WHITEPAPER

Masimo Adaptive Threshold Alarm™: Intelligent and Personalised Notification to Reduce Nuisance Alarms

SUMMARY

- Nuisance alarms and false alarms can desensitise clinicians, causing actionable alarms to be ignored
- Masimo SET® Measure-through Motion and Low Perfusion pulse oximetry is proven to reduce false alarms during challenging conditions
- Many true alarms represent brief desaturations that do not require clinical intervention, which can desensitise clinicians to actionable events
- Actionable alarms are characterised by significant and sustained SpO_2 drops from the patient baseline or SpO_2 below a severe threshold value
- Traditional alarm configurations rely on fixed thresholds and notification delays and are based on a one-size-fits-all approach
- Reducing fixed thresholds and increasing notification delays decreases alarm frequency but may cause clinically significant events to be missed
- Masimo Adaptive Threshold Alarm automatically determines each patient's baseline saturation and audibly alarms when saturation significantly changes or when fixed alarm thresholds have been crossed
- With Masimo Adaptive Threshold Alarm, nuisance alarms can be reduced, freeing clinicians to focus on patients who need care

BACKGROUND

Pulse oximetry alarms can be placed into two primary categories:

1) True alarms – alarms that occur due to correct SpO_2 or pulse rate values
2) False alarms – alarms that occur due to incorrect SpO_2 or pulse rate values

True alarms can be placed into two sub-categories:

Actionable alarms – True alarms which require clinician notification and potential intervention;
Nuisance alarms – True alarms that the clinician deems not actionable[1]

ECRI Institute has identified nuisance alarms as one of the top technology hazards in hospitals today.[2] While responding to actionable alarms is critical to prevent patient injury or death, the frequency of false and nuisance alarms can increase workload and desensitise clinicians to all alarms, putting patients at significant risk.

Multiple studies have established the performance of Masimo SET Measure-through Motion and Low Perfusion pulse oximetry with true alarm sensitivity of 95% and false alarm reduction of 97%[3] during challenging conditions. Masimo SET provides a solid foundation upon which to separate true alarms from false alarms, and therefore allows alarm management strategies to focus on notification of potentially actionable alarms. While Masimo believes that all true alarms are potentially actionable, we also believe in empowering clinicians to create alarm settings that reduce the frequency of nuisance alarms, depending on the care area, patient population, and individual patient.

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LIMITATIONS OF FIXED ALARM THRESHOLDS

Since the inception of pulse oximetry, default pulse oximetry alarm thresholds have been based on two key assumptions:

1) A patient's baseline oxygen saturation value is 98 to 100%
2) When the oxygen saturation crosses 90%, it is clinically significant

These assumptions are applied through the concepts of a fixed low SpO_2 alarm threshold and a fixed delay in alarm notification. However, this approach creates challenges in the care of diverse patient populations. For example, one patient dropping from SpO_2 of 93% to 89% triggers the same alarm as another patient dropping from 99% to 89%.

This one-size-fits-all approach leads to some true alarms that a clinician deems non-actionable. This can cause clinicians to desensitised to true alarms that are in fact actionable.

Nuisance alarms can be reduced by lowering alarm thresholds and increasing alarm delays.[4] This can significantly reduce alarm frequency but does not fully address the limitations of the core assumptions with fixed alarm thresholds and alarm delays. Neither of these strategies adjusts alarm activation based on the individual patient's condition. In addition, lowering fixed thresholds too far may cause clinicians to miss relevant events available with highly accurate SpO_2 measurements with Masimo SET.

A recent study in *Anesthesiology* conducted at a large academic medical center demonstrated a 48% reduction in ICU transfers from a post-surgical general care floor using Masimo SET pulse oximetry.[5] Nuisance alarms were substantially reduced by setting surveillance alarm conditions lower than traditional threshold alarms (80%) and setting a delay (15 sec) to the onset of the audible alarm at the bedside. Although significant improvements in patient outcomes were realised, this strategy reduced nuisance alarms at the expense of sensitivity to prolonged desaturation events above the surveillance settings and potentially actionable alarms. Peer editorial comments on this study suggested that broad adoption of this surveillance strategy may be limited by the unconventional low SpO_2 alarm setting.[6]

MASIMO ADAPTIVE THRESHOLD ALARM

Objectives and Assumptions

An optimal alarm strategy would reduce nuisance alarms while still identifying clinically relevant events. Masimo Adaptive Threshold Alarm was designed with this intent and the ability to allow the clinician to determine who defines a "nuisance" alarm. This strategy is based on different core assumptions than traditional fixed alarm threshold configurations:

1) Each patient has their own baseline "normal" saturation
2) Changes from baseline are the primary indicator of deterioration
3) Severely low or fast desaturations still require immediate notification

Description

Masimo's Adaptive Threshold Alarm is an intelligent and automatically customised alarm solution that significantly reduces the incidence of nuisance alarms while preserving actionable alarms. The Adaptive Threshold Alarm is designed to learn the patient's "baseline value" during the first 1.5 - 2 minutes of continuous monitoring and thereafter updates the baseline value based on the recent history of the parameter values. An "Adaptive Threshold Limit" is continuously determined for that patient based on the low SpO_2 threshold alarm setting, the Rapid Desat setting, and the current baseline value. SpO_2 measurement values that fall below the Adaptive Threshold Limit will trigger an audible alarm following the user-configured alarm delay.

