# DEVELOPMENT AND VALIDATION OF THE MEDTRONIC **NELLCOR™ SPD ALERT**

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MEDTRONIC RESPIRATORY AND MONITORING SOLUTIONS

## INTRODUCTION

Pulse oximetry is an optical technology that noninvasively measures the fraction of arterial hemoglobin that is saturated with oxygen ($SpO_2$) and the pulse rate (PR). Currently, pulse oximeters provide audible alarms to indicate when a patient's $SpO_2$ and/or PR values migrate beyond user-defined thresholds. The SPD Alert (SPD) function on the Nellcor™ N-600x pulse oximeter with OxiMax technology adds automated, real-time detection of specific patterns within the second-by-second $SpO_2$ trend data that indicate the presence of repetitive reductions in airflow (RRiA) through an adult patient's upper airway and into the lungs. Repetitive reductions in airflow may arise when an individual with an upper airway abnormality experiences a decreased level of consciousness. Obstructive sleep apnea is one of a number of conditions that causes repetitive reductions in airflow. As summarized by Weinger from the 2006 Anesthesia Patient Safety Foundation (APSF) workshop, obstructive sleep apnea has been identified as a significant factor in cases of brain injury and death occurring in postoperative patients receiving opioid analgesia. The APSF has recommended that all post-op patients receiving patient-controlled analgesia (PCA) or neuraxial opioids be considered for continuous respiratory monitoring.[1]

## DESCRIPTION OF SPD ALERT

The SPD alert algorithm performs three discrete functions: detecting patterns in the $SpO_2$ trend, quantifying specific characteristics of the patterns and alerting the caregiver.

First, the SPD feature detects whether cyclical saturation patterns are occurring by evaluating the shape and consistency of desaturation-resaturation events in the real-time $SpO_2$ trend data. The definition of a pattern is directly based on the definition of RRiA (see Section C), namely five or more desaturation-resaturation cycles (i.e., a fall and subsequent rise in $SpO_2$ value), where each individual desaturation-resaturation event occurs no more than 120 seconds from the previous one.

Second, once such patterns are detected, the SPD feature computes an index value based on the "severity" of the cycling $SpO_2$ pattern. Severity is defined in terms of the magnitude of the desaturations, the variability of the peaks and nadirs of the individual desaturation-resaturation cycles, and the duration of time that patterns have been continuous. Third, if the SPD index value (SPDi) exceeds the preset threshold, the caregiver will be alerted with a visual and/or audible indication.

Figure 1 provides a graph of the $SpO_2$ trend in a patient exhibiting patterns and a visual description of the Nellcor N-600x pulse oximeter with OxiMax technology display when the SPD feature is activated. The blue line is the $SpO_2$ value plotted versus time and the red line corresponds to the resulting SPD index value. The status of the SPD alert threshold is displayed in a triangle icon. (The SPD index value is not displayed; however as the index increases, the triangle indicator fills). An SPD alert is provided when the index exceeds the threshold associated with a user-defined sensitivity setting. Users can select among three alert sensitivity settings (as shown in Figure 1).

The Nellcor™ N-600x monitor display, from left to right, shows the SatSeconds alarm icon (circle), SPD alert icon (triangle), the pulse blip bar, $SpO_2$ and pulse rate values. The illustration on the left shows the SPD feature enabled and an empty triangle, indicating no pattern has been detected.

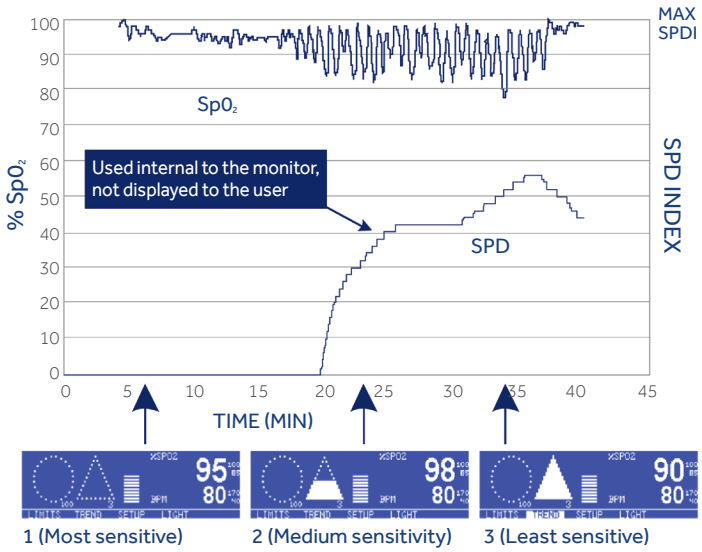


**Figure 1. Since a setting of 1 is most sensitive, the SPD alert will respond to the smallest pattern and will result in the most alerts.**

In the middle illustration, minor patterns have been detected and the SPD feature triangle begins to fill, indicating an increasing SPD index. In the last illustration, the SPD index has crossed the alert threshold and the SPD alert provides the visual and audible indication. The trend tab flashes to alert the user that trend data for SPD alert events is available for review.

