

Preventing Alarm Fatigue

Monitor alarms are designed to alert caregivers to changes in the patient's condition that may indicate the need for intervention. These alarms are essential to patient safety across the healthcare continuum and in many cases, are lifesaving.

Due to the proliferation of monitors designed to provide clinicians with more physiologic information and improve patient safety, the number of alarms encountered by clinicians has risen proportionally. It is estimated that 85 percent to 99 percent of alarms do not require an intervention. Causes include setting the alarm thresholds "too tight," default alarms not adjusted to individual patient needs, or sensors that are not correctly applied.¹⁻² Clinicians overwhelmed by the sheer multitude of beeps may ignore alarms (known as alarm fatigue) sometimes with catastrophic results.

The Boston Globe published a series of articles³⁻⁷ on the results of alarm fatigue that said between January 2005 and June 2010, 200 hospital patient deaths nationwide were linked to problems with alarms on patient monitors.³⁻⁷ The articles discussed several specific cases, including an elderly man whose electrocardiogram displayed a flat line for more than two hours without caregiver response.

The ECRI, an independent, nonprofit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care, has published the Top 10 Health Technology Hazards list annually since 2010.⁸ Alarm hazards has been on every list since 2010, and topped the list in 2012 and 2013. As a result, ECRI published additional guidance on addressing strategies for alarm management.⁹

Joint Commission Issues Sentinel Event Alert

Most recently, The Joint Commission released a Sentinel Event Alert (SEA) on Medical Device Alarm Safety in Hospitals² and a National Patient Safety Goal on Alarm Management.¹⁰ The Joint Commission alert stated this issue is a "frequent and persistent problem" with 98 alarm-related events reported between January 2009 and June 2012—80 resulting in death and 13 in permanent loss of function. The organization also recognized that alarm-related injuries are significantly under-reported, and that the total number is likely much higher. The SEA notes that the U.S. Food

and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database reported 566 alarm-related patient deaths from January 2005 to June 2010, considered by industry experts to under-represent the actual number of incidents.

The Joint Commission cites alarm fatigue as "the most common contributing factor" to alarm-related events. Many of the events occurred in areas with lower clinician-to-patient ratios including telemetry units, the emergency department and the intensive care unit. The Joint Commission makes a number of recommendations for addressing the problem.

The Joint Commission National Patient Safety Goal (NPSG) was released on June 25, 2013 and becomes effective in two phases:

- In Phase I (beginning January 2014), hospitals will be required to establish alarms as an organization priority and identify the most important alarms to manage based on their own internal situations.
- In Phase II (beginning January 2016), hospitals will be expected to develop and implement specific components of policies and procedures. Education of those in the organization about alarm system management will also be required in January 2016.

Preventing False Alarms

Reducing nuisance alarms starts with the accuracy of the monitor; a monitor providing erroneous readings will generate false alarms.

The industry-leading Nellcor™ pulse oximetry with OxiMax™ technology from Covidien is the only cardiac-based oximetry with sophisticated algorithms that qualify when conditions are appropriate for posting of the computed SpO₂ and pulse rate values.¹¹ If the signal is significantly affected by "noise" caused by venous blood and other tissue, the monitor won't post the erroneous reading. A second benefit is that technology closely tied to the patient's physiology requires less signal processing, preventing signal over-processing, which can mask true patient events from being displayed.

Nellcor™ LoSat technology also enables accurate readings when saturation is critically low, in the 60 percent to 80 percent saturation range. This key feature allows improved oxygen saturation assessment for patients that require O₂ management within certain SpO₂ ranges or during challenging conditions associated with low saturation.

