The Root of Our Inspiration
Letter from the Chairman & CEO

Delivering on Our Mission and Guiding Principles

For this year’s annual report, we selected a cover image that perfectly symbolizes our core mission. The image shows someone who cares, holding a patient who needs to be cared for. This interaction is the root of our inspiration—the healing connection between patients and their caring caregivers. From the very beginning, we have sought to revolutionize noninvasive monitoring so that patients can be better assessed and cared for by those who care. From that vision, 24 years ago, came our mission—‘improving patient outcomes and reducing cost of care by taking noninvasive monitoring to new sites and applications’. Along with our mission, we established a strong and simple set of guiding principles that stay with us today:

- Remain faithful to your promises and responsibilities
- Thrive on fascination and accomplishment and not on greed and power
- Strive to make each year better than the year before both personally and for the team
- Make each day as fun as possible
- Do what is best for patient care

At that same time, and with a gifted group of engineers, we also set out on a bold course to innovate in ways that no one had done before. For solving the measure-through-motion and low perfusion pulse oximetry problem that had stumped the industry, we got great recognition from the scientific, clinical, and business communities. And for finding a way to measure carbon monoxide, methemoglobin, hemoglobin noninvasively, and acoustically measure respiration rate, we received more recognition and accolades. We have not stopped. We continue to launch more breakthrough noninvasive measurements, monitors, and systems, but we also always strive to give our customers and partners the most caring sales and service teams. In the process, we have grown double-digits since our first year of sales and, in 2012, we once again delivered record revenue despite a challenging global economy and rapidly evolving healthcare market.

Reinforcing Our Roots

Much has changed since I founded Masimo in my home in 1989. But after more than two decades of technical innovation, broad clinical impact, and solid growth, our roots remain the same. They have just gotten stronger and broader. From the outset, Masimo resolved to be different from any other company. We didn’t just set out to create breakthrough technologies; we also wanted to improve patient lives more significantly than any other company. And, by the way we conducted ourselves, we hoped to improve the way business is done. By standing and striving for truth, while relentlessly pursuing our mission and adhering to our guiding principles, we have continued to focus on solving ‘unsolvable’ problems, protecting patients, and innovating for the future. In the process, we have cultivated an enterprise in which approximately 3,000 talented people deliver on their promises in an environment where fascination, accomplishment, and fun can thrive.

Proving We Mean It

The pages of this annual report are full of innovations that are testaments to everything we originally set out to accomplish. It has been said that the true test of character is what you do when no one else is looking. While less noticeable than our innovations, there have been many other things that happened along Masimo’s journey that also stand as proud examples of the promises we made to ourselves 24 years ago.

When we discovered our Rad-9® product (acquired in 2002 from one of our OEMs) could visually but not audibly alarm if a sensor failed, we proactively issued a recall for the device to ensure the highest level of patient safety in the midst of our IPO roadshow in 2007. Months later, the FDA stated it didn’t require a recall as the behavior met industry standards. When no other pulse oximetry company put a speaker backup in their devices to ensure that patient alarms would be heard, even in the rarest cases of a speaker failing, we proactively issued a recall for the device to ensure the highest level of patient safety in the midst of our IPO roadshow in 2007. Months later, the FDA stated it didn’t require a recall as the behavior met industry standards.
When other companies refused to provide their pulse oximeters for use in home care because of the potential liabilities vis-à-vis high-risk patients and a litigious environment, we decided to make our products available because we knew they provided the best and sometimes only solution possible for patient care. When we won the antitrust lawsuit against one of our competitors, we kept fighting for a final ruling so our case could help other companies avoid what we experienced—instead of focusing on a possibly large settlement. And when the final rulings were in, rather than banking the legal proceeds, we used a significant portion of those funds to set up the Masimo Foundation for Ethics, Innovation, and Competition in Healthcare.

In our quest for solutions to the industry’s most vexing technical and clinical problems, we are constantly challenged, but we take courage, strength, and an uncompromising commitment to our core values—ethics, innovation, and fair play. It means standing up for our rights and our beliefs so that others may benefit from our stand, then that is what we do. And if it means challenging unfair Group Purchasing Organization practices with entrenched interests, so that medical products are evaluated on their individual clinical and cost merits, that is what we do.

**Seeding a Patient Safety Movement**

The Masimo Foundation has now extended its mission even further, founding the first annual Patient Safety, Science & Technology Summit, which was held in January 2013. The Summit was held in January 2013. The Summit was designed to confront large problems with actionable ideas and innovations that can transform the process of care and dramatically improve patient safety—one solution—one hospital—and one patient at a time, to help us meet the inaugural Summit’s goal of zero preventable patient deaths by 2020. The excitement generated at the January 2013 Summit has quickly become a “movement,” which is now focused on connecting people, connecting ideas, and connecting technologies so that patients don’t die from preventable causes.

The excitement generated at the January 2013 Summit has quickly become a “movement,” which is now focused on connecting people, connecting ideas, and connecting technologies so that patients don’t die from preventable causes. The inaugural Summit attracted former President Bill Clinton, 300 leading clinicians, technologists, patient advocates, and other healthcare stakeholders to focus on specific patient safety challenges that could eliminate needless deaths and injuries due to failure to rescue, medication errors, and transfusion overuse, as well as neonatal care advancements with congenital heart disease screening and optimal oxygen targeting. The inaugural Summit also, for the first time in history, brought 8 medical technology companies together with Masimo in pledging to make medical device data open and available to whomever needs it to improve patient safety. Cercor, CareFusion, GE Healthcare Systems, Smiths Medical, Sonosite, Surgicount, and ZOLL each publicly announced commitments to share the data for which their products are purchased, for the sake of patients. In addition to these companies, clinicians and hospitals have also made public commitments to take decisive action to improve patient safety and be held accountable on those commitments.

**Continuing Innovation**

Masimo’s innovation engine has fueled many industry firsts, which have significantly improved patient care and reduced costs. Masimo SET® overcame the technological limitations of conventional pulse oximetry, making it more accurate during the challenging conditions of patient motion and low perfusion. This invention has made pulse oximetry a clinically useful tool and, for the first time since pulse oximetry was introduced in the 1970s, it has been shown in clinical studies to improve patient outcomes. Masimo SET® has now been shown to help clinicians reduce retinopathy of prematurity, detect congenital heart disease in newborns, reduce medical errors in critical care, wean patients from the ventilator faster, and save lives and costs in the care of post-surgical patients on the general floor. Approximately 10 years after the introduction of Masimo SET®, our rainbow® technology platform has ushered in noninvasive and continuous measurements that previously required invasive procedures, allowing clinicians to make earlier and better decisions to care for patients in ways they never thought possible.

As one example, our noninvasive and continuous total hemoglobin (SpHb®) monitoring has been shown to help clinicians reduce the number of risky and costly blood transfusions in surgical patients, speed up blood transfusion for those who need it, and in multiple cases has demonstrated its lifesaving potential to help clinicians detect occult bleeding. Our rainbow® technology has also been shown to help clinicians assess fluid responsiveness, improve fluid management, identify changes in breathing, and assess carbon monoxide levels for faster therapy for those with CO poisoning. With growing clinical momentum, evidence and customer advocacy, more and more OEM partners are including rainbow® technology in their products, including the leading multiparameter monitoring companies throughout the world. The list now includes 3FATOM, Dräger, Edwards Life Sciences, Fukuda Denso, GE, ES Copulare, Hamilton Medical, Philips, Physio-Control, Saadat, Schiller Welch Alyn, ZOLL, and Zondar.

In 2012, we introduced SpO2, SpCO®, SpMet®, and SpHb®. The new SpfO2 measurement allows more precise arterial oxygen saturation assessment in patients with elevated dyshemoglobins—common throughout hospital and pre-hospital settings—as compared to functional oxygen saturation (SpO2). As a result, SpfO2 should enable earlier interventions and more timely therapeutic decisions.

In 2013, we also revolutionized the Radical-7® by making it rainbow® and clinician-centric with touchscreen and embedded Wi-Fi technology. While we are proud of our past technological accomplishments, we intend to continue to introduce new, innovative products. In 2013, we intend to re-write the rules for monitoring and connectivity with the launch of Root™.

Rainbow® technology offers a patient-centric view of patient data and an unprecedented ability to identify the true clinical picture. We have focused on bringing to market an innovative line of rainbow® products that provide superior performance and reliable monitoring via third-party development and connectivity with the launch of Root™. Root is a powerful new patient monitoring and connectivity platform that integrates all of Masimo’s rainbow® products, allowing clinicians to make better decisions about patient care. Root is designed to be an ignition switch for innovation in patient monitoring, enabling third-party development of new measurements. With a dock for the Radical-7® instantaneously interpretable
display, and networking connectivity gateway. Root integrates multiple streams of data and simplifies patient care workflows, empowering caregivers to make quicker patient assessments, earlier interventions, and better clinical decisions throughout the continuum of care.

Improving Care and Lowering Cost

Hospitals around the world continue to see significant advantages provided by SET® Measure-through Motion and Low Perfusion™ pulse oximetry. We shipped 146,400 instruments and boards in 2012, increasing our estimated worldwide installed base of SET® and rainbow® instruments to 1,088,000. We estimate that over 100 million people around the world each year are better cared for with our breakthrough, life-saving, and life-improving technologies. We believe we will see increased growth in our installed base as more clinicians choose the rainbow® platform. The improvements in the process of care have resulted in real cost savings to hospitals using Masimo technologies. In total, we estimate that US hospitals alone could save over $5 billion when their clinicians use Masimo technologies to their fullest potential.

Expanding to New Markets

Masimo SET® has allowed pulse oximetry to succeed in markets where conventional pulse oximetry had failed—including home and long-term acute care facilities. Our rainbow® measurements have also allowed us to increase our impact beyond the hospital, from helping emergency personnel detect carbon monoxide poisoning at the scene of a fire to enabling noninvasive hemoglobin spot-check testing in the physician’s office. And as more caregivers gain access to our products, we know that more lives will be improved and saved. This year, we also entered the animal health market, offering a variety of differentiated solutions to domestic and large animal veterinarians, with the same appreciative feedback that we received when we introduced our solutions to the “people care” community. We also launched our first ever-monitoring device for the promising consumer health and wellness market—iSpO2®. We expect both these new markets to grow in 2013 and beyond.

Expanding Our Technology Base

In 2012, we made two important strategic acquisitions. Spirex Semiconductor (now Masimo Semiconductor) makes advanced light emitting diode (LED) and other component-level technologies—both for Masimo’s own noninvasive sensors, as well as for other applications in the biomedical, telecommunications, and consumer products markets. We are very excited about the potential for harnessing and advancing Masimo Semiconductor’s myriad optoelectronic technologies as part of Masimo’s product, technology, and market expansion strategy. Our second 2012 acquisition, Phasein, was an innovative developer and marketer of ultra-compact mainstream and sidestream capnography, multigas analyzers, and handheld capnometry solutions. The acquisition of Phasein’s multigas technology complements Masimo’s breakthrough innovations for patient monitoring with a portfolio of products ranging from OEM solutions for external “plug-in-and-measure” gas analyzers and integrated modules to handheld capnometers. With multiple measurements delivered through either mainstream or sidestream options, Masimo customers can now benefit from end tidal CO2, N2O, O2, and anesthetic agent monitoring in a variety of care areas, including operating rooms, procedural sedation, and intensive care units.

Looking to the Future, Inspired by Our Roots

From the launch of SET® in 1996 to the launch of rainbow® technology in 2005 to our 2013 IPO—one of the most successful healthcare IPOs of the year—we have always pushed ourselves to perform better while remaining committed to the root of our inspiration—the healing interaction between caring caregivers and their patients. Today, we renew our pledge made in 1989—to impact patient lives in a way that no company has done before and to continue to improve the way business is practiced in our industry.

Joe Kiani
Chairman & CEO
Root™: At the Root of Transforming Care

From the company’s inception, the root of our inspiration has been unwavering—patients, their families, and their caregivers.

