WHITEPAPER

Halo:
Assessing Global Patient Status with the Halo Index™

SUMMARY

- Physiologic deterioration often occurs long before a patient crisis and manifests through subtle and often undetected changes in multiple physiologic parameters
- Clinicians are challenged to recognise patterns in physiologic deterioration because they must focus on multiple patients at once, can become desensitised to multiple physiologic alarms, may not have access to important trend values, and are limited at processing information from multiple static sources
- Assessing multiple physiologic parameters as a single index may be advantageous in evaluating patient status and may enhance care escalation procedures
- Manual indexes have been shown to predict patient outcomes but depend on clinicians to routinely collect patient data and manually enter values, so results can be delayed, incomplete, or not available at the bedside
- Automated indexes have also been shown to predict patient outcomes but are often a simple calculation based on static parameter values and are limited by the accuracy of the underlying monitored parameters
- Masimo designed Halo Index to mimic the systematic approach that expert clinicians use in assessing patient physiologic deterioration, most notably by analysing the patient history / trend data and extracting key physiological characteristics to assess global patient status
- Halo Index currently uses available Masimo parameters but is scalable to include additional information from the patient data repository
- Each parameter's significance is weighted compared to the other available parameters before being combined into the Halo Index, a single displayed number with a range from 0 to 100 that provides a cumulative trending assessment of global patient status
- The extracted parameter characteristics in Halo Index include instability and changes in baseline value, which provide more information than just static parameter values and whether the value has crossed an alarm threshold
- Increases in Halo Index may correspond with physiologic deterioration and may indicate a need for clinicians to more closely assess the patient.
- Halo Index is now an optional feature within the Masimo Patient SafetyNet* Remote Monitoring and Clinician Notification System

BACKGROUND

Physiologic deterioration often occurs long before a patient crisis[1] and manifests through subtle and often undetected changes in multiple physiologic parameters. Late recognition puts patients at risk but earlier rescue of deterioration is dependent upon early recognition of changing patient status.[2]

Clinicians are challenged to recognise patterns in physiologic deterioration because they must focus on multiple patients at once, can become desensitised to multiple physiologic alarms, may not have access to important trend values, and are limited at processing information from multiple static sources.[3] Changes in physiologic parameters can also be subtle as they may not trigger sustained alarm-threshold-crossing events or may be transient and within normal physiologic ranges when the clinician is at the bedside.

MASIMO®

Assessing multiple physiologic parameters as a single index may be advantageous in evaluating patient status and may enhance care escalation procedures. Manual indexes have been shown to predict patient outcomes but depend on clinicians to routinely collect patient data and manually enter values, so results can be delayed, incomplete, or not available at the bedside.[4] Automated indexes have also been shown to predict patient outcomes but are often a simple calculation based on static parameter values at a given moment in time and are limited by the accuracy of the underlying monitored parameters.[5]

Indexes developed based on static parameter values and fixed inputs may not capture cumulative physiologic deterioration that may be occurring and may not be scalable if additional relevant patient information is available.

Accuracy of the underlying parameters is also an important factor. For example, conventional pulse oximetry and ECG are known to produce a large number of artifacts and false alarms. These false alarms, when expressed in an index, could mislead the clinician and may undermine the reliability of the index itself.[6] In contrast to conventional pulse oximetry, Masimo SET® Measure-through Motion and Low Perfusion pulse oximetry (SpO_2 and pulse rate) is proven to reduce false alarms and improve true alarm detection.[7] The Masimo rainbow® SET platform also offers optional breakthrough measurements, such as acoustic respiration rate (RRa™), noninvasive and continuous hemoglobin (SpHb®), methemoglobin (SpMet®), and pleth variability index (PVI®).

HALO INDEX DESCRIPTION

Masimo designed Halo Index to follow the systematic approach that expert clinicians use in assessing patient physiologic deterioration, most notably by analysing the patient history / trend data and extracting physiological parameter characteristics to assess global patient status.

Halo Index currently uses available Masimo parameters but is scalable to include additional information from the patient data repository (Figure 1). Calculation of the Halo Index starts with inputs from Masimo SET Pulse Oximetry which continuously monitors SpO_2, Pulse Rate, Perfusion Index, and Pleth Variability Index. Performance can be enhanced by the addition of the rainbow parameters of noninvasive and continuous total haemoglobin (SpHb), methaemoglobin (SpMet), carboxyhaemoglobin (SpCO), and acoustic respiration rate (RRa). The available parameters are analysed and parameter characteristics are extracted.