The Adaptive Threshold Alarm allows shallow desaturations to persist for a longer period of time than deep desaturations but will immediately alarm under either of two conditions:

1) A rapid desaturation (user configured to be 5 or 10%) that exceeds configured rapid desaturation criteria (rate of decline)
   and/or;
2) A prolonged shallow desaturation event.

Adaptive Threshold Alarm will also monitor desaturation recovery and adjust the audible alarm accordingly. This feature further reduces nuisance alarms by allowing the patient's saturation to self-recover to a safe setting without activating an audible alarm. Use of the Adaptive Threshold Alarm is optional and can be switched OFF, in which case traditional alarms limits and delays are used.

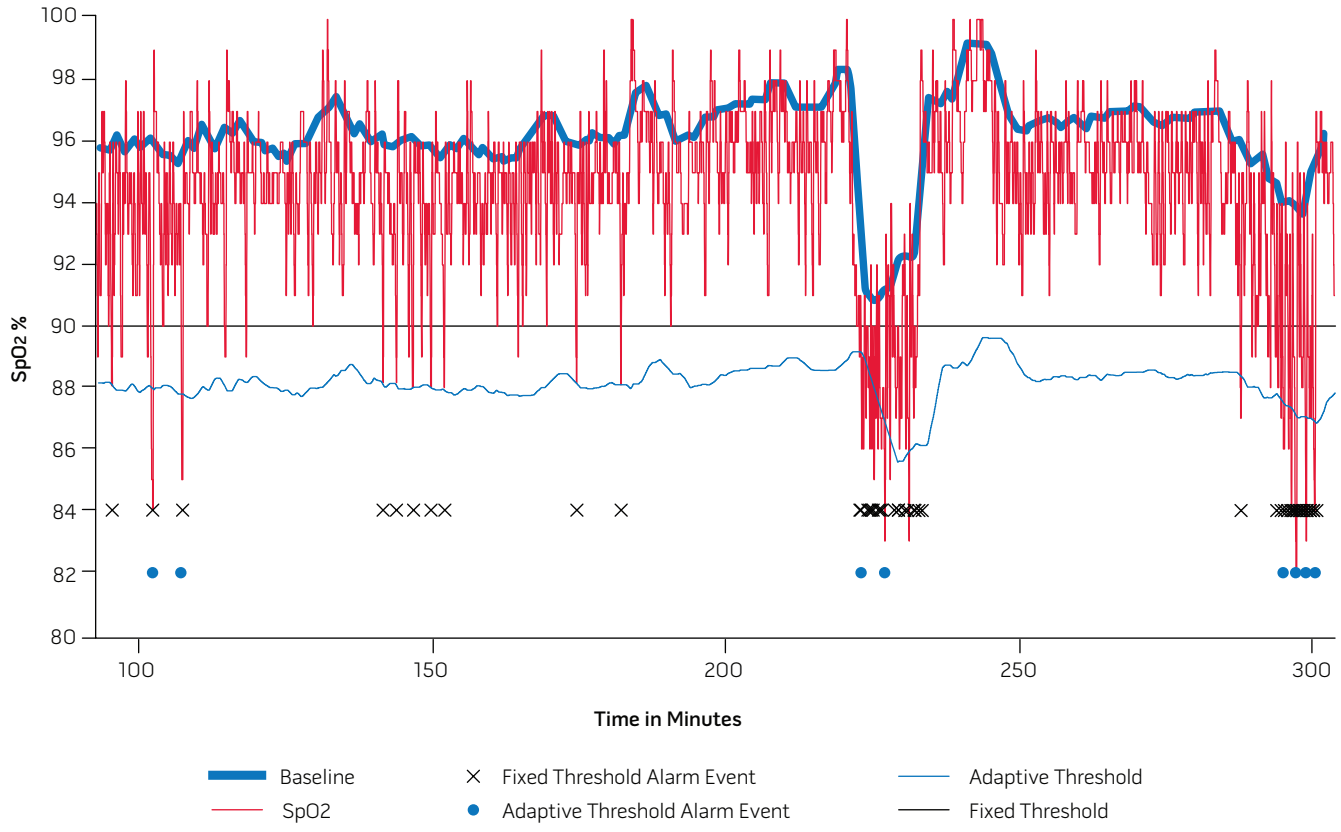

Figure 2. *The behavior of the Adaptive Threshold Alarm with the alarm delay set to 10 seconds is compared to conventional alarm settings for alarm frequency.*

Impact on Alarm Frequency

The alarm frequency of Adaptive Threshold Alarms was compared against fixed alarm thresholds of 90%, 88%, and 85% with alarm delays of 0 and 15 seconds, with and without Rapid Desat setting of 10%. A database of Masimo SET SpO2 values collected from post-surgical general care areas in 10 Hospitals and over 32 million data points was used.