This inspiration is evident every time we have set out to solve a previously “unsolvable” problem; in every new measurement we have created; and in every new software, hardware, or systems innovation we have developed. We have done all of these things for one overriding reason—to enable clinicians to get to the root of better care for their patients. In honor of this ongoing quest, we are proud to introduce the newest addition to Masimo’s product portfolio—Root™.


Root is a powerful new patient monitoring and connectivity platform that integrates our breakthrough rainbow® and SET® measurements with multiple additional parameters—including SedLine® brain function monitoring and Phasein™ capnography and gas monitoring*—in an integrated, clinician-centric platform.

Root includes a dock for the Radical-7 handheld monitor, an instantly interpretable display, and multiple networking/connectivity options. Root integrates multiple streams of data and simplifies patient care workflows, empowering caregivers to help make quicker patient assessments, earlier interventions, and better clinical decisions throughout the continuum of care.

* Root is CE Marked.

“Root integrates rainbow® measurements so at any moment I can see what I want to see and how I want to see it—a great advantage to the anesthesiologist in a data-rich operating room. Root makes it easy to use SpHb and PVI together to optimize transfusions and fluid management.”

Dr. Keith Ruskin
Professor of Anesthesiology at Yale-New Haven Hospital in New Haven, CT
Instantly Interpretable, High-visibility Display

With the Radical-7 handheld in its dock, Root enables instant interpretation of Masimo’s breakthrough noninvasive measurements. The brilliant, high-resolution, adaptive display is designed to aid clinicians rapid assessment of patient status in three distinct ways:

> “Trend” view in which each measurement value is displayed alongside its graphical trend
> “Analog” view for quick assessment through gauges showing measurement values in relation to alarm ranges
> When docked with Root, the Radical-7’s screen can transform into an alarm status visualizer, with a three-dimensional anatomical image that associates device measurements with alarm status.

Intuitive Touchscreen Navigation for Easy and Adaptable Use in Any Hospital Environment

With a simple tap, swipe, or drag-and-drop, screen views and parameter sizing can be customized to suit any hospital environment, workflow, clinician preference, or patient-specific need. This allows Root to be adaptively used across a wide variety of care areas with disparate clinical and operational requirements—from the operating room to the intensive care unit to the general floor.

The Root of Root™

The alarm visualizer associates device measurements with alarm status and is color coded to indicate no alarms (green), approaching alarm (yellow), and alarm state (red). (Color emphasis added).
Flexible Measurement Expansion in Root with Masimo Open Connect

With Root, Masimo is providing an open invitation to other companies, from small to large, to develop and commercialize their innovations and deliver them via the Root platform.

Expanding Masimo Measurements

Root offers expanded measurement capability through software upgrades and Masimo Open Connect (MOC-9™) modules. SedLine® brain function monitoring is the first measurement to utilize MOC-9, offering the exclusive ability to measure 4 simultaneous EEG channels to help clinicians assess the hypnotic state or depth of sedation. Additional MOC-9 measurements are planned with Phasein sidestream and mainstream capnography and gas analyzers. And that is just the start. We anticipate a whole new ecosystem of third-party measurements to grow from Root—expanding its capability into new areas of patient monitoring.

Designed to Stimulate Third-party Innovation

MOC-9 is designed to enable third-party development of additional measurements. Market barriers and development costs often keep small, innovative companies from delivering products to the clinicians and patients who need them most. With Root, Masimo is providing an open invitation to other companies, from small to large, to develop and commercialize their innovations and deliver them to market via the Root platform.
Root® with Brain Function Monitoring

Featuring 4 simultaneous channels of high-quality EEG data, SedLine® provides continuous information about both sides of the brain and provides information about a patient’s response to anesthesia.

The Root of Better Data

Patients respond differently to anesthetics, which can mean over- or under-administration during surgery and conscious sedation procedures. Sedline technology measures brain function on a continuous basis and provides information about a patient’s response to anesthesia. SedLine enables monitoring of both sides of the brain simultaneously. The Density Spectral Array (DSA™) provides immediate detection of asymmetrical activity.

Facilitating Individualized Titration

SedLine enables individualized titration of sedation and faster emergence, while offering reliable monitoring during challenging conditions such as electrocautery. Use of Sedline and its Patient State Index (PSI™) has been shown to help clinicians manage patients to significantly faster emergence from anesthesia and recovery.1

“SedLine gives me a better idea of where I stand at each phase of anesthesia. The PSI number helps guide me to make subtle changes in my anesthetic appropriate for the patient’s heart rate and blood pressure, and thus arrive at the end where I want to be.”

David Drover, MD
Stanford University Hospital
Stanford, CA

1 Drover DR et al. Anesthesiology. 2002;97(2):82-89.

Root with SedLine Brain Function Monitoring is CE Marked.
Capnography and Gas Monitoring Adds Even More to the Patient Safety Equation

Changes in expired respiratory gas can be an early indicator of an adverse respiratory event. Hypoventilation, hyperventilation, airway obstruction, and other potentially life-threatening conditions can be rapidly detected with capnography—enabling clinicians to intervene as early as possible. Capnography and gas monitoring also provide insight into the effectiveness of the anesthesia breathing circuit, aiding clinicians in maintaining proper gas concentrations and ventilation levels.

Our new Phasein™ capnography and gas monitoring solutions complement our breakthrough noninvasive portfolio with innovative, multispectral technologies for measuring respiratory gases. The solutions range from integrated OEM solutions to external “plug-in and measure” gas analyzers to handheld devices. With multiple measurements delivered through either mainstream or sidestream options, Masimo customers can now benefit from end-tidal CO₂, FiCO₂, RR, N₂O, O₂, and anesthetic agent monitoring in a range of hospital environments—from the operating room to intensive care to the general floor.

IRMA™—A Complete Monitor in a Probe

Designed with the latest advancements in miniaturized components and microprocessor technology, the IRMA mainstream analyzer weighs less than 1 ounce and fits in the palm of your hand. This versatile, complete mainstream capnography and gas monitoring system can be utilized with adult, pediatric, or infant patients.

ISA™—Ultimate Performance in a Sidestream Analyzer

Enabled by state-of-the-art Phasein spectrometer technology that utilizes nine different wavelengths of light and powerful signal processing algorithms, ISA provides the clinician with precise capnography and gas measurements with crisp waveforms that help depict the clinical situation for adults and neonates, from the operating room to the general floor. ISA sidestream analyzers are available as standalone or easy-to-integrate OEM modules.

Nomoline™—No Moisture Sampling Line

Nomoline fluid protection technology eliminates common problems associated with conventional sidestream gas analysis. Incorporating a special polymer and a hydrophobic bacterial filter, the Nomoline allows water in the sampling line to evaporate into the surrounding air, while leaving oxygen, carbon dioxide, and anesthetic gases unaffected. Specially designed for low-flow applications and functional in any orientation, Nomoline technology can be used in any clinical application for all types of patients from neonates to adults. Nomoline is designed to extend the product life in single-use applications, such as high humidity environments. Nomoline’s innovative design also allows multi-patient use as a reusable solution.
Integrating Measurements to Enable Meaningful Use of Health Information Technology

Today’s challenging hospital environment subjects clinicians to increasing mountains of information with expanding documentation requirements. Masimo’s innovation simplifies and automates this process, streamlining workflow and improving patient safety by empowering clinicians to focus on patients rather than technology.

Keeping Clinicians and Patients Connected

New standards for hospitals require meaningful use of the electronic health record (EHR) by charting changes in vital signs as well as documentation of interventions. Masimo enables automatic recording and transmission of key data into the EHR so clinicians spend their time caring for patients, not recording data. Masimo’s pulse oximeters also feature a built-in wireless radio for communication through a hospital’s wireless network—with seamless integration to the EHR. Patient SafetyNet™ incorporates the Masimo Adaptive Connectivity Engine™ (ACE), which enables two-way, HL7-based connectivity to the EHR. ACE significantly reduces the time and complexity to integrate and validate custom HL7 implementations, and demonstrates Masimo’s commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture.

Iris™ Integration Platform

Despite huge advances in medical technology, the lack of device communication and integration creates risks to patient safety in hospitals around the world. Existing approaches for device interoperability require separate hardware, software, and/or network infrastructure, which can clutter the patient room, burden IT management, and increase the complexity and cost of care.

Root with Iris offers a built-in connectivity gateway that can integrate multiple standalone devices such as IV pumps, ventilators, beds, and other patient monitors. Iris allows device information to be remotely viewed with Patient SafetyNet™, transmitted through notification systems or to electronic health record (EHR) systems to facilitate better patient care and meaningful use, and eventually displayed on Root at the point of care to facilitate decision support.

Third-party Device

Wireless 802.11 or Wired Connection

Patient SafetyNet Appliance

Notifications

Device Icons

Connectivity to Electronic Health Record & Central Monitoring Stations

Through Iris™, Root is designed to provide built-in integration to multiple standalone devices. Examples include:

- IV pumps
- Ventilators
- Beds
- Other patient monitors

*The use of the trademarks PATIENT SAFETYNET and PSN is under license from University Health System Consortium.
A Radical Departure from Traditional Monitoring

Breakthrough flexibility to meet clinician and patient needs.

The Radical-7 leverages Masimo’s breakthrough noninvasive measurements with a radical departure from traditional monitoring for breakthrough functionality designed to automate the process of care and enable clinicians to instantly adapt to changing monitoring needs in individual patients and care areas.

- Breakthrough measurements
- Instantly adaptable functionality
- Intuitive touchscreen operation
- Easy customization
- Flexible clinical applications
- Integrated wireless connectivity

The intuitive touchscreen operation allows for exceptionally easy operation to change displayed parameters, waveforms, or trends on the fly never losing track of vital signs. In addition, easy customization allows clinicians quick access to alarms and system settings enabling instant changes in alarm settings with a simple gesture.

Over 100 Different Sensor and Cable Combinations for Either Single- or Multi-patient Use

Masimo rainbow® sensors measure SpO2, PR, PI, PVI, RRp*, SpfO2*, SpHb, SpOC, SpMet, SpCO.

Masimo SET® sensors measure SpO2, PR, PI, PVI, RRp.

Instantly Adaptable Functionality

Three-in-one capability allows the Radical-7 to be used as:

- Standalone device for bedside monitoring
- Multiparameter monitoring interface via SatShare®, allowing hospitals to seamlessly implement rainbow® measurement capabilities
- Detachable, battery-operated, wireless handheld or wearable device to facilitate uninterrupted monitoring during transport and ambulation

The Radical-7 handheld monitor docks comfortably in Root providing an instantly interpretable display and multiple networking/connectivity options.

* RRp and SpfO2 are CE Marked
“Deciding to transfuse based on a single static measurement more often results in patients receiving unnecessary transfusions with increased risks, costs, and the depletion of an already scarce blood supply. New medical technologies and devices that continuously monitor hemoglobin, oxygen, and perfusion will become essential for transfusions.”

Dr. Aryeh Shander
Chief, Department of Anesthesiology, Pain Management and Hyperbaric Medicine, Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, New York

Supporting Clinicians in Reducing Blood Transfusions with SpHb®

With the rainbow® measurement platform including noninvasive total hemoglobin (SpHb), Masimo technologies aid some of the most common, costly, and critical decisions made in healthcare.

Risks and Costs of Red Blood Cell Transfusions

Red blood cell (RBC) transfusion is one of the most frequent procedures performed in US hospitals, with one in ten inpatients receiving one or more blood units. While blood loss during surgery is a known risk factor, RBC transfusion overuse can increase patient risk and cost of care. Meta-analysis of pooled results from multiple observational studies, each of which adjusts for risks between patients, shows that patients receiving RBC transfusions have an 88% higher mortality, 69% higher infection rate, and 250% higher rate of acute respiratory distress syndrome (ARDS). Multiple randomized controlled trials indicate that restrictive transfusion practices—those in which significantly lower hemoglobin triggers are used to determine need for transfusion—are safe. In addition, the cost of each RBC unit is estimated between $522 and $1,183 per unit, without including morbidity-associated costs. Beyond the cost of transfusion, each RBC unit transfused is associated with increased cost of care and transfusions that occur at higher hemoglobin levels increase the cost of care more than those given at lower hemoglobin levels.

