Signal Extraction Technology
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3.1 Signal Extraction Technology

Learning Objectives

Upon completion of this section the participant will be able to:

- Describe the SET pulse oximeter system and its improvements versus conventional and next generation pulse oximetry systems.
- List unique characteristics of the SET sensor and SET cables that improve the signal to noise ratio.
- State how Discrete Saturation Transform (DST) is able to remove the effects of venous motion induced false desaturations (venous averaging).
- Describe how SET reads during poor perfusion.
Vocabulary

Adaptive Filter – advanced filters that can change their performance and adapt what they filter based on feedback from the type of noise they encounter. Masimo is the innovator of adaptive filters in pulse oximetry and the only company that has them because of its patent position. The adaptive filters in Masimo’s pulse oximetry technology allow for many clinical advantages.

Conventional Pulse Oximetry – pulse oximetry technology that is not able to measure through motion and low perfusion.

Next Generation Pulse Oximetry – conventional pulse oximetry technology that has been modified by the manufacture to appear to measure through motion, when in fact it doesn’t.

Parallel Algorithms (also called parallel engines) – several advanced processing techniques that process the same signal simultaneously or in parallel, each algorithm with its own own approach to removing noise.

Recessed Detectors – detectors that are not directly on the skin but are positioned off of the skin to reduce noise created from ambient light.

Sensitivity – the percent of time that the pulse oximeter displays a value within its accuracy claims and does not miss true alarms. Higher sensitivity means fewer missed true desaturations or fewer false negatives.

Signal Extraction Technology – a breakthrough in pulse oximetry using adaptive filters and parallel algorithms that can read through motion and low perfusion. This is what gives Masimo its advantage in being able to read through motion and low perfusion.

Specificity - the percent of time that the pulse oximeter does not indicate a false alarm. Higher specificity means fewer false desaturations and fewer false alarms or false positives.

Triboelectric – the unwanted generation of electrical charges by a charge of electricity generated by friction.

Venous Averaging - the averaging of venous and arterial saturation - used in conventional pulse oximetry which cannot read through motion.
Signal Extraction Technology

In 1989, Masimo introduced Signal Extraction Technology (SET), a breakthrough in non-invasive monitoring. SET far exceeds any other pulse oximetry technology at correctly extracting the signal from the noise by using several innovative techniques to optimize the signal and reduce the noise or improve the signal to noise ratio.

SET is not just a better pulse oximeter it is a complete system redesign (Figure 3.1:1). SET improvements include the sensor, the cable, and the pulse oximeter’s hardware and software (signal processing). These improvements have allowed Masimo SET to become the gold standard in pulse oximetry.

**Figure 3.1:1 - Signal Extraction Technology System**

SET has upgraded and improved each of these components so that the entire system can extract signals up to ten times smaller than any other oximeter manufacturer. We will look at each of these components and discuss the improvements that they contribute to the overall pulse oximeter system.
Sensor

Masimo SET was the first technology to use shielding in the sensor design (image, right) and has included the low noise distinction in the name of its sensor product line, LNCS and LNOP (LN indicates “Low Noise”). The extra shielding eliminates electrical noise that might otherwise be picked up by the detector.

Recessed detectors and side shields (image, left), also reduce the amount of ambient light that can reach the detector.

This change in sensor design accounts for an estimated 20% of the overall improvement in the SET solution; therefore, customers who elect to use Masimo sensors with SpO₂ technology other than Masimo SET would experience marginal improvements. The full benefit of SET technology can only be experienced by using the complete SET system; however, no matter what SpO₂ technology is used, sensor placement is critical - the emitter and detector must be in perfect alignment in order to achieve maximum sensor performance.

Cable

The cable is vital component of SET technology and its importance is often overlooked. The cable connects the sensor to the pulse oximeter and acts just like an antenna. Like antennas, it can pick up unwanted signals which increase the amount signal noise that interferes with the real signal. Cables also create triboelectric noise (interference during motion, like swinging). Improvements to the SET cable include additional shielding which minimizes interference and optimizes the signal to noise ratio.

Figure 3.1:2 - Low Noise Set Cable
Signal Processing - Adaptive Filters and Parallel Algorithms

Although the sensor and the cable are important components to the overall noise reduction, the real strength of SET technology is in the signal processing. By using adaptive filters and parallel algorithms (engines) to extract the arterial signal from the noise, the characteristics of filtered frequencies can change based on the feedback from the noise encountered.

The ability to continually adapt to changing clinical environments greatly improved the pulse oximeters’ performance. Algorithms, step by step mathematical processes used to solve problems, are used to analyze the pulse oximetry signal. Currently SET has five different algorithms (blue boxes Figure 3.1:3) used to eliminate the noise from the signal. Each algorithm is designed for a specific type of noise. Their unique strengths are leveraged to ensure accurate readings through all patient conditions. As the signal and noise are processed through each algorithm, a confidence value is assigned. The signal is then sent to the arbitrator where the reliability of the information is determined and a final saturation value is displayed.

![SET “Parallel Engines”](image)

**Figure 3.1:3 - SET “Parallel Engines”**

The red/infrared algorithm is sufficient for well perfused, immobile patients and is most commonly applied. Its accuracy under these conditions is comparable to other oximeters. As long as a patient is well perfused and does not move the arbitrator will assign a high confidence level to the R/IR algorithm but, during motion and low perfusion, the conventional red/infrared algorithm begins to produce false desaturations. Increased noise due to venous averaging makes it difficult to determine the arterial signal. Masimo’s Discrete Saturation Transform (DST) proprietary algorithm solved this previously unsolvable problem. DST is Masimo’s most powerful algorithm and the driving force behind measure through motion technology.
The figures above illustrate the effects of venous noise on the performance of DST’s adaptive filter. A trial saturation value is tested using a reference signal at all possible saturation values beginning at 1% and continuing up through 100%. Each of these attempts is plotted along the x-axis at the corresponding saturation level. The amount of power required by the adaptive filter at each attempt is indicated on the y-axis. In well perfused, motionless patients, the adaptive filter detects only one power peak (figure 3.1:4) which is caused by the moving arterial blood. Since venous averaging does not occur during a motionless state, the DST algorithm can easily detect the saturation value correlating to the arterial peak. In contrast, during patient motion, the DST algorithm detects two “power peaks” from the adaptive filter – one at the venous saturation value (caused by moving venous blood) and the other at the arterial saturation value (See Figure 3.1:5). The algorithm then selects the power peak that correlates with the highest saturation value. This value correctly identifies the arterial saturation and the process is repeated two and one half times per second in order to continually tract the arterial saturation value during motion.

