WHITEPAPER

Masimo Advanced Alarm Performance: An Evidence-Based Approach to Reduce False Alarms and Nuisance Alarms

SUMMARY

- Masimo SET® pulse oximetry significantly reduces false alarms during the challenging conditions of motion and low perfusion. In a previous study, Masimo SET had a 5% false alarm rate and the Nellcor N-600 had a 28% false alarm rate during motion and low perfusion.
- Audible alarm frequency can be significantly reduced by changing alarm thresholds and extending alarm delays so only persistent alarms are annunciated.
  - Increasing the alarm delay to 15 seconds at 90% SpO_2 low alarm threshold can reduce alarms by 70%.
  - Lowering the alarm threshold from 90% SpO_2 to 88% can reduce alarms by 45%.
  - Lowering the alarm threshold to 88% with a 15 second delay can reduce alarms by up to 85%.
- Nellcor offers an approach called SatSeconds that reduces alarm frequency of both false and true alarms.
- A 90% low SpO_2 threshold with a 15 second delay reduces alarm frequency to the same degree as a SatSeconds setting at 100 with a 90% low SpO_2 threshold, if the underlying pulse oximeter performance were equivalent. In actuality, the underlying pulse oximeter performance is not equivalent.
- A 15 second alarm delay could further decrease Masimo SET false alarms during motion and low perfusion from 5% to 1.5%. Applying a SatSeconds setting of 100 could decrease the Nellcor false alarm rate from 28% to 9%.
- Reducing audible alarm frequency through alarm delays or SatSeconds does not change the significant reduction in false alarms with Masimo SET compared to the Nellcor N-600. Compared to the N-600, alarms would still be reduced by over 80% with Masimo SET (from 9% to 1.5%).
- The combination of Masimo SET true alarm detection and false alarm prevention with evidence-based alarm management provides an effective solution to alarm frequency, freeing clinicians to focus on patient care.

INTRODUCTION

According to the ECRI Institute[1], alarms are one of the top technology hazards in hospitals today. While responding to actionable alarms is critical to prevent patient injury or death, the frequency of false and nuisance alarms can increase workload and desensitize clinicians to all alarms, putting patients at risk.

Pulse oximeters audibly alarm based on three primary factors: the displayed SpO_2 and pulse rate value, the user-defined alarm threshold and alarm notification delay, and alarm averaging. This means that two pulse oximeters can display the same value but one can audibly alarm while the other does not if it has different alarm settings.

Alarms can be placed into three categories: true alarms – alarms which require clinician notification and potential intervention, false alarms – alarms that occur due to inaccurate SpO_2 or pulse rate values, and nuisance alarms – true alarms that do not require clinician notification and intervention.

Masimo offers a breakthrough measure-through motion and low perfusion solution to reduce false alarm frequency by providing the most accurate SpO_2 and pulse rate measurements, thus ensuring superior true alarm detection and false alarm prevention, and helping clinicians make evidence-based alarm setting decisions by examining the frequency of alarms at various settings to optimize the desired alarm frequency. Masimo's unprecedented performance and evidence-based approach to alarms ensures the delivery of actionable alarms, optimizes clinician workload, and avoids alarm desensitization—freeing clinicians to focus on patient care.

Masimo®

SUPERIOR TRUE ALARM DETECTION AND FALSE ALARM PREVENTION

Most pulse oximeters perform well with patients with good peripheral perfusion and who are not moving, but during motion and/or low perfusion, conventional pulse oximetry can freeze, zero out, or falsely alarm. Freezing or zeroing out can delay the notification of true alarms when the patient may require intervention. False alarms due to motion and/or low perfusion can significantly increase the total number of alarms so that clinicians become desensitized to true alarms when they occur.

Masimo SET measure-through motion and low perfusion pulse oximetry is a breakthrough technology that significantly improves true alarm detection and false alarm prevention compared to conventional pulse oximetry. More than 100 independent studies have established Masimo SET as the gold standard for pulse oximetry. As shown in Figure 1, in one study[2] Masimo SET was shown to prevent 95% of false alarms while detecting 97% of true alarms.