With the growing recognition of the need to reduce transfusions, noninvasive and continuous hemoglobin (SpHb) can be a key tool to help overcome the limitations of existing approaches.

Risk-adjusted analysis of multiple observational studies has shown that RBC transfusions are associated with 88% higher mortality, 69% higher infection rate, and 250% higher rate of ARDS.

How SpHb Monitoring Helps with Transfusion Decisions

Masimo’s solution provides hemoglobin both noninvasively and continuously. The noninvasive aspect makes the technology easy to apply to the patient, and the continuous aspect assists in better decision making. While SpHb monitoring is not intended to replace blood draws, it identifies significant changes in hemoglobin and lack of significant changes in hemoglobin between invasive blood sampling and laboratory analysis. Continuous hemoglobin means clinicians can determine the directional trend of hemoglobin—whether it is stable, rising, or falling. This can help avoid unnecessary transfusions when the SpHb trend is stable and the clinician may otherwise perceive hemoglobin is dropping, or when the SpHb trend is rising and the clinician may otherwise perceive it is not rising fast enough. Inside and outside the operating room, a dropping SpHb trend may also allow clinicians to identify internal bleeding and permit earlier interventions.

The Growing Recognition of the Need to Reduce Transfusions

Many transfusions are unnecessary. A systematic, expert review of 494 studies for positive impact on health outcome showed that 59% of RBC transfusions are “inappropriate.” Given the risks and costs of RBC transfusions, there is a growing recognition of the need to implement strategies to reduce RBC transfusions. The Joint Commission has introduced Patient Blood Management Measures that encourage hospitals to evaluate appropriateness of transfusions as a continuous quality indicator. The American Medical Association and The Joint Commission also recently identified RBC transfusions as one of the top five overused procedures in medicine, defining overuse as “circumstances where the likelihood of benefit is negligible or zero, and the patient is exposed to the risk of harm.”

Limitations with Existing Approaches to Assess Transfusion Need

Hemoglobin levels are used as a primary indicator for RBC transfusion, but laboratory measurements are only available intermittently and results can be delayed in the period between blood draw and laboratory analysis. This time gap of information can lead to suboptimal transfusion decisions. The most universally available information about whether a transfusion is needed during surgery is estimated blood loss, which is often overstated. Visible blood and fluid loss appears to tell one how much blood has been lost, but in a recent study at Duke University, anesthesiologists estimated blood loss at 40% more than it actually was. The implication is that the need for transfusion may appear to exist, when in fact it does not.

The Overuse of RBC Transfusions

Inappropriate          Uncertain          Appropriate

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<th>Inappropriate</th>
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<td>59%</td>
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494 studies were evaluated by an expert panel in a systematic method to assess appropriateness of RBC transfusion, revealing a significant opportunity to reduce unnecessary transfusions.

494 studies were evaluated by an expert panel in a systematic method to assess appropriateness of RBC transfusion, revealing a significant opportunity to reduce unnecessary transfusions.
Reducing Blood Transfusions and Costs

Clinical Evidence that SpHb Monitoring Helps Reduce Transfusions

There are now two studies showing that SpHb monitoring helps clinicians reduce RBC transfusions.

SpHb monitoring has been shown in a randomized controlled trial in lower blood loss surgery (orthopedic surgery) to reduce the frequency of intraoperative blood transfusions by 87% (from 4.5% to 0.6%) and the average number of RBC units transfused by 90% (from 0.1 to 0.01 units per patient).1

SpHb monitoring has also been shown in a prospective cohort study in higher blood loss surgery (neurosurgery) to reduce the percent of patients receiving three or more RBC units from 73% to 32% and reduce the average number of RBC units transfused by 47% (from 1.9 to 1.0 units per patient).2 In this study, the researchers also showed that patients who needed RBC units received them sooner by 41 minutes on average.

Projected Cost Savings from SpHb Monitoring to Reduce Transfusions

To project the potential savings from SpHb monitoring, the range of published cost estimates for RBC transfusions ($522 to $1,183) can be multiplied by the expected reduction in RBC transfusions per patient.1 In lower blood loss surgery, the 0.09 lower RBC units per patient with SpHb monitoring is projected to reduce RBC costs by $47 to $106 per patient monitored. In higher blood loss surgery, the 0.90 lower RBC units per patient with SpHb monitoring is projected to reduce RBC costs by $470 to $1,065 per patient monitored.1 These estimates do not take into account the expense of SpHb monitors or sensors, or the other costs associated with over transfusion or delayed care.
Noninvasive and Continuous Hemoglobin Monitoring to Detect Bleeding

By measuring hemoglobin continuously, clinicians can become aware of real-time drops in hemoglobin that are indicative of bleeding. Identification of low or falling hemoglobin levels allows interventions that may prevent preventable death and disability.

Risk and Cost of Undetected Bleeding

In addition to assisting with transfusion management, continuous SpHb can also help clinicians inside and outside the operating room monitor and detect internal bleeding. Bleeding affects up to 35% of patients in surgery, intensive care, and obstetric care areas. Bleeding is considered a significant risk factor for patients, and late detection further increases risk and cost. Surveys show that the majority of US hospitals have multiple patients per year with serious injury or death due to late detection of bleeding.

Post-partum Hemorrhage

Every 90 seconds around the world, a woman dies from complications related to pregnancy or childbirth. For every woman who dies, 30 more suffer injuries or disabilities. Bleeding in obstetric patients, known as post-partum hemorrhage, affects 3% of mothers giving birth in the US. Worldwide, it is the #1 cause of maternal mortality. The Joint Commission has issued a sentinel event alert on post-partum hemorrhage, calling on hospitals to develop specific protocols to systematically detect bleeding to allow earlier intervention. Unfortunately, previous efforts have failed to make significant progress.

Limitations of Current Approaches to Detect Bleeding

A significant number of injuries or deaths due to bleeding are preventable. Prevention requires identifying that a patient has experienced significant bleeding and then intervening to stop the bleeding and improve the patient’s condition. Identifying bleeding is challenging because even during surgery and childbirth, clinical estimation of blood loss is inaccurate and changes in standard vital signs can occur long after the bleeding has begun. Low hemoglobin identifies bleeding over 90% of the time, but is only assessed intermittently and requires a blood draw and laboratory analysis. In some parts of the world, laboratory testing is simply not available.

“Masimo SpHb helped prevent a potentially life-threatening event. I am now using it for all my major craniofacial procedures and can’t see doing a surgery without it.”

Jeffrey Fearon, MD
Physician for 8-year-old girl who had just completed craniofacial surgery in which SpHb signaled undetected bleeding through a dramatic drop in hemoglobin over a 5-minute period.

“In cases of severe hemorrhaging during and after childbirth, SpHb has enabled us to immediately identify and continuously assess blood loss severity to better manage internal bleeding, prevent overloading of fluid, and decrease maternal death.”

Madhava Karunarathna, MD
OB/GYN, Balangoda Hospital, Sri Lanka

While hemoglobin is one of the most common laboratory tests performed, most clinicians are unaware of variation that should be expected when comparing hemoglobin measurements—both within and between various device models. This is because clinicians do not typically measure hemoglobin more than once in the same patient at the same time. Variation is induced by physiology, blood sampling technique, device methodology, and individual device calibration.1

The results of an independent study conducted in a surgical intensive care unit illustrate the variation that can be expected between hemoglobin device methods. A total of 471 hemoglobin measurements were evaluated from 62 patients. Noninvasive and continuous hemoglobin (SpHb), a satellite laboratory CO-Oximeter (Siemens RapidPoint 405), and a point-of-care device (HemoCue 301) were all compared to reference hemoglobin from the central laboratory hematology analyzer (Sysmex XT2000i).

In this study, the absolute accuracy and trending accuracy of SpHb was similar to the two widely used invasive methods when all three methods were compared to the central laboratory hemoglobin analyzer, both in single measurement comparisons as well as trended measurement comparisons. Only SpHb provides hemoglobin noninvasively and continuously—ideal for indicating real-time visibility to hemoglobin changes, or lack of changes, in between invasive blood sampling and laboratory analysis.

### Accuracy of Noninvasive and Continuous Hemoglobin Monitoring Compared to Common Invasive Methodologies

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<th>Device</th>
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<th>Reference Value</th>
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<tbody>
<tr>
<td>SpHb</td>
<td>0.3 ± 1.3 g/dL</td>
<td>1.0 g/dL (ARMS)</td>
</tr>
<tr>
<td>CD-Oximeter</td>
<td>0.9 ± 0.6 g/dL</td>
<td>1.1 g/dL (ARMS)</td>
</tr>
<tr>
<td>HemoCue</td>
<td>0.0 ± 1.0 g/dL</td>
<td>1.3 g/dL (ARMS)</td>
</tr>
</tbody>
</table>

#### Single Hemoglobin Measurement Comparison Between Three Devices and the Central Laboratory Hematology Analyzer

<table>
<thead>
<tr>
<th>Device</th>
<th>Difference in Consecutive Hemoglobin Values (tHb) (g/dL)</th>
<th>R²</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpHb</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>CD-Oximeter</td>
<td>0.60</td>
<td></td>
</tr>
<tr>
<td>HemoCue</td>
<td>0.39</td>
<td></td>
</tr>
</tbody>
</table>

#### Trended Hemoglobin Measurement Comparison Between Three Devices and the Central Laboratory Hematology Analyzer

| Device          | Difference in Consecutive Hemoglobin Values (HbABG) (g/dL) R² |
|-----------------|-------------------------------------------------------------|---|
| SpHb            | 0.64                                                        |
| CD-Oximeter     | 0.60                                                        |
| HemoCue         | 0.39                                                        |

The Radic®7 enabled with rainbow® technology allows noninvasive and continuous monitoring of blood constituents.
Quick and Painless Hemoglobin Assessment

The Pronto-7® is designed specifically for noninvasive total hemoglobin (SpHb) spot-check testing, along with SpO2, pulse rate, and perfusion index.

A Revolutionary Device for a Variety of Clinical Settings

Hemoglobin is one of the most commonly ordered tests in both hospital and non-hospital settings because it is critical to assessing anemia. However, traditional lab testing involves delayed results.

The Pronto-7 represents a breakthrough solution for measuring hemoglobin quickly in under a minute—without needles, time-consuming laboratory analysis, or the risk of blood contamination or hazardous medical waste.

The palm-sized Pronto-7—approximately 5” x 3” x 1” and weighing just 11 ounces—puts the power of noninvasive hemoglobin spot-check testing into any clinician’s hands in almost any environment, including hospitals, clinics, blood donation centers,” and emergency medical services.

Operation is easy and intuitive with the Pronto-7’s touchscreen interface. Embedded 802.11 b/g and Bluetooth capability enable wireless printing or emailing of test results, as well as transmission to EHR systems. In addition, new tests can be downloaded directly to the device via WiFi.

The newest features are designed to improve calibration and motion support for measuring SpO2 and SpHb. New parameters include hematocrit (SpHct) and Pleth Variability Index (PVI). In addition, the new Active Pulse Sensor™ generates a pulsatile signal for more robust measurements—especially in patients with low perfusion.