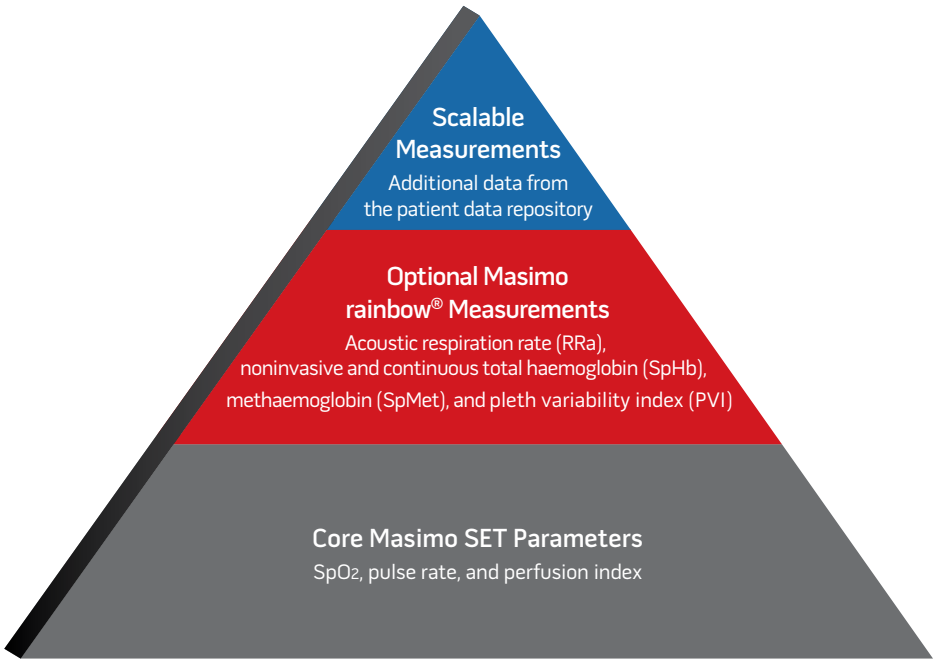

Figure 1. Halo Index Components

The Halo Index, a single displayed number with a range from 0 to 100 provides a cumulative trending assessment of global patient status. Increases in Halo Index may correspond with physiologic deterioration and may indicate a need for clinicians to more closely assess the patient. The Halo Index methodology is show in Figure 2.

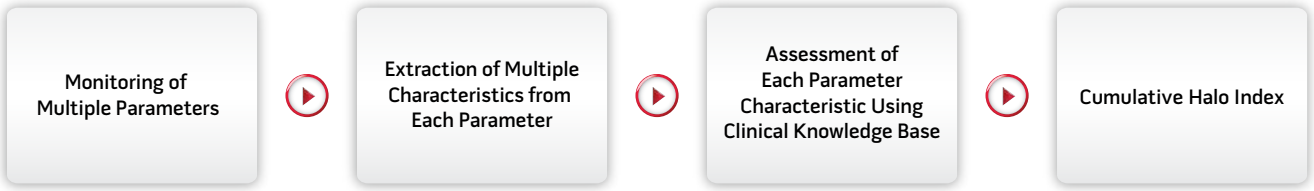

Figure 2. *Halo Index Methodology*

Halo Index is an optional feature within the Masimo Patient SafetyNet Remote Monitoring and Clinician Notification System, which links multiple bedside monitoring devices through wired or wireless transmission to the Patient SafetyNet display, which subsequently relays clinician alerts through pager or standard hospital notification systems. Halo Index is currently implemented in a dedicated secure IT appliance that interfaces to the Masimo Patient SafetyNet Server with sufficient capacity to support up to 80 patients simultaneously.