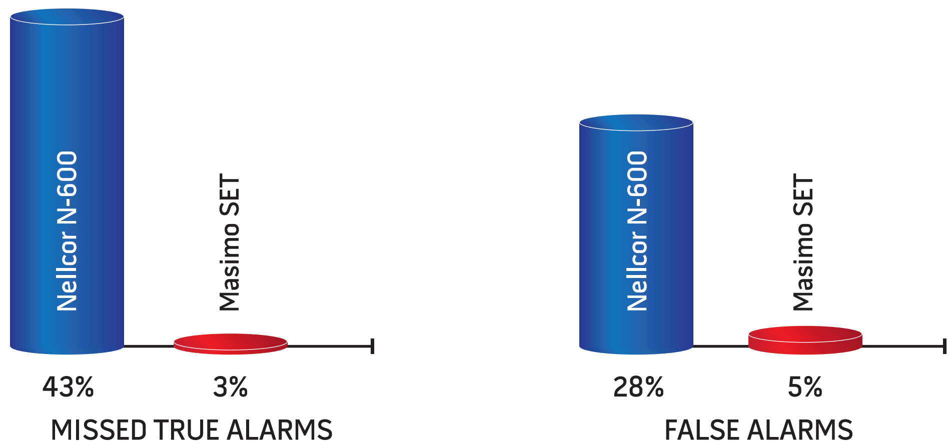


Figure 1. *The occurrence rate of missed true alarms during 40 low saturation events and false alarms during 120 fully oxygenated periods, both during conditions of motion. Pulse oximeters were set with no alarm delay.*

HOW MASIMO ALARM SETTINGS WORK

SpO2 Averaging

The displayed SpO_2 value is averaged over time, based on user-defined settings (2, 4, 8, 10, 12, 14, or 16 seconds). Modest changes in SpO_2 averaging times have a small impact compared to alarm thresholds and alarm delays at reducing alarm frequency. Modest extensions in averaging times (e.g. from 8 to 16 seconds) can filter out short duration saturation dips that rebound in a few seconds. Figure 2 illustrates the impact of longer averaging times based on a controlled reference signal.

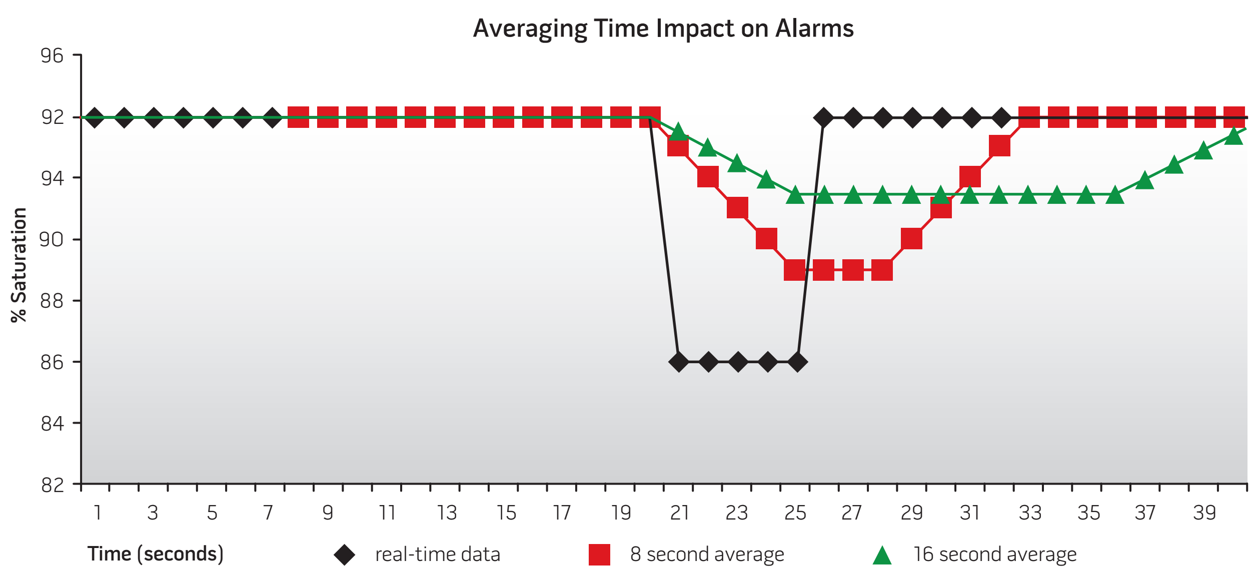


Figure 2. *The effect of averaging times in identifying actual changes in saturation.*

Masimo does not recommend an averaging time greater than 16 seconds because it can mask clinically significant desaturations and delay the notification of actionable alarms. Nellcor pulse oximetry does not utilize fixed averaging and does not limit averaging to 16 seconds. The Nellcor N-600 Directions for Use state:

> *"The N-600 automatically adjusts the signal processing during degraded conditions such as those caused by low perfusion, interference, (e.g. external interference such as ambient light, elecromagnetic interference, and patient motion), or a combination of these, which results in an increase in the dynamic averaging beyond the minimum as set by the response mode…If the dynamic averaging time for SpO_2 reaches 40 seconds, and/or 50 seconds for pulse rate, a low priority alarm state results."*

Therefore, the Nellcor N-600 can display an SpO_2 or pulse rate number primarily based on old values before finally alarming after an extended period of time.