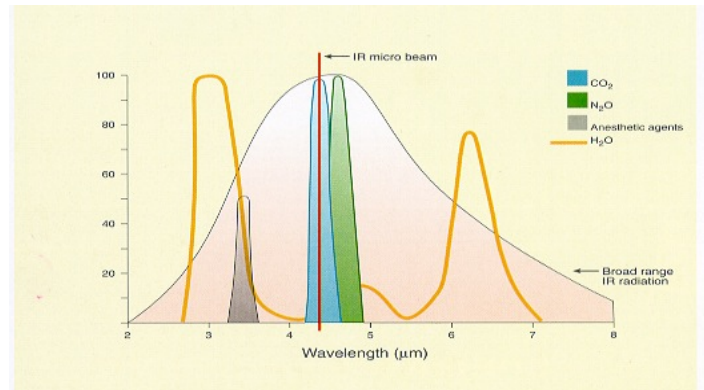
Capnography accuracy begins with capturing a quality breath sample. Only Covidien offers the patented Uni-junction™ design¹², which samples from both nares and across the mouth capturing a quality breath sample in changing breathing patterns common during respiratory distress. (See the photo below.) Other sampling designs may only sample from the nose and many from only one nare while delivering oxygen to the other.



The fluidic valve design of the Uni-junction shifts from nasal to oral sampling based on the patient's breathing pattern. This enables quality sampling even under challenging monitoring conditions, such as shallow oral breathing. Up to 5 l/m of oxygen can be delivered through small openings along the top and bottom of the oral-nasal sampling interface without significantly diluting the sample.

Once a quality breath sample is delivered, Microstream® technology with patented Molecular Correlation Spectroscopy™ (MCS) measures only CO₂, using a micro bandwidth infrared (IR) beam. MCS provides the only CO₂-specific measurement currently available, screening out N₂O, H₂O, oxygen and anesthetic agents, unlike competing

capnography monitoring technology which uses a broad bandwidth IR source.¹³ MCS requires no individual patient calibration or zeroing and automatically adjusts for changes in barometric pressure.



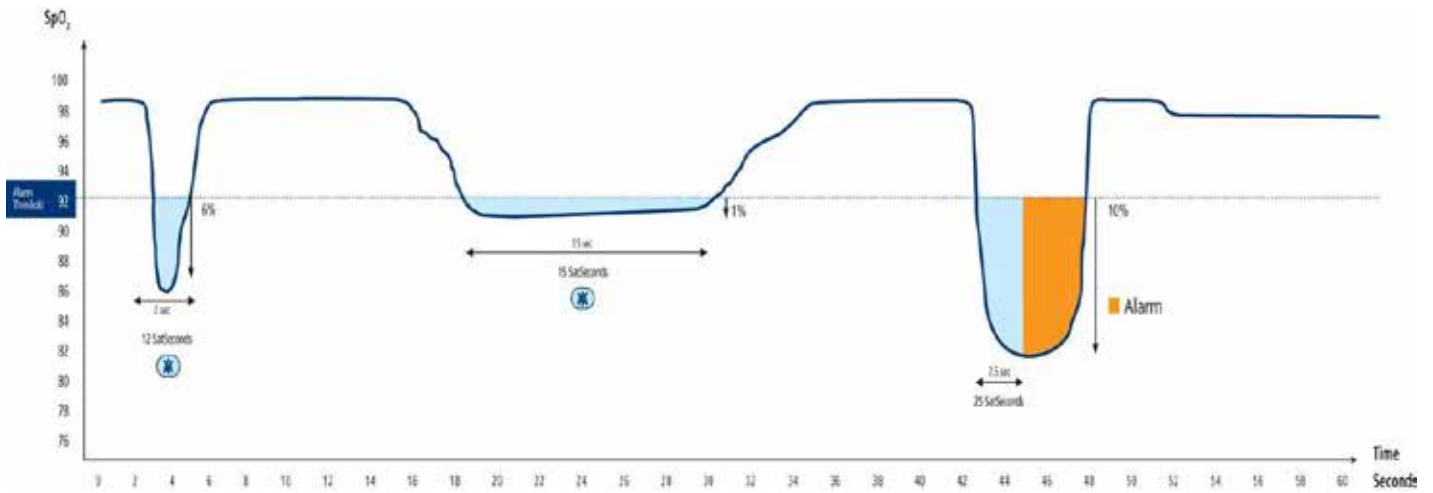
Smart Alarm Management

Recommendations from the Anesthesia Patient Safety Foundation on Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period recognized the need to create “smarter” alarm management systems,¹⁴ and state:

