# Nellcor Oximax SatSeconds:
# Transferring Liability to the Clinician

## Introduction

SatSeconds™ is a feature of the Nellcor 04 algorithm that is intended to manage Nellcor's high incidence of what they refer to as "clinically insignificant" nuisance and false alarms.[1] SatSeconds attempts to reduce false alarms caused by the weakness of their algorithm. Nellcor asks the clinician to assume the responsibility of deliberately adding delays between desaturation events and audible alarms in the hope that the pulse oximeter will eventually recover.

Masimo's advanced algorithm has a superior ability to reduce false alarms while detecting true alarms through the use of advanced signal processing. This eliminates the need to mask critical and diagnostic alarms.

## SatSeconds Eliminates Real and Clinically Significant Alarms

In order to use SatSeconds, Nellcor instructs clinicians to evaluate the clinical conditions of the patient and then program a SatSeconds alarm, which is described as "the product of the magnitude and time a patient exceeds $SpO_2$ alarm limits."[2]

In daily operation, a clinician sets a high and low oxygen saturation limit (96% high and 88% low). The clinician then estimates how far above or below that alarm limit and for what length of time a patient can safely saturate or desaturate without causing harm to the patient or inconvenience to the clinician. The clinician then programs the SatSeconds value according to his/her estimation of what is acceptable in terms of safety.

The product of time and saturation calculates SatSeconds, so 3 points above or below the alarm limit for 10 seconds equals 30 SatSeconds. Therefore, a patient can have an oxygen saturation of 3 points above or below the set alarm limit for 10 seconds before the Nellcor oximeter will alarm and alert the clinician. So if the clinician programs 100 SatSeconds on the oximeter, the same patient can be 3 saturation points above or below his/her limit for 33 seconds before an alarm actually occurs. At the same settings, a drop of 1 point below or 1 above the alarm limit would result in a 100 second delay. Similarly, 2 points above or below would result in a 50 second delay. As the clinician sets the SatSeconds higher, the potential is increased that a deeper desaturation or a higher over saturation will be masked. A longer delay of potentially critical alarms is possible.

Nellcor claims that a "safety net" does exist.[1,2] The SatSeconds safety net triggers an alarm if the alarm limit is exceeded three or more times within a minute. If a minute with only 0, 1 or 2 alarm limit violations occurs, SatSeconds resets. SatSeconds eliminates both false alarms and "true" alarms. These true alarm violations can be clinically significant diagnostic alarms.

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## SatSeconds - Transferring Responsibility

The Nellcor SatSeconds "Operator's Manual" contains the following statement: "The decision to utilize the SatSeconds feature and at what limit, or not to use it at all, must be made based on the medical assessment of the patient's clinical signs and symptoms."[1] Nellcor then warns clinicians regarding SatSeconds use: "Clinicians who choose to employ the SatSeconds function should select a limit suitable to their clinical environment and patient conditions".[1,2] This statement transfers all responsibility for its application (or misapplication) to the clinician. Unfortunately, it is well known that patient conditions can change very rapidly, so the SatSeconds alarm threshold could very quickly place the patient in a unsafe situation.

In Figure 1 below, a neonatal patient experiences four prognostic desaturations prior to a crash. In this example, a setting of 100 SatSeconds would have prevented an audible alarm until the final desaturation. The SatSeconds "safety net" 2 would not have engaged since these desaturations did not occur within a 60 second window.