The strength of Signal Extraction Technology lies in its flexibility and adaptability. SET is the only system that can eliminate the most difficult type of noise, movement and venous averaging. Although other oximeter manufacturers have tried to measure through motion, they have never achieved the success of Masimo SET. Figure 3.1:6 illustrates the power of SET technology. The signal in conventional oximetry
can be masked by noise (movement, venous averaging, and low perfusion). In these difficult situations conventional pulse oximetry will either create a false alarm or freeze the value on the screen until it is able to acquire the signal again. Masimo SET, on the other hand, filters through the noise and is able to extract the signal - even when other manufactures can’t. SET is the only solution that works continually (97% to 98% of the time) in the clinical environment. During periods of motion and low perfusion, Masimo SET devices are the most sensitive (the ability to detect true desaturations) and specific (the ability to reject false desaturations) pulse oximetry devices available today.

**Figure 3.1:6 - Signal and Noise Relationship**
Sensitivity and Specificity

Masimo SET is clinically proven to have the highest sensitivity and specificity by far over competitive devices making it the gold standard. The chart below\(^1\) (Figure 3.1:7) indicates Masimo’s technology results in far more true alarms and far fewer false alarms. In fact, Masimo demonstrated specificity at 95%. In other words, 95% of the time, when a SET device alarmed, a real event took place (only 6 of 120 alarms were false alarms). During motion or low perfusion, the N-600 had a specificity of only 71%. In other words, 34 of 120 alarms generated by the N-600 did not coincide with an actual event, or were “false alarms”. GE TruSat had a specificity of 82%; 21 of 120 alarms generated by GE were false.

<table>
<thead>
<tr>
<th></th>
<th>Missed Event</th>
<th>Sensitivity</th>
<th>False Alarm</th>
<th>Specificity</th>
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</thead>
<tbody>
<tr>
<td>Masimo SET</td>
<td>1/40</td>
<td>97.5%</td>
<td>6/120</td>
<td>95.0%</td>
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<td>Nellcor N600</td>
<td>17/40</td>
<td>57.5%</td>
<td>34/120</td>
<td>71.5%</td>
</tr>
<tr>
<td>GE-D/O TruSat</td>
<td>33/40</td>
<td>17.5%</td>
<td>21/120</td>
<td>82.5%</td>
</tr>
</tbody>
</table>

Figure 3.1:7 - Independent study comparing Masimo SET vs. N600 and GE’s “TruSat” Technology

**IMPORTANT:** All Pulse Oximeters have False Positive States – False Alarms. All Pulse Oximeters have False Negatives States – Missed true desaturations. Masimo SET has vastly fewer false positives and fewer false negatives than other pulse oximetry technologies.

**Important Clinical Issues**

Due to Masimo’s technological superiority, clinician should be made aware of the following:

- First, since there is a 95% chance that a real event is occurring when a Masimo device alarm sounds, clinicians need to reset their thinking and relearn to respond to device alarms. Over time the numerous false alarms generated by conventional pulse oximeters has desensitized clinicians to the sound of alarms. Patient safety may be comprised if a clinician chooses to ignore alarms produced by Masimo SET devices.

- Second, all pulse oximeters have false negative states- i.e. desaturation is occurring but the oximeter doesn’t detect it. Masimo SET devices are highly sensitive and therefore have the fewest missed real events when compared to other pulse oximetry technology. So while you can count on Masimo SET more often, you still must be vigilant for scenarios where even a Masimo SET device is not reading correctly- such as malpositioned sensors, anemia, presence of carboxy- or methemoglobin, or a sensor that has fallen off but may still be reading.

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\(^1\) Nitin Shah, M.D., Laverne Estanol, M.S. *Anesthesiology*, 2006 Long Beach VA Medical Center, UC Irvine Medical Center, Long Beach, California Comparison of Three New Generation Pulse Oximeters During Motion and Low Perfusion in Volunteers.
3.2 Sensitivity Settings and Probe Off Detection

Learning Objectives

Upon completion of this module you will be able to:

- Define the three sensitivity levels of Masimo SET and the clinical areas where each should be used.
- Discuss the appropriate clinical necessity of utilizing multiple sensitivity settings.
- Discuss the trade-offs between increasing sensitivity to reading during low perfusion versus the ability to detect ‘probe off’ conditions.
- State probing questions to identify selectable sensitivity settings as a key feature that separates Masimo SET from conventional oximetry.
- Identify pertinent sales tools and support material for Sensitivity and Probe Off detection, and know when to use them.
Vocabulary

Test your knowledge

Adaptive Probe-Off Detection (A POD) – a sensitivity mode that enhances probe-off detection

OEM – Original Equipment Manufacturer, Masimo Partners that incorporate SET technology in their products

Probe-Off Detection – the ability of the oximeter to determine when the probe has come off the patient
Signal to Noise Ratio

The ability to measure during very low perfusion

Low perfusion results in a very small amplitude signal. It can actually reach a point where it becomes difficult to distinguish the small signal from the background noise. Detecting the actual SpO₂ signal during low perfusion situations is made more difficult during periods of motion. In effect, the motion raises the background noise level thereby making it even more difficult to distinguish the small amplitude SpO₂ signal during low perfusion. The clear advantage of Masimo SET is in the ability to accurately measure SpO₂ during the most difficult of clinical situations, periods of low perfusion and patient motion.