“Continuous electronic monitoring systems should integrate multiple physiologic parameters to identify clinically significant changes earlier and more reliably. Threshold-based alarm limits on individual physiologic parameters may result in the caregiver failing to recognize early signs of progressive hypoventilation by either being too sensitive (excess false alarms) or insufficiently sensitive.”

Covidien Smart Alarm Management technologies are designed to reduce the number of nuisance alarms while alerting caregivers to clinically-significant events. Smart alarm technology has been built into both Nellcor™ pulse oximetry with OxiMax™ technology and Microstream® technology capnography monitoring platforms.

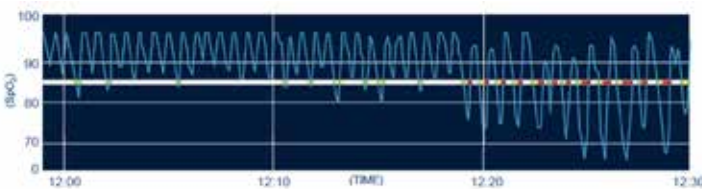
Nellcor™ SatSeconds alarm management is a clinician-controlled feature that differentiates between serious hypoxemia and minor transient events without exposure to the dangers associated with alarm delays. It generates alarms based on both the depth and the duration of a patient's desaturation, reducing nuisance alarms. For example, if the SatSeconds feature or alarm is set by the clinician to 50, a desaturation of 5 percent lasting for 10 seconds (5% X 10 seconds = 50) or desaturation of 10 percent for 5 seconds (10% X 5 seconds = 50) would trigger a SatSeconds alert.



This enables clinicians to evaluate brief desaturation events in context with their depth and shallow desaturations in context with their duration. So, rather than having an alarm sound every time a patient crosses the threshold (e.g., $SpO_2 < 90\%$), an alarm sounds when a desaturation event is clinically significant to the patient's condition, based on the clinician-designated settings.

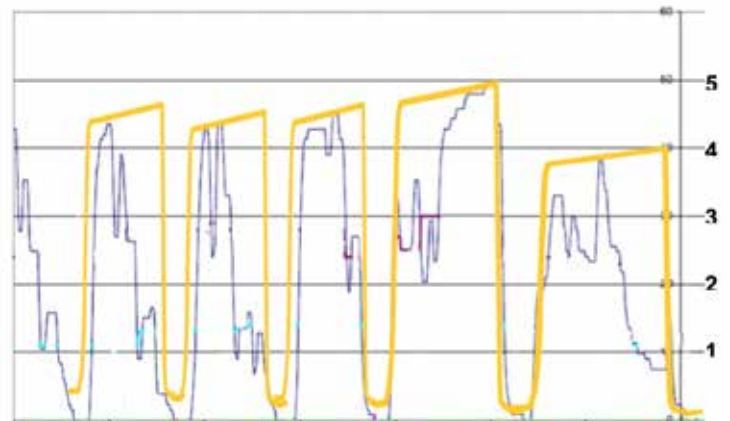
Data shows that SatSeconds alarm management enables clinicians and nurses to respond to alarms that are clinically relevant and reduces the number of clinically insignificant alarms.¹⁵ With the use of the SatSeconds alarm management feature, total alarms were reduced by 60 percent.

Another feature designed to minimize nuisance alarms is the OxiMax™ Saturation Pattern Detection (SPD) Alert, which identifies patterns of desaturation that are indicative of repetitive reductions in airflow in adults.¹⁶ The alert occurs even if the SpO_2 levels do not fall below alarm limits. The OxiMax SPD alert feature uses an algorithm based on the speed, severity, frequency and duration of the patient's desaturation events.



