New Study Shows Masimo SET@ Pulse Oximetry Outperforms Competing Technologies

The Associated Press

Masimo (NASDAQ: MASI) announced today a new study in the Journal of Clinical Anesthesia demonstrates the Masimo Radical@ with Masimo SET@ pulse oximetry had higher oxygen saturation (SpO2) specificity and sensitivity and lower failure rates during conditions of motion and low perfusion than other "new-generation" pulse oximeters.(1) Monitoring of SpO2 enables clinicians to detect hypoxemia (deficient blood oxygen) at an early stage. However, conventional pulse oximetry can fail during patient motion and low perfusion, triggering false alarms. More than 100 independent clinical studies have shown Masimo SET Measure-through Motion and Low Perfusion pulse oximetry has overcome the technological limitations of conventional pulse oximetry, and has made pulse oximetry accurate during challenging conditions, reducing false alarms and increasing true alarm detection.

In the study, conducted at the Long Beach Veterans Affairs Healthcare System in California, researchers evaluated 10 healthy volunteers and compared the Masimo Radical (SET V 5.0), the Nellcor N-600 (OxiMax V 1.1.2.0) and the GE TruSat (formerly Datex-Ohmeda) during motion and induced low perfusion. A total of 160 motion tests were performed, 80 with machine- and 80 with volunteer-generated motion. Researchers lowered room temperature to 16 degrees C - 18 degrees C (60.8F - 64.4F) to induce low perfusion. Sensitivity was calculated by dividing the number of tests in which the test device read <90% when the control device read <90% during hypoxia. Specificity was calculated by dividing the number of events that the test device reported SpO2 values >90% when the control device also reported values >90% during normoxia. Failure rate for each device was calculated by dividing the amount of time that each instrument displayed no SpO2 value by the total time of the test.

The study showed that during both machine- and volunteer-generated motion, Masimo SET had the highest SpO2 specificity (93% and 97%, respectively) and the highest SpO2 sensitivity (100% and 95, while the Nellcor OxiMax had specificity of 67% and 77% and sensitivity of 65% and 50%, and the GE TruSat had 83% and 82% specificity and 20% and 15% sensitivity, respectively ($p<0.05$).

Masimo SET had failure rates of 0% during both machine and volunteer motions for SpO2. SpO2 failure rates during machine and volunteer motions were 9.3% and 16.4% for the Nellcor OxiMax and 1.3% and 1.7% for the GE TruSat ($p<0.05$ for volunteer, p value not significant for machine). Pulse rate failure rates for machine and volunteer motions were 0% for Masimo and 22.2% and 33.9% for the the Nellcor OxiMax and 1.7% and 4.4% for the GE TruSat ($p<0.05$ for machine, $p<0.01$ vs Nellcor for volunteer).