TRANSLATION OF VITAL SIGN PARAMETER CHARACTERISTICS INTO THE HALO INDEX

To calculate Halo Index, parameters are continuously analysed over relevant time intervals in order to extract parameter characteristics. Parameter Baseline, Instability, and Average Slope are some important characteristics that apply to multiple parameters. Other significant characteristics include Desat Pressure and Pulse Rate Efficiency. It is important to note that the parameter characteristics are not merely instantaneous values, but include historical parameter data and parameter relationships to produce an integrated and cumulative assessment of a patient's underlying physiology. Descriptions of the significant parameter characteristics comprised in the Halo Index are as follows:

Parameter Instability

Parameter instability is a measure of the degree to which the instantaneous parameter values tend to deviate from their baseline, where large and/or frequent deviations are indicative of high parameter instability. Instability calculations make use of historical data to produce a smooth, slowly changing measurement that conveys information about the underlying trends in the patient's status. For example, a persistently decreased SpO_2 can often be a relatively late finding of respiratory distress. In contrast, difficulty maintaining a normal SpO_2 can manifest as increased SpO_2 variability much earlier and may alert the clinician to a patient's decreased functional reserve. Parameter instability is illustrated in Figure 3, where increasing SpO_2 instability leads up to a sustained decrease in baseline SpO_2 and frequent desaturations.

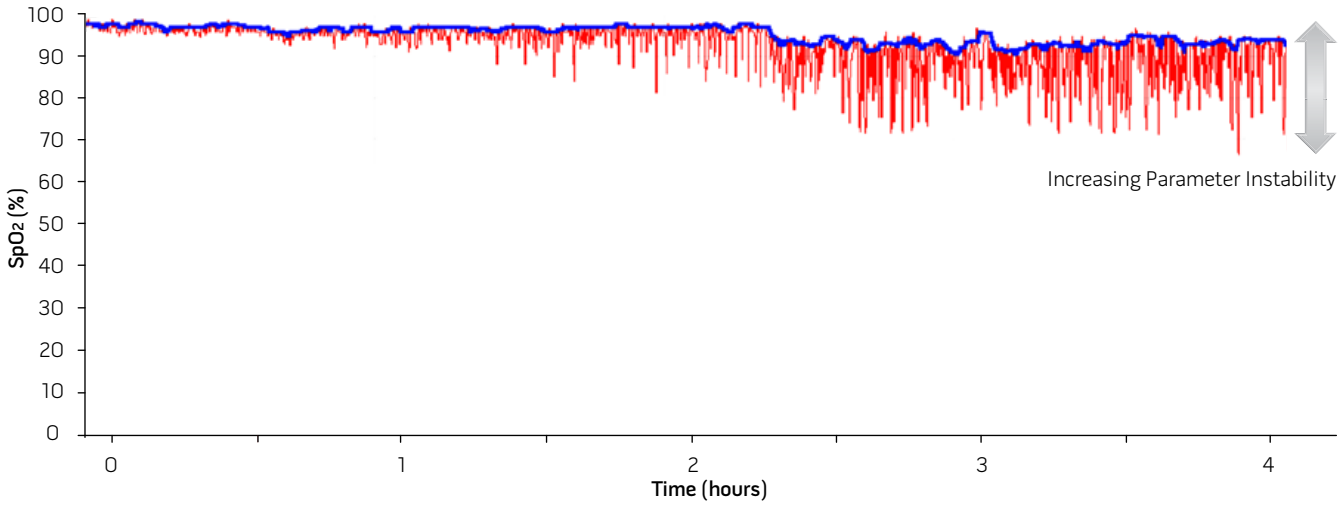

Figure 3. *Parameter Instability Characteristic.* In this four hour trend plot, the red line is the instantaneous SpO_2 and the blue line is the baseline SpO_2. The patient is displaying gradually increasing SpO_2 variability leading up to a sustained decrease in baseline SpO_2 and frequent de-saturations.

Parameter Baseline

A parameter's baseline is representative of the instantaneous parameter values, but changes in baseline occur slowly over the course of minutes rather than seconds. As such, the parameter baseline provides a more generalised view of a patient's condition. For example, it would not be unusual for a patient's pulse rate to vary noticeably from moment to moment due to painful stimuli or their level of exertion as they move in bed. In the absence of such conditions a patient's pulse rate will tend towards its baseline. Figure 4 shows the parameter baseline characteristic and emphasises an increasing trend in the patient's pulse rate which could easily be overlooked due to the high variability of their instantaneous pulse rate.

