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New Clinical Study Finds Masimo Noninvasive SpMet is Accurate Compared to Invasive Methemoglobin Testing

Study Published in Anesthesia & Analgesia Indicates SpMet Offers Advantages Including Immediate Detection and Less Time and Effort Than Traditional Methods

Irvine, California – September 21, 2010 – [Masimo](#) (NASDAQ: MASI) announced today that a new clinical study published in *Anesthesia & Analgesia* demonstrates that Masimo noninvasive and continuous methemoglobin (SpMet®) measurements provide a high degree of agreement in measurements with corresponding laboratory values of methemoglobin obtained by invasive methemoglobin testing. In addition, the authors concluded that SpMet could facilitate early diagnosis and treatment of methemoglobinemia during high-risk procedures.¹

Methemoglobin (metHb) is an oxidized form of hemoglobin that is incapable of oxygen transport. Methemoglobinemia is defined as higher than normal methemoglobin levels and can be induced by common topical anesthetics (e.g. Benzocaine, Cetacaine, Prilocaine, Lidocaine) and over 30 other therapeutic drugs prevalent in both the hospital and outpatient settings. If undetected and untreated, methemoglobinemia can result in significant reduction in oxygen delivery to the tissues resulting in vital organ damage.² Prevention of vital organ injury requires prompt detection and treatment as significant organ injury can occur in as little as five minutes. However, traditional methods of detection rely on physical signs and symptoms, which may be non-specific and subtle or invasive laboratory blood tests that can take a long time. Masimo SpMet provides an accurate, quick, and easy-to-use way to noninvasively and continuously measure methemoglobin levels in the blood, which helps clinicians assess methemoglobinemia to determine treatment and additional test options.

In the current study, researchers from the University Clinic of Schleswig-Holstein in Luebeck, Germany, compared the accuracy of SpMet from the Masimo Radical-7 Pulse CO-Oximeter with invasive arterial blood gas measurements in 40 patients receiving prilocaine as a regional anesthetic for orthopedic surgery. A total of 20 patients received an interscalene brachial plexus block with 300 mg prilocaine while the other 20 patients received a combined femoral-sciatic nerve block with two 300 mg injections of prilocaine (600mg total). Continuous monitoring of SpMet and SpO₂ was initiated before the onset of regional anesthesia and blood gas analysis of methemoglobin and oxygen saturation (SaO₂) was performed at the first injection of prilocaine and at 15, 30, 60, 120, 180, 240, 300, and 360 minutes. Study results showed a "high degree of agreement in measurement" between noninvasive and continuous SpMet and SpO₂ and corresponding laboratory values of methemoglobin and SaO₂ with a bias of 0.27% and 95% confidence limits of +1.33%—leading researchers to conclude that Masimo SpMet "may facilitate early diagnosis and treatment, when necessary, of dyshemoglobinemia."

According to Steven J Barker, PhD, MD, Professor and Head of the Department of Anesthesiology at University of Arizona and Masimo Board Member, "I've seen the lifesaving benefits of Masimo SpMet monitoring first-hand when a surgical patient developed potentially fatal methemoglobin levels from local anesthetic toxicity. Traditional laboratory blood testing did not provide results quickly enough to diagnose and treat this critically-ill patient. Thankfully, SpMet provided immediate detection of her methemoglobinemia and successfully guided our treatment."

SpMet is available as part of the Masimo rainbow® SET platform—the first-and-only technology to noninvasively and continuously measure total hemoglobin (SpHb®), oxygen content (SpOC™),



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carboxyhemoglobin (SpCO[®]), methemoglobin (SpMet[®]), Pleth Variability Index (PVI[®]), and acoustic respiration rate (RRa[™]), in addition to the 'gold-standard' Measure-Through Motion and Low Perfusion performance of Masimo SET[®] oxyhemoglobin (SpO2), perfusion index (PI), and pulse rate (PR).

"Unrecognized methemoglobinemia is a patient safety problem in every hospital on the planet; however, most healthcare providers are not aware of the number of drugs that cause methemoglobinemia, which is not uncommon and often goes unrecognized," stated Michael O'Reilly, MD, EVP of Medical Affairs at Masimo "Over 30 drugs have been shown to induce severe methemoglobinemia, including commonly-used local anesthetics such as Lidocaine, Benzocaine, and Prilocaine; antibiotics like Trimethoprim, Sulphonamides, and Dapsone; and many other therapeutic drugs such as Metoclopramide, Chlorates, Nitrates and Bromates to name a few. The morbidity risks associated with methemoglobin, which significantly decreases oxygen delivery, is completely underappreciated and neonates and infants less than 6 months of age are particularly susceptible because of their immature metabolic pathways. Given its prevalence and susceptible populations, I believe that SpMet offers a critical opportunity to noninvasively and continuously monitor every patient for this very serious, unrecognized and potentially deadly problem."

¹Soeding, Peter, Deppe, Matthias, Gehring, Hartmut. "Pulse-Oximetric Measurement of Prilocaine-Induced Methemoglobinemia in Regional Anesthesia." *Anesthesia & Analgesia*. August 2010.

²Ash-Bernal R, Wise R, Wright SM. "Acquired Methemoglobinemia: A Retrospective Series of 138 Cases at 2 Teaching Hospitals." *Medicine* 2004; 83:265-272.

About Masimo

Masimo (NASDAQ: MASI) develops innovative 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[®] Pulse CO-Oximetry[™], allowing noninvasive and continuous monitoring of blood constituents that previously required invasive procedures, including total hemoglobin (SpHb[®]), oxygen content (SpOC[™]), carboxyhemoglobin (SpCO[®]), methemoglobin (SpMet[®]), and Pleth Variability Index (PVI[®]), in addition to SpO2, pulse rate, and perfusion index (PI). In 2009, Masimo introduced rainbow Acoustic Monitoring[™], the first-ever noninvasive and continuous monitoring of acoustic respiration rate (RRa[™]). Masimo's rainbow platform offers a breakthrough in patient safety by helping clinicians detect life-threatening conditions and helping guide treatment options. 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.

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 regarding the repeatability of clinical results, risks related to our belief that Masimo SpMet will facilitate early diagnosis and treatment of methemoglobinemia for all surgical patients receiving local anesthesia, 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. 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 forward-looking 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.

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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, and SEDLine are trademarks or registered trademarks of Masimo Corporation.