Masimo has accomplished this feat through its proprietary algorithm, hardware and sensor design. Through the use of specially designed low noise sensors, cables, and circuit boards, Masimo engineers were able to obtain the accurate arterial signal, SpO₂ and pulse rate during very weak pulsations. Masimo SET algorithms assist in picking up the pulsations in the midst of artifacts caused by motion and other interference; however, there has been important trade off. By increasing the oximeter’s ability to measure during very low perfusion (weak signals) a small loss in the ability to determine if sensor has come off the patient occurs.

Three Sensitivity Settings Let Clinicians Choose the Balance of Sensitivity during Low Perfusion and Ability to Detect Probe-Off

Masimo SET provides clinicians the opportunity to select from three levels of device sensitivity whereas conventional and next generation oximeters offer only a single, fixed level of device sensitivity. Masimo SET sensitivity settings include Adaptive Probe-Off Detection (APOD), Normal and Max, and as you can see in the graphic below, each these settings overlaps portions of the others.

![Diagram showing three sensitivity settings: Normal, Max, and APOD](image)

**Figure 3.2:1 Sensitivity Settings**
All clinical monitors, including the pulse oximeter, are affected by specific circumstances that can impair accuracy and reliability. For example, pulse oximeter systems may erroneously display numbers when the sensor is detached from the patient (undetected probe-off). In most cases, when a sensor is accidentally dislodged from a patient and continues to display readings, the pulse oximeter readings will not be in the normal physiological range and therefore will trigger an alarm alerting the clinician of the problem; however, in rare circumstances the pulse oximeter can give erroneous readings within the normal physiological range. Because the pulse oximeter is no longer reading the patient’s actual oxygen saturation or issuing an alarm to alert the caregiver of the problem, this undetected probe-off condition, if desaturations occur, can potentially endanger the patient. The undetected probe-off condition is a serious limitation of pulse oximetry and no pulse oximetry manufacturer appears to be immune from the undetected probe-off condition.

Normal sensitivity mode, when compared to APOD, moderately broadens the spectrum or criterion for what is an acceptable pulsatile signal received by the oximeter. As the perfusion deteriorates the pulse signal becomes dampened and compromised by artifact noise. In this situation, medical personnel may increase the sensitivity setting from APOD to Normal. At this setting, when the patient’s physiology is slightly compromised and low signal quality or a low perfusion state is detected by the Masimo pulse oximeter, a “Low Signal IQ” or “Low Perfusion” system message appears.

Masimo pulse oximeters used in the Max sensitivity mode are more susceptible to the undetected probe-off condition because the algorithms interpreting the incoming signals have been sensitized to see a physiological signal from even small variations in the source. On the other hand, algorithms developed to enhance probe-off detection will result in lower sensitivity and therefore decrease pulse oximetry low perfusion performance.

**Weaknesses of conventional and 'next generation' pulse oximeters**

- Conventional and ‘next generation’ pulse oximeters offer only one sensitivity setting that cannot be changed.

- Conventional and ‘next generation’ pulse oximeters lack the technology that for reliable measurement during low perfusion states. Competitive pulse oximetry vendors recommend the use of expensive specialty sensors (forehead, ear, and nose) to continue monitoring low perfusion patients; however, studies indicate that the use of specialty sensors is greatly affected by the patient’s physiological status and by mechanical artifact.
The N-600 operators manual states, "...The N-600 algorithm automatically extends the amount of data required for measuring SpO2 and pulse rate depending on the measurement conditions." This means the N-600 may hold or freeze old data during motion or low perfusion for prolonged periods of time. Thus, the N600 may transition from a real time monitor to a static display during the most challenging clinical conditions.

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>BENEFIT</th>
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<tbody>
<tr>
<td>Selectable Sensitivity settings, including advance Probe off detection, Normal, and Max sensitivity for use on patients with increasingly difficult or compromised perfusion.</td>
<td>Dramatically improves signal acquisition on patients in very low perfusion states. This reduces or eliminates the need to place multiple sensors, or high cost specialty sensors on patients unnecessarily, thereby reducing costs and saving valuable caregiver’s time</td>
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</tbody>
</table>

Probing Questions on Issues Specific to Multiple Sensitivity Settings

- What do you currently do to improve sensitivity on your pulse oximeter if your patient’s physiological status deteriorates and their perfusion becomes progressively worse?
- How would an oximeter that enables you to continue using finger sensors on your most difficult, critically ill patients without having to put on multiple sensors or use expensive specialty sensors (forehead, ear, and nose) effect your clinical practice?
- How would it affect your clinical practice if you had a feature on your pulse oximeter that allows you to enhance the sensitivity of the instrument and enable the oximeter to monitor during low perfusion or low signal quality?
OEM and Multiple Sensitivity Settings

Some Masimo OEM partners have implemented multiple SET sensitivity settings - usually Normal and Max. However, few have implemented APOD. Refer to the specifics of each OEM device when representing the presence of this feature in an OEM device.

Reference Materials/Sales Tools (can be presented or given to customers)

<table>
<thead>
<tr>
<th>DOCUMENT</th>
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<tbody>
<tr>
<td>Adaptive Probe-Off Detection – A Common Limitation of Pulse Oximetry</td>
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</tr>
<tr>
<td>Super User Training slides</td>
<td>PowerPoint</td>
<td>Clinical Specialists</td>
</tr>
</tbody>
</table>

Note: Whitepapers noted with an *asterisk are papers that are highly recommended for carrying with you when visiting customers.
3.3 Advanced Sensitivity Settings and Probe-Off Detection

Learning Objectives

Upon completion of this module you will be able to:

- Identify and explain common scenarios when undetected probe off may occur.
- Set proper customer expectations regarding the possibility of undetected probe off.
Vocabulary

**Electrocautery** - a process of destroying tissue with electricity to stop bleeding and is widely used in modern surgery (outside US known diathermy)

**Max Sensitivity** - a sensitivity setting on Masimo SET enabled device that allows the measurement of saturation values to very low levels (PI < 0.2%).
**Max vs. APOD Sensitivities in Probe-Off Detection**

Masimo’s max sensitivity is designed to measure during perfusion levels at least 10 fold lower than conventional pulse oximeters. In fact, Masimo SET SpO₂ technology is more sensitive than an indwelling arterial line in detecting arterial pulsations during conditions of low perfusion. [See Masimo Low Perfusion Whitepaper (LAB4793A) and Masimo Performance Comparison DVD for more details.]