First, alarm occurrence was evaluated, defined as the occurrence of an audible alarm of any duration. Table 1 shows a comparison of three alarm configurations: low threshold alarm with a 15 second delay, low threshold alarm with 15 second delay and a Rapid Desat setting of 10%, and Adaptive Threshold Alarm with a 15 second delay and a Rapid Desat setting of 10%. The greatest improvement in reduction of alarm frequency is when the Adaptive Threshold Alarm is activated at the low SpO2 threshold setting of 90%.

Table 1. Adaptive Threshold Alarm: Reduction in Alarm Occurrence

	Reduction in Alarm Occurrence		
Low SpO2 Alarm Setting (with No Alarm Delay, Rapid Desat off)	**15 sec delay, Rapid Desat off**	**15 sec delay, Rapid Desat at 10%**	**Adaptive Threshold Alarm** (15 sec delay, Rapid Desat at 10%)
90%	70%	68%	86%
88%	85%	83%	92%
85%	94%	94%	96%

Alarm duration is defined as the total time in which an audible alarm would sound, if the clinician did not silence the alarm. An additional benefit to Adaptive Threshold Alarms is the duration in audio annunciation at the bedside. Table 2 shows a comparison of the reduction of audio alarm duration after activation for the same alarm configurations as in Table 1.

Table 2. Adaptive Threshold Alarm Performance: Reduction in Alarm Duration

	Reduction in Alarm Duration		
Low SpO2 Alarm Setting (with No Alarm Delay, Rapid Desat off)	**15 sec delay, Rapid Desat off**	**15 sec delay, Rapid Desat at 10%**	**Adaptive Threshold Alarm** (15 sec delay, Rapid Desat at 10%)
90%	41%	40%	86%
88%	77%	76%	93%
85%	94%	94%	97%

The reductions in both the occurrence of alarms and the duration of audible alarms at bedside provide a potential improvement in the patient's environment by reducing the number of nuisance alarm events.

The reduction in alarm occurrence and duration with Adaptive Threshold Alarm is greatest when compared to traditional SpO_2 alarm setting of 90%. The reduced impact of Adaptive Threshold Alarm at lower settings may occur because fewer alarms occur as the fixed threshold is moved lower. Researchers have demonstrated that it is possible to reduce low SpO_2 alarm limits to 80% with a 15 second alarm delay to primarily detect extreme hypoxia events.[5] These alarm settings resulted in a 98% reduction in overall alarm occurrences in the Masimo Database, but may result in missed alarms for prolonged desaturations above 80%. In comparison, applying Adaptive Threshold Alarm to the same data set with a low SpO_2 threshold setting of 88% achieved a 92% reduction in alarm frequency. In this comparison, the additional alarms also allow increased sensitivity to potential actionable events for SpO_2 levels between 80% and 88%. This approach to alarm functionality addresses concerns raised over the 80% low SpO_2 settings while still reducing the large majority of nuisance alarms.

CONCLUSION

Masimo SET Measure-through Motion and Low Perfusion technology provides an important foundation to any alarm management strategy because it significantly reduces false alarms and increases true alarm detection. With Masimo Adaptive Threshold Alarm, true alarms can be separated by the severity of desaturation event, based on the patient's baseline value. Masimo Adaptive Threshold Alarm is a patient-centric, smart alarm that addresses the reduction of nuisance alarms without sacrificing sensitivity to sustained shallow desaturation events that can be missed by just lowering alarm thresholds. Unlike other alarm filtering attempts that either suspended alarms in the presence of motion artifact or integrate desaturation events with time, Adaptive Threshold Alarm adjusts to patient baseline values.

REFERENCES

1 IEC 60601-1-08 General requirements for basic safety and essential performance –Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. 2006.

2 ECRI Institute. "Top 10 Technology Hazards for 2011." *Health Devices,* Vol 39, No 11;386-398.

3 Shah N et al. *Journal of Clinical Anesthesia*. 2012. In press.

4 Whitepaper: "Masimo Advanced Alarm Performance: An Evidence-Based Approach to Reduce False Alarms and Nuisance Alarms." Masimo Corp. 2010.

5 Taenzer A et al. "Impact of Pulse Oximetry Surveillance on Rescue Events and Intensive Care Unit Transfers A Before-and-After Concurrence Study." *Anesthesiology*, 2010; 112:282–7.

6 Abenstein P et al. "An Ounce of Prevention May Equate to a Pound of Cure Can Early Detection and Intervention Prevent Adverse Events?" *Anesthesiology*, 2010; 112: 272-3.

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