* Use in blood donation settings is CE Marked. ** Pronto-7 with Active Pulse and other features are under development.
Fluid administration is one of the most common hospital interventions. Although it is critical to improving patient status and enabling end organ preservation, unnecessary fluid administration is associated with increased morbidity and mortality.1

Assessing Fluid Responsiveness
Masimo continuous and noninvasive Pleth Variability Index (PVI) has been shown in multiple studies to help clinicians assess fluid responsiveness in adult and pediatric surgical and intensive care patients under mechanical ventilation.2-7 PVI has also been shown to help assess which patients will become hemodynamically unstable with the addition of Positive End Expiratory Pressure (PEEP), which may allow clinicians to more carefully select ventilator settings and monitor effects more closely.7

Aiding Clinician Assessment of Fluid Responsiveness and Fluid Management with PVI
Fluid administration is one of the most common hospital interventions. Although it is critical to improving patient status and enabling end organ preservation, unnecessary fluid administration is associated with increased morbidity and mortality.1

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“With Masimo PVI, I can predict when my patients will benefit from fluid administration—and when it might harm them.”
Maxime Cannesson, MD
University of California, Irvine, CA

Aiding Clinicians in Reducing Patient Risk
A recent randomized controlled trial showed that compared to standard care without PVI, clinicians using PVI PEEP were able to improve fluid management and as a result, reduce patient risk—as evidenced by lower lactate levels.2 By helping clinicians maintain appropriate fluid and oxygen levels in the blood, important organs may be protected.

Inclusion in Fluid Management Guidelines
The positive and expanding evidence for PVI has led to its inclusion in guidelines and best practices for fluid management. In 2012, the United Kingdom’s National Health Service (NHS) included PVI in its Intra Operative Fluid Management Pack, which serves as a guide for hospitals implementing fluid responsiveness monitoring to improve patient outcomes.8 In 2013, the French Society for Anaesthesia and Intensive Care (SFAR) added PVI to its guidelines for optimal hemodynamic management of surgical patients.9

The other dynamic monitoring technologies that have been shown to help clinicians assess fluid responsiveness and improve fluid management are invasive, complex, and/or costly. In contrast, PVI is noninvasive, easy to use, and has no incremental procedural cost because pulse oximetry monitoring is already performed on all surgical and intensive care patients. PVI monitoring should be considered in all mechanically ventilated patients in which an invasive arterial line or more complex or costly monitoring technologies may not be justified.
Twenty-four years ago, two young engineers asked themselves why pulse oximetry wouldn’t work during patient motion and low perfusion—and by doing so, set a new course that created a revolution in patient monitoring.

Overcoming the Limitations of Conventional Pulse Oximetry

Since its inception, pulse oximetry was plagued by unreliability when it was needed most—during patient motion and low perfusion. The industry had given up and considered the problem “unsolvable.” Clinicians were forced to live with the results—excessive false alarms, delayed notification due to long averaging times, inaccurate data, and an inability to obtain data on the most critical patients.

Conventional pulse oximetry works under the assumption that by looking at only the pulse and normalizing the pulsating signal over the non-pulsating signal, oxygen saturation (SpO2) can be measured without calibration. Although this was a big step forward in the evolution of pulse oximetry, it has one major flaw—it assumes the only pulsating component is arterial blood. Unfortunately for conventional pulse oximetry, venous blood moves every time the patient moves or breathes. This causes conventional pulse oximeters to display false low or high SpO2 and pulse rates—resulting in false alarms as high as 90% in ICUs and recovery rooms.

Validated by Independent and Objective Research

To date, more than 100 independent and objective studies have shown that Masimo SET® outperforms all other pulse oximetry technologies, providing clinicians with unmatched sensitivity and specificity to make critical patient care decisions.
When Joe Kiani and Mohamed Diab looked at the same pulse oximetry signal differently than anyone had before, they created new possibilities. By employing advanced signal processing techniques—including parallel engines and adaptive filters—they believed they could find the true arterial signal that would allow accurate monitoring of arterial oxygen saturation and pulse rate, even during the most challenging conditions. Signal Extraction Technology, or Masimo SET®, assumes that both the arterial and venous blood can move and uses parallel signal processing engines—DST®, FST®, SST™, and MST™—to separate the arterial signal from sources of noise (including the venous signal) to measure SpO2 and pulse rate accurately, even during motion.

After six years of dedicated and focused research and development, Masimo SET® debuted in 1995 at the Society for Technology in Anesthesia and won the prestigious Excellence in Technology Innovation Award. Thereafter, skeptical clinicians around the world sought actively to compare Masimo SET® to the best pulse oximetry technologies other companies had to offer. But in study after study, the breakthrough signal processing of Masimo SET® consistently resulted in significantly fewer false alarms and improved true alarm detection.

With Masimo SET®, clinical studies have shown false alarms can be reduced by over 95%, while true alarm detection was shown to be over 97%—even during the challenging conditions of motion and low perfusion.1

“Conventional pulse oximeters are a fair-weather friend. Masimo SET® is a foul-weather friend.”

Jeremy Swan, MD
Former Chairman of Masimo's Scientific Advisory Board and Chairman Emeritus Cedars-Sinai Medical Center's Division of Cardiology

**Unleashing Breakthrough Performance**

**True Alarm Performance During Motion and Low Perfusion**

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nellcor N-600</td>
<td>43%</td>
<td>3%</td>
</tr>
<tr>
<td>Masimo SET®</td>
<td>97%</td>
<td>95%</td>
</tr>
</tbody>
</table>

*In this hospital-based study, investigators measured SpO2 in 10 subjects during motion and low perfusion conditions and calculated the false alarm rate during 120 fully oxygenated events (specificity) and true alarm rate during 40 de-oxygenated events (sensitivity).1

**False Alarm Performance During Motion and Low Perfusion**

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nellcor N-600</td>
<td>28%</td>
<td>5%</td>
</tr>
<tr>
<td>Masimo SET®</td>
<td>95%</td>
<td></td>
</tr>
</tbody>
</table>

False Alarm Rate
100 - Specificity (%)

True Alarm Detection
Sensitivity (%)

Performance During Motion and Low Perfusion

Industry-leading Pulse Oximetry Solution

Masimo SET® is the world’s leading pulse oximetry technology, proven by both independent and objective research and the real-world success of our customers and partners.

The Choice of Clinicians in the World’s Leading Hospitals

Because of its unmatched reliability during challenging conditions of motion and low perfusion, clinicians at thousands of hospitals around the world count on Masimo SET® every day to help them care for patients. And while many leading hospitals have already integrated Masimo SET® pulse oximetry technology, more are converting every day.

These hospitals and clinicians trust Masimo SET® to help them deliver the most effective and efficient patient care possible. With fewer false alarms, clinicians can focus on the patients who need the most attention. With more trustworthy measurements, clinicians can more tightly control oxygenation levels. And with more timely detection of true events, clinicians can intervene earlier for better patient outcomes and improved patient safety.

Integrated in More Industry-leading Products Than Any Other Pulse Oximetry Technology

Each company manufacturing multiparameter patient monitors chooses which pulse oximetry solution to offer in its products. Today, Masimo SET® is integrated in more industry-leading products than any other pulse oximetry technology—available in more than 100 OEM monitors from 50 leading brands. In many of these monitors, Masimo SET® is the only pulse oximetry technology provided.

In addition, more and more of our OEM partners are enhancing the capabilities of their monitoring solutions by integrating our rainbow® technology.

Philips 24C
Philips CMS 6
Datex-Ohmeda 3140
Nellcor N-395
Datex-Ohmeda 45-3
Datex-Ohmeda 3800
Datex-Ohmeda 3900
Nellcor N-200
Philips OMS
Nellcor N-295
GE 8000
Novametrix MARS
Nellcor NPB-190
Nellcor NPB-180
Novametrix S20A
Spacelabs 90308
Narin 8600
BCI 3304
Criticare 5040

Integrated in More Industry-leading Products Than Any Other Pulse Oximetry Technology

Dräger® with rainbow®
ZOLL® with rainbow®
MS-2040™
Philips® with Masimo SET®
Physio-Control® with rainbow®
Welch Allyn® with rainbow®

Very low power SET® OEM Board
Low power SET® OEM Board
Low power rainbow® OEM Board

Helping Improve Outcomes on the General Floor with Masimo Patient SafetyNet™

In August 2012, The Joint Commission Sentinel Event Alert on the safe use of opioids in hospitals recommended implementation of better dosing along with continuous oxygenation and ventilation monitoring (instead of spot checks) in post-surgical patients. Patient SafetyNet™—combined with Masimo SET® pulse oximetry and rainbow Acoustic Monitoring™ or standard capnography—offers a clinically proven, cost-effective approach to continuous post-operative monitoring with high nursing satisfaction and patient compliance.

Reducing Rescues and ICU Transfers

For many years, clinicians have understood the risks of not continuously monitoring patients on the general floor. However, excessive false alarms due to patient motion made improving the safety of these patients an elusive goal. In the last decade, Masimo SET® has been shown in multiple studies to improve the process of care in neonates and pediatric patients due to its Measure-through Motion and Low Perfusion performance. However, a landmark study in 2010 showed that Masimo SET® also improves clinical outcomes in adults. Just as pulse oximetry has become a standard of care in the OR, PACU, and ICU, we now believe that Measure-through Motion and Low Perfusion pulse oximetry will become a standard of care on the general floor. With Masimo technologies on the general floor, clinicians can be confident their patients are being watched even when they aren’t at the bedside, while families can be assured their loved ones are receiving maximum protection.

Proven Cost-effectiveness

When translated into financial impact, the Dartmouth-Hitchcock study showed that implementing Masimo SET™ and Patient SafetyNet to more safely monitor post-surgical patients could also have a significant impact on the hospital’s bottom line by increasing ICU bed availability and reducing costs associated with emergency rescue events. With both the clinical and financial rationale now in place, hospitals are increasingly implementing general floor monitoring with Masimo technologies.

Halo Index™ Enables Assessment of Patient Status

Halo Index is a new indicator for cumulative trending assessment of the global patient status. Physiologic deterioration often occurs long before a patient crisis and manifests through subtle and often undetected changes in multiple physiologic parameters. Masimo designed Halo Index to mimic the systematic approach that expert clinicians use in assessing patient physiologic deterioration—analyzing the patient history and extracting key vital sign parameter characteristics to assess global patient status. Halo Index currently uses available Masimo parameters but is scalable to include additional information from the patient data repository. Each parameter’s significance is weighted and combined into the Halo Index, a single displayed number with a range from 0 to 100 that provides a cumulative trending assessment of global patient status. Increases in Halo Index suggest physiologic deterioration and may indicate a need for clinicians to more closely assess the patient.

In this example, Halo Index indicates a declining patient condition while displaying parameter trends and their contribution (the size of the bubbles below the parameter) to the Halo Index.*

* Halo Index is CE Marked. Not available in the US.
Clinician-centric Monitoring with MyView™

Empowering Clinicians to See What They Want, When They Want to See It.

The level of information required can change dramatically by clinician and care area, but medical devices historically function in a static manner with the same parameters, waveforms, and trends displayed the same way. While Masimo measurements and display flexibility continue to expand, this doesn’t mean that all clinicians need to see all of the information in the same way. MyView™ technology—featured in Masimo Patient SafetyNet—is being expanded to allow wireless sensing of the device, clinician, patient, and care area to provide the parameters, waveforms, and trends that clinicians want to see and what their patients and family see. While a physician may want to see all parameters and waveforms, a medical assistant may only want to see Halo Index® or a few parameters and no waveforms. If no clinician is in the room, the patient and family may be best served with no specific device information, but rather a visual indicator with a green, yellow, or red color indicating device alarm status.

Empowering Clinicians to See What They Want, When They Want to See It.

MyView in Patient SafetyNet automatically senses when the physician approaches and highlights his or her patients for easy viewing.

When no clinicians are in the room, the clinician may select a device display that is entirely green, yellow, or red—depending on the alarm status. This eliminates a common distraction for the patient and family while limiting unnecessary concerns or questions for caregivers.

When the clinician re-enters the room, MyView recognizes the clinician and displays the measurements that interest the particular clinician.**

With the use of a presence tag, upon approach, the information displayed on Root will change based on clinician-set preferences.

* CE Marked.
** This feature is under development.

Clinician-centric view with the use of a presence tag or smart phone allows caregivers to see the customized information most important to them upon approach to a patient.**
Protect More Patients by Monitoring Every Breath with rainbow Acoustic Monitoring™

To expand the rainbow® platform's promise of breakthrough noninvasive measurements, we have grown beyond our optically based technologies to include clinical measurements derived from sound.