To obtain these levels of increased sensitivity Masimo SET makes every effort to seek out even very small pulsations. Masimo’s patented probe-off detection algorithms analyze the relationship between the integrity of the plethysmographic waveform and the perfusion index to determine whether the probe is on or off the patient. Depending on the sensitivity mode set on the device, different combinations of pleth quality and perfusion index will deliver different probe-off alarms.

![Diagram of Probe-Off Detection Limits, APOD and Max Sensitivities]

**Figure 3.3:1**

**IMPORTANT:** In Max Sensitivity setting a Masimo SET device will only go to the “Probe-Off Condition Mode” if the perfusion index falls below 0.02%. However, while in the APOD Sensitivity mode, the monitor will also take into consideration the quality of the pleth waveform in determining whether a probe-off condition exists.
How the Undetected Probe-Off Condition Can Occur

Because conventional pulse oximetry is sensitive to an oscillating signal from the sensor, any interference at the sensor that is pulsatile in nature has the potential to produce a false signal that could be interpreted by the pulse oximeter as a true physiological signal. In addition, emitted light reflected by colored fabrics that are positioned in or near the photo emitter or detector path can also produce an artifactual SpO₂ reading.

Types of Signal Interference that Can Produce an Undetected Probe-Off Condition

**Ambient Light or Light from the Emitter:** The most common type of signal interference that can result in the undetected probe-off condition is ambient light. Surgical lights, bilirubin lights and infrared radiant warmers are all potential sources of false signal that may be interpreted as the physiological signal if the sensor has come off the patient.

**Electrocautery:** Another external factor that can lead to an undetected probe-off condition is electrocautery interference. Electrocautery generates high-frequency currents, which can radiate to the pulse oximetry sensor and interfere with the accuracy of readings when the sensor is correctly positioned on the patient or can result in an undetected probe-off condition if the sensor has become dislodged from the patient.

**Incompatible Sensor Type:** ECRI MDSR and FDA Medwatch reports have documented occurrences of the undetected probe-off condition when a sensor type that is incompatible with the pulse oximeter is used on the patient. In addition, reprocessed sensors might be more prone to interference than new sensors.

Set Proper Expectations with Customers during Evals and Installs Regarding Probe-Off Detection

Internal testing has shown that in all sensitivity settings Masimo SET performs significantly better than Nellcor OxiMax and Philips FAST SpO₂ technology in terms of the time for a device to display zero after sensor removal from a subject (see Adaptive Probe-Off Detection Whitepaper, LAB4546A, for more details and data); however, as stated previously, as with all pulse oximeters there will be times that even a Masimo SET device may continue to display physiologically reasonable values during a probe-off condition. It is therefore important to set clear expectations with your customers that while this condition is not common, and will be less common with Masimo than with other pulse oximetry technologies, undetected probe-off is possible.
The most common scenarios where an oximeter may continue to display readings during probe-off are:

- Sensor that is connected to operating monitor, hanging lose in the OR or ED, waiting for next patient
- Sensor that has fallen off a patient continues to read clinically reasonable values, while under the sheets….in Max or Normal sensitivity. Note that this could be contribute to a ‘false negative’ as the device may not alarm during a true event

**Undetected Probe-Off in Clinical Scenarios**

Even when you set realistic expectations with your Super Users and Clinical Champions, you may run across a scenario where a Masimo user has experienced an undetected probe-off condition and requests an explanation. In this situation touch on the key points outlined below and use the APOD Whitepaper:

- In rare circumstances the pulse oximeter can continue to give erroneous readings within the normal physiological range during ‘probe off’
- No pulse oximetry manufacturer appears to be immune from the undetected probe-off condition
- Any pulsatile interference at the sensor can produce a false signal that could be interpreted by the pulse oximeter as a true physiological signal
- The most common cause is light from surgical lights, bilirubin lights and infrared radiant warmers.
- Emitted light can reflect off colored fabrics that are positioned in or near the photo emitter - detector path can also produce a SpO2 reading that is artifactual.
- Use the sensitivity setting appropriate for the care area and patient
- Only use Max sensitivity when you can visualize the sensor
3.4 Masimo SET Signal Identification and Quality

Learning Objectives:

Upon completion of this module you will be able to:

- Define Signal IQ and its clinical applications.
- Explain the value proposition of Signal IQ.
- Verbalize probing questions to identify customer needs and establish value for Signal IQ.
- Identify and discuss the pertinent sales tools and support material for Signal IQ.
Vocabulary

Test your knowledge

Plethysmograph – infrared pleth waveform displayed on many pulse oximeters, it is used as an indicator of signal quality for conventional oximetry.

Confidence – the degree of quality of the signal, the higher the confidence in the signal the better the quality

Vocal Credible Clinical Champion (VCCC) – a clinician that understands the value of Masimo SET and will drive the conversion process to completion
Clinical Issue

With conventional pulse oximeters, clinicians question measurements when the plethysmogram looks corrupt or the pulse rate does not correlate with ECG heart rate, but with Masimo SET devices a clean pleth waveform is not necessary. The device will continue to report accurate arterial oxygen saturation and pulse rate readings during motion and low perfusion, even when the plethysmographic waveform is distorted from excessive motion; inappropriate sensor type, application or placement; or excessive environmental interference. For this reason the Signal IQ tool was developed. It alerts clinicians when it’s appropriate to question measurements.