Alarm Settings

User-defined alarm settings include the high and low SpO_2 threshold and the alarm delay. When the SpO_2 value crosses the alarm threshold, the device will always visually alarm by displaying a flashing SpO_2 value. If the SpO_2 value remains below the low SpO_2 alarm threshold or above the high SpO_2 alarm for the user-defined time delay (zero, 5, 10, or 15 seconds), the device audibly alarms. Masimo SET pulse oximeters also have a Rapid Desat setting that enables an immediate audible alarm if the SpO_2 value exceeds the low SpO_2 threshold by a specified amount (5% or 10%), regardless of the user-defined alarm delay. Alarm behavior examples are shown in Figure 3.

Alarm Behavior Examples

SpO_2 alarm settings: 88% low SpO_2 threshold, 15 second alarm delay, Rapid Desat alarm 5% below threshold

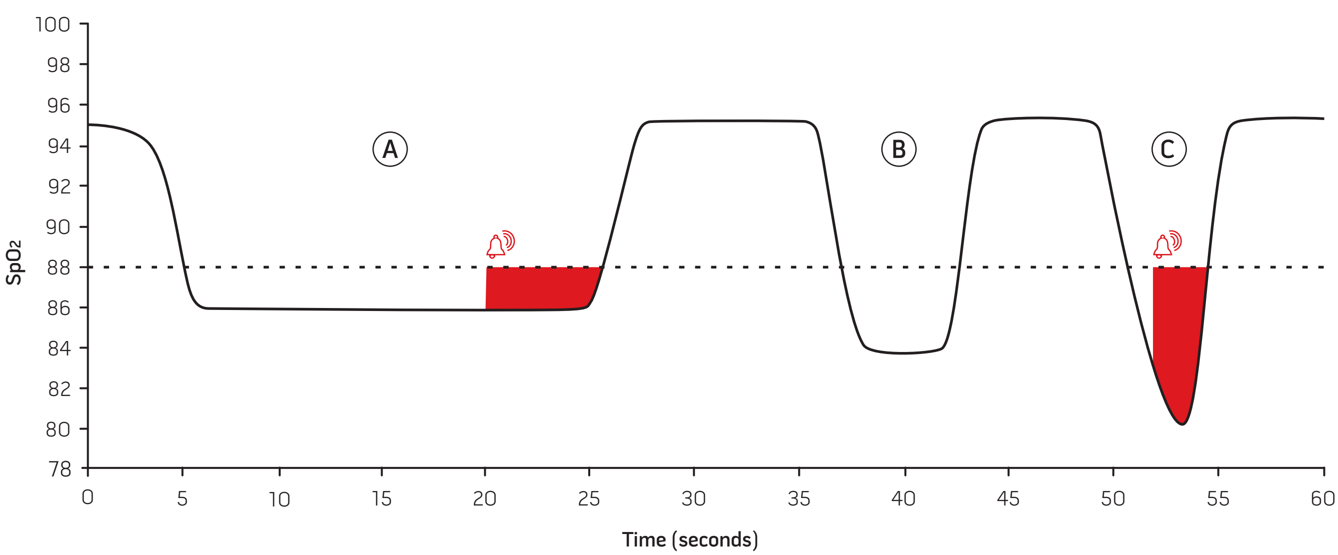


Figure 3. *Alarm behavior during three SpO_2 event examples. In all cases the visual alarm activates as soon as the low SpO_2 alarm threshold is crossed.*

(A) With a desaturation to 86% with a duration of 20 seconds, the audible alarm becomes active only after the alarm condition has persisted for 15 seconds.

(B) With a desaturation to 84% with a duration of 5 seconds, no audio alarm occurs.

(C) With a sudden desaturation to 80%, the audible alarm activates immediately due to the Rapid Desat feature (5% below the alarm threshold of 88% SpO_2).