Protecting More Patients by Monitoring Every Breath

Continuous monitoring of respiration rate is especially important for post-surgical patients receiving patient-controlled analgesia for pain management. Conscious sedation can induce respiratory depression and place patients at considerable risk of serious injury or death. The Anesthesia Patient Safety Foundation (APSF) and The Joint Commission recommend continuous oxygenation and ventilation monitoring in all patients receiving opioid-based pain medications.1 However, current methods for respiration rate monitoring are limited by patient tolerance. While we offer the best-in-class capnography solution, we believe rainbow Acoustic Monitoring™ is better suited for post-surgical monitoring and conscious sedation.

Masimo’s rainbow Acoustic Monitoring™ now provides noninvasive and continuous respiration rate that has been shown to be accurate, easy to use, and enhance patient compliance.2 Acoustic Respiration Rate (RRa™) may help clinicians reliably and continuously assess breathing—facilitating earlier detection of respiratory compromise and patient distress—offering a breakthrough in patient safety for post-surgical patients on the general floor and for procedures requiring conscious sedation.

Allowing More Patients to Be Monitored, More Safely than Ever Before

When rainbow Acoustic Monitoring™ is used in conjunction with rainbow® Pulse CO-Oximetry and the Patient SafetyNet system, clinicians can follow key indicators of oxygenation with industry-leading Masimo SpO₂; ventilation with breakthrough acoustic respiration rate (RRa); circulation with Masimo Measure-through Motion pulse rate (PROM); and hemoglobin levels with Masimo’s continuous and noninvasive hemoglobin (SpHb)—enabling clinicians to monitor more patients, more safely than ever before.

Ability to Detect Respiratory Pause3

<table>
<thead>
<tr>
<th>RESPIRATION RATE METHOD</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oridion Capnostream SARA v4.5</td>
<td>62%</td>
</tr>
<tr>
<td>Masimo rainbow Acoustic Monitoring™ v7804</td>
<td>81%</td>
</tr>
</tbody>
</table>

Retrospective analysis of 34 PACU subjects. Reference respiration rate determined by expert observer. A total of 21 episodes of respiratory pause were identified, defined as 30 seconds with no breathing activity.

“Our research shows RRa has greater accuracy, precision, and sensitivity to pauses in ventilation than capnometry.”

Michael Ramsay, MD
Chief of the Department of Anesthesiology and Pain Management, Baylor University Medical Center, Dallas, TX

Helping Screen for Congenital Heart Disease and Reduce Eye Damage and Blindness

From the very beginning, infants and children have been the focus of our research development. As a result, Masimo leads the industry in solutions designed exclusively for these most vulnerable patients.

Enabling Critical Congenital Heart Disease Screening

The breakthrough performance of Masimo SET® is often most appreciated by the clinicians caring for fragile newborns. Up to 30% of all congenital heart disease (CHD) deaths occurring in the first year of life are unrecognized at the time of hospital discharge after birth. Masimo SET® pulse oximetry has been shown to reliably assist clinicians in the screening for critical congenital heart disease (CCHD) — spurring the US Secretary of Health and Human Services to add Measure-through Motion and Low Perfusion pulse oximetry to the recommended Uniform Screening Panel for newborns. Masimo SET® pulse oximeters and sensors meet the recommended criteria for newborn screening, were exclusively used in the two studies that were the basis for the CCHD workgroup decision to recommend newborn screening, and were the first to receive FDA 510(k) clearance with labeling for CCHD screening.

Empowering Care for Cyanotic Patients

In cyanotic infants, Masimo SET® with the Blue® Sensor is the only pulse oximeter proven accurate—enabling accurate maintenance of targeted oxygen saturation levels. And for very low birth weight babies, only the Masimo NeoPt-500™ Sensors are designed for both size and performance in infants as small as 500 grams.

Real-time Newborn Monitoring and Assessment

When each second matters during newborn resuscitation, the Masimo Newborn Sensor ensures the fastest response time at the highest sensitivity—allowing clinicians to focus on real-time patient management instead of the device. In addition, Masimo SET® is increasingly being used to supplement the standard APGAR score to more reliably assess general newborn health.

CCHD Detection Screening with Masimo SET®

<table>
<thead>
<tr>
<th>N = 39,821 babies</th>
<th>Physical Exam Alone</th>
<th>Physical Exam + Masimo SET® Pulse Oximetry Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity for CCHD Detection</td>
<td>63%</td>
<td>83%</td>
</tr>
<tr>
<td>Specificity for CCHD Detection</td>
<td>98%</td>
<td>99.8%</td>
</tr>
</tbody>
</table>

SpO2 screening was conducted on 39,821 newborn babies, preductally (palm of right hand) and postductally (either foot) before routine physical examination. The baby was considered to be screening positive if: 1) either preductal or postductal SpO2 measurement was ≤90%; 2) if in three repeat measurements, both preductal and postductal SpO2 were ≤95%, or the difference between the two measurements was ≥3%.

Reduction of ROP with Masimo SET®

<table>
<thead>
<tr>
<th>Center</th>
<th>Severe Retinopathy of Prematurity (ROP) Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Period 1 (pre-policy change)</td>
</tr>
<tr>
<td>A</td>
<td>12% with Nellcor</td>
</tr>
<tr>
<td>B</td>
<td>13% with Nellcor</td>
</tr>
</tbody>
</table>

In period one, the baseline rate for severe ROP in two centers, both using Nellcor pulse oximetry, is established. In period two, the oxygen targeting policies, caregivers, and patient characteristics were the same at both centers, but only Center A switched to Masimo SET®, which led to a significant reduction in ROP (from 12% to 5%). In period three, Center B switched to Masimo SET® and experienced a reduction in ROP from period two (from 13% to 6%).

References

2. de-Wahl Granelli AD et al. BMJ. 2009;338.
3. Secretary of Health & Human Services letter to the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC); dated September 21, 2011.
Helping Protect Patients from Hidden Dangers with SpMet®

Monitoring for unintended consequences of drugs commonly given in hospitals and during certain procedures.

Addressing the Risk of Dangerous Drug Reactions

Many drugs commonly used in hospitals—such as lidocaine, benzocaine, dapsone, and nitrates—cause a dangerous reaction known as acquired methemoglobinemia that reduces the delivery of oxygen to the tissues. While methemoglobinemia can occur in all care areas and patients, it is often unrecognized and undiagnosed. If not detected and treated immediately, it can result in avoidable injury or death.

Medications Known to Cause Methemoglobinemia:
- Benzocaine, Cetacaine, Chloroquine, Dapsone, EMLA topical, Metronidazole, Lidocaine, Metoclopramide, Nitrates, Nitric oxide, Nitroglycerin, Nitrous oxide, Phenazopyridine (Pyridium), Prilocaine, Primaquine, Riluzole, Silver nitrate, Sodium nitrate, Sulfonamides.

“Acquired methemoglobinemia is fairly common and causes morbidity and mortality in both the inpatient and outpatient settings. Acquired methemoglobinemia is often unrecognized and thus untreated.”

Rachel Ash-Bernal, MD
and other researchers at Johns Hopkins Hospital
Baltimore, MD

Enabling Quick Treatment with SpMet

Masimo noninvasive methemoglobin (SpMet) helps clinicians assess for methemoglobinemia, facilitating earlier detection and immediate treatment to reduce patient risk—especially in care areas where drugs that cause methemoglobinemia are used most often, such as procedure labs and the operating room. This enables them to quickly adjust exposure to the dangerous drug and initiate potentially life-saving treatment.

Prevalence of Methemoglobinemia

<table>
<thead>
<tr>
<th>Number of Methemoglobinemia/Cases</th>
<th>Patient Age</th>
<th>Care Areas</th>
<th>Fatalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>138 (2.5 cases per hospital per month)</td>
<td>4 days to 86 years</td>
<td>Surgery, intensive care, outpatient clinics, pediatrics, emergency department, cardiac cath lab</td>
<td>1 fatality</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 near fatalities</td>
</tr>
</tbody>
</table>

Results from a retrospective study at two Johns Hopkins Hospitals over a 28-month period, using laboratory CO-Oximeter results, and patient electronic medical records.1

“Masimo SpMet helps detect methemoglobinemia, allowing clinicians to accurately diagnose and treat this life-threatening condition.”

Mark Macknet, MD
Assistant Professor of Anesthesiology
Loma Linda University
Loma Linda, CA

“Acquired methemoglobinemia is fairly common and causes morbidity and mortality in both the inpatient and outpatient settings. Acquired methemoglobinemia is often unrecognized and thus untreated.”

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Mark Macknet, MD
Assistant Professor of Anesthesiology
Loma Linda University
Loma Linda, CA

Helping Detect Carbon Monoxide Poisoning with SpCO®

A Deadly Poison Revealed with SpCO
Carbon monoxide (CO) poisoning is the most common cause of poisoning in industrialized countries, but is often misdiagnosed because its symptoms are similar to the flu, and moderate poisoning is possible with no symptoms at all. Our first rainbow® measurement was noninvasive carboxyhemoglobin (SpCO), helping clinicians assess CO levels in the blood, facilitating earlier detection and treatment of CO poisoning. A recent study examined data from the Undersea Hyperbaric Medicine Society’s CO poisoning surveillance system (supported by the Centers for Disease Control) and found that patients who were initially measured using Pulse CO-Oximetry had an almost one-hour reduction in time from the end of CO exposure to treatment.1

Saving Lives Every Day
In emergency medical services, SpCO is helping protect both victims and first responders from the dangers of CO poisoning. SpCO helps paramedics and emergency medical technicians to detect CO poisoning—enabling prompt treatment and removal of those exposed to deadly CO in homes, hotels, and places of work.

SpCO is also helping firefighters reduce the risk of CO poisoning that they face every day. Just one severe CO poisoning nearly doubles the risk of premature death, and consistent CO exposure may cause long-term heart and brain damage.2 When even mild levels of CO are circulating in the blood, the heart and brain are robbed of critical oxygen. This can cause mental confusion that leads to poor decision making and also increases the risk of heart disease or stroke—two conditions already accounting for nearly 50% of on-duty firefighter deaths.3 These factors are why industry-leading organizations have lined up to support CO education, and the National Fire Protection Association (NFPA) introduced a new fire rehabilitation standard—NFPA 1584—that supports on-scene CO assessment of firefighters.

“We believe that all 50-plus people in the hotel would have been dead at dawn if it were not for this lifesaving intervention from Masimo.”

Skip Kirkwood, MS, JD, EMT-P
Chief EMS Division, Wake County Dept. of Emergency Services
Raleigh, NC

References:
EMMA™ (Emergency Mainstream Analyzer)

Capnographs measure carbon dioxide (CO2) concentrations in expired gases. They are used during anesthesia, emergency care, and intensive care—where capnography is often used as a substitute for blood gas measurement or to monitor the performance of assisted ventilation. EMMA is a compact, portable, lightweight mainstream capnograph that requires virtually no warm-up time with full accuracy in 15 seconds. The continuous capnogram allows for confirmation and continuous monitoring of endotracheal tube placement, enables clinicians to assess the depth and effectiveness of compressions, and allows clinicians to recognize return of spontaneous circulation (ROSC). Its primary use is short-term monitoring of end-tidal CO2 and respiration rate in adults, pediatric, and infant patients.

Immediate Capnography at Your Fingertips

“Monitoring respiratory rate and end-tidal carbon dioxide in the positive-pressure ventilated patient represents the greatest opportunity to avoid harm and improve clinical outcomes in all of resuscitation.”

Daniel Davis, MD
Professor of Clinical Emergency Medicine
Director, Center for Resuscitation Science
UCSD Emergency Medicine
San Diego, CA

EMMA fits onto a breathing circuit, facilitating CPR.