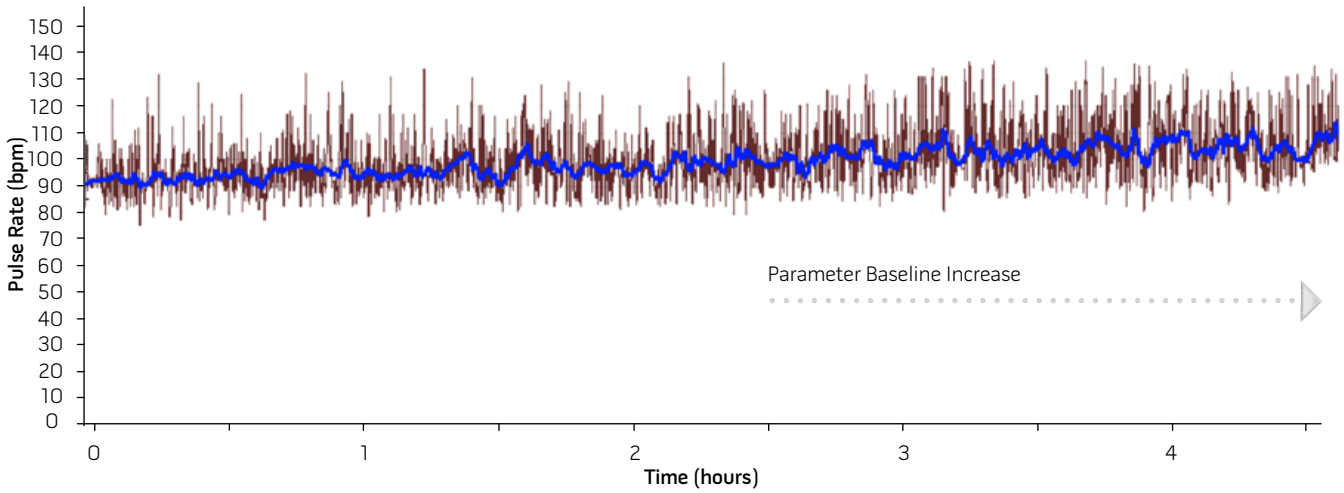

Figure 4. *Parameter Baseline Characteristic.* In this four hour trend plot, the brown line is the instantaneous pulse rate and the blue line is the baseline pulse rate. The increasing trend in the patient's pulse rate could be overlooked due to the high variability of the instantaneous pulse rate.

Parameter Average Slope

Parameter average slope is a measure of the average rate of change of a parameter's value over time. As a result, rapid changes in a parameter, even if relatively small in magnitude, are emphasised.

Desat Pressure

Desat pressure is defined as the downward movement of the instantaneous SpO_2 parameter. This downward movement shows instability, an inability to keep the oxygen saturation higher, and may be a precursor to a significant and prolonged drop in saturation.

Pulse Rate Efficiency

Pulse rate efficiency is a cross-parameter index of oxygen delivery with each heartbeat. A high saturation and a normally low pulse rate is considered efficient, while a low saturation and a high pulse rate is considered inefficient.

To calculate Halo Index, each parameter characteristic's importance is weighted based on the degree of abnormality. The overall parameter assessment is the weighted sum of each of its combined characteristics. The parameter weightings in Halo Index are unique to each patient and can change over time in a patient based on their physiologic condition. The Halo Index is the weighted accumulation of all of the individual parameter assessments. The displayed Halo Index is also graphically trended to show changes in patient status over time. As shown in Figure 5, the individual parameter values at any point in time may not indicate physiologic deterioration, but the trended Halo Index illustrates significant global patient status changes.