EVIDENCE-BASED ALARM MANAGEMENT

While Masimo SET reduces false alarms over 95% of the time, Masimo SET's fidelity may cause instances where alarm thresholds are crossed for what some clinicians believe to be clinically insignificant periods of time. This can require alarm management strategies that provide clinician-controlled notification delays. Patients in acute care settings can have desaturation events that fall below the traditional alarm threshold of 90% but recover within a few seconds without the need for immediate therapeutic interventions. Figure 4 shows a distribution of Masimo SET SpO_2 values in post-surgical patients on a 36-bed floor over an 11 month period.[3] SpO_2 values less than 90%, the most common alarm threshold setting, occurred 4.4% of the entire monitoring time.

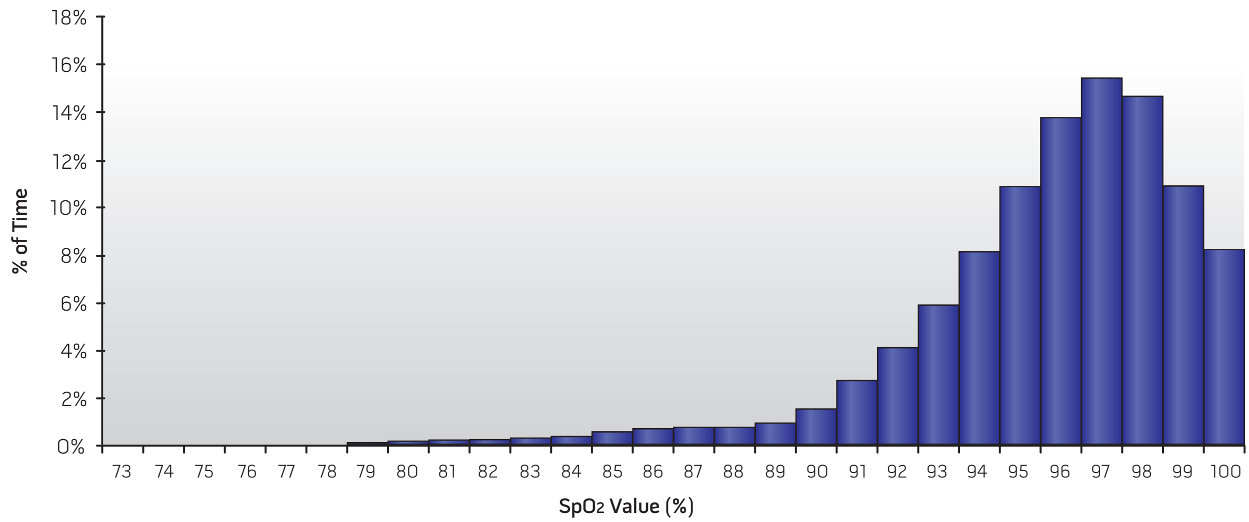


Figure 4. *The frequency of SpO_2 values in post-surgical patients shows SpO_2 values under 90% occurred 4.4% of the time – approximately 1 hour per day with up to 190 separate alarms, if each desaturation event lasted 20 seconds.*

Analysis of the Impact of Various Alarm Settings on Alarm Frequency

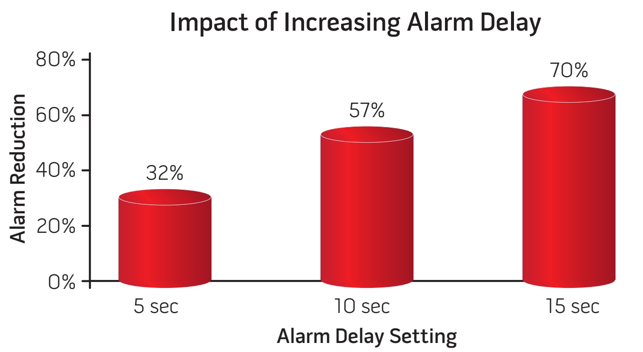
To help clinicians make evidence-based decisions on alarm parameters, Masimo has performed a comprehensive analysis of 32 million SpO_2 data points from 10 hospital care areas. Each hospital was equipped with a Masimo Patient SafetyNet™ Remote Monitoring and Clinician Notification System, which continuously captures and stores time-stamped SpO_2 data. A retrospective analysis was conducted to determine the incidence of alarms at various alarm threshold and delay settings.

