

#### T<mark>hrough</mark> Movement

1



#### Letter from the Chairman & CEO

# We Are Always in Motion

As we mark the 10-year anniversary of our Initial Public Offering, I am happy to report that, as a public company, we have done what few companies ever do-build a 10-year plan and not let quarterly earnings reports impede the sustainable and meaningful progress that is only possible with a long-term view, strategy, and execution.

We thank the patient shareholders who have stuck by us, who are now being rewarded with sustainable revenue and earnings growth fueled by revolutionary noninvasive monitoring technologies that are saving peoples' lives, sold and serviced by a professional and dedicated clinical sales team in 21 countries directly.

#### MISSION STATEMENT

Improve patient outcomes and reduce the cost of care by taking noninvasive monitoring to new sites and applications."

#### GUIDING PRINCIPLES

- 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





111.5111

#### EARNINGS PER SHARE

The first phase of our 10-year plan was to invest in R&D and key functional areas, allowing the company to gain a worldwide presence sufficient to facilitate long-term growth. Phase two leveraged these investments with a growing base of breakthrough technologies and products, resulting not only in solid growth, but due to value engineering that started in the last trimester, bottom-line financial growth. While we didn't think investors would have to wait this long, a few unexpected events, including a dramatic hospital census drop and foreign exchange headwinds in 2013 and 2014, delayed the emergence of such results even though we continued to grow product revenue at multiple times the market's rate. Long-term planning is necessary to push forward the life-saving innovations that others deemed impossible

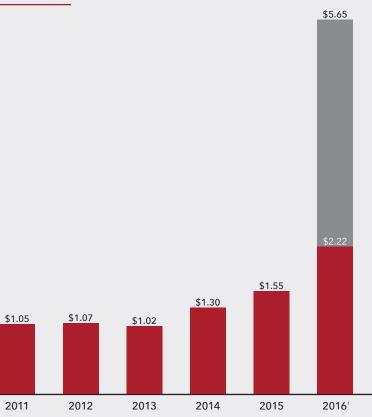
while building a sustainable growing business. At 28 years old, Masimo remains as idealistic and fascinated by new possibilities as ever. While we hope to continue to deliver product revenue growth at multiple times the market's rate, we know that shareholders will be rewarded reliably when management plans and executes a longterm strategy.

Our bodies and our world depend and thrive on movement. Masimo thrived by making products that dealt with movement. Progress is only possible through collective movement. And, like ripples on a pond, our success moves us away from the safety of where we were, in an outward direction, seeking answers, seeking solutions to patient safety problems. So, that collectively we can solve broader problems facing us.

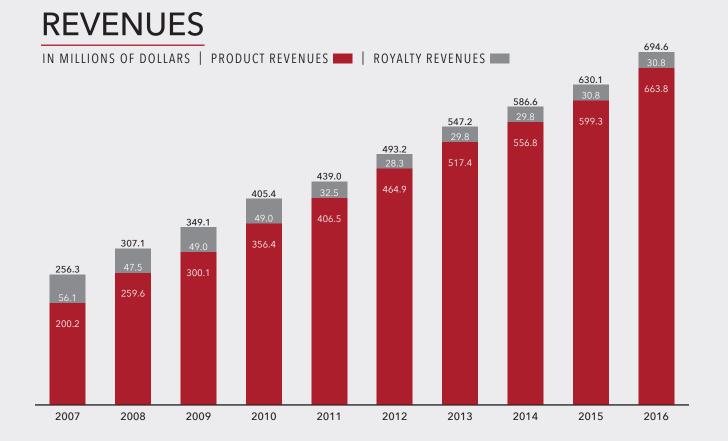


This Annual Report is dedicated to all of those who move the world forward and who help preserve our hope by continuing to improve lives.



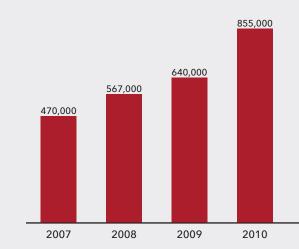


<sup>1</sup> Included in the FY2016 Historical GAAP Earning Per Share was \$3.43 per diluted share related to a \$300.0 million settlement agreement, of which \$270.0 million was recognized as a gain on the Statement of Operations at December 31, 2016.



