MASIMO CORP
Form 10-K
February 14, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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FORM 10-K

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(Mark One)

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 28, 2013

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-33642

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Masimo Corporation
(Exact name of registrant as specified in its charter)

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| Delaware | 33-0368882 |
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification Number) |
| 40 Parker Irvine, California | 92618 |
| (Address of Principal Executive Offices) | (Zip Code) |

(949) 297-7000
(Registrant's telephone number, including area code)

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Securities registered pursuant to Section 12(b) of the Act:

| Title of each class: | Name of each exchange on which registered: |
|---|---|
| Common Stock, par value $0.001 | The NASDAQ Global Select Market |

Securities registered pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No ý

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one).

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|---|---|
| Large accelerated filer ý | Accelerated filer ¨ |
| Non-accelerated filer ¨ (Do not check if a smaller reporting company) | Smaller reporting company ¨ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 29, 2013, the last business day of the registrant's most recently completed second fiscal quarter, as reported on the NASDAQ Global Select Market, was approximately $789.9 million. Shares of stock held by officers, directors and 5 percent or more stockholders have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At January 31, 2014, the registrant had 56,705,362 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant's proxy statement for the registrant's 2014 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Form 10-K, contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. The forward-looking statements are contained principally in Item 1—"Business," Item 1A—"Risk Factors" and Item 7—"Management's Discussion Analysis of Financial Condition and Results of Operations" but appear throughout this Form 10-K. Examples of forward-looking statements include, but are not limited to, any projection or expectation of earnings, revenue or other financial items; the plans, strategies and objectives of management for future operations; factors that may affect our operating results, including accounting and tax estimates; our success in pending litigation; new products or services; the demand for our products; our ability to consummate acquisitions and successfully integrate them into our operations; future capital expenditures; effects of current or future economic conditions or performance; industry trends and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "opportunity," "plan," "potential," "predicts," "seek," "should," "will," or "v expressions and variations or negatives of these words. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which is subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause our actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed under Item 1A—"Risk Factors" in this Form 10-K. Furthermore, such forward-looking statements speak only as of the date of this Form 10-K. We undertake no obligation to update or revise publicly any forward-looking statements to reflect events or circumstances after the date of such statements for any reason, except as otherwise required by law.

PART I

ITEM 1. BUSINESS

Overview

We are a global medical technology company that develops, manufactures, and markets a variety of noninvasive monitoring technologies. Our mission is to improve patient outcomes and reduce the cost of care by taking noninvasive monitoring to new sites and applications. We were incorporated in California in May 1989 and reincorporated in Delaware in May 1996.

Our core business is measure through motion and low perfusion arterial blood oxygen saturation and pulse rate monitoring, known as Masimo SET® pulse oximetry, but our product offerings have expanded significantly over the years to also include noninvasive blood constituent, brain and breath monitoring, including rainbow® Pulse CO-Oximetry, brain function electroencephalogram (EEG) monitoring, respiration rate, capnography and anesthetic agent monitoring. In addition, we have developed the Root™ patient monitoring and connectivity platform and Patient SafetyNet™ remote patient surveillance monitoring system. We provide our products directly and through distributors and OEM partners to hospitals, emergency medical service (EMS) providers, physician offices, veterinarians, long term care facilities and consumers.

Pulse oximetry enables the noninvasive measurement of the oxygen saturation level of arterial blood, which delivers oxygen to the body's tissues. Pulse oximetry also enables the measurement of pulse rate, which when measured by ECG is called heart rate. Pulse oximetry is one of the most common measurements taken in and out of hospitals around the world. Most pulse oximeter technologies work well when patients are well perfused and are not moving. However, when either or both of these conditions occur, conventional pulse oximeters frequently do not provide any measurements, or provide inaccurate measurements. We invented Masimo Signal Extraction Technology® (Masimo SET®) which for the first time, allowed pulse oximeters to provide accurate measurements even during patient motion and low perfusion conditions.

The performance of Masimo SET® pulse oximetry is proven by more than 100 independent and objective studies and thousands of clinical evaluations. We believe that Masimo SET® is trusted by clinicians to safely monitor approximately 100 million patients each year and is used hospital-wide by eight of the top 10 hospitals on the U.S. News & World Report Best Hospitals Honor Roll (2013-2014). Compared to other pulse oximeters during patient motion and low perfusion, Masimo SET® provides measurements when other pulse oximeters cannot, dramatically reduces false alarms (specificity), and accurately detects true alarms (sensitivity) that can indicate a deteriorating patient condition. Masimo SET® pulse oximetry has also been shown to improve patient outcomes by helping clinicians reduce retinopathy of prematurity (ROP) in neonates, screen newborns for critical congenital heart disease (CCHD), reduce ventilator weaning time and arterial blood gas measurements in the intensive

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care unit (ICU), and save lives and costs while reducing rapid response activations and intensive care unit transfers on the general floor.

Our pulse oximetry technology is contained on a circuit board which is placed inside a standalone pulse oximetry monitor, placed inside original equipment manufacturer (OEM) multiparameter monitors, or included as part of an external "Board-in-Cable" solution which is plugged into a port on an OEM or other device. All of these solutions use our proprietary single-patient use and reusable sensors and cables. We sell our products to end-users through our direct sales force and certain distributors, as well as our OEM partners, for incorporation into their products. In 2013, we also began selling our pulse oximetry products in the consumer market. As of December 28, 2013, we estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET® and rainbow® SET was more than 1.2 million units, excluding handheld devices . Our installed base is the primary driver for the recurring sales of our pulse oximeter and Pulse CO-Oximeter sensors, most notably, single-patient adhesive sensors. Based on industry reports, we estimate that the worldwide pulse oximetry market is nearly $1.5 billion in 2014, the largest component being sensors.

After introducing Masimo SET®, we have continued to innovate by introducing breakthrough noninvasive measurements that go beyond arterial blood oxygen saturation and pulse rate, and which create new market opportunities in both the hospital and non-hospital care settings. In 2005, we launched rainbow® Pulse CO-Oximetry, utilizing both Masimo SET® and licensed rainbow® technology. We believe rainbow® Pulse CO-Oximetry includes the first devices cleared by the U.S. Food and Drug Administration, or FDA, to noninvasively and continuously monitor multiple blood based measurements using multiple wavelengths of light and which previously were only possible through intermittent invasive procedures. In 2005, we launched noninvasive carboxyhemoglobin, or SpCO®, allowing measurement of carbon monoxide levels in the blood. Carbon monoxide is the most common cause of poisoning in the world. When used with other clinical variables, SpCO® may help clinicians and emergency responders detect carbon monoxide poisoning and help determine treatment and additional test options. In 2006, we launched noninvasive methemoglobin, or SpMet®, allowing for the measurement of methemoglobin levels in the blood. Methemoglobin in the blood leads to a dangerous condition known as methemoglobinemia, which occurs as a reaction to some common drugs used in hospitals and outpatient procedures. When used with other clinical variables, SpMet® may help clinicians detect methemoglobinemia and help determine treatment and additional test options. In 2007, we launched a measurement available in both Masimo SET® and rainbow® SET® sensors called Pleth Variability Index, or PVI®. Fluid administration is critical to optimizing fluid status in surgery and critical care, but traditional invasive methods to guide fluid administration often fail to help clinicians assess fluid responsiveness and newer methods are complicated and costly and considered appropriate only for the highest-risk patients. When used with other clinical variables, PVI® may help clinicians assess fluid responsiveness and help determine treatment options. In March 2008, we launched noninvasive total hemoglobin (SpHb®). Hemoglobin is the oxygen-carrying component of red blood cells (RBC), and along with oxygen saturation, determines the oxygen content of blood. Hemoglobin measurement is one of the most frequent invasive laboratory measurements in the world, and is often measured as part of a complete blood count (CBC), which measures multiple other blood components. A low hemoglobin status is called anemia, which is generally caused by bleeding or the inability of the body to produce red blood cells. SpHb® is available as a continuous monitor or a spot check measurement. Continuous SpHb® monitoring provides real-time visibility into the changes, or lack of changes in hemoglobin, which can otherwise only be measured through intermittent, invasive blood testing. SpHb® has been shown to help clinicians reduce the number of RBC transfusions and in multiple cases, demonstrated its lifesaving ability to detect internal bleeding. Spot check SpHb® measurement, when used with other clinical variables, may help clinicians assess whether a patient's hemoglobin is lower or higher than they may otherwise assess without any hemoglobin measurement, which in turn, may help determine additional test options.

