood gas analyses and hastens oxygen weaning after cardiac surgery: a prospective, randomized trial of the clinical impact of a new technology. *Critical Care Medicine.* 2002;30:1735-1740.
2. Patel DS, Rezkalla R. Weaning protocol possible with pulse oximetry technology. *Advance for Respiratory Care Managers* 2000;9(9):86.
3. Chow LC, Wright KW, Sola A, et al, Can changes in clinical practice decrease the incidence of severe retinopathy of prematurity in very low birth weight infants? *Pediatrics.* 2003;111:339-345.

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