A separate analysis was conducted to determine how alarm frequency at various low SpO_2 threshold and delay settings compares to the alarm frequency of the same data run through the Nellcor "SatSeconds" alarm calculation. Based on publicly available information, SatSeconds works by multiplying the percentage of the desaturation below the alarm threshold by the number of seconds the value remains below the alarm threshold. For example, a 10% drop below a 90% alarm threshold for 10 seconds would equal 100 SatSeconds.

While it is helpful for comparison purposes, this analysis is expected to significantly underestimate the frequency of alarms with SatSeconds. This is because Masimo SET measure-through motion and low perfusion SpO_2 values are being used in the SatSeconds calculation, while in a clinical setting, Nellcor technology is used to calculate SpO_2 values. <u>Nellcor pulse oximetry has been proven in multiple studies to have significantly more false alarms during motion and low perfusion.</u>

Results of Alarm Delay Settings on Alarm Frequency

Alarm delays are the single most influential factor to reduce alarm frequency. Separation of events between short-duration and longer-duration alarms can be realized by modest alarm delays. Most desaturations below 90% recover within a short period of time. These self-correcting desaturations represent the vast majority of alarms. Figure 5 shows the impact of 5, 10, and 15 second delays on the number of alarms at a low SpO_2 threshold setting of 90%. An alarm delay of 15 seconds reduces alarm frequency by 70%.

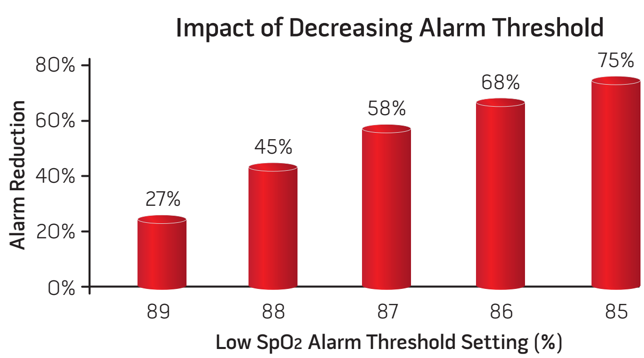


Increasing alarm delays from 5 to 15 seconds can decrease alarms by 70%.

Figure 5. *Alarm delays and their impact on alarm frequency.*

Results of Alarm Threshold Settings on Alarm Frequency

The low SpO_2 alarm threshold can also have a significant effect on the number of alarms generated. Ideally, alarm thresholds should be set to the individual patient condition. Modest lowering of the alarm threshold in the absence of any alarm delay can help reduce the total number of alarms generated. Figure 6 shows that lowering the low SpO_2 alarm threshold from 90% to 88% reduces alarms by 45%. Further reducing the low SpO_2 alarm threshold from 90 % to 85% decreases alarms by 75%.



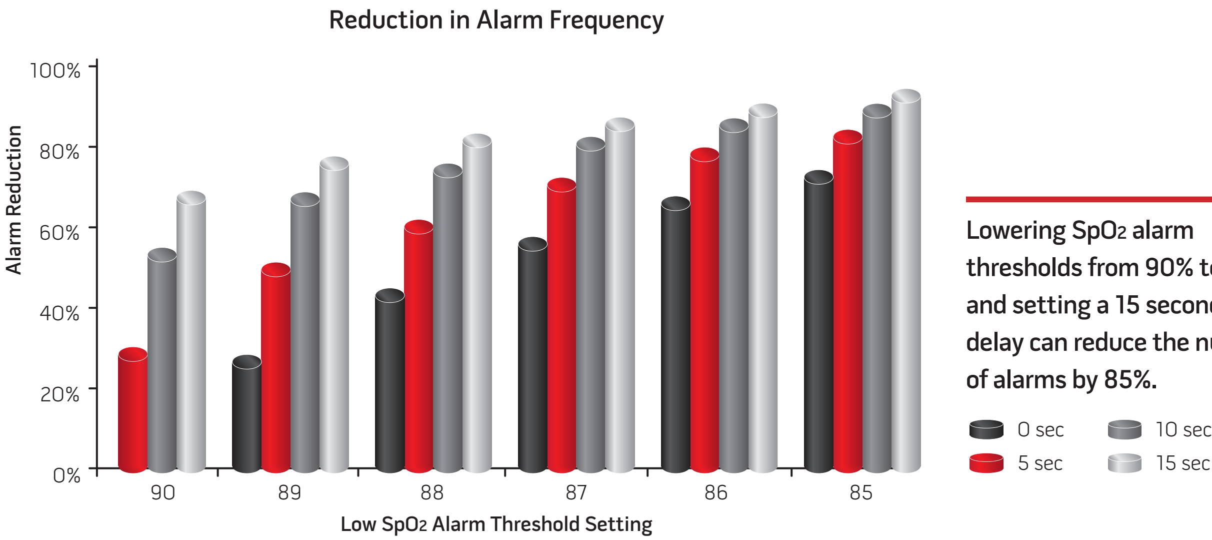
Decreasing alarm thresholds from 90% to 88% decreases alarms by 45%.