In June 2010, we introduced a sound-based monitoring technology called rainbow Acoustic Monitoring™ (RAM™), which enables continuous and noninvasive monitoring of respiration rate (RRa®). Respiration rate is the number of breaths per minute. A low respiration rate is indicative of respiratory depression and high respiration rate is indicative of patient distress. Traditional methods used to measure respiration rate are often considered inaccurate, such as impedance pneumography, or are not tolerated well by some patients, such as capnography. When used with other

clinical variables, RRa® may help clinicians assess respiratory status and help determine treatment options. RAM™ technology is available from the same circuit board as Masimo SET® and rainbow® Pulse CO-Oximetry measurements, which together we refer to as the rainbow® SET technology platform.

In July 2010, we acquired and began selling our SedLine® brain function monitor, which measures the brain's electrical activity and provides information about a patient's response to anesthesia.

In 2011, we received the CE Mark for respiration rate from the plethysmograph waveform (RRp)™. Although not currently available for sale in the U.S., RRp™ enables monitoring of breathing status from a standard Masimo SET® pulse oximetry or rainbow® Pulse CO-Oximeter sensor®. The RRp™ measurement is determined by the variations in the plethysmograph waveform due to respiration, although the measurement is not possible in all patients or many conditions and may not immediately indicate changes in respiration rate. For patients requiring accurate and sensitive respiration rate monitoring, we believe that our acoustic respiration rate (RRa®) measurement has been shown to better detect pauses in breathing than respiration rate

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measurements from Oridion capnography. The RRa® measurement also provides an important visual indication of breathing through the displayed acoustic waveform.

We also offer a patient surveillance or remote monitoring and clinician notification solution called Patient SafetyNet,™ which includes Masimo SET® or rainbow® SET platform measurements at the patient's bedside along with a central assignment station and wired or wireless server. Patient SafetyNet™ wirelessly notifies clinicians caring for multiple patients in different rooms when one of their patients has an alarm, allowing them to become aware of changing conditions and intervene sooner, at times with life-saving support. Masimo SET®, along with Patient SafetyNet,™ is proven to help clinicians avoid deaths while preventing ICU transfers and rapid response activations on the general floor. In October 2010, we debuted Halo Index,™ which allows continuous global trending and assessment of multiple physiological measurements of a patient with a single number displayed on the Patient SafetyNet™ screen. Halo Index™ is CE marked, but not currently available for sale in the U.S.

In October 2012, we received both FDA clearance for uSpO2,™ a universal "Board-in-Cable" pulse oximetry solution, enabling easier and faster integration for OEM partners due to the ability to integrate Masimo SET® through software only. In October 2012, we also received CE mark for SpfO2,™ a new parameter not currently available for sale in the U.S., which for the first time, allows the measurement of fractional arterial oxygen saturation noninvasively. Previously, pulse oximeters could only measure and display functional oxygen saturation (SpO2), so when patients had elevated carboxyhemoglobin and/or elevated methemoglobin, the displayed functional oxygen saturation overestimated the actual oxygen saturation value. SpfO2™ allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting compared to functional oxygen saturation.

In March 2012, we acquired Spire Semiconductor, LLC, a maker of advanced light emitting diode and other advanced component-level technologies. Masimo Semiconductor, Inc. (Masimo Semiconductor), our wholly owned subsidiary, operates this business and specializes in wafer epitaxy, foundry services, and device fabrication for biomedical, telecommunications, consumer products and other markets. This acquisition provided us with an advanced ability to develop custom components, accelerate development cycles, and optimize future product costs.

In July 2012, we acquired PHASEIN AB, or Phasein,™ a developer and manufacturer of ultra-compact mainstream and sidestream capnography and gas monitoring technologies. The acquisition of the Phasein™ technologies complements our breakthrough innovations for patient monitoring with a portfolio of products ranging from OEM solutions for external "plug-in-and-measure" capnography and gas analyzers and integrated modules to handheld devices. With multiple measurements delivered through either mainstream or sidestream options, our customers can benefit from $CO_2$, $N_2O$, $O_2$, and anesthetic agent monitoring in many hospital and pre-hospital environments, such as the operating room (OR), procedural sedation, ICU and EMS scenarios.

In December 2012, we released iSpO2®, a pulse oximeter cable and sensor with technology for use with an iPhone, iPad or iPod touch. iSpO2® uses Masimo SET® technology for Measure-Through Motion and Low Perfusion performance. The first version of iSpO2® allows consumers to use their iPhone, iPad or iPod touch to check their own arterial blood oxygen saturation (SpO2), pulse rate, and perfusion index measurements. In the U.S., iSpO2® is available online for sports and aviation use only, and is not intended for medical use. In October 2013, iSpO2® was released in Japan for iPhone, iPad, and iPod touch. In December 2013, we received the CE mark on iSpO2® for the Android operating system, enabling functionality on select Android based phones outside of the U.S. The iSpO2® Rx, the professional version for medical use, also received the CE mark in December 2013. The iSpO2® Rx product is not yet available in the U.S. but is available outside of the U.S.

In June 2013, we announced the CE Mark, and limited international market release of our Root™ platform. Root™ is a powerful new patient monitoring and connectivity platform that integrates our breakthrough rainbow® and SET® measurements with multiple additional parameters being made available through Masimo Open Connect™ (MOC-9)™ in an integrated, clinician-centric platform. The first two MOC-9™ technologies for Root™ are SedLine® brain function monitoring and Phasein capnography. Iris™ connectivity in Root™ enables 3rd party devices such as intravenous pumps and ventilators to connect through Root™ enabling display, notification, and documentation to the electronic medical record through Masimo Patient SafetyNet.™ In combination with a Radical-7® handheld device using rainbow® Pulse CO-Oximetry and rainbow® Acoustic Monitoring,™ Root™ will help clinicians instantly interpret and quickly change

display of multiple measurements, helping to simplify patient care workflows, empower caregivers to help make quicker patient assessments, earlier interventions and better clinical decisions throughout the continuum of care. Phasein capnography and some other Root™ features such as wireless radio and Iris™ connectivity are not available for sale in the U.S. as of December 28, 2013.

In July 2013, we released EMMA™ Capnograph with waveform display, offering clinicians greater assessment of end-tidal carbon dioxide ($EtCO_2$) and respiration rate, as well as assisting in recognition of return to spontaneous circulation, for a variety of clinical settings, including emergency medicine and transport, ORs, ICUs, patient rooms, and clinics. EMMA™ fits in the palm of the hand, and we believe is the smallest and most portable capnograph in the world.