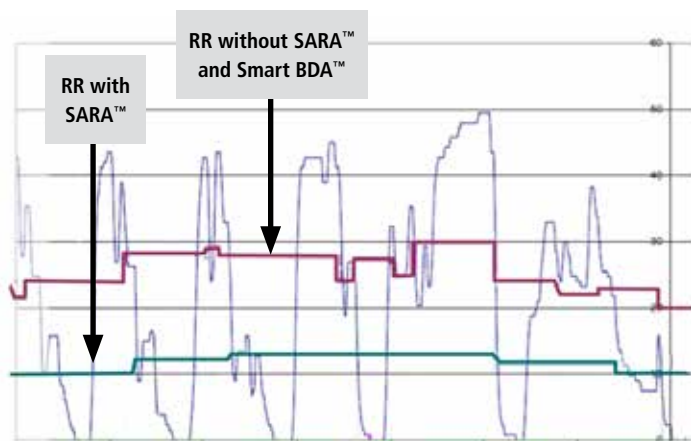
For an OxiMax SPD alarm to sound, the algorithm must identify five discrete desaturation/resaturation cycles. The SPD alert can show a caregiver that although a patient's current SpO_2 snapshot may be acceptable, the patient has developed troubling patterns of desaturation, which could be indicative of an event down the road, enabling the caregiver to intervene and assess the situation.

Microstream® technology employs two important algorithms shown to reduce clinically insignificant alarms: Smart Breath Detection Algorithm (BDA) and Smart Alarm for Respiratory Analysis (SARA™). The Smart Breath Detection Algorithm differentiates shallow CO_2 excursions common during activities, such as talking, eating and snoring, capturing the entire exhalation cycle (see figure). Without SBD, the shallow excursions would be counted as breaths, resulting in a falsely elevated respiratory rate and potentially a false high respiratory rate alarm. With SBD, only the entire cycle is counted as a breath.



Once Smart Breath Detection is providing reliable breath detection, the SARA algorithm provides a reliable respiratory rate. SARA calculates the respiration rate by averaging a number of breath-to-breath intervals. To determine how many intervals to use, SARA evaluates the variability of breath intervals. During periods of regular breathing, SARA uses five breath intervals to calculate the RR, but as variability in the breathing pattern increases, the RR averaging is adjusted to include more breaths, capping at 11 breath intervals during periods of maximum variability.

The algorithm employed in the respiration rate calculation reduces false positive alarms by filtering out noise and instantaneous fluctuations without missing true alarms that may indicate a clinically significant change to respiration rate. By employing the adaptive averaging algorithm, the respiration rate accurately reflects the patient's condition and significantly reduces the generation of nuisance alarms by the host.¹⁷⁻¹⁹



Data shows that with SARA, respiratory rate (RR) alarms were reduced by 53 percent overall, and short duration alarms lasting less than 10 seconds were reduced by an additional 19 percent. No significant RR alarms were missed with SARA.¹⁹

Summary

Alarm fatigue is recognized by multiple clinical organizations as a significant challenge to patient safety, leading to a significant number of patient deaths and injuries. There is a need to develop more intelligent alarm management systems to reduce clinically insignificant alarms while identifying alarm conditions that require intervention. Covidien patient monitoring solutions are designed for ease of use by busy clinicians and feature Smart Alarm Management systems that have been proven to reduce clinically insignificant alarms.