Figure 6. *Alarm thresholds and their impact on alarm frequency.*

The significant alarm reduction demonstrated in this analysis by decreasing the alarm threshold was also shown by clinicians at a major academic hospital. In their analysis, reducing low SpO_2 threshold to 88% from 90% led to an even greater reduction in alarm frequency, 65%, and led them to change their default alarm threshold.[4]

Results of Combining Alarm Delay and Threshold Settings on Alarm Frequency

Combining both an alarm delay and a lower threshold produces the greatest reduction in alarms, as shown in Figure 7. Lowering alarm limits to 88% with a 15 second delay reduces alarms by over 85%.



Lowering SpO_2 alarm thresholds from 90% to 88% and setting a 15 second alarm delay can reduce the number of alarms by 85%.

Figure 7. *The combined effects of alarm delay and lower alarm thresholds on alarms.*

For reference purposes, Table 1 shows the full range of alarm reductions possible by lowering alarm thresholds and increasing alarm delays, compared to a 90% low SpO_2 threshold at a zero second delay.

Table 1. Percent reduction in alarms at various low SpO_2 alarm thresholds and alarm notification delays, compared to a 90% low SpO_2 threshold at a zero second alarm delay

Reduction in Alarm Frequency				
	Alarm Delay			
Low SpO_2 Alarm Threshold (%)	**0 sec**	**5 sec**	**10 sec**	**15 sec**
90	Reference	32%	57%	70%
89	27%	51%	69%	79%
88	45%	64%	78%	85%
87	58%	74%	84%	89%
86	68%	80%	87%	91%
85	75%	85%	87%	91%
84	80%	89%	93%	95%
83	84%	91%	95%	97%
82	87%	93%	96%	97%
81	89%	95%	97%	98%
80	90%	96%	97%	98%

If clinicians are concerned about delayed notification of a sudden drop in saturation, Masimo offers its Rapid Desat feature, which enables an immediate alarm when a specified drop in desaturation occurs, overriding other alarm settings.

COMPARISON OF ALARM DELAYS VS. SATSECONDS CALCULATION

Nellcor offers an approach called SatSeconds that reduces alarm frequency of both false and true alarms. Masimo believes the feature is primarily used to overcome Nellcor technology's inability to reliably measure through motion and low perfusion. As previously noted, this analysis uses the SpO_2 results from Masimo SET pulse oximetry, which measures through motion by extracting the signal out of the noise. Because Nellcor devices do not reliably measure through motion and low perfusion, this analysis is expected to underestimate the alarm frequency when SatSeconds is used on a Nellcor pulse oximeter and therefore demonstrates better than actual performance for Nellcor. The reduction in alarm frequency at various SatSeconds settings is shown in Table 2. Table 3 provides a comparison guide between Masimo alarm settings and Nellcor SatSeconds for the estimated reduction in alarm frequency. Please note that while alarm frequency at the various settings is similar, the actual events that activate alarms under each approach can vary.

Table 2. Estimated percent reduction in alarms at various SatSeconds settings, compared to a 90% low SpO_2 threshold at a zero second delay

Estimated Reduction in Alarm Frequency				
SatSeconds Setting at 90% Low SpO_2 Alarm Threshold				
SatSeconds Setting	**10**	**25**	**50**	**100**
Percent Reduction in Alarms	27%	46%	56%	67%

Table 3. Estimated alarm thresholds and delay settings that result in a similar alarm frequency as SatSeconds

Estimated Alarm Setting Equivalence to SatSeconds	
SatSeconds Setting at 90% Low SpO_2 Alarm Threshold	Equivalent Alarm Threshold and Delay Settings at Reducing Alarm Frequency
100	90% Low SpO_2 threshold, 15 second delay
50	90% Low SpO_2 threshold, 10 second delay*
25	90% Low SpO_2 threshold, 10 second delay*
10	90% Low SpO_2 threshold, 5 second delay