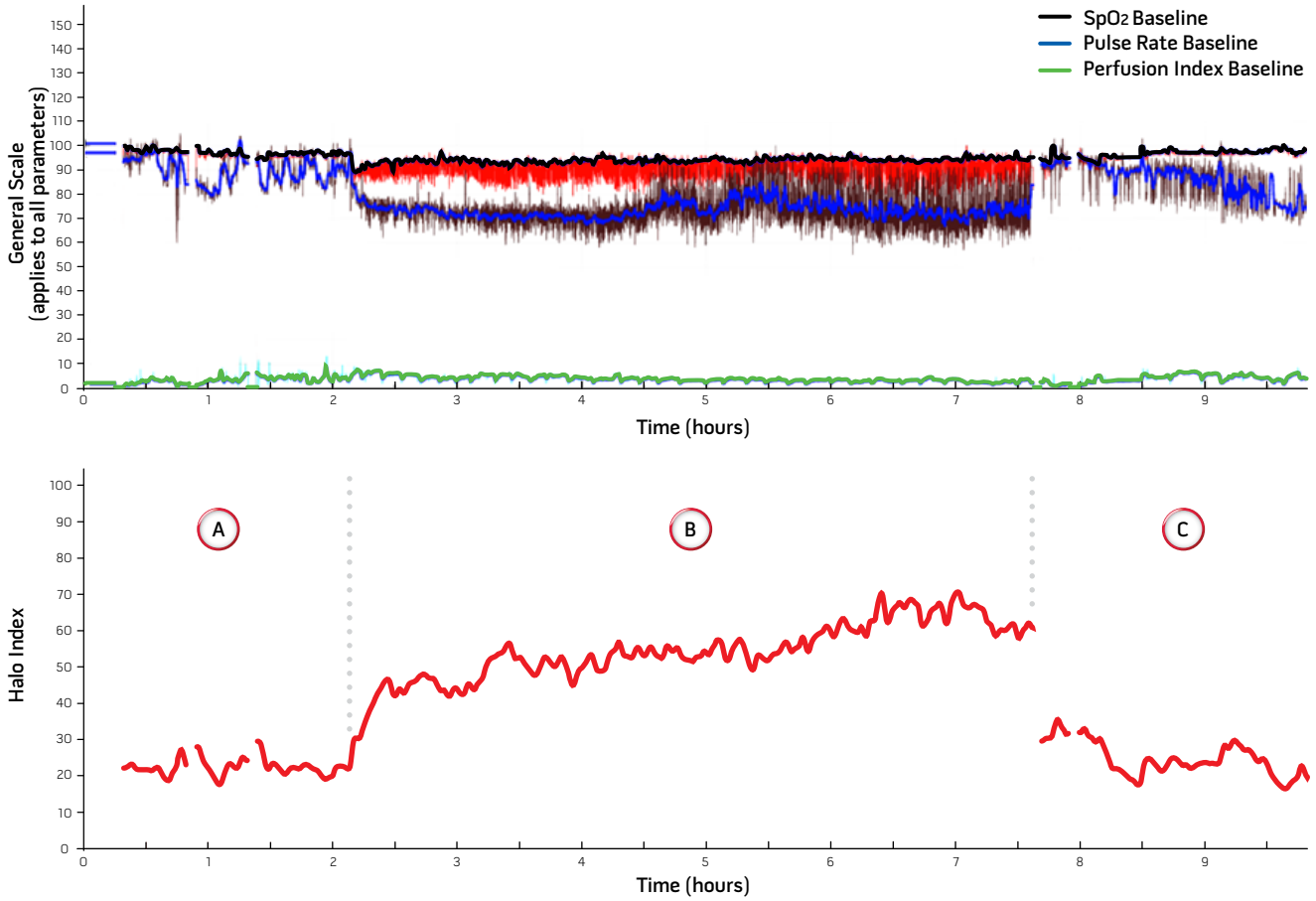

Figure 5. The top window shows individual parameter trends (SpO_2, pulse rate, and perfusion index). The bottom window shows the trended Halo Index through period of (a) stable status; (b) increasing physiologic deterioration; and (c) after a presumed intervention, resumed stable status.

HALO INDEX DISPLAY ON PATIENT SAFETYNET

In the Masimo Patient SafetyNet System, Halo Index is graphically trended along with trends from each of the physiologic parameters from which it is determined (Figures 6 - 10). The current weighting contribution of each parameter in the Halo Index is indicated by the size of the bubble next to the parameter trend plot, with a larger bubble indicating a higher weighting. A cursor is available that allows the user to select any time point for Halo Index and determine the parameter weighting contribution at that point in time.

Figure 6. Patient SafetyNet display components.