References

- Graham KC, Cvach M. Monitor alarm fatigue: standardizing use of physiological monitors and decreasing nuisance alarms. *Am J Crit Care*. 2010;19(1):28-35.
- The Joint Commission. Medical device alarm safety in hospitals. Sentinel Event Alert. April 8, 2013; issue 50. Available at: http://www.jointcommission.org/assets/1/18/SEA_50_alarms_4_5_13_FINAL1.PDF.
- Kowalczyk L. No easy solutions for alarm fatigue. *Boston Globe*. February 11, 2011. Available at: http://www.boston.com/lifestyle/health/articles/2011/02/14/no_easy_solutions_for_alarm_fatigue/?page=full.
- Kowalczyk L. Patient alarms often unheard, unheeded. *Boston Globe*. February 13, 2011. Available at: http://www.boston.com/lifestyle/health/articles/2011/02/13/patient_alarms_often_unheard_unheeded/.
- Kowalczyk L. For nurses, it's a constant dash to respond to alarms. *Boston Globe*. February 13, 2011. Available at: http://www.boston.com/lifestyle/health/articles/2011/02/13/for_nurses_its_a_constant_dash_to_respond_to_alarms/.
- Kowalczyk L. Ventilator errors are linked to 119 deaths. *Boston Globe*. December 11, 2011. Available at: http://www.boston.com/news/local/massachusetts/articles/2011/12/11/ventilator_errors_are_linked_to_119_deaths/.
- Kowalczyk L. Alarm fatigue a factor in second death. *Boston Globe*. September 21, 2011. Available at: http://www.boston.com/lifestyle/health/articles/2011/09/21/umass_hospital_has_second_death_involving_alarm_fatigue/.
- ECRI Institute. Top 10 Health Technology Hazards. Available at: <https://www.ecri.org/Forms/Pages/ECRI-Institute-2013-Top-10-Hazards.aspx>.
- ECRI Healthcare Risk Control. Clinical Alarms. Executive Summary. *Critical Care* 5. May 2008.
- The Joint Commission. Prepublication Requirements. National Patient Safety Goal on Alarm Management. June 25, 2013. Available at: <http://www.jointcommission.org/assets/1/18/PREPUB-06-25-2013-NPSG060101.pdf>.
- Covidien. Pulse oximetry monitors. Available at: www.covidien.com/rms/pages.aspx?page=OurProducts/Oximetry/Monitors&product=3.
- Oridion Capnography. Breath sampling technology. Available at: <http://www.oridion.com/eng/technology/co2-breath-sampling-technology.asp>.
- Oridion Capnography. Oridion measurement technology. Available at: <http://www.oridion.com/eng/technology/oridion-measuring-technology.asp>.
- Stoelting RK, Overdyk FJ. Essential Monitoring Strategies to Detect Clinically Significant Drug- Induced Respiratory Depression in the Postoperative Period Conclusions and Recommendations. Anesthesia Patient Safety Foundation. 2010. Available at: <http://www.apsf.org/announcements.php?id=7>.
- Brostowicz HM, Khodayar Rais-Bahrami K. Oxygen saturation monitoring in the neonatal intensive care unit: evaluation of a new alarm management. In: Program and abstracts of the American Academy of Pediatrics National Conference & Exhibition; October 17-20, 2009; Washington, D.C.
- Branson R, Davis B, Davis K, Singh C, Blakeman C, Johannigman J. A comparison of reflective and transmission oximetry in patients with poor perfusion. Presented at: American Association for Respiratory Care 49th Annual International Respiratory Congress; December, 2003; Las Vegas, Nev.
- Oridion Capnography. 510(k) submission K082268. January 6, 2006.
- Hockman S, Glembo T, Niebel K. Comparison of capnography derived respiratory rate alarm frequency using the SARA algorithm versus an established non-adaptive respiratory rate alarm management algorithm in bariatric surgical patients. *Resp Care*. 2009 Open Forum Abstracts. December 2009.
- Colman J, Cohen J, Lain D. Smart Alarm Respiratory Analysis (SARA™) used in capnography to reduce alarms during spontaneous breathing. Poster presented at: Society for Technology in Anesthesia (STA) annual meeting, January 16-19, 2008; San Diego, CA.



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