## REPETITIVE REDUCTIONS IN AIRFLOW (RRIA)

Two important factors define an RRiA. First, reduction in airflow through the upper airway and into the lungs must be sufficiently large to cause a decrease in the patient's arterial oxygen saturation. Second, reduction in airflow must be repetitive, causing recurring desaturation-resaturation cycles. These recurring cycles are characteristic of individuals experiencing airway instability or central apnea.[2,3]

RRiA is defined by four measured parameters from a common polysomnographic (PSG) recording: airflow, chest wall motion, abdominal motion and $SpO_2$ reading. In order to be considered an RRiA, each of the following must occur:

1. At least a 40% reduction in the nasal thermistor signal envelope for at least 10 seconds, i.e., a reduction in air flow (RAF)
2. At least a 3% fall in $SpO_2$ value during or within 30 seconds after the RAF
3. At least a 40% reduction in chest or abdomen signal during at least half of the RAF duration
4. At least five RAF events where the interval between the start of any two sequential RAF events is less than 120 seconds

The definition of a RAF event presented here is similar to the definition of an apnea/hypopnea as recommended by the American Association of Sleep Medicine (AASM), but is more stringent in terms of the nasal thermistor parameter.

## CLINICAL VALIDATION

The effects of deep sleep, heavy sedation or anesthesia on the upper airway are qualitatively similar. Patterns of desaturation indicative of diminished airflow should occur regardless of the environment in which a patient is being monitored. Because the sleep lab is a controlled environment in which patients exhibiting these patterns frequently appear, Medtronic chose to validate the SPD feature at three independently operated and accredited sleep labs. Study results established the system's sensitivity, specificity and ROC curve statistics in detecting RRiAs.

With Institutional Review Board (IRB) approval and informed consent, more than 100 patients undergoing a standard sleep lab evaluation were enrolled consecutively. Subjects were connected to a Medtronic Sandman PSG (Ottawa, Canada) and a Nellcor N-600x pulse oximeter. Continuous data was recorded for the duration of each standard sleep study. Subjects who were awakened for CPAP placement continued to have their data collected for the remainder of the sleep study. Potential facility bias was mitigated by using common standardized procedures and the same model of equipment at each site and by employing a centralized, blinded, standardized scoring procedure independent of the site.

The presence of RRiA (as defined in Section C) was determined using an automated scoring of the four noted PSG channels: Airflow, Chest, Abdomen and $SpO_2$. Comparisons between the scored PSG results and SPD predictions were based on the maximum SPD index computed on a 10-minute, epoch-by-epoch basis. Figure 2 shows an example from a portion of one measured epoch in which an RRiA was present.

A total of 104 patients were studied. Twelve recorded data sets were disqualified as invalid due to violations of the data collection protocol, leaving 92 valid patient recordings. The average and standard deviation of included patient characteristics were: age = 52.7 + 13 years, body mass index = 36.0 + 9.6, and 45.1% were female. Data from 4,299 10-minute epochs were available, with an average of 46.7 + 5.9 epochs per patient (range 30 to 64). RRiA from the PSG data were characterized as being present in 228 epochs (5.3%), absent in 1,482 epochs (34.5%) and indeterminate in 2,589 epochs (60.2%). Epochs scored as indeterminate were due to issues such as sensor disconnection and/or excessive signal interference in one or more of the PSG channels resulting from CPAP titration during split-night PSG studies.

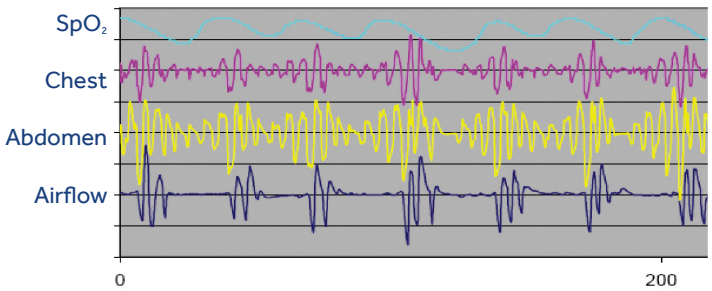


**Figure 2. Since a setting of 1 is most sensitive, the SPD alert will respond to the smallest pattern and will result in the most alerts.**

Table 1

| SPD ALERT SETTING | TRUE POSITIVE | TRUE NEGATIVE | FALSE POSITIVE | FALSE NEGATIVE | SENSITIVITY TP/(TP=FN) | SPECIFICITY TP/(TN+FP) |
|---|---|---|---|---|---|---|
| HIGH (1) | 187 | 1,329 | 153 | 41 | 82.0% | 89.7% |
| MEDIUM (2) | 95 | 1,449 | 33 | 133 | 41.7% | 97.8% |
| LOW (3) | 39 | 1,480 | 2 | 189 | 17.1% | 99.9% |

While the SPD alert data was available from all 4,299 epochs, only the 1,710 epochs in which the RRiA could be determined from the PSG were included in the final analysis. Sensitivity and specificity were computed from the count of instances in which the SPD index value within the discrete 10-minute epoch correctly identified an RRiA being present within that epoch (True Positive), absent (True Negative) or incorrectly identified presence or absence (False Positive and False Negative, respectively). Table 1 summarizes these results at the three different SPD alert sensitivity settings.