Expanding Impact Outside of the Hospital

Industry-leading Masimo SET® is increasingly being used to enhance the quality of patient care outside of the hospital.

A New Level of Care in the Home
For pediatric patients requiring continuous monitoring at home, Masimo SET® offers the best pulse oximetry monitoring for parents caring for special needs children—dramatically reducing false alarms during motion and low perfusion that can complicate an already difficult situation.

Adding a Safety Net in Post-acute Care
As hospital costs rise, more patients are receiving care in long-term acute care and skilled nursing facilities. A major challenge in these facilities is weaning patients off ventilator care, which can put patients at increased risk of adverse events. Post-acute care facilities integrating Masimo SET® bedside pulse oximeters and Patient SafetyNet remote monitoring and notification systems have experienced considerable reduction in rapid response activations as well as emergency “transfer outs.”

Reliable Sleep Lab Monitoring
During sleep lab monitoring, conventional pulse oximetry fails to provide the fidelity and accuracy required to help clinicians detect clinically relevant physiologic events. Masimo SET® technology is integrated in leading sleep lab monitoring systems, enabling clinicians and patients to benefit from its unmatched reliability in this challenging environment.

“The sensitivity and motion artifact rejection characteristics of the non-Masimo SET® pulse oximeters we tested were not adequate for a pediatric sleep laboratory setting.”

Bob Brouillette, MD
Montreal Children’s Hospital
Montreal, Canada

“Masimo technology has raised the bar in the quality of care that can be delivered in a post-acute setting—the right thing to do for patient safety.”

Gene Gantt, RRT
Linde Respiratory Support Services
“This pulse oximeter is without a doubt the best one available for the consumer market. Masimo uses impressive digital signal processing combined with proprietary LED technology. If you need a serious pulse oximeter, this is the one to get.”

Kirk Shelley MD, PhD
Professor of Anesthesiology
Yale University
New Haven, CT

“This pulse oximeter is without a doubt the best one available for the consumer market. Masimo uses impressive digital signal processing combined with proprietary LED technology. If you need a serious pulse oximeter, this is the one to get.”

Kirk Shelley MD, PhD
Professor of Anesthesiology
Yale University
New Haven, CT

The Future of Healthcare Is at Hand

We are witnessing an exciting convergence of medical device and mobile device technology that promises to transform healthcare positively.

Our iSpO2™ device is the world’s first pulse oximeter for iOS and Android mobile platforms.

iSpO2 combines a Masimo “board-in-cable”, reusable or disposable sensor, and an application running on a smart phone or tablet device. It features Masimo’s proven Measure-through Motion and Low Perfusion pulse oximetry—SpO2, pulse rate, and perfusion index. Masimo iSpO2 also allows both consumers* and healthcare providers** to trend measurements and email trend data.

* For sports and aviation use only in the US.
** CE Marked.

We are witnessing an exciting convergence of medical device and mobile device technology that promises to transform healthcare positively.

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** CE Marked.

“Just tried this new mobile iSpO2 app for blood oxygenation saturation. Love it!”

Dr. Eric Topol
Director of the Scripps Translational Science Institute
La Jolla, California
First Ever Noninvasive Fractional SpO2 Measurement

Until now, pulse oximeters could only measure and display functional oxygen saturation (SpO2). So, when patients had elevated carboxyhemoglobin (from carbon monoxide poisoning) and/or elevated methemoglobin (negative reaction to more than 30 common drugs used in hospitals, like caines, nitrates, and Dapsone), the displayed functional oxygen saturation overestimated the actual oxygen saturation value.

In 2012, we introduced SpfO2™*—the first truly fractional, noninvasive oxygen saturation monitor—along with the rainbow® SuperSensor™* which allows for simultaneous measurement of SpO2, SpCO, SpMet, and SpHb. The new SpfO2 measurement allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins—common throughout the hospital and pre-hospital settings—as compared to functional oxygen saturation (SpO2). As a result, SpfO2 should enable earlier interventions and more timely therapeutic decisions. For example, in a patient who is a smoker with an SpO2 of 97%, carboxyhemoglobin level of 12%, and methemoglobin of 1%, if SpfO2 were available, it would be displayed at 84%. It is well accepted that clinicians would frequently make different diagnostic and therapeutic decisions at an oxygenation of 84% versus 97%.

The rainbow® SuperSensor also elevates the utility of noninvasive and continuous oxygen content (SpOC™) monitoring. Since we introduced rainbow® Pulse CO-Oximetry, clinicians have been leveraging noninvasive and continuous hemoglobin (SpHb) and functional oxygen saturation (SpO2) for real-time oxygen content monitoring (SpOC). Now, with the advent of fractional, noninvasive oxygen saturation (SpfO2), SpOC becomes an even more accurate indicator of patient oxygenation—especially in rapidly changing clinical situations.

* CE Marked.
Automated, Patient-centric Approach with Adaptive Threshold Alarm™

With false alarm problems largely solved with Masimo SET®, Masimo’s Adaptive Threshold Alarm was designed to help clinicians manage the frequency of alarms, improving on the limited alarm paradigms of the past to notify clinicians when significant changes in physiology have occurred. Adaptive Threshold Alarm helps clinicians reduce alarms and reduces the time required to set patient-specific alarms by automatically adjusting the audible alarm to the patient’s baseline (Figure 1).

* CE Marked.

While standard SpO2 and pulse rate alarms can sometimes provide a signal of deteriorating patient conditions, Masimo's advanced 3D alarms give you another dimension of advanced notification of parameter conditions that may precede clinically significant events.

> 3D Desat Index Alarm™ helps clinicians detect multiple transient desaturation events that may identify patients at risk for respiratory failure.

> 3D Perfusion Index Alarm™ helps clinicians quickly detect critical changes in peripheral perfusion.

> Changes in peripheral perfusion can reflect significant underlying cardiovascular changes. 3D Perfusion Index Alarm notifies clinicians when there is a 25% change in Perfusion Index (PI) within a period of 60 minutes or less (Figure 3).

### Core Technology Advantages

The Joint Commission, the ECRI Institute, the Anesthesia Patient Safety Foundation and numerous other leading industry bodies have repeatedly cited alarm fatigue among the most pressing patient safety hazards. Conventional approaches to alarm management were developed mainly to address the problems of conventional pulse oximetry’s inability to measure through motion. Fixed alarm thresholds and delays sometimes reduce non-actionable alarms, but with potentially delayed notification of significant events. Masimo SET® broke through past barriers and reduced false alarms by over 95%. In an area like the ICU where up to 90% of all alarms used to be false, Masimo has helped reduce the false alarm incidence to just 5%. *

### Automated, Patient-centric Approach with Adaptive Threshold Alarm™

With false alarm problems largely solved with Masimo SET®, Masimo’s Adaptive Threshold Alarm was designed to help clinicians manage the frequency of alarms, improving on the limited alarm paradigms of the past to notify clinicians when significant changes in physiology have occurred. Adaptive Threshold Alarm helps clinicians reduce alarms and reduces the time required to set patient-specific alarms by automatically adjusting the audible alarm to the patient’s baseline (Figure 1).

* CE Marked.

### Providing Earlier Notification of Potential Risk with Advanced Alarms

While standard SpO2 and pulse rate alarms can sometimes provide a signal of deteriorating patient conditions, Masimo’s advanced 3D alarms give you another dimension of advanced notification of parameter conditions that may precede clinically significant events.

> 3D Desat Index Alarm™ helps clinicians detect multiple transient desaturation events that may identify patients at risk for respiratory failure.

> Low SpO2 alarm limits are typically set too low to spot multiple transient desats that could indicate increased patient risk. 3D desat index alarm signals after five desaturations below 93% over a period of 60 minutes or less (Figure 2).

> 3D Perfusion Index Alarm™ helps clinicians quickly detect critical changes in peripheral perfusion.

> Changes in peripheral perfusion can reflect significant underlying cardiovascular changes. 3D Perfusion Index Alarm notifies clinicians when there is a 25% change in Perfusion Index (PI) within a period of 60 minutes or less (Figure 3).

### Figure 1. Alarm frequency of fixed threshold alarm and Adaptive Threshold Alarm, both with 10-second delay.

### Figure 2. 3D Desat Index Alarm Example

### Figure 3. 3D PI Outta Alarm Example

---

X-Cal™ Technology for Enhanced Patient Safety and Improved Clinician Efficiency

Masimo has implemented a new technology called X-Cal in its sensors, cables, and monitors to enhance patient safety and improve clinician efficiency. All Masimo components work together as an integrated system to measure through challenging conditions including motion and low perfusion. When all components are fully functioning, the system works as intended. In contrast, when any of these system components is compromised, erroneous measurements can occur.

X-Cal is designed to address three common factors that can impact measurement accuracy and patient safety due to reliability risks associated with:

1. Imitation Masimo sensors and cables
2. Cables and sensors used far beyond their expected life
3. Third-party reprocessed pulse oximetry sensors

X-Cal Components

Masimo SET® Measure through Motion and Low Perfusion pulse oximetry has three system components:

1. The sensor that connects to the patient
2. The patient cable that connects the sensor to the Masimo circuit board in the monitor
3. The Masimo circuit board (SET™ SpO2 or rainbow® Pulse CO-Oximetry) installed in a multiparameter patient monitor or Masimo Pulse Oximeter®

Poor Quality and Performance of Imitation Masimo Sensors and Cables

Multiple third-party manufacturers have attempted to copy or imitate Masimo sensors and cables. Imitation cables and sensors (also known as "knockoffs," "copy cat," "pirated" products, etc.) use components without the same design, manufacturing process, or quality controls as Masimo and as such, do not meet Masimo quality or performance specifications. This becomes particularly problematic in challenging conditions. With X-Cal, when an imitation sensor or cable connects to an X-Cal enabled monitor a message is displayed to replace the sensor or cable.

Reliability Risks Associated with Cables and Sensors When Used Beyond Their Expected Life

Eventually, all cables and sensors wear out and fail, and it is widely accepted that the longer any brand of cable or sensor is in service, the more likely that it will reach that point of failure. Masimo is aware of situations in which the monitor has displayed false saturation valves because of cable or sensor malfunction or failure. Often, hospital personnel are not aware of the age of a particular cable and the failure is only discovered during active patient monitoring. To avoid these situations and as a matter of policy, some hospitals replace their cables before their expected life is exhausted.

It is also important to note that as cables and sensors become worn, they may also cause intermittent problems with measurement accuracy which lead to false alarms or mask true alarming events such as hypoxemia. Damaged components that lead to intermittent performance issues can cause care inefficiencies and frustration such as repeated returns of the patient cable with intermittent faults to Biomedical Engineering, or repeated, inconclusive biomedical testing and investigation.

X-Cal provides an automatic method to detect when cables and sensors have been used far beyond their expected life, allowing the aging inventory to be replaced. With X-Cal, biomedical engineers are expected to spend less time troubleshooting faulty nuisance alarms and even less time investigating, testing, and replacing faulty patient cables.

X-Cal does not prevent the use of reprocessed sensors but does provide an automatic method to detect when reprocessed sensors have been used far beyond their expected life.

Poor Quality and Performance of Third-Party Reprocessed Pulse Oximetry Sensors

Customers often assume third-party reprocessed sensors function to the same specification as Masimo sensors. This is not the case. Masimo testing of third-party reprocessed sensors identified a variety of performance issues including biological debris, functional defects, risk of component failure, and adhesive properties that are likely to cause discomfort with infants and neonates.

Third-party reprocessing alters single-patient-use sensors from their original form and function, which may have an adverse effect on the consistency and accuracy of oxygen saturation and pulse rate measurements. Because third-party reprocessors do not understand the intricacies of Masimo products, they do not have controls to evaluate the extent of sensor use or condition of components prior to repackaging previously used sensors. Consequently, third-party reprocessed sensors often have damage to both optical and electrical components.

Masimo ran multiple tests on sensors produced by a third-party reprocessor to evaluate the performance on three important sensor characteristics: Light transmission, electrical noise immunity, and sensor adhesion.