Definition of Signal IQ

Signal IQ is a visual indicator of the system’s confidence level. The output measurement and confidence signal from each of the five Masimo SET algorithms is evaluated and combined for composite arterial oxygen saturation. The composite signal quality is represented by the height of the Signal IQ spike. As it becomes more difficult to find the arterial pulse signal, the height of the Signal IQ, or ‘spike’, will decrease. When device confidence is very low, erroneous readings are possible. The "Low Signal IQ" message will flash on the display. Even when the "Low Signal IQ" message is flashing, there is a high probability that the measurement is correct - otherwise the device would not display any values.

Pleth

No motion, high SIQ, high reading confidence

Signal IQ ‘spike’ with each pulse

Motion artifact, high SIQ, high reading confidence

Motion artifact, diminished SIQ and reading confidence

Excessive motion artifact, “Low Signal IQ” message indicates need to consider taking action

Signal IQ is a standard feature of Masimo SET and is available in all Masimo SET devices.
Weaknesses of current methods or competitive devices

Conventional pulse oximeters use the pleth waveform as their primary indication of signal quality. Because the N-600x’s pleth is often significantly corrupted and the interference light is often on, they are a poor indicator of clinically actionable events. In other words, Although N-600 pleth has a signal quality indicator, it is sensitive to non specific motion induced reading errors and produces many false alarms.

Masimo's Differentiated Value Proposition for Signal IQ

Masimo SET Signal IQ is a continuous, objective measure of signal quality that research has shown provides far superior performance. Irregularities do not occur frequently and may save clinicians time and reduce chances of inappropriate interventions.

Probing questions for discovering the need and establishing value for Signal IQ

- How often do you see that the Nellcor ‘Interference’ and/or ‘Pulse Search’ lights are on?
- If a care giver makes an intervention based on erroneous pulse oximetry readings, what are the potential problems from those interventions?
- How much time and frustration do you think it would save clinicians, especially in the NICU, if their pulse oximeters indication of potentially unreliable readings was sensitive and specific?

**KEY SALES ISSUE:** Clinicians may be taught to use a filtered pleth waveform as their indication of the reliability of their pulse oximeter readings. A Masimo SET device can display accurate readings even with a visibly corrupt pleth waveform. Therefore, you must really drive this point home during a side by side demonstration and during a side by side evaluation...

Sales Tools

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<thead>
<tr>
<th>Document</th>
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<td>Masimo SET Bibliography (LAB-1942)</td>
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<tr>
<td>Super User Training</td>
<td>PowerPoint</td>
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</table>
Signal IQ whitepaper

- Explains Signal IQ and gives visual examples of Signal IQ during high and low confidence.
- Describes how to use Signal IQ in clinical settings.
- Explains how Signal IQ works and describes how Signal IQ has been clinical validated.

Target audience: Use primarily as a leave-behind with nurse educators and super users who would like to learn details of Signal IQ and its application.

Masimo SET Bibliography

- Includes summaries of independent journal articles regarding the clinical value of Signal IQ.

Target audience: Use primarily as leave-behind with VCCC’s and product champions who want objective and independent feedback on Masimo SET performance, clinical applications and value.
3.5 Basic Masimo SET
Perfusion Index

Learning Objectives:
Upon completion of this module you will be able to:

- Define Perfusion Index and its clinical applications.
- Explain the value proposition of Perfusion Index.
- Verbalize probing questions to identify customer needs and establish value for Perfusion Index.
- Identify and discuss the pertinent sales tools and support material for Perfusion Index.
Vocabulary

Test your knowledge

**Perfusion** – the amount of blood flow to a given site, calculated by the infrared waveform absorption.

**Pulsatile** - dealing with measurement of the movement of blood with the contraction of the heart.

**Non-pulsatile** - dealing with the non-moving components of the blood and tissue.
Clinical Issues

Accurate pulse oximetry readings require adequate perfusion at the measurement site. On poorly perfused patients nurses often struggle and must invest additional time to find an adequate measurement site. Users of non-Masimo pulse oximetry technology are unable to quickly and reliably determine the optimal pulse oximetry monitoring site and view peripheral perfusion changes.

Definition of Perfusion Index

Perfusion Index is a noninvasive and continuous measure of peripheral perfusion status (local blood flow) of the selected monitoring site and

- It is a measure of signal strength from the measurement site - not signal quality
- It is a measure of local vasomotor tone
- It is a relative number that falls between 0.02 – 20% with normal >1%
- It varies between monitoring sites and from patient to patient, as physiologic conditions vary.
- Perfusion Index (PI) is the ratio of the AC of the DC component (see Equation 1 below)

\[
\text{Equation 1} \quad \text{PI} = \frac{\text{AC}}{\text{DC}} \times 100 \%
\]

Diagram and Equation 1: A constant amount of light (DC) emitted from the pulse oximeter is absorbed by skin, other tissues, and non-pulsatile components such as venous blood. A variable amount of light (AC) is absorbed by pulsating arterial flow. Perfusion Index (PI) is the ratio of the AC over the DC component.
### Features and Benefits PI

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>BENEFIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placing sensor at site with the highest PI value improves performance during motion.</td>
<td>Helps ensure quick and optimal sensor placement which will save nurses time from dealing with false alarms and unreliable readings due to poor sensor location.</td>
</tr>
<tr>
<td>A drop in Perfusion Index indicates a reduction in blood flow at the measurement site.</td>
<td>Objective and easy to understand indication of potential vasoconstriction, reduction in blood volume or acute illness in neonates.</td>
</tr>
<tr>
<td>Low Perfusion message or warning</td>
<td>Useful during challenging conditions and does not occur so frequently that it becomes useless to clinicians.</td>
</tr>
<tr>
<td>Radical-7: Perfusion Index Trend Graph available with push of single button</td>
<td>Clinicians can easily determine if Perfusion Index is trending better or worse</td>
</tr>
</tbody>
</table>

**Weaknesses of competitive devices**

Nellcor devices do not offer a visual measure of peripheral perfusion or signal strength.