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We offer Masimo SET® and rainbow® SET through our OEMs for integration in their products and through our own end-user products, including the Root™, Radical-7®, Rad-87®, Rad-57®, Pronto-7®, Pronto®, Rad-8®, Rad-5® and Rad-5v.™ Our strategy is to utilize the accuracy and broad clinical benefits of our technologies to:
1) be the leading choice for pulse oximetry in traditionally monitored areas, in and out of the hospital;
2) expand the use of pulse oximetry beyond the critical care settings, including to the general floor of the hospital;
3) create demand for the use of breakthrough rainbow® measurements by our hospital customers;
4) offer rainbow® measurements to new markets such as emergency medical services, or EMS, and the physician office;
5) penetrate existing noninvasive specialty monitoring markets such as capnography, gas, brain function, and other modalities with technologies that offer clinical and financial advantages; and
6) leverage the revolutionary Root™ platform to provide open access to third-party developers for additional measurements, as well as connectivity to electronic health record systems and for third-party devices.
Our solutions and related products are based upon our proprietary Masimo SET® and rainbow® algorithms. This software-based technology is incorporated into a variety of product platforms depending on our customers' specifications. Our technology is supported by a substantial intellectual property portfolio that we have built through internal development and, to a lesser extent, acquisitions and license agreements. As of December 28, 2013, we had 674 issued and pending patents worldwide. We have exclusively licensed from Cercacor Laboratories, Inc. (Cercacor), the right to OEM selected rainbow® technology and to incorporate selected rainbow® technology into our products intended to be used by professional caregivers, including, but not limited to, hospital caregivers and alternate care facility caregivers.
Pulse Oximetry: Technical and Clinical
Pulse oximeters use sensors attached to an extremity, typically the fingertip. These sensors contain two light emitting diodes that transmit red and infrared light from one side of the extremity through the tissue to a photodetector on the other side of the extremity. The photodetector in the sensor measures the amount of red and infrared light absorbed by the tissue. A microprocessor then analyzes the changes in light-absorption to provide a continuous, real-time measurement of the amount of oxygen in the patient's arterial blood. Pulse oximeters typically give audio and visual alerts, or alarms, when the patient's arterial blood oxygen saturation level or pulse rate falls outside of a user-designated range. As a result, clinicians have the opportunity to immediately initiate treatment to prevent the serious clinical consequences of hypoxemia, or low oxygen saturation levels, and hyperoxemia, or high oxygen levels. Pulse oximetry has gained widespread clinical acceptance as a standard patient vital sign measurement because it can give clinicians an early warning of low arterial blood oxygen saturation levels, known as hypoxemia. Early detection is critical because hypoxemia can lead to a lack of oxygen in the body's tissues, which can result in organ damage or death in a matter of minutes. Our pulse oximeters are used primarily in critical care settings, including surgery, recovery rooms, ICUs, emergency departments and alternative care settings, such as long-term care facilities and for home monitoring of patients with chronic conditions.
Clinicians also use pulse oximeters to estimate whether there is too much oxygen in the blood, a condition called hyperoxemia. In premature babies, hyperoxemia can lead to permanent eye damage or blindness. By ensuring that oxygen saturation levels in babies remain under 96%, clinicians believe they can lower the incidence of hyperoxemia. Hyperoxemia can also cause problems for adults, such as increased risk of postoperative infection and tissue damage. In adults, to prevent hyperoxemia, clinicians use pulse oximetry monitoring to guide the administration of oxygen to maintain normal saturation levels.
Limitations of Conventional Pulse Oximetry
Conventional pulse oximetry is subject to technological limitations that reduce its effectiveness and the quality of patient care. In particular, when using conventional pulse oximetry, oxygen saturation measurements can be distorted by motion artifact, or patient movement, and low perfusion, or low arterial blood flow at the measurement site. Motion artifact can cause conventional pulse oximeters to inaccurately measure the arterial blood oxygen saturation level, due mainly to the movement and recognition of venous blood. Venous blood, which is partially depleted of oxygen, may cause falsely low oxygen saturation readings. Low perfusion can also cause conventional pulse oximeters to report inaccurate measurement, or in some cases, no measurement at all. Conventional pulse oximeters

cannot distinguish oxygenated hemoglobin, or the component of red blood cells that carries oxygen, from dyshemoglobins, which are hemoglobin bound with carboxyhemoglobin or methemoglobin and are therefore incapable of carrying oxygen. In addition, conventional pulse oximetry readings can also be impacted by bright light and electrical interference from the presence of electrical surgical equipment. Independent, published research shows that conventional pulse oximeters are subject to operating limitations, including:

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- inaccurate measurements, which can lead to the non-detection of a hypoxemic event or improper and unnecessary treatment;
- false alarms, which occur when the pulse oximeter falsely indicates a drop in the arterial blood oxygen saturation level, and which can lead to improper therapy, the inefficient use of clinical resources as clinicians respond to false alarms, or the non-detection of a true alarm if clinicians become desensitized to frequently occurring false alarms; and
- signal drop-outs, which is the loss of a real-time signal as the monitor attempts to find or distinguish the pulse, and which can lead to the non-detection of hypoxemic events.

Independent research shows that over 70% of the alarms outside the operating room are false when using conventional pulse oximetry. In addition, in the operating room, conventional pulse oximeters can fail to give measurements due to weak physiological signals, or low perfusion, in up to 9% of all cases studied. Manufacturers of conventional pulse oximeters have attempted to address some of these limitations with varying degrees of success. Some competing devices have attempted to minimize the observed effects of motion artifact by repeating the last measurement before motion artifact is detected, until a new, clean signal is detected and a new measurement can be displayed, known as freezing values. Other competing devices increase the averaging time during motion, known as long-averaging, in an attempt to reduce the observed effect of motion on their measurements. Still other competing devices extend the audible alarm notification delay, which reduces the awareness of inaccurate measurements. These competing solutions, commonly referred to as "motion tolerant" or "alarm management" techniques, mask the limitations of conventional pulse oximetry. Several published studies have demonstrated that these also contribute to increased occurrences of undetected true alarms, or events where hypoxemia occurs, but is not detected by the pulse oximeter.

Conventional pulse oximetry technology also has several practical limitations. Because the technology cannot consistently measure oxygen saturation levels of arterial blood in the presence of motion artifact or low perfusion, conventional pulse oximetry is limited in non-critical care settings of the hospital, such as general care areas, where the hospital staff-to-patient ratio is significantly lower and the staff has lower tolerance for false alarms. In order for pulse oximetry to become a standard patient monitor in these settings, these limitations must be overcome.

In addition, two-wavelength pulse oximeters cannot distinguish oxygenated hemoglobin from dyshemoglobin, including the most prevalent forms of carboxyhemoglobin and methemoglobin. As a result of these dyshemoglobins, pulse oximeters will report falsely high oxygen levels when they are present in the blood.

Masimo SET® Pulse Oximetry and rainbow® Pulse Co-Oximetry

Masimo SET® was designed to overcome the primary limitations of conventional pulse oximetry, which involve maintaining accuracy in the presence of motion artifact and weak signal-to-nose situations.

Masimo SET® technologies and products offer multiple clinical and financial benefits, including:

- Fewer false alarms and better true alarm detection.
- Increased detection of critical congenital heart disease through newborn screening.
- Reduced retinopathy of prematurity in very low birth weight neonates.
- Fewer arterial blood gas measurements, faster oxygen weaning time, and lower length of stay in the ICU.
- Lower sensor utilization.
- Earlier detection of patient distress on the general floor, enabling reduced ICU transfers and rapid response activations.

The rainbow® SET platform, which includes rainbow® SET Pulse Co-Oximetry and rainbow® Acoustic Monitoring also allows for monitoring of arterial oxygen saturation even under the presence of carboxyhemoglobin and methemoglobin, known as fractional arterial oxygen saturation (SpfO2)™. In addition, rainbow® has enabled hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), and methemoglobin (SpMet®) monitoring, which is not possible with pulse oximetry alone. The rainbow® SET platform allows for measurement of Pleth Variability Index (PVI®) and Acoustic Respiration Rate (RRa)™ with the clinical benefits noted below.

Market Opportunities for Masimo SET® Pulse Oximetry

Market Share Capture in Existing Areas

The pulse oximetry market consists of pulse oximeter devices, boards, and consumables, including single-patient use and reusable sensors, cables and other pulse oximetry accessories. These products are primarily sold to the hospital and alternative care markets, except for boards, which are sold directly to OEM manufacturers to be incorporated into

their own

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multiparameter products. For 2014, iData estimates the U.S. pulse oximetry market at $869 million and the European market at over $160 million. Based on available estimates for the U.S. and international markets, we estimate that the worldwide pulse oximetry market is nearly $1.5 billion in 2014.

According to a 2014 iData research report, the pulse oximetry market is expected to continue to grow, primarily due to an aging baby boomer population which will contribute to the increasing use of healthcare services. In addition, the market for peripheral pulse oximetry is expected to continue to grow with an industry-wide push for expanded use of low-acuity monitoring in both hospitals and alternate care facilities.

We believe that Masimo SET® pulse oximetry is being chosen by hospitals because it offers fewer false alarms and better true alarm detection, the ability to both obtain measurements when other pulse oximeters cannot and to improve the process of care, and lower sensor utilization. In addition, converting to Masimo SET® typically results in a net cost savings when sensor price, sensor utilization, and process of care benefits are considered.