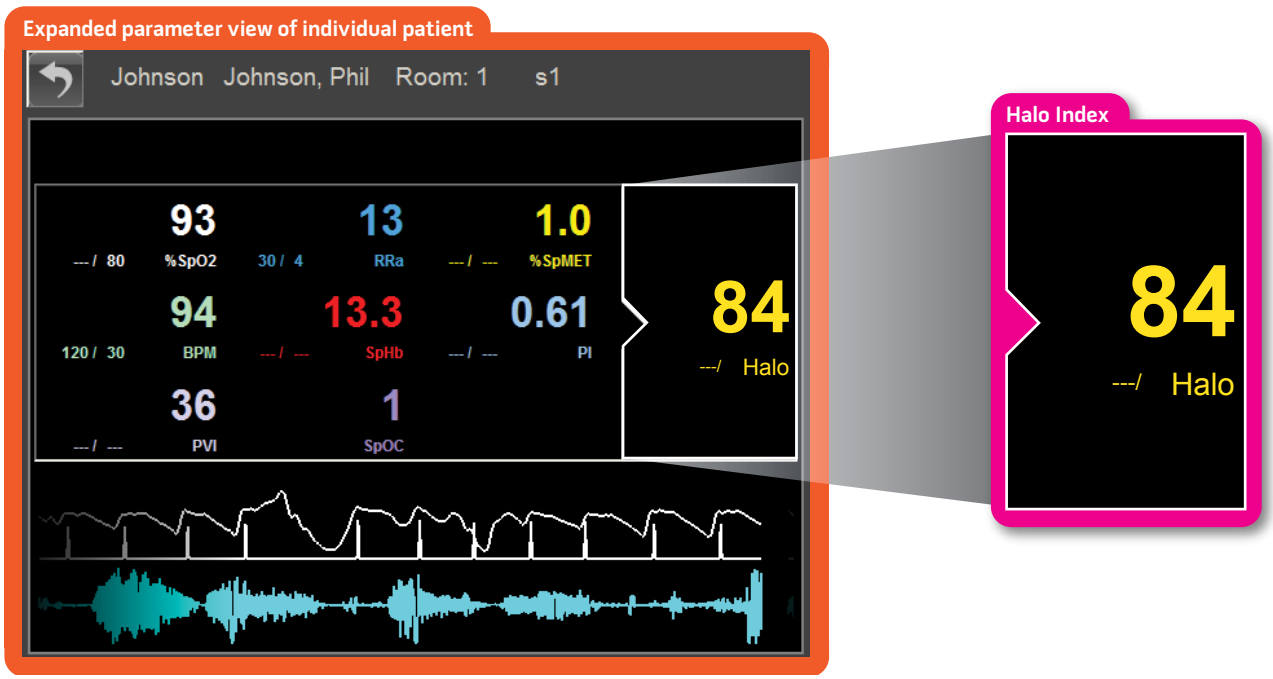

Figure 7. Expanded parameter view of an individual patient, with pleth and acoustic waveforms along with each monitored parameter, and the Halo Index.

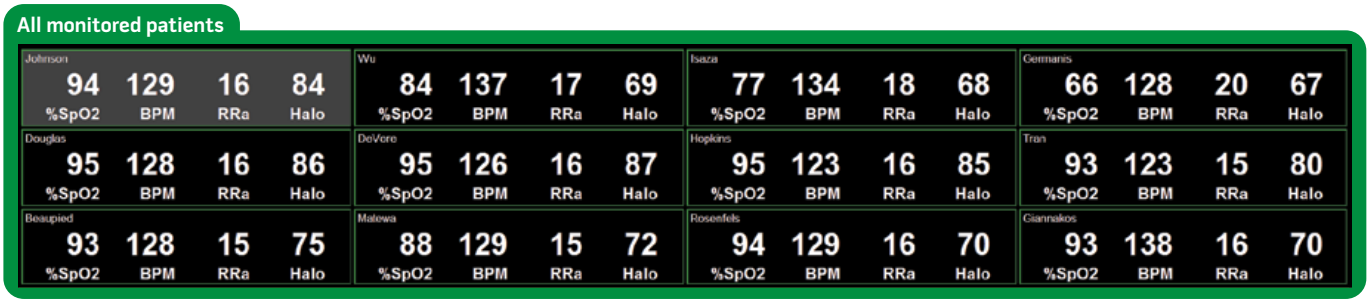

Figure 8. All monitored patients can be quickly assessed for parameter values and alarm conditions.