91% Light Transmission
Failed to meet Masimo specifications for light transmission.

3x Electrical Noise Immunity
Failed to meet Masimo specifications for electrical noise immunity testing.

9% Visible Defects
Visual quality inspection revealed that 9% of third-party sensors had visible defects, which would not meet Masimo’s acceptance criteria. Six percent had some form of biological debris including hair, skin, and red and yellow stains from bodily fluids.

How X-Cal Works

X-Cal is seamlessly integrated into Masimo sensors, cables, and circuit boards and is provided at no additional cost to end users. X-Cal can detect imitation cables and sensors and measures the active patient monitoring time of each cable and sensor. Monitors equipped with X-Cal enabled circuit boards will not function with imitation cables and sensors and will display a message to replace cables and sensors that have been used beyond their useful life.

Furthermore, the indication to change a sensor or cable only occurs outside of active patient monitoring to avoid disruption to clinical practice. For example, if the end of a single-patient-use sensor’s expected life is reached while actively monitoring a patient, the sensor will continue to operate until monitoring with that sensor is stopped. At the next reaplication of the same sensor, the monitor will display a message to advise the clinician to replace the sensor.

79% Sensor Adhesion Pull Force
Testing of infant and Neonatal versions of third-party reprocessed sensors showed that almost three times the pull force was required to remove the sensor compared to Masimo Infant and Neonatal sensors.

Masimo ran multiple tests on sensors produced by a third-party reprocessor to evaluate the performance on three important sensor characteristics: Light transmission, electrical noise immunity, and sensor adhesion.
Masimo offers products to help hospitals meet environmental objectives while reducing costs.

Sustainability Without Sacrificing Safety and Performance

Hospitals are facing more pressure than ever to reduce costs and implement green initiatives while maintaining infection control practices that protect patients and staff from the risks of cross-contamination. Disposable pulse oximetry sensors have historically offered the best performance, greatest ease of use, and most comfort—but they do generate more waste. Reprocessing sensors may appear to reduce waste and the per-sensor price, but third-party reprocessed sensors do not offer the same performance or quality as new sensors and are labor-intensive. In addition, reprocessing itself requires additional manufacturing and transportation, which negatively impacts the environment. Reusable sensors may offer lower environmental impact, but do not offer the same performance, comfort, or reduction of cross-contamination risk as disposable sensors.

Multiple Options to Reduce Waste and Cost

Masimo LNOP® Sensors were the first green single-use sensors to work accurately through motion and low perfusion. In addition, our reprocessed sensors are the only reprocessed sensors guaranteed to provide new sensor performance because we replace every emitter and detector. For hospitals seeking the best in performance, waste and carbon footprint reduction, and cost-effectiveness, our new ReSposable™ Sensor line offers a revolutionary combination of benefits—equivalent to 100% recycling at the point of care with a real reduction in the carbon footprint.

Reusable + Disposable = ReSposable™

Our ReSposable Sensor system was created after more than ten years of research and development, incorporating feedback from hundreds of clinicians on what they wanted most in a sensor—less waste, more value, and superior performance. The ReSposable system combines the best features of our LNOP, LNCS®, M-LNCS™, and rainbow® sensors into an innovative design that features a reusable optical sensor (ROS™) for use over multiple patients and a disposable optical sensor (DOS™) for single-patient use. The revolutionary ReSposable sensor system offers the performance and comfort of a single-use disposable sensor with the cost-effectiveness and environmental advantages of a reusable sensor.

Universal ReSposable™ SpO2 Sensor System

Two-piece design includes a reusable sensor and a disposable sensor

Choose Your Reusable Optical Sensor (S-ROS™) Based on Your Device

Choose Your Single-Patient-Use Disposable Optical Sensor (S-DOS™) Based on Your Patient

Up to 41% Lower Carbon Footprint than New Disposable Sensors vs 43% Higher Carbon Footprint with a Mix of New and Reprocessed Sensors**

New Disposable Sensors
Mix of New + Reprocessed Sensors
ReSposable™ Sensors

* Waste calculated by sensor weight for 40% reprocessed sensors with a mix of 80% Adult and Pediatric sensors, 20% Neo and Infant sensors. Carbon footprint comparisons calculated by lbs. CO2 emissions with same reprocess mix as waste.

** Carbon footprint calculations validated by Carbonfund.org in November, 2011.
Innovations for Increased Patient Comfort and Expanded Applications

Enhancing Comfort During Long-term Monitoring with Cabled Sensors

In the past, single-use pulse oximeter sensors with integrated wiring have been limited in their comfort and flexibility by the size of the emitter and detector. After an intense development effort, Masimo’s new SpO2 sensor components are much thinner than ever before—increasing patient comfort by increasing sensor flexibility and reducing bulk while maintaining the Masimo SET® performance that clinicians expect.

Smaller Boards that Consume Less Power for Expanded Applications

Masimo’s technology board innovation has continued with reduced size (as small as 1.8” x 1.2” x 0.5”) and power consumption (less than 45 mW), allowing Masimo SET® performance to be integrated where it was not previously feasible, inside multiple new OEM products with the MS-2040 board or externally as part of the patient cable with uSpO2® and iSpO2™.

Select OEM Partners

- 3P Medical
- ATOm
- BEl-BiOlight
- Bitmos
- bmeva
- CareFusion
- CASMed
- Dalascope
- Dräger
- Fukuda Denshi
- GE Healthcare
- Getmed
- getmed
- corpuls
- Hamilton Medical
- Impact
- Impact
- Medtronic
- Medtronic
- NHK Kohren
- Ohtsu
- Philips
- Physio Control
- SAADAT
- Schiller
- SPACELAB
- Welch Allyn
- Zoll
- Zondan
Technologies and Products

Technologies and Parameters

Masimo SET®
- Measure-through Motion and Low Perfusion pulse oximetry and fluid responsiveness monitoring
  - Functional Oxygen Saturation (SpO2)
  - Pulse Rate (PR)
  - Perfusion Index (PI)
  - Pleth Variability Index (PVI™)
  - Respiration Rate from Pleth (RRp™)

rainbow®
- Complete rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring™, upgradeable, color touchscreen display, standard wireless radio, MyView™, expandable measurements with MOC-9™, and connectivity with Iris™

Pronto®
- rainbow® with SpHb spot-check, wireless communication

Pronto-7®
- rainbow® with SpHb spot-check, Pulse CO-Oximetry

Rad-8®
- Maximo SET®, LED display

Rad-87™
- Complete rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring™, upgradeable, color touchscreen display, standard wireless radio, MyView™

Radical®
- Complete rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring™, upgradeable, LED display, optional wireless radio

Radical®
- Masimo SET®, Monochrome LCD display

Root™
- rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring™, upgradeable, color touchscreen display, standard wireless radio, MyView™, expandable measurements with MOC-9™, and connectivity with Iris™

SedLine®
- Complete rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring™, upgradeable, color touchscreen display, standard wireless radio, MyView™

SedLine® Brain Function Monitoring
- Patient State Index (PSI™)

Phasein™ Capnography and Gas Monitoring
- End-tidal Carbon Dioxide (EtCO₂)
- Fractional Concentration of Inspired Carbon Dioxide (FiCO₂)
- Respiration Rate (RR)
- Nitrous Oxide (N₂O)
- Oxygen (O₂)
- Anesthetic Agent Identification (Agent ID)

EMMA™ Capnometer
- Portable mainstream capnometer

EMMA™ Capnograph
- Portable mainstream capnograph

External Measurement Technologies

Cannulas and Adapters

Patient SafetyNet™ System

Remote monitoring and notification system
- Direct alarms to nurse via pager
- HL7 interface to hospital EHR
- MyView for clinician-centric monitoring
- Monitor up to 200 patients on a single server

Circuit Boards

Cannula

Nomoline™

Adapter

IRMA™ Capnography and Gas Monitoring

ISA™ Capnography and Gas Monitoring

SedLine® Brain Function Monitoring

IRMA™

MS-2011

MS-2040

MX-5

MS-2013

SedLine®

Cannula

Nomoline™

Adapter

SedLine® Sensor PSI™

The sensors above are part of Masimo’s Rainbow Technology. The different sensors and features allow for enhanced monitoring and patient care.
### National and International Awards for Excellence

- **1995**: STA Excellence in Technology Innovation for Measure-through Motion and Low Perfusion Pulse Oximetry
- **2000**: SCCM Technology Excellence
- **2000**: Outstanding Medical Device Company
- **2001**: Innovative Product and Technology
- **2001**: Distinguished Leadership
- **2001**: Excellence in Leadership
- **2001**: Medical Design Excellence
- **2003**: New Standard of Care
- **2003**: Technology of the Year in Patient Monitoring
- **2003**: Platform ABBY for Innovations in Healthcare
- **2005**: Innovative Product and Technology
- **2006**: STA Application of Technology for Noninvasive Methemoglobin and Carboxyhemoglobin Monitoring
- **2006**: Medical Design Excellence
- **2007**: STA Excellence in Technology Innovation for Noninvasive Total Hemoglobin Monitoring
- **2007**: Groundbreaking Innovation of rainbow® SET Technology
- **2007**: Patient Monitoring Technology Leadership of the Year
- **2007**: Brand Development Strategy Leadership
- **2008**: Excellence in Medical Technology
- **2008**: Outstanding Growth
- **2008**: Outstanding Medical Device Company
- **2008**: Best in Class
- **2008**: AARC Zenith Award
- **2009**: Best in Class
- **2009**: AARC Zenith Award
- **2009**: Patient Monitoring CEO of the Year
- **2010**: GHX Respiratory Product Best-in-Class Award
- **2010**: AARC Zenith Award
- **2011**: IF Product Design Award for the Pronto-7
- **2011**: Medical Design Excellence — Gold for the Pronto-7
- **2011**: TechAmerica High-Tech Innovation for the Pronto-7
- **2012**: Gold “Stevie” Award for Best New Health Product for the Pronto-7
- **2012**: Ernst & Young National Entrepreneur of the Year—2012 Life Sciences Award Winner
- **2013**: STA Best Clinical Application of Technology Award for SpHb
- **2013**: EMS Hot Product Award for EMMA and iSpO2

### Financial Performance

#### Consolidated Balance Sheets (in thousands)

<table>
<thead>
<tr>
<th></th>
<th>December 24, 2012</th>
<th>December 31, 2011</th>
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<tbody>
<tr>
<td><strong>ASSETS</strong></td>
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<tr>
<td>Current assets</td>
<td>$71,554</td>
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<td>Accounts receivable</td>
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<td>Royalties receivable</td>
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<tr>
<td>Inventories</td>
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<td>Prepaid expenses</td>
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<td>Prepaid income taxes</td>
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<tr>
<td>Deferred tax assets</td>
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<tr>
<td>Other current assets</td>
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<tr>
<td>Total current assets</td>
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<td>10,242</td>
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<tr>
<td>Deferred cost of goods sold</td>
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<td>51,679</td>
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<tr>
<td>Property and equipment, net</td>
<td>23,924</td>
<td>15,239</td>
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<tr>
<td>Intangible assets, net</td>
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<td>11,913</td>
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<tr>
<td>Goodwill</td>
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<td>Deferred tax assets</td>
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<tr>
<td>Other assets</td>
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<tr>
<td>Total assets</td>
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<td>$366,104</td>
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<tr>
<td><strong>LIABILITIES AND EQUITY</strong></td>
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<td></td>
</tr>
<tr>
<td>Current liabilities</td>
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<tr>
<td>Accounts payable</td>
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<td>Accrued compensation</td>
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<td>Accrued liabilities</td>
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<td>Income taxes payable</td>
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<td>Deferred revenue</td>
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<tr>
<td>Current portion of capital lease obligations</td>
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<td>48</td>
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<tr>
<td>Total current liabilities</td>
<td>89,959</td>
<td>65,061</td>
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<tr>
<td>Deferred revenue</td>
<td>576</td>
<td>584</td>
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<tr>
<td>Capital lease obligations, less current portion</td>
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<td>74</td>
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<tr>
<td>Other liabilities</td>
<td>10,103</td>
<td>8,422</td>
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<td>Total liabilities</td>
<td>$100,278</td>
<td>$64,458</td>
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<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
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<tr>
<td>Masimo Corporation stockholders' equity:</td>
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<td></td>
</tr>
<tr>
<td>Common stock</td>
<td>57</td>
<td>58</td>
</tr>
<tr>
<td>Treasury stock</td>
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<td>(123,956)</td>
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<td>Additional paid-in capital</td>
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<tr>
<td>Accumulated other comprehensive income</td>
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<td>1,274</td>
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<tr>
<td>Retained earnings</td>
<td>24,361</td>
<td>26,364</td>
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<tr>
<td>Total Masimo Corporation stockholders' equity</td>
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<td>279,062</td>
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<tr>
<td>Noncontrolling interest</td>
<td>2,589</td>
<td>2,838</td>
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<tr>
<td>Total equity</td>
<td>$280,635</td>
<td>$281,900</td>
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<tr>
<td>Total liabilities and equity</td>
<td>$375,040</td>
<td>$366,104</td>
</tr>
</tbody>
</table>
## Financial Performance