**Masimo’s Differentiated Value Proposition for Perfusion Index**

As an objective measure of perfusion at the measurement site, Perfusion Index may reduce clinician time and frustration spent finding adequate SpO2 monitoring sites and can help clinicians easily identify clinically relevant peripheral perfusion changes.

**Probing questions for discovering the need and establishing value for Perfusion Index**

- What criteria do you use to select the optimum SpO2 sensor site?
- How much time do you think it would save users if they had an objective, reliable method of selecting the optimum sensor site rather than using trial and error?
- How might an objective measure of peripheral perfusion help clinicians spot significant patient status changes earlier?
Sales Tools

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<tr>
<td>Clinical Applications of Perfusion Index Whitepaper (LAB-3410)</td>
<td>Whitepaper</td>
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<tr>
<td>Masimo SET Bibliography (LAB-1942)</td>
<td>Brochure</td>
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<td>Super User Training</td>
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</tbody>
</table>

Clinical Applications of Perfusion Index Whitepaper – Explains additional potential clinical applications for Perfusion Index that have some early clinical data but have not been fully proven or FDA cleared for promotion.

Target audience: Use primarily as a detail aide and leave-behind with VCCCs and product champions who would like to learn more about additional potential applications and value of Perfusion Index.

Masimo SET Bibliography – Includes summaries of independent journal articles regarding the clinical application and value of Perfusion Index.

Target audience: Use primarily as leave-behind with VCCC’s and product champions who want objective and independent feedback on Masimo SET performance, clinical applications and value.
3.6 Pleth Variability Index

Learning Objectives

Upon completion of this module you will be able to:

- Define Pleth Variability Index (PVI).
- Discuss the appropriate clinical necessity of utilizing PVI.
- Pose probing questions which identify PVI as a key feature that separates Masimo SET from conventional oximetry.
- Identify and discuss the pertinent sales tools and support material for PVI.
Vocabulary

Test your knowledge

**Autoscaling** – a technique used by some pulse oximeter manufacturers that keeps the size of the pleth waveform relatively constant regardless of the perfusion level. This prevents clinicians from determining the amount of perfusion or perfusion changes by the size of the pleth waveform.

**Photoplethysmograph** – a graphical display of the infrared signal indicating the changing light absorption of pulsatile blood flow.

**Pulsus Paradoxus** – an abnormal variation of the pulse during respiration. It can have cardiac, pulmonary and vascular causes.

**Frank-Starling Relationship** – the greater the volume of blood entering the heart the greater the cardiac output. Once the heart muscle is fully stretched any further volume will cause a decrease in cardiac output.
What is PVI and how is it measured?

- Pleth Variability Index (PVI) is a measure of the dynamic changes in PI that occur due to respiration.
- It is calculated by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred.
- PVI is a percentage from 1 – 100; 1 represents no variability, and 100 represents maximum variability.
- PVI is a continuous noninvasive quantified measurement of changes in the plethysmographic waveform that may be indicative of blood volume status.

\[
PVI = \frac{P_{\text{MAX}} - P_{\text{MIN}}}{P_{\text{MAX}}} \times 100\%
\]

Figure 3.6:1

Respiratory effect on plethysmographic waveform

The heart and lungs interact physiologically in a number of ways. The heart is positioned within the thoracic cage in such a way that its pumping action is directly influenced by relative changes in airway pressure, blood pressure and/or blood volume within the thorax. The heart’s normal pumping ability results from many factors including a balance between intrathoracic airway pressure and intravascular fluid volume.

As the relationship between blood volume and airway pressure varies, the change in cardiac pumping ability may be seen as cyclical changes in the pleth waveform occurring during the respiratory cycle. As the relationship between airway pressure and intravascular pressure or volume becomes more variable the impact of this respiratory variation on the pleth waveform becomes more pronounced. Intrathoracic pressure changes have a direct effect on the filling of the heart (Pre-load) and this can lead to an increase or decrease in stroke volume and ultimately a change in the cardiac output. These changes in the cardiac function are reflected as changes in the systolic and diastolic blood pressure waveform. The changes in blood pressure associated with the phases of respiration have been observed with the continuous invasive recording of arterial blood pressure. This change in blood pressure results in changes to the peripheral perfusion.

Photoplethysmography of the peripheral perfusion can be visually displayed on pulse oximeters. The photoplethysmographic (pleth) signal is derived from the absorption of the infrared light and varies beat to beat. Changes in this infrared waveform have been shown to correlate well with local blood volume changes. While the pulse oximeter plethysmogram represents a volume change, the arterial line blood pressure tracing represents a pressure change. Early studies have indicated that cyclical shifts in the plethysmogram reflect similar cyclical changes in the blood pressure tracing and that these changes reflect
changes in the intravascular volume status of patients. As mentioned previously, these cyclic changes in blood pressure and pleth waveform can also be caused by changes in intrathoracic pressure relative to the intravascular volume.

As the heart is in the middle of the chest, the heart and lungs interact physiologically in a number of ways

Cardiac Output is affected by:
- Changes in the airway pressure
- Changes in the blood pressure
- Changes in the blood volume

The heart's normal pumping ability results from many factors including a balance between intrathoracic airway pressure and intravascular fluid volume.

Figure 3.6:2

By measuring cyclic changes in PI during respiration, physiological data related to the volume of blood flow is revealed by pleth waveform pattern changes.