Saturation
Masimo Alarm Active
Nellcor 100 SatSeconds Alarm Active
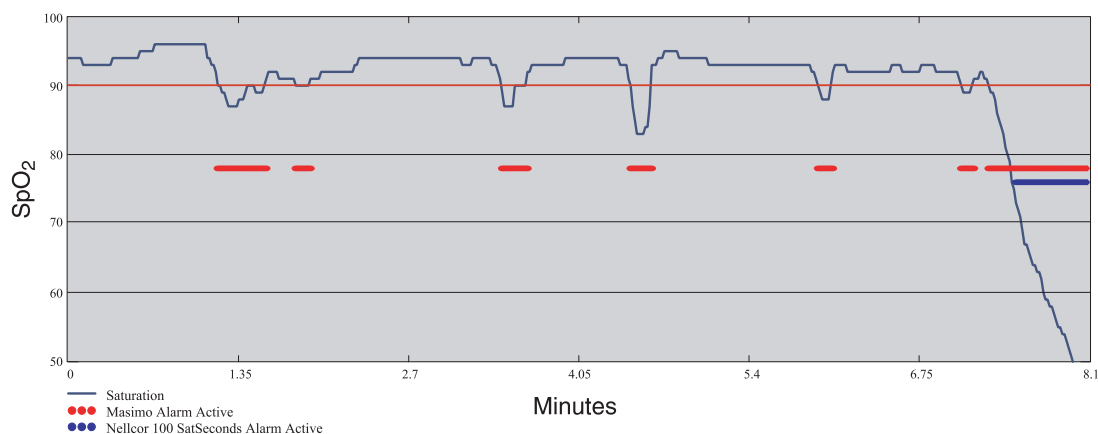
## There are No Insignificant True Desaturations

In explaining SatSeconds, Nellcor describes brief desaturation events that they consider clinically insignificant or nuisance alarms. Nellcor's belief in these insignificant events provide the logic behind their employing SatSeconds. According to clinical literature, this is not a clinically legitimate belief. Brief desaturations are known to often be precursors to life threatening desaturations, and they have been linked to a decreased quality of life.  Most recently, Dr. Joel L. Bass et al. from the Department of Pediatrics, Newton-Wellesley Hospital, Mass General Hospital for Children, reported that over 50 independent studies have shown that intermittent hypoxia in children has markedly adverse effects on development, behavior, and academic achievement.[3]

Masimo's belief is that all devices should reflect the stated performance claims and that the clinician should not be required to accept responsibility and liability for any shortcomings in a manufacturers technology by being asked to mask potentially harmful events. If the device is failing or displaying false information it should acknowledge and identify that failure and alert the clinician so that appropriate actions or care can be given.

## The Masimo Alternative - False Alarm Rejection, True Alarm Capture

The Masimo SET technology truly reduces false alarms while accurately reporting true alarms. SatSeconds, on the other hand, reduces the incidence of alarms - false, or true -through the use of an alarm management system that also compromises true alarms. While the promise of fewer alarms is clinically attractive, turning off the pulse oximeter alarm is not the way to do it. Some non-critical clinical conditions might allow support for a brief delay of a minor alarm violation, but owing to the unpredictability of the critical care hospital environment, the risk and liability is high. The Masimo alternative is to eliminate false alarms through superior performing technology while continuously capturing true alarms. Many clinical studies conclude that Masimo SET eliminates more false alarms and reports more true alarms than any other oximeter [4,5,6] - without the use of unsophisticated alarm masking tricks like SatSeconds.

## Conclusion

SatSeconds alarm management scheme decreases the response time of the alarms and may hide true as well as false alarms from the clinician. SatSeconds may also mask clinically relevant precursor events from the caregiver.

## References

1.  Nellcor Operator's Manual.

2.  Nellcor SatSeconds Alarm Management brochure (MN18002).

3.  Bass JL, Corwin M, Gozal D, Moore C, Nishida H, Parker S, Schonwald A, Wilker RE, Stehle S, Kinane TB.  The Effect of Chronic or Intermittent Hypoxia on Cognition in Childhood: A Review of the Evidence.  *Pediatrics* 2004;114(3):805-816.

4.  Brouillette RT, Lavergne J, Leimanis A, Nixon GM, Laden S, McGregor CD.  Differences in Pulse Oximetry Technology Can Affect Detection of Sleep Disorders in Children.  *Anesthesia and Analgesea* 2002;94(S1):S47-53.

5.  Torres A, Skender K, Wohrley J, Aldag J, Raff G, Geiss D.  Assessment of 2 New Generation Pulse Oximeters During Low Perfusion in Children. *Critical Care Med.* 2002;29(12):A117.

6.  Hay WW, Rodden DJ, Collins SM, Melara DL, Hale KA, Fashaw LM.  Reliability of conventional and neonatal oximetry in neonatal patients.  *Journal of Perinatology.* 2002;22:360-366.