

Masimo's rainbow® Acoustic Monitoring was Associated with Fewer Alarm Events in New Clinical Study



For Breath Rates Less Than or Equal to 4 Breaths Per Minute, RAM Showed 78% True Positives and 22% False Positives, While Capnography Showed 30% True Positives and 70% False Positives

Masimo (NASDAQ: MASI) has announced that Masimo's rainbow®Acoustic Monitoring (RAM[™]) was associated with fewer alarm events during planned moderate sedation in a new clinical study.¹

This two-part pilot study used RAM and SedLine® brain function monitoring as the additional monitoring parameters during planned moderate sedation to (1) determine the incidences of alarm events (desaturation, respiratory depression and deeper than intended sedation), and (2) determine whether monitoring with these parameters is associated with fewer alarm events.

RAM noninvasively and continuously measures respiration rate using an innovative adhesive sensor with an integrated acoustic transducer that is applied to the patient's neck.

In the two-part study, published in the journal Anesthesia & Analgesia by Dr. Richard Applegate II and colleagues from the Loma Linda University School of Medicine, data were collected from adult patients undergoing gastroenterology or interventional radiology procedures under moderate sedation. The patients were monitored per standard protocols (electrocardiography, blood pressure, pulse oximetry, and capnography) along with the additional parameters RAM and SedLine. RAM and SedLine were not visible to the care teams in part one of the study (standard) but were visible to the care teams in part two of the study (advanced). Alarm events were defined as desaturation (SpO2 <=92%), acoustic respiration rate <=8 breaths per minute, and PSI <=50.

Data were analyzed from 90 patients (44 standard and 46 advanced). There were 55% fewer alarm events in advanced patients compared with standard patients (median 2.5 vs. 5.5, p=0.038). Fewer advanced patients had >=1 respiratory depression event (17 vs 26; p=0.035) or >=1 desaturation event (15 vs 25; p=0.02).

The investigators also compared respiratory rate events between capnography (using the Covidien Capnostream[™] 20p) and RAM in the standard group and conducted a retrospective analysis to determine the true positive rates for capnography and RAM. The true positive rates were 30% and 78% respectively; the false positive rates were 70% and 22% respectively.

There were no significant differences between groups in the number of deeper than intended sedation events using SedLine.

The authors concluded that "the use of advanced monitoring during planned moderate sedation was associated with fewer alarm events, patients experiencing desaturation, and patients experiencing respiratory depression alarm events. ... The findings The findings of this pilot study suggest that further study into the safety and outcome impacts of advanced monitoring during procedure-related sedation is warranted."

References

¹ Applegate RL II, Lenart J, Malkin M, Meineke MN, Qoshlli S, Neumann M, Jacobson JP, Kruger A, Ching J, Hassanian M, Um M. Advanced Monitoring Is Associated with Fewer Alarm Events During Planned Moderate Procedure-Related Sedation: A 2-Part Pilot Trial. Anesth Analg. 2016 Feb 1. [Epub ahead of print].

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