"This study reaffirms that Masimo SET delivers outstanding patient-monitoring, particularly in real-world conditions of patient motion and low perfusion," said Dr. Michael O'Reilly, Masimo's Chief Medical Officer. "We believe this performance difference is why clinicians are getting great results in different clinical scenarios, helping clinicians to reduce retinopathy of prematurity (ROP),(2) screen for critical congenital heart disease (CCHD),(3) and enabling continuous surveillance of patients in post-surgical wards.(4) With fewer false alarms and greater true-alarm detection, Masimo SET offers clinicians and hospitals confidence that they are giving their patients the best care possible." 1 Shah N, Ragaswamy H, Govindugari K, Estanol L. "Performance of three new-generation pulse oximeters during motion and low perfusion in volunteers." Journal of Clinical Anesthesia. 2012 (10.1016/j.jclinane.2011.10.012) Available online here 2 Chow L.C., Wright K.W., Sola A.; CSMC Oxygen Administration Study Group. "Can Changes in Clinical Practice Decrease the Incidence of Severe Retinopathy of Prematurity in Very Low Birth Weight Infants?" Pediatrics. 2003 Feb;111(2):339-45. 3 Anne de-Wahl Granelli, Margareta Wennergren, Kenneth Sandberg, Mats Mellander, Carina Bejlum, Leif Inganäs, Monica Eriksson, Niklas Segerdahl, Annelie Agren, Britt-Marie Ekman-Joelsson, Jan Sunnegårdh, Mario Verdicchio, Ingegerd Ostman-Smith. "Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39?821 newborns." British Medical Journal (BMJ) January 2009; 338:a3037. Available here. 4 Taenzer A, Blike G, McGrath S, Pyke J, Herrick M, Renaud C, Morgan J. "Postoperative Monitoring - The Dartmouth Experience." Anesthesia Patient Safety Foundation Newsletter Spring-Summer 2012. Available online About Masimo Masimo (NASDAQ: MASI) is the global leader in innovative noninvasive monitoring technologies that significantly improve patient care-helping solve "unsolvable" problems. In 1995, the company debuted Measure-Through Motion and Low Perfusion pulse oximetry, known as Masimo SET@, which virtually eliminated false alarms and increased pulse oximetry's ability to detect life-threatening events. More than 100 independent and objective studies demonstrate Masimo SET provides the most reliable SpO2 and pulse rate measurements even under the most challenging clinical conditions, including patient motion and low peripheral perfusion. In 2005, Masimo introduced rainbow SET@ Pulse CO-OximetryT technology, allowing noninvasive and continuous monitoring of blood constituents that previously required invasive procedures, including total hemoglobin (SpHb@), oxygen content (SpOCT), carboxyhemoglobin (SpCO@), methemoglobin (SpMet@), and Pleth Variability Index (PVI@), in addition to SpO2, pulse rate, and perfusion index (PI). In 2008, the company introduced Masimo SafetyNetT, a remote monitoring and wireless clinician notification system designed to help hospitals avoid preventable deaths and injuries associated with failure to rescue events. In 2009, Masimo introduced rainbow Acoustic MonitoringT, the first-ever noninvasive and continuous monitoring of acoustic respiration rate (RRaT).

Masimo's rainbow SET technology platform offers a breakthrough in patient safety by helping clinicians detect life-threatening conditions and helping guide treatment options. In 2010, Masimo acquired SEDLine@, a pioneer in the development of innovative brain function monitoring technology and devices. Masimo SET and Masimo rainbow SET technologies can also be found in over 100 multiparameter patient monitors from over 50 medical device manufacturers around the world.

Founded in 1989, Masimo has the mission of "Improving Patient Outcome and Reducing Cost of Care ... by Taking Noninvasive Monitoring to New Sites and Applications@." Additional information about Masimo and its products may be found at www.masimo.com [1].

Forward-Looking Statements This press release includes forward-looking statements as defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, in connection with the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations about future events affecting us and are subject to risks and uncertainties, all of which are difficult to predict and many of which are beyond our control and could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements as a result of various risk factors, including, but not limited to: risks related to our assumptions of the repeatability of clinical results obtained using the new Masimo Pronto-7 and noninvasive sensor sizes, risks related to our belief that the Pronto-7 enables quick and easy noninvasive spot-checking of hemoglobin (SpHb@), SpO2, pulse rate, and perfusion index at the point-of-care for all patients, as well as other factors discussed in the "Risk Factors" section of our most recent reports filed with the Securities and Exchange Commission ("SEC"), which may be obtained for free at the SEC's website at www.sec.gov [2]. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. We do not undertake any obligation to update, amend or clarify these statements or the "Risk Factors" contained in our most recent reports filed with the SEC, whether as a result of new information, future events or otherwise, except as may be required under the applicable securities laws.

Media Contact: Mike Drummond Masimo Corporation Phone: (949) 297-7434 Email: mdrummond@masimo.com [3] Masimo, SET, Signal Extraction Technology, Improving Patient Outcome and Reducing Cost of Care... by Taking Noninvasive Monitoring to New Sites and Applications, rainbow, SpHb, SpOC, SpCO, SpMet, PVI, rainbow Acoustic Monitoring, RRa, Radical-7, Rad-87, Rad-57,Rad-8, Rad-5,Pulse CO-Oximetry, Pulse CO-Oximeter, Adaptive Threshold Alarm, and SEDLine are trademarks or registered trademarks of Masimo Corporation. The use of the trademarks Patient SafetyNet and PSN are under license from University HealthSystem Consortium.

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