- Small variations in the pleth waveform occur with respiration.
- When the variations occur, cardiac and oxygen delivery pathophysiology may be revealed.
- These variations may indicate changes in cardiovascular pathophysiology.
- These variations may also provide information pertaining to the degree of fluid responsiveness in patients.
In spontaneous breathing, BP decreases on inspiration. Normal peak decreases in systolic pressure has been reported between 5 – 10 mmHg. The slight variation can be seen in the pleth waveform below.

The exaggeration of this phenomenon, called pulsus paradoxus, reports pressure changes > 10 mmHg. The large variation can be seen in the pleth waveform below.

**Initial Studies: Fluid Responsiveness**

Fluid responsiveness is not a new concept, but it has certainly gained more attention and favor over the past several years. What is fluid responsiveness? Simply put, a patient is deemed fluid responsive if they will benefit from additional intravascular volume. The benefit would be an increase in Stroke Volume (SV) and Cardiac Output (CO) which should ultimately increase oxygen delivery. There are certain conditions where the administration of addition fluids would not generate increased oxygen delivery (example: a patient with unstable blood pressure). In this situation, additional fluids would not improve SV and CO because the problem is with the pump (heart) not the lack of fluid.
What is preload and how is it measured?

«…the degree of tension of the cardiac muscle when it begins to contract…is the preload… » Guyton AC, Textbook of Medical Physiology, 1996

There are several ways to measure preload, invasive and non invasive. The invasive methods include: central venous pressure (CVP), pulmonary capillary wedge pressure (PCWP), and arterial line pressure measurements. All of these methods share the same limitations, they require a skilled practitioner for catheter placement and all have an increased risk of infection. Non-invasive methods include echocardiography and Doppler. Echocardiography is expensive and the results are highly dependent upon the skill of the operator. Doppler has been used to assess fluid responsiveness via changes in the Doppler waveform.

Frank-Starling Law

The ability of the heart to change its force of contraction and therefore stroke volume in response to changes in venous return is called the Frank-Starling mechanism.

In the late 19th century, Otto Frank conducted experiments using frog hearts to determine the strength of ventricular contractions. He concluded that when the ventricle was stretched prior to contraction the strength of the contraction increased. This observation was further developed by the studies of Ernest Starling and colleagues in the early 20th century. They found that increasing venous return, and therefore the filling pressure of the ventricle, led to increased stroke volume in dogs. However, when the left ventricle (LV) was overfilled, the muscle fibers no longer contracted effectively. This means that there will no longer be an increase in stroke volume or cardiac output, despite adding volume (or preload) to the LV.

THE SPRING EXAMPLE: If you pull a spring out to its optimum resistance it will spring back; however, if you continue to extend the spring beyond the point of optimum resistance, the spring becomes damaged and will longer be able to return to its original form and the return force of the recoil will be greatly reduced. This simple example illustrates what happens when you overfill the left ventricle - the maximum force of contraction is severely reduced. This phenomenon can be observed in heart failure patients where increases in preload yield a decrease in stroke volume.

Figure 3.6.3 - Frank-Starling Relationship
Cardiopulmonary Interactions

“The more sensitive a ventricle is to preload, the more the stroke volume will be impacted by changes in preload due to positive pressure ventilation.”

\[
\Delta SV = \frac{SV_{\text{max}} - SV_{\text{min}}}{(SV_{\text{max}} + SV_{\text{min}})/2}
\]

The waveforms above are a graphical representation of the effect of respiration on pulse pressure. The graph on the left lacks respiratory variability suggesting that the patient would not have a favorable response to a fluid challenge (fluid non-responsiveness). In normal physiology, the waveform would illustrate some degree of respiratory variability. The graph on the right illustrates an exaggerated degree of respiratory variability on pulse pressure which investigators have proposed to be a good indicator of fluid responsiveness in mechanically ventilated patients. The degree of respiratory variability on pulse pressure is represented by the PVI value. Since there is an inverse relationship between PVI and volume status, PVI will increase with a decrease in intravascular volume and theoretically, the higher the PVI, the greater the degree of hypovolemia (less volume/fluid).

A Case Study: Ability of a Novel Algorithm for Non-invasive Automatic Estimation of the Respiratory Variations in the Pulse Oximeter Waveform to Detect Changes in Ventricular Preload (Cannesson et al. 2007)

The Cannesson study attempted to determine if PVI could detect changes in preload in mechanically ventilated patients. The investigators looked at 25 intubated patients under mechanical ventilation in volume controlled mode (tidal volume 10 ml/kg.) They collected data from an arterial-line, central venous pressure (CVP) line and measured mean arterial pressure, and Pleth Variability in a baseline supine position. They then collected data with the patient up to a 30 degree tilt, and with the head down 30 degrees. Changing the patient’s position stimulated hemodynamic changes, largely due to the effect of gravity.
The variability in the Pleth waveform tracks the variability in the arterial-line. The graph (Figure 3.6:5) shows the difference in variability from a head up to a head down position. When the patient's head is down, the effect is a non-invasive fluid challenge via gravity. If the patient responds favorably to the fluid, the variability in the Pleth waveform will decrease as seen here and the PVI will go down. Remember, there is an inverse relationship between PVI and hypovolemia. The constant airway pressure via mechanical ventilation eliminates the variability that breathing influences the changes seen vs. fluid volume.

**Results of study**

![Graph showing Pleth Variability Index (%) for different positions](image)

**Figure 3.6:6**
Various body positions were used to simulate high, low and normal fluid volume states (Figure 3.6:6). At baseline, the patients were in the supine position (lying flat) and had a mean PVI of 13% (+/-7). When the patients were placed in a head-up position, the PVI increased to 19% (+/-8). Gravity caused the intravascular volume to move to the patient’s feet, thereby decreasing the intrathoracic fluid volume. And conversely, when the patient is placed in head down position, the fluid moves from the feet to the chest and the variability decreases as does the PVI (10%+/-6).

![Graph showing the relationship between Pleth Variability Index (PVI) and changes in pulse pressure (ΔPP)].

