



RespiraSense Vs Capnography

White Paper, February 2016

Respiratory Compromise (RC) can result from many conditions including cardiac arrest, sepsis, and respiratory depression from the use of opiates. Each adverse event can increase patient length of stay by between 3 to 7 days [1].

Respiratory Rate (RR) has been shown to be an important predictor of many of these conditions. Additionally, it has also been shown that the long term trend of RR is the best predictor of clinical outcome, and slight changes can predict clinical outcome several days in advance [2]. Therefore a method to accurately and continuously monitor a patient's RR is drastically required to help reduce the average patient length of stay and unplanned Intensive Care Unit (ICU) admissions.

The current status quo for the monitoring of respiratory rate, in the general ward environment, is manual nurse evaluation. This procedure involves the nurse counting the number of breaths taken by the patient over a predetermined

Lower alarm fatigue while increasing patient compliance

time period (i.e. 15, 30 or 60 seconds) and then determining the number of breaths per minute. However manual methods can be inaccurate due to, for example, the difficulty in observing the mechanical action of breathing or extrapolation error, and it often leads to this important vital sign to not be recorded at all [3].

Addressing the Need

PMD Solutions premier product, RespiraSense (Figure 1), aims to solve these problems by continuously and noninvasively monitoring the patient's respiratory rate, from admission to discharge.

In order to prove the efficacy of RespiraSense, the system was tested against the next best available method of respiration monitoring, capnography. Capnography is a realtime direct monitor of the inhaled and exhaled concentration or partial pressure of CO₂, monitored using a nasal cannula. Capnography is not used widely throughout the general ward environment due to its high system cost, uncomfortable cannula and high false alarm rate in conscious patients.

Reliable and continuous monitoring of respiratory rate

Methodology

Two separate datasets were collected to benchmark the RespiraSense. In both, respiration data was obtained from the subject using both the RespiraSense and capnography simultaneously.

The first benchmark dataset represented a cohort of seven subjects producing 13 trials, performing routine office tasks while seated, over the course of one hour. Subjects were instructed not to talk over the hour period and to only breathe through their noses. Following this, a second cohort of patients from Nenagh General Hospital (Ireland) were recruited. The second cohort consisted of 13 patients in the general ward. These subjects were not provided with any instructions. The duration of these recordings was dependent on the duration of the patient stay.

The RespiraSense continuously monitors the patient's respiration and calculates the average respiratory rate of the patient over each 15 minute period using the PMD's proprietary algorithm. Any data points which did not comprise of a full 15-minutes worth of data were discarded. The first dataset resulted in a total of 50 data points across all subjects. The testing within the hospital environment resulted in 46 data points for the second dataset.

The Capnograph outputs the calculated real-time respiratory rate of the subject every 1 second. These data points were averaged to produce the 15 minute average result for each epoch of the available data.

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Figure 1 - RespiraSense Lobe and Consumable

Results

Table 1 provides the results of the analysis performed on both datasets.

	Office	Nenagh
# of data points	50	46
Bias	-0.05	0.50
Standard Deviation	0.99	1.35
+95% Confidence Limit	1.89	3.15
-95% Confidence Limit	-1.98	-2.16
Correlation	0.96	0.87

Table 1 - Results analysing RespiraSense Vs Capnography



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Examining the results from the office dataset, it can be observed that there is a low bias (-0.05) between the two modalities. Furthermore, the 95% CL lie between ± 2 providing very accurate results across all tested RR (approximately 9-21 breaths per minute (BPM)).

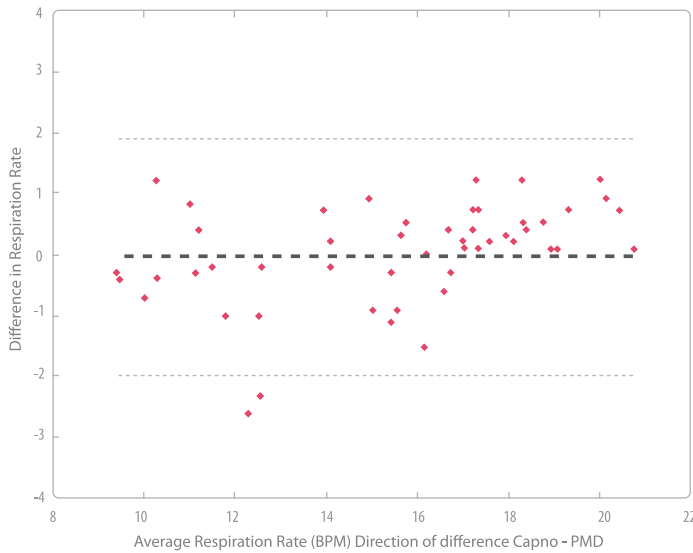


Figure 2 - Database 1: RespiraSense Vs Capnography during routine office activity