#### **INSTALLED BASE**

ESTIMATED UNITS EXCLUDES HANDHELDS



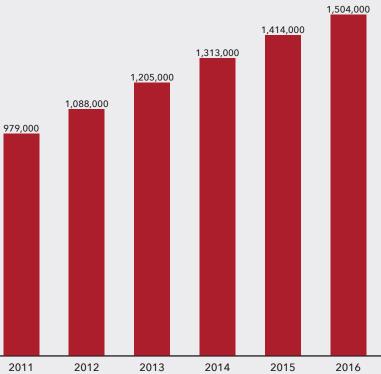
This Annual Report is dedicated to all of those who move the world forward, who help preserve our hope by continuing to improve lives: doctors, nurses, respiratory therapists, engineers, and first responders-among countless others. Every day, all over the world, medical professionals and other amazing individuals are, through their thoughtful movement, saving lives, healing the

sick, rescuing accident victims, and engineering the amazing, life-saving, life-enhancing technologies that help so many in distress. Their relentless movement helps to keep us all in motion that much longer. At Masimo, we are proud to play a part in their heroic endeavors, to develop and provide the tools that help save countless lives and the eyesight of newborns. From solving the "unsolvable" problem of motion artifact in pulse oximetry-to measure through the motion that is the hallmark of life-to inventing the noninvasive measurements of total hemoglobin, carboxyhemoglobin, methemoglobin, ORi<sup>™</sup> and

PVi®, and other technologies such as Root®, we help those who help us all stay in motion.

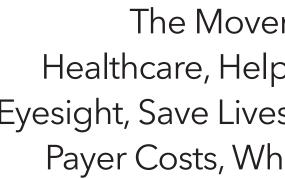
In this Annual Report, we not only reflect on our financial performance but on the technologies and products we have created to help our heroes sustain and accelerate their miracles of healing. We thank them for the opportunity to be part of our everimproving healthcare system. We also thank our innovative engineers, dedicated sales and clinical teams, and the manufacturing, finance, quality, and regulatory affairs teams who keep our innovation engine moving. Finally, we thank our shareholders,

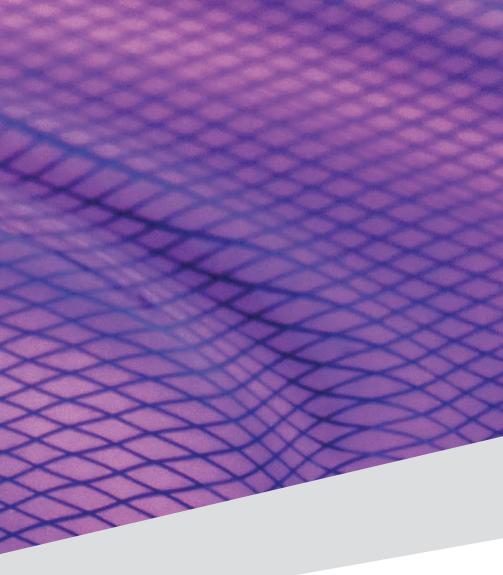
6



who have trusted us to advance the business of patient care with a long-term view. I hope we can continue rewarding our employees, customers, and shareholders through our long view on humanity and the advancement of medicine.

Joe Kiani Chairman & CEO





# Solving Motion Artifact with SET<sup>®</sup>:

The Movement that Rippled Through Healthcare, Helping Clinicians Save Babies' Eyesight, Save Lives, and Reduce Hospital and Payer Costs, While Challenging an Industry

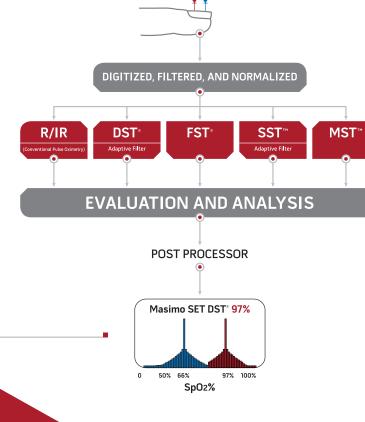
# Solving the "Unsolvable" with SET

Our first breakthrough, **Signal Extraction Technology**<sup>\*</sup>, was invented to overcome the limitations of conventional pulse oximetry, which is unreliable when patients are moving or poorly perfused.

