

Continuous and Noninvasive Respiration Rate with Rainbow Acoustic Monitoring™

BACKGROUND AND OBJECTIVE

Respiration rate is an important vital sign. Manual methods of determining respiration rate are intermittent and have proven to be unreliable. Continuous methods have limitations; either they are not accurate or are poorly tolerated by patients. Masimo® Rainbow Acoustic Monitoring solves these challenges by noninvasively and continuously measuring respiration rate using an innovative adhesive sensor with an integrated acoustic transducer that is easily and comfortably applied to the patient's neck. Using acoustic signal processing that leverages Masimo's patented revolutionary Signal Extraction Technology (SET®), the respiratory signal is separated and processed to display continuous respiration rate (RRa™). Clinical studies demonstrate RRa is equivalent to the respiration rate derived from capnography and is well tolerated by patients.

CLINICAL BACKGROUND

Respiration rate is a key indicator of ventilation. Abnormal respiration rate, either too high (tachypnea), too low (bradypnea), or absent (apnea), is a sensitive indicator of physiologic distress that requires immediate clinical intervention. In spite of its clinical importance, respiration rate is the last core vital sign without a reliable and continuous monitoring method that patients can easily tolerate.¹ The lack of a reliable respiration rate measurement is a major contributor to avoidable adverse events.² A retrospective study of over 14,000 cardiopulmonary arrests in acute care hospitals showed 44% were respiratory in origin.³ In addition, a study by HealthGrades showed respiratory failure, a key Patient Safety Indicator (PSI), has increased in US Acute Care Hospitals. The reported incidence is 17.4 per 1,000 hospital admissions leading to over 15,000 avoidable deaths at a cost to the healthcare system of over \$1.8 billion.⁴ The high incidence of respiratory-related adverse events associated with the administration of opioids for pain management has led to recommendations by the Anesthesia Patient Safety Foundation (APSF) to continuously monitor SpO₂ and ventilation for all patients receiving narcotic analgesics.⁵ The continuous monitoring of respiration rate as an indicator of ventilation is particularly important for patients receiving supplemental oxygen. It is well recognized that changes in oxygen saturation can be delayed following an apneic event in patients receiving supplemental oxygen.^{5,6}

The compelling need for a reliable respiration rate monitor to improve patient safety led Masimo to develop Rainbow Acoustic Monitoring technology.

LIMITATIONS OF CURRENT METHODS

Manual Method

The most common method for respiration rate measurement is by physical assessment, either by counting chest wall movements or by auscultation of breath sounds with a stethoscope. Multiple studies have shown manual methods to be unreliable in acute care settings, especially on the general care floor, where the majority of patients receive care.⁷ Even if they were reliable, manual methods are limited by their intermittent nature.

Two continuous methods for respiration rate monitoring are used in multiparameter monitors, thoracic impedance pneumography and capnography monitoring.

Thoracic Impedance Pneumography

The thoracic chest wall expands and contracts during the respiratory cycle from which respiration rate can be determined by measuring changes in electrical impedance associated with this movement. Impedance is measured by passing a very small alternating current across the chest via ECG Electrodes placed on either side of the chest that measure changes during the respiratory cycle. The respiration rate is then calculated by the repeated cycle of chest wall expansions and contractions. Monitoring of respiration rate by thoracic impedance is convenient if the patient is already monitored for ECG, but the method is prone to inaccurate readings due to a number of factors including: ECG electrode placement, motion artifact, and physiologic events non-related to respiration rate that cause chest wall movement (e.g. coughing, eating, vocalization, crying).^{8,9} Another significant limitation is insensitivity to obstructive apnea where chest wall movement is often present in the absence of any actual air exchange (obstructive apnea). These limitations have rendered thoracic impedance monitoring for respiration rate unreliable in acute care settings.