General Floor Monitoring Expansion

By applying the proven benefits of Masimo SET® from critical care settings to non-critical care settings, as well as settings outside of the hospital, we believe there are opportunities to expand the market for pulse oximetry. The 8th annual HealthGrades Patient Safety in American Hospitals Study looked at patient safety indicators for 40 million U.S. hospitalized patients and concluded that many deaths and permanent disabilities could be avoided if hospitals adopted safe practices and implemented systems that facilitate patient safety. The cost associated with post-operative respiratory failure is estimated to be over $2 billion in the U.S.

A landmark study published in January 2010 by the Journal of Anesthesiology from Dartmouth-Hitchcock Medical Center demonstrated that clinicians using Masimo SET® and Patient SafetyNet™ identified patient distress earlier, which decreased rapid response team activations by 65% and ICU transfers by 48%, and reduced ICU days by 135 days annually. A follow up report in the Anesthesia Patient Safety Foundation journal by Dartmouth-Hitchcock in 2012 reported that since December 2007, no patients have died or had serious brain injuries as a result of respiratory depression from opioids. In addition, Dartmouth-Hitchcock reported that expanding the use of Masimo SET® and Patient SafetyNet™ to all general and thoracic-vascular post-surgical units produced similar results to those seen in the original orthopedic unit. They also reported savings of $58,459 per patient, or $1.5 million annually, for patients who were not transferred to the ICU from the original orthopedic unit.

In August 2012, the Joint Commission issued a sentinel event alert, urging all hospitals to introduce measures to improve safety for patients receiving opioids, including systematic protocols to assess pain and appropriate opioid dosing, as well as continuous monitoring of oxygenation and ventilation. We believe that the increasing recognition by scientific and safety and quality organizations of the need for continuous monitoring will significantly increase the adoption of Masimo SET® and Patient SafetyNet™ on the general floor, also referred to as the medical-surgical floor. The American Hospital Association estimated that there were more than 900,000 staffed beds in all U.S.-registered hospitals in 2012. In 2000, according to a study published in the Journal of Critical Care Medicine, 87% of all hospital beds in the U.S. were located in a non-critical care setting, which suggests a non-critical care market potential of 820,000 beds in the U.S. alone. While some of these non-critical care beds have some form of monitoring capabilities today, we believe that 15% or more of the 820,000 beds in the U.S. alone could become continuous monitoring beds. We believe that the ability of Masimo SET® to dramatically minimize false alarms due to patient motion while maximizing the sensitivity of pulse oximeters to report true alarms will allow hospitals to reliably and continuously monitor their patients in the general floors.

Alternate Care

According to a 2014 iData market research report, the fastest growing portion of the U.S. pulse oximetry equipment market is in the alternate care market. We believe that Masimo SET® technology offers significant advantages in some segments of this market, including home care, post-acute care hospitals, and sleep diagnostics. The proven ability of Masimo SET® to dramatically reduce false alarms and increase true alarm detection enables clinicians to make more reliable diagnoses of those who have pulmonary or cardiac abnormalities, need oxygen therapy, or need Continuous Positive Airway Pressure (CPAP) therapy. We plan to leverage this opportunity and expand our presence in this market.

Consumer

Some people, typically those with life-threatening disorders, receive personal pulse oximeters for use in their home through a prescription provided by their physician and paid for by their insurance provider. Consumers also purchase pulse oximeters on their own without a prescription when they want to monitor their own or someone else's oxygen saturation and pulse rate on a frequent or even occasional basis. The most common people who choose to "self monitor" are those with lung or heart problems, such as chronic obstructive pulmonary disease (COPD), asthma, or heart failure. In addition, an increasing number of people use pulse oximeters for health, wellness, and fitness assessment. Airplane pilots and high altitude hikers use them to

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assess their oxygen saturation for safety, as the concentration of oxygen is reduced at high altitudes. Consumers have typically purchased fingertip pulse oximeters, which are a combined device and sensor powered by batteries. Consumer pulse oximeters are sold through online and retail outlets. While pulse oximeters are used by consumers for a variety of reasons, the FDA restricts their intended use for sports and aviation.

Consumer pulse oximeters, available for $25 to $150, do not offer the same performance as Masimo SET® pulse oximeters, which means that signal drop out and inaccurate measurements occur much more frequently. It is also believed that consumers use pulse oximeter measurement values without any formal training in pulse oximetry or medical conditions to make decisions about whether to seek medical care or even to monitor response to self-administered therapy such as oxygen to treat COPD, inhalants to treat asthma, or diuretics to treat heart failure. We believe that the use of non-Masimo SET® pulse oximeters may result in the inability to assess oxygen saturation or pulse rate, incorrect decisions about whether to seek medical care, and inaccurate assessment about whether a therapy is working or not working. Each of these situations may have negative clinical and financial implications for the institutions that choose to use these consumer pulse oximeters in place of hospital-grade pulse oximeters. Despite the risks of using consumable pulse oximeters in place of hospital-grade pulse oximeters, we believe there is a growing market for more accurate pulse oximetry for use by consumers. We also believe that consumers will increasingly use their smart phones and tablets to obtain, store, and report physiologic measurements. As a result, Masimo entered the consumer pulse oximeter market with iSpO2®, which allows consumers to use their iPhone, iPad or iPod touch to check their own arterial blood oxygen saturation (SpO2), pulse rate, and perfusion index measurements with the same performance as the Masimo SET® technology for medical use. We believe that the consumer pulse oximeter market will continue to grow and, as a result, we intend to continue to introduce additional solutions to address the consumer need for accurate pulse oximeters.

Market Opportunities for Masimo rainbow® SET®

Masimo rainbow® SET® creates additional demand for our pulse oximetry circuit boards, monitors and sensors because customers desire the rainbow® SET noninvasive measurement capabilities that are not available with any other pulse oximeter technology. To date, over twenty-five OEM companies have released rainbow® SET®-equipped products or announced rainbow® integration plans. Companies with released rainbow® SET® products include Dräger, Physio-Control, ZOLL, GS Corpuls, Welch Allyn, Fukuda Denshi, Edwards, Schiller, and Saadat. Companies that have announced rainbow® SET integration, but have not yet released products, include Atom Medical, CareFusion, Hamilton Medical, GE Medical Systems and Philips. In addition, more than twenty-five additional companies are actively working on rainbow® integration but have not yet publicly announced their integration plans.

There are significant opportunities with rainbow® SET® to create new hospital and alternate care markets by enabling the monitoring of additional noninvasive measurements beyond arterial blood oxygen saturation and pulse rate.

Hemoglobin (SpHb®)

Hemoglobin is the part of a red blood cell that carries oxygen to the body, and therefore, a measurement of the hemoglobin parameter is an indicator of the oxygen carrying capacity of the blood. A low hemoglobin status is called anemia, which is generally caused by bleeding or the inability of the body to produce red blood cells. As a chronic disorder, anemia can be treated by iron supplements, diet changes or drugs that increase the production of red blood cells. As an acute disorder, anemia due to bleeding requires stoppage of the bleeding before organ dysfunction or death occurs, or a blood transfusion to sustain organ function and life. Because of its clinical importance, hemoglobin is one of the most commonly ordered lab diagnostic tests in the hospital and physician office. Each year in the U.S., over 400 million invasive hemoglobin tests are performed.