** SatSeconds at 25 reduces alarm frequency by 46%. SatSeconds at 50 reduces alarm frequency by 56%. At 90% low SpO_2 threshold and a 10 second delay, alarms are reduced 57%. At 90% low SpO_2 threshold and a 5 second delay, alarms are reduced 32%. Therefore, the equivalent setting to SatSeconds at 25 and 50 is closest at the same setting, at 90% low SpO_2 threshold with a 10 second delay.*

ADVANCED PREDICTIVE ALARMS AND ADAPTIVE THRESHOLD ALARMS

Repetitive desaturation patterns may or may not create an audible alarm, but can predict pending respiratory failure.[5] In 2005 Masimo introduced 3D Desat Index Alarm and 3D Perfusion Index (PI) Delta Alarm, and both are now standard features. Masimo 3D Desat Index Alarm notifies clinicians of repetitive desaturation patterns, which may identify patients at risk for respiratory depression such as obstructive sleep apnea patients and those receiving opioids for pain management (more information is available in Masimo's Advanced Alarm Performance brochure). In 2009, Nellcor introduced a similar comparable feature, but it is important to note that it is based on the same limited pulse oximeter technology that has been proven to produce higher false alarm rates due to motion and low perfusion. Masimo has continued its advanced alarm leadership position by debuting Adaptive Threshold Alarms,* which automatically adjust audible alarm triggers to the patient's physiologic norm (more information is available in Masimo's Adaptive Threshold Alarm whitepaper).

** Adaptive Threshold Alarms do not have FDA 510(k) clearance*

CONCLUSION

Masimo SET pulse oximetry significantly reduces false alarms during the challenging conditions of motion and low perfusion. In addition, audible alarm frequency can be significantly reduced by changing alarm thresholds and extending alarm delays so only persistent alarms are annunciated. A 90% low SpO_2 threshold with a 15 second delay reduces alarms by 70% compared to a 90% low SpO_2 threshold with a zero second delay. An 88% low SpO_2 threshold with a 15 second delay can reduce alarms by 85% compared to a 90% low SpO_2 threshold with a zero second delay.

A 90% low SpO_2 threshold with a 15 second delay reduces alarm frequency to the same degree as a Nellcor's SatSeconds setting at 100 with a 90% low SpO_2 threshold, if the underlying pulse oximeter performance were equivalent. In actuality, the underlying pulse oximeter performance is not equivalent. Masimo SET has been shown to have up to five times fewer false alarms during motion and low perfusion.

In the study results presented in Figure 1, Masimo SET had a 5% false alarm rate and the Nellcor N-600 had a 28% false alarm rate during motion and low perfusion. Applying the same alarm reduction shown in this analysis to that study, a 15 second alarm delay could decrease Masimo SET false alarms by 70%, from 5% to 1.5%. Applying a SatSeconds setting of 100 could decrease the Nellcor false alarm rate by 67%, from 28% to 9%. Therefore, reducing audible alarm frequency through alarm delays or SatSeconds does not change the significant reduction in false alarms with Masimo SET compared to the Nellcor N-600. Compared to the N-600, alarms could still be reduced by over 80% with Masimo SET (from 9% to 1.5%).

In addition, a fixed alarm delay offers clinicians the advantage of knowing exactly how long an alarm is delayed and limits this delay, while SatSeconds alarms can delay alarms much longer than 15 seconds due to the multiplication of seconds under the low SpO_2 alarm threshold by the degree of desaturation.

SUGGESTED ALARM SETTINGS ON MASIMO PULSE OXIMETERS

Based on the information presented in this white paper, clinicians can now make evidence-based decisions about where to configure alarm settings.

Suggested Alarm Settings		
	Adult	**Neonatal**
High SpO_2 Alarm	Off	Off*
Low SpO_2 Alarm Threshold	88%	88%
Alarm Audio Delay	15 sec	10 sec
Averaging	8 sec	12 sec

**In neonatal patients receiving supplemental oxygen, the high SpO_2 alarm threshold should be set no higher than 95%.*[6]

As always, clinicians must ensure proper application of the SpO_2 Sensor and set alarm thresholds to the individual patient and care setting.

Please note: The projected alarm frequencies in this analysis do not take into account the effect of the audible alarm on a patient's physiology.

REFERENCES

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