Capnography

Continuous end tidal CO₂ monitoring with capnography is the standard of care in surgical settings to establish end tracheal intubation. Since intubated patients have a clear respiratory pattern without entrainment of room air, it is easy for the capnometer to report the respiration rate. However, capnometers that continuously monitor ventilation for non-intubated patients require a nasal airway cannula that draws a continuous gas sample for spectrographic measurements within the capnometer. Capnometry measurement of respiration rate is the most frequent technology used by anesthesiologists. This method is sensitive to central, obstructive, and mixed apneas.¹⁰ The primary limitations of continuous respiration rate monitoring by capnometry are low patient tolerance of the nasal cannula and the added nursing workload to respond to dislodged or clogged cannulas during the patient stay.¹¹ In addition, any entrainment of room air by the sampling cannula can result in erroneous end-tidal values. A PACU study of pediatric patients showed premature cannula dislodgement in 14 out of the 16 patients enrolled in the study.¹¹

Rainbow Acoustic Monitoring Method

Masimo developed the Rainbow Acoustic Monitoring method for respiration rate (RRa) to overcome the limitations of manual methods and existing continuous monitoring methods, thoracic impedance pneumography and capnography. Rainbow Acoustic Monitoring was designed for ease of use, high patient tolerance, and accuracy in all patient care settings.

The Rainbow[®] Acoustic Sensor detects upper airway acoustical signals produced by the turbulent airflow that occurs during both inhalation and exhalation. Figure 1 is a sample of the acoustic signal and shows several complete breaths, each one characterized by a pair of envelopes, the first during inhalation and the second during exhalation.

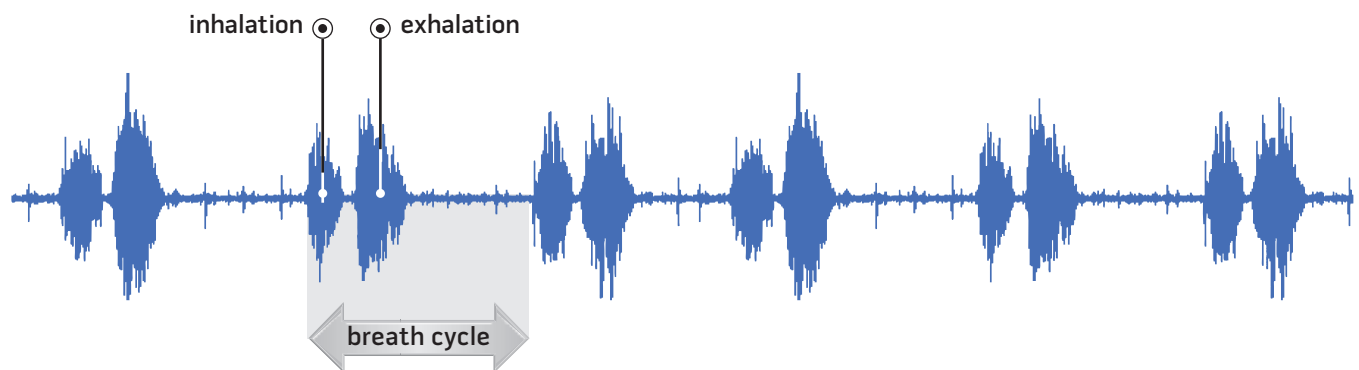


Figure 1 – Acoustic signal showing several complete breaths. Note the strength of the breathing envelope in relation to the baseline environmental noise signal.

The amplitude of the acoustic signal is related to the strength of the breath, sensor placement, and conduction of sound from the trachea through the muscle and skin in the patient's neck to the sensor. The mechanical coupling of the sensor to the body surface helps separate the breathing signal from ambient background noise. Signal processing algorithms convert these acoustic patterns into breath cycles and calculate the respiration rate. Rainbow Acoustic Monitoring algorithms distinguish breath patterns from other biological signals such as carotid pulses, vocalization, coughs, and ambient background noise, as well as respiratory synchronous signals such as snoring or wheezing to produce a reliable measurement. The algorithm constantly measures breath signal strength compared to background noise. When the signal falls below the minimum threshold, as could occur during shallow breathing (hypopnea), the algorithm forces the respiration rate to zero resulting in an alarm condition. The acoustic waveform amplitude is affected by a variety of factors preventing comparisons between patients for other physiologic determinations, however changes within the same patient may indicate relative physiologic changes such as changes in Tidal Volume.