In May 2008, we received clearance from the FDA for Radical-7®, our noninvasive and continuous hemoglobin monitoring technology, and in September 2008, we began shipping, in a limited market release, these monitors and sensors. In March 2009, we fully launched our continuous noninvasive hemoglobin device. In October 2011, In Vivo Adjustment™ received CE marking in the European Union but is not currently available for sale in the U.S. Radical-7® and In Vivo Adjustment™ enable clinicians, for the first time, to adjust the noninvasive measurement of SpHb® to the specific patient and laboratory reference device they use for invasive blood testing. In Vivo Adjustment™ is considered helpful to clinicians because the reference standard used in their hospital may differ from the reference standard used by Masimo for calibration, inducing differences in the noninvasive measurement and the invasive measurement. In

addition, while calibration curves are developed over a large number of patients, variation can occur from the calibration curve for any single patient. A low or falling hemoglobin measurement provides the primary indication for whether a patient receives a blood transfusion. A blood transfusion is the most frequent procedure performed in U.S. hospitals, with one in ten inpatients receiving one or more units of blood. Blood transfusions are highly variable by institution, procedure and physician. Evidence from observational studies shows blood transfusions can increase mortality by 69% and morbidity by 88%, while restrictive transfusion practices have been proven safe in multiple randomized controlled trials. Blood transfusions are costly - between $522 and $1,183 per unit - not accounting for morbidity costs. Many transfusions are unnecessary - a systematic review of 494 studies showed that 59% are “inappropriate”. There is a growing recognition of the need to implement strategies to reduce transfusions by groups such as The Joint Commission and the American Medical Association, with blood transfusions recently targeted as one of the top five procedures that are overused. In

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spite of the strong need to reduce blood transfusions, existing tools for transfusion decision making are limited and may contribute to inappropriate transfusions. For example, estimated blood loss is commonly much higher than actual blood loss, and laboratory hemoglobin values are only available intermittently and are often delayed. We believe that with appropriate tools, processes and application of evidence-based medicine, blood transfusions could be reduced and save the U.S. healthcare system up to $5 billion per year, while significantly improving quality and safety.

At the American Society of Anesthesiologists scientific meeting in October 2010, investigators from Massachusetts General Hospital presented the results of their study in which they evaluated the impact of SpHb® monitoring in a randomized controlled trial in orthopedic surgery patients. Patients in the standard care group had a 4.5% transfusion rate and patients in the SpHb® monitoring group had a 0.6% transfusion rate, an 87% reduction in transfusion frequency with SpHb®. Patients in the standard care group had an average of 0.10 units transfused and patients in the SpHb® monitoring group had an average of 0.01 units transfused, a 90% reduction in average units transfused.

SpHb® monitoring has also been shown in a prospective cohort study in high blood loss surgery (neurosurgery) conducted at Cairo University 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). In this study, the researchers also showed that patients with SpHb® monitoring who needed RBC units received them sooner by 41 minutes on average.

We believe that the potential savings from SpHb® monitoring can be estimated by taking the range of published cost estimates for blood transfusions ($522 to $1,183) multiplied by the expected reduction in blood transfusions per patient. Based on this methodology, in lower blood loss surgery, the 0.09 lower RBC units per patient with SpHb® monitoring is estimated 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 be estimated to reduce RBC costs by $470 to $1,065 per patient monitored. 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.

A low or falling hemoglobin measurement also helps determine whether a patient has internal bleeding that requires further investigation and intervention. The later bleeding is discovered, the greater the patient risk and greater the potential for increased cost of treatment. Significant bleeding occurs in up to 35% of surgical and ICU patients. A low hemoglobin measurement is associated with almost 90% of patients with bleeding. However, traditional laboratory measurements are both delayed and infrequent, and as a result, are late in identifying bleeding.

According to a study published in January 2010 by Anesthesia and Analgesia, undetected bleeding also occurs in otherwise healthy patients, such as mothers who have just delivered babies. Postpartum hemorrhage (PPH) is the leading cause of maternal mortality. The direct pregnancy-related maternal mortality rate in the U.S. is 7 to 10 women per 100,000 live births and 19% of in-hospital maternal deaths are caused by PPH. In the developing world, statistics suggest that 25% of maternal deaths are due to PPH, accounting for more than 140,000 maternal deaths per year, or 1 woman every 4 minutes.

When used with other clinical variables, Masimo SpHb® may help clinicians detect bleeding and help determine treatment and additional test options. While clinical research studies on SpHb® are ongoing, clinicians inherently understand the value of continuous and noninvasive hemoglobin monitoring. A study by the consulting firm Capgemini concluded that the average 500 bed hospital would save $468,000 annually by implementing SpHb® and other rainbow® measurements. Because of the potential clinical and cost advantages of measuring hemoglobin noninvasively and continuously, we believe that a greater number of hospitals will adopt Masimo rainbow® SET technology.

A significant portion of invasive hemoglobin measurements are made outside of hospital settings, in the physician office to aid patient assessment and treatment, and in the blood donation market to qualify potential donors for eligibility to donate blood. While neither spot nor continuous SpHb® measurements are intended to replace invasive hemoglobin tests, we believe that a significant number of the estimated 200,000 U.S. physician offices and donations could be aided by the noninvasive and immediate assessment of hemoglobin.

Beginning in January 2010, the American Medical Association approved a Current Procedural Terminology, or CPT, code and Medicare implemented pricing on the Medicare Clinical Lab Fee Schedule for noninvasive hemoglobin, enabling U.S. hospitals and physician offices that perform testing to recover their costs, in addition to the clinical

benefits they receive from this measurement. In 2014, the Medicare reimbursement for SpHb® is $6.84 per test when testing eligible patients.

Carboxyhemoglobin (SpCO®)

Carbon monoxide is a colorless, odorless and tasteless gas that is undetectable by humans and is often unknowingly inhaled from combustion fumes, or during fires by victims and first responders. Carbon monoxide poisoning is the leading cause of accidental poisoning death in the U.S., responsible for up to 50,000 emergency department visits and 500 unintentional deaths annually. Carbon monoxide poisoning, which involves carbon monoxide binding with hemoglobin cells, thereby preventing them from carrying oxygen, can cause severe neurological damage, permanent heart damage or death in a matter of minutes.

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Quick diagnosis and treatment of carbon monoxide poisoning in the emergency department is critical in saving lives and preventing long-term damage, but the condition is often misdiagnosed because symptoms are similar to the flu. Lack of timely diagnosis can delay treatment or, worse, patients assessed with an incorrect diagnosis can be re-exposed to CO. Therefore, failure to diagnose CO poisoning can have disastrous consequences for patients and potentially other family members of affected households.

Historically, carbon monoxide levels in the blood have been measured using a laboratory CO-Oximeter, which requires a patient or a patient's blood sample to be transported to a hospital with laboratory CO-Oximetry capability. In one region of the country, it is estimated that only one-half of acute care hospitals has laboratory CO-Oximetry capabilities. Additional delays occur if a patient needs hyperbaric oxygen therapy, which often requires transfer to yet another medical center with hyperbaric capability. Outside the hospital, laboratory measurements of carboxyhemoglobin are not considered feasible. Historically, this meant that carbon monoxide levels in the blood could not be assessed in environments in which it would be very useful, such as in the home of a patient or in the medical evaluation of first responders exposed at the scene of a fire. As a result, these people had no way of knowing whether they or others were at risk or had suffered carbon monoxide poisoning.

While SpCO® is not intended to replace invasive carboxyhemoglobin tests, when used with other clinical variables, SpCO® may help clinicians detect carbon monoxide poisoning and help determine treatment and additional test options. According to a 2008 study by Brown University, an emergency department using Masimo rainbow® SET® carbon monoxide monitoring identified 60% more carbon monoxide poisoning cases than the conventional approach, and estimated that as many as 11,000 carbon monoxide poisoning cases per year in the U.S. were being missed with the conventional approach. In a 2012 study, based on three years of U.S. data from the Undersea and Hyperbaric Medicine Society's carbon monoxide poisoning surveillance system (supported by the Centers for Disease Control), researchers analyzed cases of carbon monoxide poisoning treated with hyperbaric oxygen with initial carboxyhemoglobin level measured by either laboratory CO-Oximetry or with SpCO® from a rainbow® Pulse CO-Oximeter®. Patients who were initially measured using rainbow® Pulse CO-Oximetry had a significantly shorter time to measurement of carbon monoxide (1.1 versus 1.7 hours) and a shorter period of time from the end of carbon monoxide exposure to treatment (4.4 versus 5.3 hours). Three hours after exposure, 45% of patients evaluated by using SpCO® and rainbow® Pulse CO-Oximetry had started treatment versus just 25% of patients evaluated by laboratory CO-oximetry that had started treatment. In a 2013 study, in which elevated SpCO® was used to help indicate a need for invasive testing in patients presenting to the emergency department with headaches, 23% of the cases which were ultimately diagnosed with carbon monoxide poisoning were only identified after elevated SpCO® levels had been tested.