The results arising from the data recorded in Nenagh Hospital have a slightly higher bias of 0.5 BPM. The 95% CL for this dataset lies between -2.16 and +3.15 which is just slightly outside the desired ± 3 BPM range. However, only a single data point actually sits outside this range (as can be observed in Figure 3 as the data point highlighted by a green circle). One possible explanation for this higher variance can be traced to the recording method of the Capnograph. As recording is performed through the nasal passage, prolonged periods of talking or breathing through the mouth can severely affect the results.

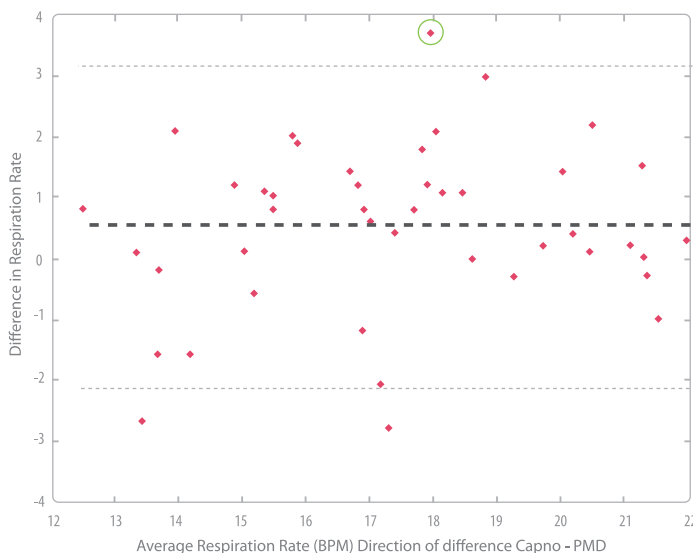


Figure 3 - Database 2: RespiraSense Vs Capnography from Nenagh Hospital

As an example, Figure 4 shows the Capnograph output for the outlier highlighted in Figure 3. This data illustrates how variable the output can be. For example, between 10 and 11 minutes the instantaneous RR can be seen to vary from approximately 9 BPM to above 70. These spikes cause inaccuracies within the averaged results for the Capnograph thus increasing the variance between the Capnograph and RespiraSense. These fluctuations are a well-known issue when monitoring with Capnograph and can often contribute to alarm fatigue.

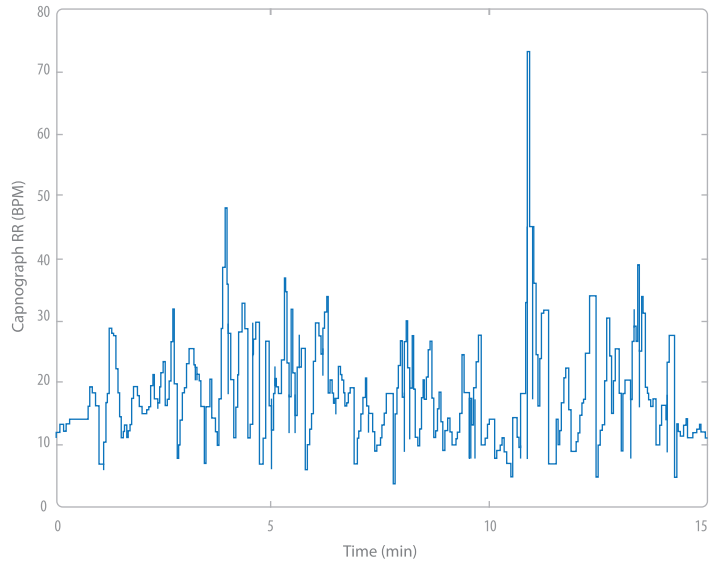


Figure 4 - Example of Capnograph variability over 15 minutes

Conclusion

PMD's RespiraSense allows for the accurate and continuous monitoring of RR, therefore enabling the early detection of RC. The discrete solution improves both patient comfort and, as a consequence, patient compliance while the on-board accurate analytics help reduce alarm fatigue observed with other recording modalities.

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