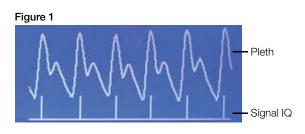
Signal IQ Technology

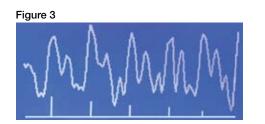
WHAT IS SIGNAL IQ?

Signal IQ is a Signal Identification and Quality indicator of the Masimo pulse oximetry waveform data, and directly relates to both the reported SpO₂ and pulse rate data.

Previously, clinicians questioned measurements when the plethysmograph looked corrupt or the pulse rate did not correlate with ECG heart rate. With the advent of Masimo SET[®] measure-through motion pulse oximeters, the Signal IQ tool was developed to warn clinicians when to question measurements. Signal IQ is a visual indicator of the system's confidence level in the displayed arterial oxygen saturation and pulse rate measurements. Masimo SET will continue to report accurate arterial oxygen saturation and pulse rate readings during motion and low perfusion, even when the plethysmographic waveform is suboptimal. Many other oximeters freeze readings, read erroneously, or do not read at all when the pleth waveform shape diminishes. Other oximeters are reliant on a strong pulsatile waveform to produce a reading, whereas Masimo SET is able to read through these challenging, yet rather common clinical conditions and provide good clinical data. Signal IQ is an indicator that our advanced signal processing algorithms are extracting and displaying reliable information.

In some clinical situations it becomes more difficult to find the arterial pulse signal. In these cases the height of the Signal IQ spike-indicator will decrease. When system confidence in the detected signal becomes very low, the clinical rigor of the data may be compromised and the "Low Signal IQ" message will begin flashing on the display. It is important to note that even with "Low Signal IQ," the measurement has a high probability of being correct; otherwise the system would not display values at all.





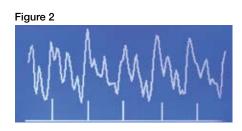




Figure 1 shows a typical pleth during no motion. Signal IQ is displayed below the pleth as a horizontal bar with vertical spikes. Each spike indicates the occurrence of an arterial pulse. The height of the spikes indicates the confidence level of the reported oxygen saturation and pulse rate. The taller the spike, the higher the confidence level. Signal IQ becomes particularly valuable during motion, low perfusion or environmental interference (or combinations), when the pleth can be completely obscured by artifact.

In Figure 2, the pleth is obscured by motion artifact, but the Signal IQ spikes remain high. In Figure 3, increased motion has completely obscured the pleth, yet Signal IQ provides you with both the pulse timing and the confidence of the measurement. The confidence measurement in Figure 3 is still relatively high, as compared to Figure 2 (high confidence) and Figure 4 (low confidence).



Figure 4 shows continued <u>excessive</u> motion. The Signal IQ bars become very small (in red circles) and the "Low Signal IQ" message begins to flash. This indicates a need to consider taking action.

Clinical studies have shown that in excessively high motion and low perfusion environments, the "Low Signal IQ" message is a highly sensitive indicator of <u>potentially</u> erroneous data.



The LED-based Masimo pulse oximeters, such as Rad-5 and Rad-5v, display Signal Quality (SQ) combined with the pulse timing in a "bouncing bar" where the height of the bar represents the Signal Quality. Low Signal Quality is indicated by the lower two bar segments turning red.

HOW DO I USE SIGNAL IQ IN A CLINICAL SETTING?

Use Signal IQ to be sure that valid O_2 saturation and pulse rate readings are displayed during motion and low perfusion, or as a check against the readings when you receive a remote alarm from the Masimo Patient Safety Net(PSN) remote alarm and clinical notification system.

The Signal IQ spike occurs at each arterial pulse, so you can potentially spot changes in the pulse rate even if motion artifact obscures the pleth.

Use the "Low Signal IQ" message as a clue to reassess patient condition and sensor placement. In addition, look for:

- proper sensor type, application and placement
- excessive motion
- occlusion or perturbation of blood flow
- excessive environmental interference
- severely decreased peripheral perfusion, such as during early shock

HOW DOES SIGNAL IQ WORK?

The Masimo SET algorithms employ different breakthrough techniques to analyze the incoming signal and remove noise or motion components to measure arterial oxygen saturation and pulse rate. Each of these algorithms is able to produce its own 'relative confidence' output signal, which represents the degree of success the algorithm had in finding and extracting a signal based upon its particular specialty. The output measurement and confidence signal from each algorithm is evaluated and combined for a composite arterial oxygen saturation; the composite signal quality is displayed as the height of the Signal IQ spike.

HAS SIGNAL IQ BEEN CLINICALLY VALIDATED?

Researchers evaluating Signal IQ and the Low Signal IQ message during desaturation events in neonates have found these parameters to be very sensitive for identifying erroneous data.¹⁻⁴ The Low Signal IQ message alerts the user that the data may be erroneous when a false desaturation is occurring because of excessive artifact, blood flow occlusion, or sensor malpositioning. Research has also shown that the Low Signal IQ message has good specificity and thus does not occur so frequently that it becomes useless.¹⁻³

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