### Consolidated Statements of Income (in thousands, except per share information)

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<thead>
<tr>
<th></th>
<th>December 29, 2012</th>
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<tbody>
<tr>
<td><strong>Revenue:</strong></td>
<td></td>
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<tr>
<td>Product</td>
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<tr>
<td>Royalty</td>
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<tr>
<td><strong>Total revenue:</strong></td>
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<td><strong>Cost of goods sold:</strong></td>
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<tr>
<td><strong>Gross profit:</strong></td>
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<td>$294,183</td>
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<tr>
<td><strong>Operating expenses:</strong></td>
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<tr>
<td>Selling, general and administrative</td>
<td>193,948</td>
<td>162,205</td>
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<tr>
<td>Research and development</td>
<td>41,077</td>
<td>38,413</td>
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<tr>
<td><strong>Total operating expenses:</strong></td>
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<tr>
<td><strong>Operating income:</strong></td>
<td>$87,141</td>
<td>$93,565</td>
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### Financial Performance

#### Research and development

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<tr>
<td><strong>Research and development:</strong></td>
<td>$47,077</td>
<td>$38,412</td>
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#### Selling, general and administrative

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<tr>
<td><strong>Selling, general and administrative:</strong></td>
<td>$193,948</td>
<td>$162,205</td>
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#### Diluted

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<td><strong>Diluted:</strong></td>
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#### Basic

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<td><strong>Basic:</strong></td>
<td>$57,445</td>
<td>$59,659</td>
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#### Cash dividend declared per share

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<tbody>
<tr>
<td><strong>Cash dividend declared per share:</strong></td>
<td>$0.57</td>
<td>$0.55</td>
</tr>
</tbody>
</table>

### Consolidated Statements of Cash Flows (in thousands)

#### Year ended: December 29, 2012

|                          | $1,038,432         | $1,045,053         |

#### Year ended: December 31, 2011

|                          | $1,038,432         | $1,045,053         |

### CASH FLOWS FROM OPERATING ACTIVITIES:

<table>
<thead>
<tr>
<th>Description</th>
<th>December 29, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net income including noncontrolling interest</td>
<td>$62,272</td>
<td>$63,700</td>
</tr>
<tr>
<td>Add: Depreciation and amortization</td>
<td>9,369</td>
<td>7,412</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>14,047</td>
<td>13,376</td>
</tr>
<tr>
<td>Provision for doubtful accounts</td>
<td>231</td>
<td>231</td>
</tr>
<tr>
<td>Provision for obsolete inventory</td>
<td>1,063</td>
<td>2,130</td>
</tr>
<tr>
<td>Provision for warranty costs</td>
<td>2,489</td>
<td>2,552</td>
</tr>
<tr>
<td>Benefit from deferred income taxes</td>
<td>(6,806)</td>
<td>(3,271)</td>
</tr>
<tr>
<td>Income tax benefit from exercise of stock options granted</td>
<td>338</td>
<td>1,650</td>
</tr>
<tr>
<td>Excess tax benefit from share-based comp. arrangements</td>
<td>747</td>
<td>(61)</td>
</tr>
<tr>
<td>Realized foreign exchange gain on forward contracts</td>
<td>(586)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Changes in operating assets and liabilities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase in accounts receivable</td>
<td>(10,130)</td>
<td>(5,149)</td>
</tr>
<tr>
<td>(increase) decrease in inventories</td>
<td>(28)</td>
<td>4,816</td>
</tr>
<tr>
<td>Increase in income taxes</td>
<td>(524)</td>
<td>(5,496)</td>
</tr>
<tr>
<td>Increase in deferred costs of goods sold</td>
<td>(409)</td>
<td>(4,520)</td>
</tr>
<tr>
<td>(increase) decrease in prepaid expenses</td>
<td>186</td>
<td>(1,839)</td>
</tr>
<tr>
<td>Decrease in prepaid income taxes</td>
<td>1,265</td>
<td>966</td>
</tr>
<tr>
<td>Increase in other assets</td>
<td>(2,113)</td>
<td>(1,512)</td>
</tr>
<tr>
<td>(increase) decrease in accounts payables</td>
<td>(1,726)</td>
<td>5,159</td>
</tr>
<tr>
<td>(increase) decrease in accrued compensation</td>
<td>4,827</td>
<td>(3,333)</td>
</tr>
<tr>
<td>(increase) decrease in accrued liabilities</td>
<td>450</td>
<td>(7)</td>
</tr>
<tr>
<td>(increase) decrease in income taxes payable</td>
<td>180</td>
<td>(88)</td>
</tr>
<tr>
<td>Increase in deferred revenue</td>
<td>2,850</td>
<td>(21)</td>
</tr>
<tr>
<td>(increase) decrease in other liabilities</td>
<td>(2,203)</td>
<td>(16)</td>
</tr>
<tr>
<td><strong>Net cash provided by operating activities:</strong></td>
<td>$3,445</td>
<td>$3,962</td>
</tr>
</tbody>
</table>

### CASH FLOWS FROM INVESTING ACTIVITIES:

<table>
<thead>
<tr>
<th>Description</th>
<th>December 29, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchases of property and equipment</td>
<td>(10,926)</td>
<td>(5,057)</td>
</tr>
<tr>
<td>Increase in intangible assets</td>
<td>(3,364)</td>
<td>(2,483)</td>
</tr>
<tr>
<td>Cash paid for acquisitions, net of cash acquired</td>
<td>(33,990)</td>
<td>(33,990)</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities:</strong></td>
<td>(31,881)</td>
<td>(31,597)</td>
</tr>
</tbody>
</table>

### CASH FLOWS FROM FINANCING ACTIVITIES:

<table>
<thead>
<tr>
<th>Description</th>
<th>December 29, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repayments on capital lease obligations</td>
<td>(26)</td>
<td>(10)</td>
</tr>
<tr>
<td>Proceeds from issuance of common stock</td>
<td>(642)</td>
<td>5,043</td>
</tr>
<tr>
<td>Dividends paid</td>
<td>(76)</td>
<td>—</td>
</tr>
<tr>
<td>(increase) decrease in cash and cash equivalents</td>
<td>(572)</td>
<td>(36,187)</td>
</tr>
<tr>
<td><strong>Net cash used in financing activities:</strong></td>
<td>(58,044)</td>
<td>(31,654)</td>
</tr>
</tbody>
</table>

### Effect of foreign currency exchange rates on cash

<table>
<thead>
<tr>
<th>Description</th>
<th>December 29, 2012</th>
<th>December 31, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net increase (decrease) in cash and cash equivalents:</strong></td>
<td>$18,238</td>
<td>$41,377</td>
</tr>
<tr>
<td>Cash and cash equivalents at beginning of period</td>
<td>$129,482</td>
<td>$84,975</td>
</tr>
<tr>
<td>Cash and cash equivalents at end of period</td>
<td>$111,744</td>
<td>$126,383</td>
</tr>
</tbody>
</table>

Note: The Consolidated Balance Sheets, Consolidated Statements of Income, and Consolidated Statements of Cash Flows are derived from our Audited Consolidated Financial Statements as published in our Form 10-K filed with the Securities and Exchange Commission on February 7, 2013.
Masimo’s Global Reach

Masimo is committed to improving patient care globally, with approximately 3,000 talented people worldwide and operations in North America, Europe, Latin America, the Middle East, Asia, and Australia.
Forward-looking Statements

All statements other than statements of historical facts included in this document that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. These statements include but are not limited to statements about our business generally, expectations regarding our ability to design and deliver innovative new noninvasive technologies; demonstrate our technologies; estimates regarding potential cost savings through using our technologies; and expectations regarding the growth of our installed base of users. These forward-looking statements are based on management’s current expectations and beliefs and are subject to uncertainties and factors, all of which are difficult to predict and many of which are beyond our control and could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to, those related to: our dependence on Masimo SET and Masimo rainbow SET products and technologies for substantially all of our revenue; any failure in protecting our intellectual property; exposure to competitors’ awareness of intellectual property claims; the highly competitive nature of the markets in which we sell our products and technologies; any failure to continue developing innovative products and technologies; the lack of acceptance of any of our current or future products and technologies; obtaining regulatory approval of our current and future products and technologies; the risk that the implementation of our international realignment will not continue to produce anticipated operational and financial benefits, including a continued lower effective tax rate; the loss of our customers; the failure to retain and recruit senior management; product liability claims exposure; ability to obtain expected returns from the amount of intangible assets we have recorded; the maintenance of our brand; the impact of the decline in the worldwide credit markets on us and our customers; the amount and type of equity awards that we may grant to employees and service providers in the future; and other factors discussed in the “Risk Factors” section of our most recent periodic reports filed with the Securities and Exchange Commission (“SEC”), including our most recent Annual Report on Form 10-K and Quarterly Report from 10-Q, all of which you may obtain for free on the SEC’s website at www.sec.gov.

Some of the products featured in this Annual Report are currently or planned to be marketed worldwide by Masimo. Not all products or features profiled in this report have US FDA 510(k) or other regulatory agencies’ clearances (such as EU, Canada, Japan, etc.) at the time of printing. As of July 2013, products/features that have not been FDA 510(k) cleared for sales and marketing in the US include SpCo, SpvO2, SpO2, RA. Active Pulse, the Super Sensor, MyView, Halo Index, Root with all of the described functions, and Adaptive Threshold Alarm. Submissions for some of these products or features either have been filed or are planned to be filed in other regulated markets.

Regulatory Notice

NOTE REGARDING THIS ANNUAL REPORT: Please note that this annual report does not constitute the Company’s “annual report to security holders” for purposes of the requirements of the SEC. For a copy of the Company’s annual report to security holders required under Rule 14a-3 of Regulation 14A of the Securities Exchange Act of 1934, as amended, please refer to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2012, which you may obtain for free on the SEC’s website at www.sec.gov.

Senior Management Team

Joe Kiani
Chief Executive Officer
Matthew Anacone
Vice President, US Acute Care Sales
Jon Coleman
President, Worldwide Sales, Professional Services and Medical Affairs
Mark de Raad
Executive Vice President & Chief Financial Officer
Paul Jansen
Executive Vice President, Market Development

Yongsam Lee
Executive Vice President, Operations and Chief Information Officer
Tetsuro Manika
President, Masimo Japan
Tom McClennahan
Executive Vice President, General Counsel
Amanand Sampath
Executive Vice President, Engineering
Stacey Taggart
President, Europe, Middle East & Africa
Robert Zyzanski
President, Masimo Sweden

Board of Directors

Joe Kiani
Chairman of the Board of Directors
Steven Barker, MD, PhD
Director
Edward Cahill
Director
Robert Coleman, PhD
Director
Sanford Fitch
Director
Jack Lasersohn
Director