Sensitivity and specificity data of the SPD feature as a predictor of RRiA are translated into a receiver-operator characteristic (ROC) curve in Figure 3. The ROC curve is generated by calculating the sensitivity and specificity at different hypothetical SPD index alert thresholds, referred to as cutoff values. For each possible value of SPD index, starting with zero and incrementing up through the maximum possible value, pairs of sensitivity and specificity values are calculated and plotted as shown in Figure 3. The area under the ROC curve has a value of 0.89, reflecting an excellent predictive capability of the SPD alert relative to RRiA.

For a clinical test, the "best" sensitivity and specificity combination is often a subjective judgment related to the type of error that is clinically most acceptable. As the cutoff threshold gets larger (moving from right to left along the ROC curve), the sensitivity is reduced and the specificity is increased. This means that higher cutoff values are associated with (1) increasing numbers of subjects who have RRiA not receiving a desirable intervention, and (2) fewer subjects who receive interventions that are unnecessary because they do not have RRiA. If the clinical judgment is that failing to intervene in subjects who do have RRiA is a more severe error then intervening unnecessarily, then it is best to select a low cutoff value (sensitivity setting of 1). However, if the clinical judgment is that intervening unnecessarily in subjects without RRiA is the more severe error, then higher cutoff values are preferable (sensitivity of 2 or 3).

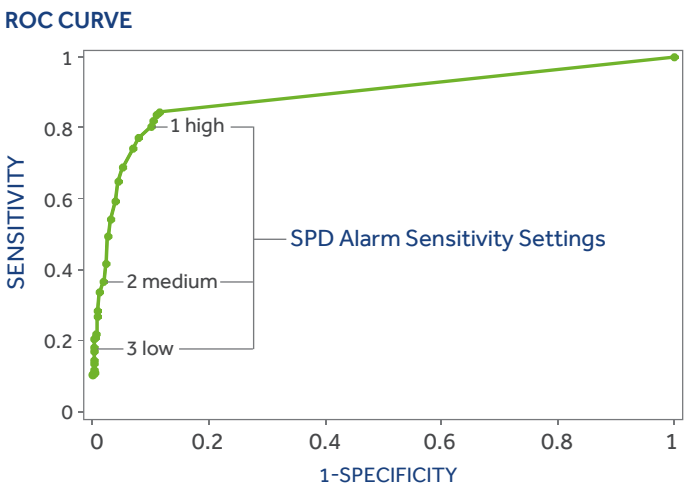


**Figure 3 . ROC curve using the maximum SPD alert index to predict the presence of RRiA.**

Another way of interpreting the impact of the sensitivity setting is in terms of the severity of the pattern that will trigger an SPD alert. At a lower sensitivity setting (2 or 3) SPD index will need to reach a larger value prior to an alert being given. The SPD index is proportional to the severity of the associated desaturation patterns as described in **Section B.**

Patients receiving supplemental $O_2$ may have attenuated patterns of desaturation since for a given RAF event there will be a smaller fall in $SpO_2$, resulting in a smaller value of SPD index. This may reduce the sensitivity of SPD alerts in detecting RRiA. Clinicians will need to consider use of higher SPD sensitivity setting for their patients receiving supplemental $O_2$.

## CONCLUSIONS

In summary, the need to continuously monitor patients receiving opioids who may be at risk due to airway abnormalities was addressed by the APSF 2006 workshop.[1] In some cases, patients with an abnormal airway who experience a decreased level of consciousness will develop RRiA.[1] The SPD alert feature provides a real-time capability to detect patterns in the $SpO_2$ trend that are indicative of RRiA. As shown in a prospective clinical study, the SPD feature has excellent sensitivity and specificity for detecting RRiA. Furthermore, the three different sensitivity settings allow caregivers to adjust the behavior of the SPD alert to meet the particular needs of their patients.

1. Weinger MB. Dangers of postoperative opioids. Anesthesia Patient Safety Foundation (APSF) Newsletter. 2006-2007; 21(4). http://www.apsf.org/resource_center/newsletter/2007/winter/01_opioids.htm

2. Hillman DR., Platt PR, Eastwood, PR. The upper airway during anesthesia. *Br J Anesth*. 2003;91(1):31-39.

3. Dempsey JA, Smith CA, Harms CA, Chow C, Saupe KW. Sleep-induced breathing instability. *Sleep*. 1996; 19(3): 236-247.



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