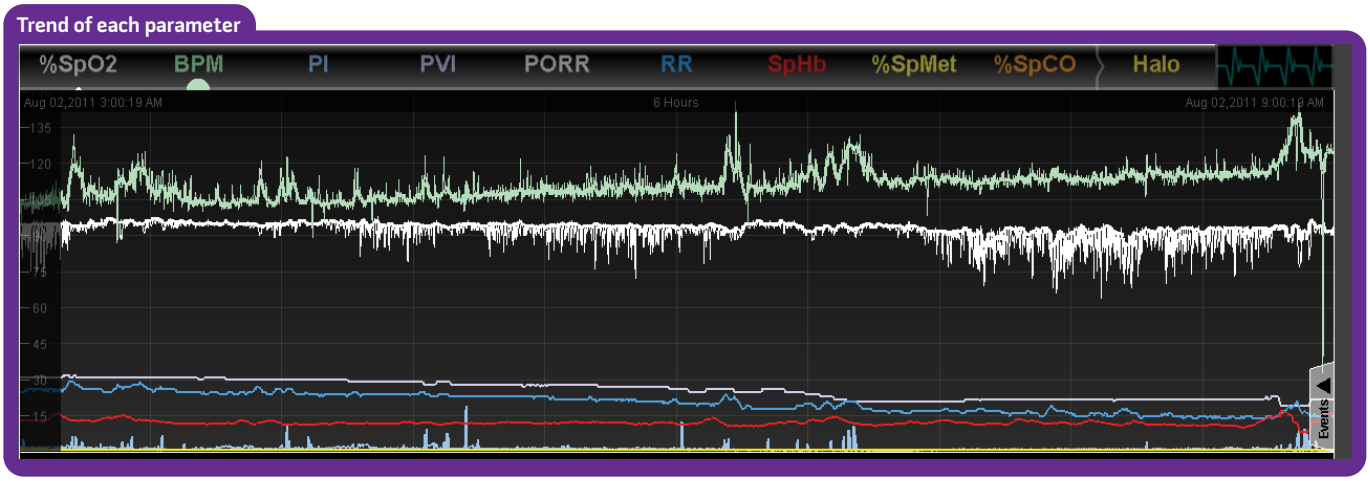

Figure 9a. Each parameter is individually trended using a universal scale shown on the left side of the screen. The variable contribution of each parameter to the Halo Index is shown by the size of the bubble next to each parameter.

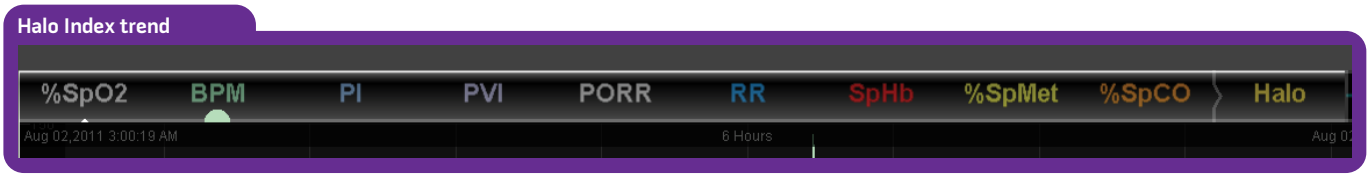

Figure 9b. The variable contribution of each parameter to the Halo Index is shown by the size of the bubble next to each parameter.

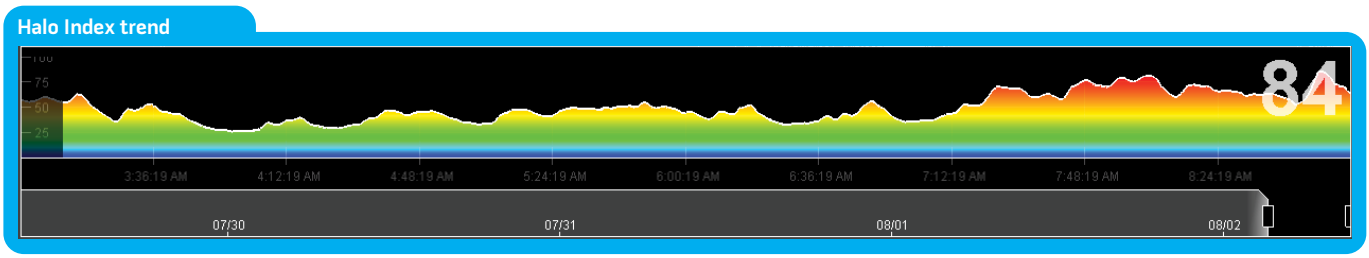

Figure 10. Halo Index trend, with changing colors as Halo Index increases (from blue to green to yellow to orange to red)

*Halo Index is pending US 510(k) clearance

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