Pulse oximetry is an important patient monitoring tool. However, conventional pulse oximeters made it difficult to determine the true arterial blood signal during patient motion because moving venous blood appears to pulsate like arterial blood.<sup>1</sup>

Masimo SET<sup>®</sup> works by recognizing that both arterial and venous blood can move, using parallel signal processing engines–DST<sup>®</sup>, FST<sup>®</sup>, SST<sup>™</sup>, and MST<sup>™</sup>–to separate the true arterial signal from sources of noise, including the venous signal.<sup>2</sup> By measuring *through* patient motion and low perfusion, **Masimo SET**<sup>\*</sup> has helped pulse oximetry become a clinically reliable tool in operating rooms, intensive care units, general wards, and other healthcare settings all over the world.<sup>3</sup>

Conventional pulse oximetry uses the standard red over infrared algorithm to provide SpO2, while Masimo SET\* includes four additional algorithms, running in parallel. These algorithms distinguish between arterial signal and venous noise during motion and low perfusion by identifying and isolating the non-arterial and venous noise SpO2 (left peak, shown in blue) from the true arterial SpO2 components (right peak, shown in red) in the signal.



<sup>1</sup> Mardirossian G et al. *Anesth Prog.* 1992;39(6):194-196. <sup>2</sup> Szocik J et al. *Published in Miller's Anesthesia, 8<sup>th</sup> edn*. Phila, PA: Elsevier; 1315-1344 (1334). <sup>3</sup> Ortega R et al. *N Engl J Med*. 2011; 364 16:e33-36.



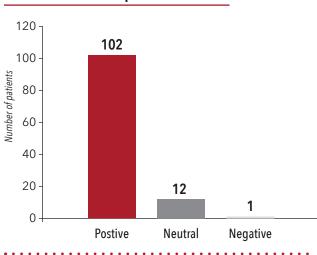
# Advancing **Patient Safety**

Before Masimo SET<sup>®</sup>, approximately 70%-90% of alarms that occurred outside the OR were false alarms.<sup>1,2,3</sup> In a study of twenty-thousand surgical patients, not only did pulse oximeters fail to monitor 7% of the time on ASA IV patients in the OR, but the study showed no evidence to indicate a reduction in the overall rate of postoperative complications using pulse oximetry. After the introduction of Masimo SET<sup>®</sup>, false alarms dropped by over 90% and true alarm detection increased to 97% during motion and low perfusion.<sup>4</sup> Significantly, outcome studies have shown that Masimo SET<sup>®</sup>, in conjunction with clinician assessment, helps clinicians reduce severe retinopathy of prematurity in neonates<sup>5</sup> and improve CCHD screening in newborns.<sup>6</sup>

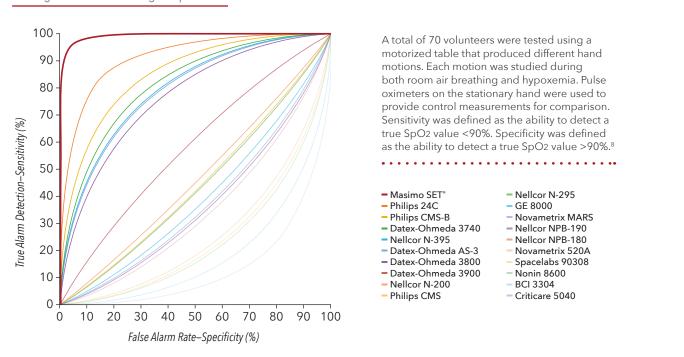
#### Validated by Independent and **Objective Research**

Over 100 independent and objective studies<sup>7</sup> have shown that Masimo SET<sup>®</sup> outperforms other pulse oximetry technologies, providing clinicians with the sensitivity and specificity required to make critical patient care decisions.

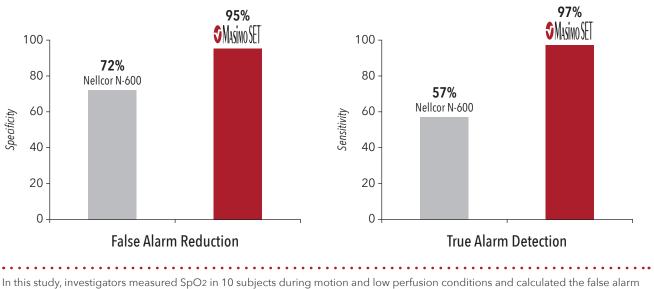
Masimo SET<sup>®</sup>: Comparative Studies







**Performance During Motion and Low Perfusion** 



rate during 120 full oxygenation events (specificity) and true alarm rate during 40 de-oxygenated events (sensitivity). Results shown are calculated by combining sensitivity and specificity outcomes of machine-generated and volunteer-generated motion.<sup>9</sup>