RAINBOW ACOUSTIC MONITORING ACCURACY

The respiration rate measurement from Rainbow Acoustic Monitoring was compared against capnography-determined respiration rate in a study of healthy adult volunteers. Simultaneous raw waveform and respiration rate from Rainbow Acoustic Monitoring and capnography devices were collected from 26 subjects. Breaths were annotated for each subject by an independent observer reviewing the time synchronized raw waveforms to establish a reference respiration rate data set. The accuracy of the respiration rate values from Rainbow Acoustic Monitoring and capnography were then determined. Table 1 summarizes the results:

Table 1 – Accuracy of Rainbow Acoustic Monitoring and Capnography in Normal Subjects

	Number of Samples	Bias (brpm)	Standard Deviation (brpm)	Root Mean Square Accuracy (brpm)
Rainbow Acoustic Monitoring RRa	21,369	0.18	1.31	1.63
Capnography RR	21,405	0.22	1.62	1.63

RRa accuracy was similar to capnography respiration rate accuracy, suggesting that Rainbow Acoustic monitoring is equivalent to capnography for measurement of respiration rate.

In a separate study in a short-stay surgical recovery area that specializes in osteotomy patients, 187 manual auscultatory respiration rate measurements from 25 patients were compared to acoustic respiration rate measurements. Patients were routinely prescribed opioids for post surgical pain management. Respiration rates shown in Table 2 ranged from 8 to 36 breaths per minute. Bias, Precision, and A_{RMS} were 0.8, 3.4, and 3.5 breaths per minute (brpm) respectively.

Table 2 – Accuracy of Rainbow Acoustic Monitoring in Post-Surgical Subjects

	Number of Samples	Bias (brpm)	Standard Deviation (brpm)	Root Mean Square Accuracy (brpm)
Rainbow Acoustic Monitoring RRa	187	0.8	3.4	3.5

Results show a favorable comparison of Rainbow Acoustic Monitoring RRA to manual respiration rate. Only 5 comparison measures (3% of total) were greater than two standard deviations from the average value, and two of these data were from sequential measurements from the same patient. During this study, several incidents of true positive apnea events were observed, supporting the clinical need for continuous monitoring of respiration rate. In the same study, Rainbow Acoustic Monitoring did not work reliably on patients with medium to high levels of Continuous Positive Airway Pressure (CPAP) (above 8 cm H₂O) due to high ambient noise generated by these CPAP devices. No skin sensitivity to the sensor was reported, however, skin adhesion challenges were observed in highly diaphoretic patient conditions. Therefore, a diaphoretic adhesive option will be available. Nursing feedback on the clinical utility of RRA from this evaluation has led this hospital to wide adoption.

In a separate study at a leading teaching hospital, Rainbow Acoustic Monitoring performance was compared to capnography in a pediatric PACU. Accuracy between the two methods was comparable; however patient tolerance of the Rainbow Acoustic Sensor was much better than the end-tidal CO₂ nasal cannula. Patients removed the nasal cannula 87% of the time while recovering in the PACU, while there was no detachment of the Rainbow Acoustic Sensor.⁷

CONCLUSION

Rainbow Acoustic Monitoring is a significant advancement in the accurate and reliable monitoring of respiration rate. Clinical accuracy is comparable to respiration rate measurements by capnography methods. Patient comfort and tolerance to the Rainbow Acoustic Sensor is significantly better than with the nasal cannulas required for capnography. The availability of this new method will allow respiration rate to be reliably monitored in significantly more patients than are monitored today. Rainbow Acoustic Monitoring will improve patient safety by identifying patients with abnormal respiration rates.

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