Multiple leading emergency first responder associations, including the National Association of Emergency Medical Technicians, the National Association of EMS Educators, the International Association of Fire Fighters and the International Association of Fire Chiefs, now educate their members that noninvasive assessment for carbon monoxide poisoning is appropriate when exposure is suspected or when an individual presents symptoms that could indicate such poisoning. In addition, the National Fire Protection Association, or NFPA, included carbon monoxide screening by rainbow® Pulse CO-Oximetry as an available method as part of a new national healthcare standard for firefighters potentially exposed to carbon monoxide poisoning. NFPA's consensus codes and standards serve as the worldwide authoritative source on fire prevention and public safety.

In addition, the United Kingdom House of Commons All Party Parliamentary Gas Safety Group, in a report published in January 2009, aimed at increasing the awareness of carbon monoxide poisoning among medical professionals, recommended noninvasive carbon monoxide testing for Emergency Department and alternate care market providers as a way to improve the country's rate of detection and diagnosis of carbon monoxide poisoning. For the preparation of this report, the United Kingdom Group used Masimo rainbow® SET® Rad-57® devices for 12 months and reported successful cases with the Rad-57® devices.

Beginning January 2009, the American Medical Association approved a CPT code and Medicare implemented pricing on the Medicare Clinical Lab Fee Schedule for noninvasive carboxyhemoglobin, enabling U.S. hospitals that perform testing to recover their costs, in addition to the clinical benefits they receive. In 2014, the Medicare reimbursement for SpCO® is $6.84 per day when testing eligible patients.

We believe that the greatest opportunity for SpCO® monitoring is in the EMS, fire and hospital emergency department settings. In the U.S. alone, there are 30,000 fire departments / alternate care market locations and 5,000 hospitals that would benefit from noninvasive carbon monoxide testing.

Methemoglobin (SpMet®)

Methemoglobinemia reduces the amount of oxygen bound to hemoglobin for delivery to tissues and forces normal hemoglobin to bind more tightly to oxygen, releasing less oxygen to the tissues. Methemoglobinemia is often unrecognized or diagnosed late, increasing risk to the patient. Commonly prescribed drugs can introduce methemoglobin into the blood and cause methemoglobinemia. Some of the 30 drugs that are known to cause methemoglobinemia are benzocaine, a local anesthetic, which is routinely used in procedures ranging from endoscopy to surgery; inhaled nitric oxide, routinely used in the Neonatal

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Intensive Care Unit; nitroglycerin, used to treat cardiac patients, and dapsone, used to treat infections for immune deficient patients, such as HIV patients.

According to a study published in September 2004 by researchers at Johns Hopkins University, over a 28 month period there were 414 cases, or 19% of all patients reviewed, of acquired methemoglobinemia. In these cases, the methemoglobinemia resulted in one fatality and three near-fatalities. Warnings, cautions and alerts regarding the clinical significance and prevalence of methemoglobinemia have been generated by the FDA, Veterans Administration, Institute for Safe Medication Practices and the National Academy of Clinical Biochemistry. The American Academy of Pediatrics recommends monitoring methemoglobin levels in infants who receive nitric oxide therapy.

While SpMet® is not intended to replace invasive methemoglobin tests, when used with other clinical variables, Masimo SpMet® may help clinicians detect methemoglobinemia and help determine treatment and additional test options. We believe the initial opportunity for methemoglobin monitoring is in outpatient procedure labs in hospitals, such as esophageal echocardiography and gastrointestinal labs where use of topical “caines”, such as benzocaine, is prevalent, monitoring HIV patients who receive dapsone, as well as monitoring neonates who receive inspired nitric oxide in the neonatal ICUs.

Beginning January 2009, the American Medical Association approved a CPT code and Medicare implemented pricing on the Medicare Clinical Lab Fee Schedule for noninvasive methemoglobin, enabling U.S. hospitals that perform testing to recover their costs, in addition to the clinical benefits they receive. In 2014, the Medicare reimbursement for SpMet® is $6.84 per day when testing eligible patients.

Pleth Variability Index (PVI®)

Fluid is administered through intravenous catheters to surgical and intensive care patients as part of a key objective to ensure that vital tissues are getting enough oxygen by increasing the amount of blood flow the heart pumps per minute, also known as cardiac output. However, too much or too little fluid may cause harm to patients. Therefore, the decision of whether to administer fluid is of fundamental importance in critically-ill and surgical patients. Ideally, a clinician would know prior to giving fluid whether the patient would respond favorably to the fluid, which is known as “fluid responsiveness”, and means that after giving fluid, the patient’s cardiac output actually increased. However, traditional methods such as central venous pressure monitoring often fail to predict fluid responsiveness, and newer methods are invasive, complicated and/or costly.

Multiple studies have shown that, when used with other clinical variables, PVI® helps clinicians assess fluid responsiveness. All of the methods that help assess fluid responsiveness, including PVI®, require that the patient be under mechanical ventilation, which means that a machine called a respirator is controlling patient breathing. PVI® has been shown to help clinicians reduce the amount of fluid given to surgical patients, which lowered their patient risk as evidenced by a lowering of a key patient risk marker called lactate level.

In 2012, the United Kingdom's National Health Service included PVI® amongst other technologies in its Intra Operative Fluid Management pack, which serves as a guide for hospitals wishing to implement fluid responsiveness monitoring to improve patient outcomes. In 2013, the French Society for Anesthesia and Intensive Care, or SFAR, added PVI® to its guidelines for optimal hemodynamic management during surgery. PVI® is unique in the technologies that have been shown to help assess fluid responsiveness, as it has no incremental procedural price. This means that if Masimo SET® pulse oximetry with PVI® is available at the bedside for required pulse oximetry monitoring, the same Masimo sensor used for pulse oximetry also provides PVI®.

We believe that the large majority of surgical patients are not being monitored for fluid responsiveness. Because the highest risk patients typically receive invasive monitoring to monitor blood pressure continuously and often to assess fluid responsiveness, we believe the primary opportunity for PVI® monitoring is in patients in which they would not otherwise use invasive monitoring. These include moderate and lower-risk mechanically ventilated adult patients during surgery and in the ICU, septic patients in the emergency department and ICU, and higher-risk patients in which invasive monitoring is not otherwise possible in the setting or indicated in the patient. It is also possible that future studies may reveal an application for PVI in non-mechanically ventilated adult patients in the hospital and other out-of-hospital patient populations.

Respiration Rate (RRa®)

We received FDA clearance for RRa® with rainbow Acoustic Monitoring™ (RAM™) technology in November 2009, announced initial market release of the parameter in December 2009, and announced full market release in June 2010. Respiration rate is defined as the number of breaths per minute, and changes in respiration rate provide an early warning sign of deterioration in patient condition. Current methods to monitor respiration rate include end tidal $CO_2$ monitoring, which requires a special tube to be inserted in the patient's nose and therefore has low patient compliance, and impedance monitoring, which is considered unreliable. Multiple clinical studies have shown that RRa® provides as good or better accuracy to monitoring respiration rate as end tidal $CO_2$ monitoring, and can reliably detect respiratory pause episodes, defined as a cessation of

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breathing for 30 seconds or more. Our noninvasive respiration rate parameter became available in our Masimo rainbow® SET® platforms with the launch of our MX-3 circuit board, in November 2009. These devices with the RRa® software and our acoustic respiration sensor are placed on the patient's neck and connected to the bedside monitor with a separate cable. Should the respiration rate change or stop, an alarm will be displayed on the device and in addition, can be sent to the Patient SafetyNet™ system. Patient SafetyNet™ can then notify the attending clinician or nurse of the condition, directly on the monitor or remotely via a pager.

In May 2013, we received FDA clearance for RAM™ for pediatric patients, enabling noninvasive monitoring of RRa® in a population that is often not tolerant of capnography because it requires a nasal cannula or mask. A 2013 multicenter study conducted at Cincinnati Children's Hospital Medical Center, University of Arizona Medical Center, and Children's Medical Center at Dallas showed that RAM™ had similar accuracy, yet improved better patient tolerance compared to capnography (nasal cannula) in post-surgical pediatric patients.

When used with other clinical variables, RRa® may help clinicians assess respiratory status and help determine treatment options. We believe this noninvasive measurement will become a key and important measurement in the general floor environment, in the post-anesthesia care unit, during procedural sedation such as in the gastrointestinal lab, as well as in the monitoring of non-mechanically ventilated patients during surgery.