**Figure 3.6:7 – PVI vs. Changes in Pulse Pressure**

P<.05 compared to baseline; p<.05 compared to head-up position

This graphic shows that there is reasonable trending of the PVI to change in pulse pressure measured from the indwelling arterial catheter. As the pulse pressure goes up, the PVI goes up.

**Authors’ Conclusions**

- Further studies are required to test the ability of PVI to predict fluid responsiveness
- PVI could be used for perioperative fluid optimization in the operating room
- Other possible clinical applications:
  - PVI and fluid depletion/restriction
  - PVI and respiratory settings
  - PVI to detect changes in contractility
  - PVI in the emergency setting (tamponade)
PVI article: The Ability of a Novel Algorithm for Automatic Estimation of the Respiratory Variations in the Arterial Pulse Pressure to Monitor Fluid Responsiveness in the Operating Room. (Cannesson et al. 2008)

Using 25 coronary bypass patients, 10 women and 15 men, Dr Cannesson followed up the study from the previous section with a study conducted in the Operating Room. Hemodynamic data from five different sources (Pleth waveform: PVI; Art line: Arterial Pulse Pressure; Central Venous Pressure: CVP; Pulmonary Capillary Wedge Pressure: PCWP; and Cardiac Index: CI) were recorded before and after volume expansion. The graph below was created using the information gathered. Parameters in the top left corner of the graph have fewer false negatives and false positives than parameters elsewhere on the graph. As you can see from the graph below, PVI and the art line waveform (Arterial Pulse Pressure) were very good predictors of fluid responsiveness while CI, CVP and PCWP were poor predictors of fluid responsiveness.

Figure 3.6:8
The graph below uses a bar graph to express that same information. The higher the bars, the better the parameter predicts fluid responsiveness.

![Graph showing bar chart]

Figure 3.6:9

The study determined that patients who most often responded to fluid expansion demonstrated a reduction in PVI from a pre-volume expansion PVI level of 14% to post expansions levels of 9% (high specificity and sensitivity).

In conclusion:

- The prediction of fluid responsiveness by PVI is optimized in mechanically ventilated patients during general anesthesia.
- Continuous and noninvasive guide to assess fluid therapy
- Helps identify when to give fluid
- Helps know when to avoid giving fluid
- Aids clinician decision-making when fluid administration and/or blood transfusions are under consideration-
## Features and Benefits of PVI

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>BENEFIT</th>
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</table>
| Trending of PVI          | - May be useful in monitoring patients with respiratory or cardiac failure, helping to evaluate the interrelationship of fluid responsiveness and cardiac function  
                           - Accurate and potentially faster patient care                                                                                                                                                     |
| Trending of PVI indicates the cyclic changes in the plethysmographic waveform. Trending of PVI may be useful in monitoring surgical patients, both intraoperatively and postoperatively, for appropriate fluid status. | - Better clinical decisions in fluid management                                                                                                                                                       |
| PVI has the potential to provide useful information concerning changes between intrathoracic airway pressure and intravascular fluid volume. For example: PVI may be used to monitor mechanical ventilatory parameters. | - Improved patient care                                                                                                                                                                               |
| PVI may prove to be a valuable clinical tool with significant advantages over currently available indicators of changes in functional hemodynamics that are invasive, operator dependent, not continuous and of relatively higher cost. | - Improved cardiac function management                                                                                                                                                               |
In Summary

- Trending of PVI may be useful in monitoring patients with respiratory or cardiac failure, helping to evaluate the interrelationship between intrathoracic pressure and cardiac function.
- Trending of PVI indicates the cyclic changes in the plethysmographic waveform. Trending of PVI may be useful in monitoring surgical patients, both intraoperatively and postoperatively, for appropriate intravascular fluid volume states.
- PVI has the potential to provide useful information concerning changes in the balance between intrathoracic airway pressure and intravascular fluid volume. For example, PVI may be used to monitor severity of asthma attacks and the response to appropriate therapy. It may also be used to monitor intravascular fluid volume and the response to appropriate therapy.
- PVI may prove to be a valuable clinical tool with advantages over currently available indicators of changes in functional hemodynamics that are invasive, operator dependent, inaccurate, and expensive.

Clinical questions on issues specific to application of PVI

What would be the clinical value to be able to trend changes in the intravascular volume status of your patients before, during, and after surgery?

What would be the clinical value to be able to see demonstrable changes and response to therapy in status asthmaticus patients that were previously unattainable?

What would be the clinical value to be able to see the effects of increased ventilator pressures on intrathoracic pressure and hemodynamic function?

Weaknesses of current methods or competitive devices

There is no consistency among pulse oximeter manufacturers in the way they display the pleth waveform. Indeed there may be differences between various models from the same manufacturer. Some manufacturers attempt to keep the waveform the same size at all times (autoscaling) to make it easier to see. However, this may not reflect the actual perfusion to the site being measured.

Sales Tools

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<td>Technical Bulletin 3</td>
<td>Literature Order Form Radnet\Marketing\Technical Whitepapers</td>
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</table>
PVI changes may reflect disease states or physiology

<table>
<thead>
<tr>
<th>Cardiac causes</th>
<th>Non-cardiac, non-pulmonary causes</th>
<th>Pulmonary causes</th>
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<tr>
<td>Cardiogenic Shock</td>
<td>Hypovolemia</td>
<td>Asthma</td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
<td>Septic Shock</td>
<td>Tension Pneumothorax</td>
</tr>
<tr>
<td>Pericardial Effusion</td>
<td>Anaphylactic Shock</td>
<td>Pulmonary Embolism</td>
</tr>
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<td>Diaphragmatic Hernia</td>
<td></td>
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<tr>
<td>Restrictive Cardiomyopathy</td>
<td>Superior Vena Cava Obstruction</td>
<td></td>
</tr>
<tr>
<td>Acute Myocardial Infarction</td>
<td>Extreme Obesity</td>
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