Fractional Arterial Oxygen Saturation (SpfO2)™

In October 2012, we debuted SpfO2,™ a new parameter which, for the first time, allows the measurement of fractional arterial oxygen saturation noninvasively. This parameter has received CE mark for the European Union, but it is currently not available for sale in the U.S. Until now, pulse oximeters could only measure and display functional oxygen saturation (SpO2). Therefore, 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. Utilizing more than seven wavelengths of light and breakthrough signal processing, Masimo rainbow® Pulse CO-Oximeters can measure and display fractional arterial oxygen saturation. SpfO2™ allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to functional oxygen saturation. SpfO2™ may also allow earlier interventions and more timely therapeutic decisions.

Halo Index™

In October 2010, we debuted Halo Index,™ which has received CE mark for the European Union, but is not currently available for sale in the U.S. Halo Index™ is a dynamic indicator that facilitates continuous global trending and assessment of multiple physiological measurements to quantify changes in patient status. Currently, clinicians monitor multiple clinical measurements on each patient and respond independently to each of the measurements. Halo Index™ is a single displayed value on our Patient SafetyNet™ remote monitoring and notification system, which facilitates simple and comprehensive assessment within a single index. This may allow clinicians to identify patient risk that was otherwise not apparent and may also help clinicians, in the presence of individual parameter alarms, to assess that a patient's risk remains low, allowing them to focus on other higher risk patients. In the future, subject to FDA clearance, we expect Halo Index™ will also be available as part of our standalone devices and OEM boards. As more clinical evidence is collected on Halo Index,™ its clinical utility in a variety of care areas and patient types will become more specific.

Market Opportunities for Noninvasive Specialty Measurements

SedLine® Brain Function Monitoring

In July 2010, we acquired and began selling the SedLine® brain function monitoring standalone monitor, which measures the brain's electrical activity by detecting EEG signals. In contrast to whole scalp EEG monitoring which is used for diagnostic purposes, this form of EEG monitoring is often referred to as processed EEG monitoring, or brain function monitoring. Brain function monitors display the patient's EEG waveforms, but these are difficult for clinicians to interpret, so the EEG signals are processed and displayed as a single index that gives a continuous, quantitative indication of the patient's depth of anesthesia and sedation. Brain function monitoring is most commonly used during surgery to avoid over- and under-titration of anesthesia and sedation. A market research report from iData estimates that in 2014, the size of the U.S. market for brain function monitoring will be almost $100 million.

We discontinued the standalone SedLine® monitor, and in June 2013, we introduced the SedLine® Module for Masimo Open Connect™ (MOC-9)™ in Root,™ a powerful new patient monitoring and connectivity platform that integrates our breakthrough rainbow® and SET® measurements with multiple additional parameters. SedLine® displays include raw EEG waveforms, the Patient State Index (PSI), and the Digital Spectral Array view.

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We believe SedLine® has advantages over other brain function monitors because it monitors both sides of the brain simultaneously (instead of only one side or by switching from one side to the other) to enable detection of asymmetrical brain activity. We also believe, and studies have shown, that compared to other brain function monitors, SedLine® offers more reliable brain function monitoring during challenging conditions such as the use of electrocautery. Electrocautery is an electronically powered surgical instrument frequently used during surgery to make incisions. In addition, because raw EEG signals are difficult to interpret, a single index may not provide a complete indication of the patient status. The Digital Spectral Array view allows a color-coded indication of the relative power, or strength of signal, at various EEG frequencies over time. The significance of the Digital Spectral Array view is developing, but it is believed that it may provide clinicians with the ability to discriminate more clearly the unique effects of various anesthetic agents and agent combinations, versus the raw EEG signals and index alone.

Capnography and Gas Monitoring

In July 2012, we acquired Phasein™, a developer and manufacturer of ultra-compact mainstream and sidestream capnography and gas monitoring technologies. The acquisition of the Phasein™ technologies complements our existing breakthrough monitoring technologies with the ability to measure multiple expired gases, such as carbon dioxide, ($CO_2$), nitrous oxide, ($N_2O$), an oxygen ($O_2$), and anesthetic agents. In the case of capnography, respiration rate is also calculated from the $CO_2$ waveform. These measurements are possible through either mainstream monitoring, which samples gases from a ventilated patient's breathing circuit, or sidestream monitoring, which samples gases from a breathing circuit in mechanically ventilated patients or through a cannula or mask in spontaneously breathing patients. These capnography and gas measurements are standard-of-care in many hospital environments, such as operating rooms, procedural sedation and intensive care units.

We offer a portfolio of capnography and gas products ranging from external "plug-in-and-measure" capnography and gas analyzers, integrated modules, and handheld capnograph and capnometer devices. In June 2013, we received the CE-Mark for, and launched, the Phasein capnography MOC-9™ module for Root.™ We believe that our Phasein capnography offers advantages over other available capnography technologies because it requires virtually no start-up time. In addition, with the Nomoline™ "No Moisture" sample line, customers can choose from a single patient use Nomoline™ version - designed for extended life in high humidity environments - or the multi-use Nomoline™ adapter for cost-effective, repeated use on different patients with only the cannula itself being replaced with each patient.

Future Measurements

We believe that our core signal processing and sensor technologies are widely applicable and may develop and launch future applications utilizing our proprietary technology platforms. However, we do not plan to communicate the priority, status or timing of future measurements in development until such time as that they have reached feasibility and/or received regulatory clearance.

The Masimo Value Proposition

We have continued to expand beyond our core pulse oximetry, by creating multiple breakthrough noninvasive measurements, offering systems for remote monitoring and notification and now offering the new Root™ monitor. Root™ allows for the continuous monitoring of all these measurements in a platform that is capable of adding future specialty noninvasive measurements from Masimo and other third-parties while, at the same time, also allowing for connectivity to third-party devices such as IV pumps and ventilators.

Masimo SET® Pulse Oximetry

Masimo SET® was designed to overcome the primary limitations of conventional pulse oximetry, which involve maintaining accuracy in the presence of motion artifact and weak signal-to-noise situations. Our Masimo SET® platform, which became available to hospitals in the U.S. in 1998, is the basis of our pulse oximetry products and we believe represented the first significant technological advancement in pulse oximetry since its introduction in the early 1980s. Masimo SET® utilizes five signal processing algorithms, four of which are proprietary, in parallel to deliver high precision sensitivity and specificity in the measurement of arterial blood oxygen saturation levels. Sensitivity is the ability to detect true events and specificity is the ability to reject false alarms. One of our proprietary processing algorithms, Discrete Saturation Transform®, separates the signal from noise in real-time through the use of adaptive filtering and an iterative sampling technique that tests each possible saturation value for validity. Masimo SET® signal processing can therefore identify the venous blood and other noise, isolate them, and extract the arterial signal.

To complement our Masimo SET® platform, we have developed a wide range of proprietary single-patient use (disposable) and multi-patient (reusable) sensors, cables and other accessories designed specifically to work with Masimo SET® software and hardware. Although our technology platforms operate solely with our proprietary sensor lines, our sensors have the capability to

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work with certain competitive pulse oximetry monitors through the use of adapter cables. Our neonatal adhesive sensors have been clinically proven to exhibit greater durability compared to competitive sensors.

Adhesive sensors are single patient-use items, but the FDA allows third-parties to reprocess pulse oximetry sensors. In response to the hospital market's growing needs to implement environmentally friendly, or "green", products and to decrease costs to remain competitive, we developed the rainbow ReSposable® sensor system and began a limited market release in December 2010.The rainbow ReSposable® sensor, part reusable and part disposable, combines the performance and comfort of single-use adhesive sensors with the economic and green advantages of reusable sensors. Based on an internal Masimo study of 974 third-party reprocessed sensors, we estimated that rainbow ReSposable® sensors produce 90% less waste and 41% fewer carbon emissions than disposable sensors, while reprocessed sensors only decrease waste by 34% and actually increase carbon emissions by 43% compared to disposable sensors.

Masimo SET® technologies and products offer multiple clinical and financial benefits, including:

- Fewer false alarms and better true alarm detection. Over 100 independent and objective studies have now proven Masimo SET® accuracy during challenging conditions in adult, pediatric and neonatal patients.
- Increased detection of critical congenital heart disease through newborn screening. Four studies totaling 118,000 patients have shown that adding Masimo SET® to the standard physical exam helps clinicians to increase the detection of this potentially fatal disease before the baby leaves the hospital. The published evidence for Masimo SET® led the American Academy of Pediatrics and the U.S. Department of Health and Human Services to recommend mandatory screening for all newborns using "motion-tolerant pulse oximeters that report functional oxygen saturation and have been validated in low perfusion conditions". In 2012, we received FDA 510(k) clearance for Masimo SET® pulse oximeters and neonatal sensors with labeling for screening newborns for CCHD, marking the first time the FDA cleared specific labeling for the use of pulse oximeters, in conjunction with a physical exam, to screen newborns for CCHD.
- Reduced retinopathy of prematurity in very low birth weight neonates. In a two-phased study of two centers that previously used competing pulse oximetry, both centers simultaneously changed their neonatal oxygen targeting policy, and one of the centers switched to Masimo SET® pulse oximetry. In the first phase of the study, there was no decrease in retinopathy of prematurity at the center using competing pulse oximetry but there was a 58% reduction in significant retinopathy of prematurity and a 40% reduction in the need for laser eye treatment at the center using Masimo SET®. In the second phase of the study, the center still using competing pulse oximetry switched to Masimo SET® and it experienced similar results as the center already using Masimo SET®
- Fewer arterial blood gas measurements, faster oxygen weaning time, and lower length of stay in the ICU. Due to the more accurate measurements from Masimo SET® during challenging conditions and the ability to monitor in low perfusion patients, studies have shown reduced need for arterial blood gas, helped clinicians reduce weaning times from the ventilator, and resulted in a lower length of stay.
- Lower sensor utilization. Masimo SET® sensors provide enhanced durability for greater sensor longevity, and the underlying performance of Masimo SET® in challenging conditions makes it easier to obtain measurements on digits with low perfusion, which reduces the use of multiple sensors on the same patient.

Expansion of Pulse Oximetry into Non-Critical Care Settings

We believe the ability of Masimo SET® products to provide reliable monitoring with fewer false alarms has expanded and will continue to expand the use of pulse oximetry into other settings where patient motion and false alarms have historically prevented its use.

We market our Patient SafetyNet™ remote monitoring and clinician notification system for use with our Masimo SET® pulse oximeters, rainbow® Pulse CO-Oximeters®, and rainbow Acoustic™ Monitors, which allow monitoring of the oxygen saturation, pulse rate, perfusion index, hemoglobin, methemoglobin, and respiration rate of up to 80 patients simultaneously. Patient SafetyNet™ offers a rich user interface with trending, real-time waveform capability at the central station and remote notification via pager or smart phones. Patient SafetyNet™ also features the Adaptive Connectivity Engine,™ which enables two-way, HL7-based connectivity to clinical/hospital information systems. The Adaptive Connectivity Engine™ significantly reduces the time and complexity to integrate and validate custom HL7 implementations, and demonstrates our commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture. Patient SafetyNet™ also allows the display of Halo Index,™ discussed earlier.

We believe that the advanced performance of the Masimo SET® platform coupled with reliable, cost effective, and easy to use wireless remote monitoring will allow hospitals to create continuous surveillance solutions on general care floors where patients are at risk of avoidable adverse events and where direct patient observation by skilled clinicians is cost prohibitive.

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Masimo SET® technologies and products offer multiple clinical and financial benefits in non-critical care settings, including:

- Earlier detection of patient distress on the general floor, enabling reduced ICU Transfers and Rapid Response Activations. Many patients in the general care areas are at risk of dying due to inadequate oxygenation. To mitigate this risk, patients in the general care areas need to be continuously monitored. Our Patient SafetyNet™ systems enable the Masimo SET® and rainbow® SET® platforms to wirelessly and remotely monitor patients in the general care areas of the hospital that are not under the constant supervision of clinicians. A landmark study published in 2010 by Dartmouth-Hitchcock Medical Center demonstrated that clinicians using Masimo SET® and Patient SafetyNet™ identified patient distress earlier, which decreased rapid response team activations, ICU transfers and ICU days. Hospitals and other care centers can reduce their costs by moving less critically ill patients from the ICU to the general care areas where these patients can be continuously and accurately monitored in a more cost-effective manner.

Upgradeable rainbow® SET® Platform

In 2005, we introduced our Masimo rainbow® SET® platform, leveraging our Masimo SET® technology and incorporating licensed rainbow® technology to enable reliable, real-time monitoring of additional measurements beyond arterial blood oxygen saturation and pulse rate. The Masimo rainbow® SET® platform has the unique ability to measure and distinguish oxygenated hemoglobins from certain dyshemoglobins, hemoglobins incapable of transporting oxygen, and allows for the rapid, noninvasive monitoring of hemoglobin, carboxyhemoglobin, methemoglobin, which together we refer to as Pulse CO-Oximetry. Along with the release of our rainbow® Pulse CO-Oximetry products, we have developed multi-wavelength sensors that have the ability to monitor multiple measurements with a single sensor. We believe that the use of Masimo rainbow® Pulse CO-Oximetry products will become widely adopted for the noninvasive monitoring of these measurements. We believe the addition of RRa® with rainbow Acoustic® Monitoring technology for noninvasive and continuous monitoring will strengthen the clinical demand for the rainbow® platform, especially in the growing general floor market.

Products with our MX circuit board contain our Masimo SET® pulse oximetry technology as well as circuitry to support rainbow® measurements. At the time of purchase, or at any time in the future, our customers and our OEMs' customers will have the option of purchasing a software measurement, which will allow the customer to expand their patient monitoring systems to monitor additional measurements with a cost-effective solution.

Our rainbow® SET® technologies and products offer multiple clinical and financial benefits, including:

Hemoglobin (SpHb®)

- Helping clinicians reduce the risk and cost associated with red blood cell transfusions
- Helping clinicians identify undetected bleeding earlier in surgical, intensive care, trauma, and obstetric patients
- Helping clinicians identify unexpected low hemoglobin for further testing
- In developing health care systems around the world, laboratory testing is often unavailable. In these countries, SpHb® can provide previously unavailable information to help assess patients for low hemoglobin levels and monitor the effects of low hemoglobin treatment.

Carboxyhemoglobin (SpCO®)

- Helping clinicians identify unsuspected and deadly carbon monoxide poisoning earlier and more often, reducing incorrect diagnoses

Methemoglobin (SpMet®)

- Helping clinicians identify dangerous methemoglobinemia earlier and more often, reducing incorrect diagnoses

Pleth Variability Index (PVI®)

- Helping clinicians assess fluid responsiveness and improve fluid management in surgical and intensive care patients who are mechanically ventilated

Respiration Rate (RRa®)

- Helping clinicians identify respiratory depression and respiratory distress earlier and more often to potentially enable earlier interventions

Fractional Arterial Oxygen Saturation ($SpfO_2$)™

- Allowing more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to functional oxygen saturation (SpO2)

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Halo Index™

- Potentially helping clinicians identify patient distress earlier, more effectively, more easily, and more efficiently
- Potentially identifying patients at low risk, even in the presence of individual physiologic alarms

Noninvasive Specialty Measurements

Masimo's new noninvasive specialty measurements provide differentiated and cost-effective solutions in existing monitoring modalities and offer multiple clinical and financial benefits, including:

SedLine® Brain Function Monitoring

- Simultaneous monitoring of both sides of the brain to identify asymmetry
- Performance in challenging conditions such as the use of electrocautery
- Digital spectral array for enhanced ability to assess depth of anesthesia with multiple agents and agent combinations
- Cost-effective consumables

Capnography and Gas Monitoring

- Allowing continuous monitoring of ventilation in mechanically ventilated patients, monitoring ventilation during cardiopulmonary resuscitation, and monitoring gas concentrations to help titrate anesthesia
- Quick start up time to avoid waiting for valid measurements, especially important during emergency resuscitation efforts
- Cost-effective consumables through Nomoline™ for both single and multi-patient use

Third-party Measurement Expansion

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