1 Lawless ST et al. Crit Care Med 1994;22:981-5. 2 Wiklund L et al. J Clin Anesth 1994;67:182-8. 3 Dumas C et al. Anesth Analg 1996;83:269-72. 4 Shah N et al. J Clin Anesth 2012 Aug;24(5):385-91. Published clinical studies can be found on our website at: http://www.masimo.com/cpub/clinical-evidence.htm <sup>5</sup> Castillo A et al. Acta Paediatr. 2011 Feb;100(2):188-92. <sup>6</sup> de-Wahl Granelli A et al. BMJ. 2009;338. <sup>7</sup> Published clinical studies on pulse oximetry and the benefits of Masimo SET<sup>\*</sup> can be found on our website at n/home/clinical-evidence/clinical-evidence/ \* Barker SJ. Anesth Analg. 2002;95(4):967-72. \* Shah N et al. J Clin Anesth. 2012;24(5):385-91.



# Industry-leading Pulse Oximetry

Clinicians all around the world count on Masimo SET<sup>®</sup> to help them care for patients. With significantly fewer false alarms, clinicians can focus on the patient, not the monitor.

With more accurate measurements, clinicians can more tightly control oxygenation levels.<sup>1</sup> And with timely detection of true events, clinicians can intervene earlier.





Over 100 multi-parameter monitors from 50 leading brands have integrated Masimo SET<sup>®</sup> pulse oximetry. In addition, more and more of our partners are enhancing their monitoring solutions by integrating rainbow<sup>®</sup> noninvasive blood constituent monitoring technology.



Dräger<sup>®</sup> Infinity M540 with rainbow SET™ technology



Physio-Control® LIFEPAK 15 with rainbow SET<sup>™</sup> technology

<sup>1</sup>Durbin et al. Crit Care Med. 2002;30(8):1735-1740.

#### The Pulse Oximetry Technology of Choice



GE<sup>®</sup> CARESCAPE VC150 with rainbow SET<sup>™</sup> technology



Philips<sup>®</sup> MX800 with rainbow SET<sup>™</sup> technology



Welch Allyn<sup>®</sup> Connex 6300 Series with rainbow SET™ technology



ZOLL<sup>®</sup> X Series with rainbow SET<sup>™</sup> technology

# Advancing Newborn Care

Masimo offers a unique portfolio of core technologies and specialty sensors that enable clinicians to care for newborns requiring resuscitation, cyanotic infants requiring accurate saturation measurements, and premature infants at risk for retinopathy of prematurity.

#### **Newborn Resuscitation**

Every second matters during newborn resuscitation. The Masimo Newborn Sensor together with Masimo **SET**<sup>®</sup> technology ensures the fastest response time with maximum sensitivity-allowing clinicians to focus on the patient, not the device.

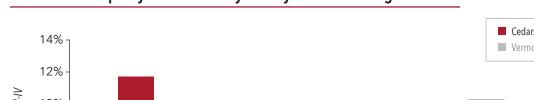
#### **Better Care for Cyanotic Patients**

In a clinical study on cyanotic infants, Masimo SET<sup>®</sup> pulse oximetry with the Blue® sensor has been shown to enable accurate maintenance of targeted oxygen saturation levels.<sup>1</sup> Researchers have demonstrated improved accuracy at saturations

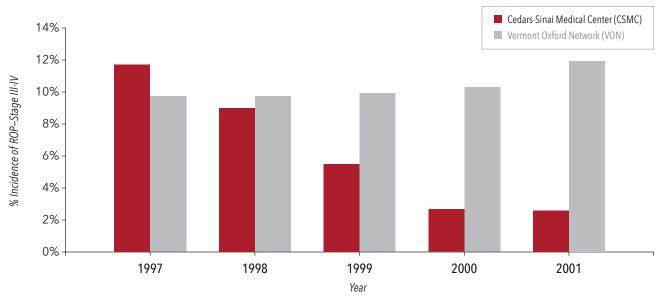
75-85% in cyanotic infants and children with Blue sensor versus the Nellcor and standard Masimo sensors.<sup>3</sup> Additionally, researchers have found that, following cardiac surgery, th combination of Masimo SET<sup>®</sup> and the Blue se provided more accurate and reliable informa compared to old generation pulse oximeters.

#### Retinopathy of Prematurity

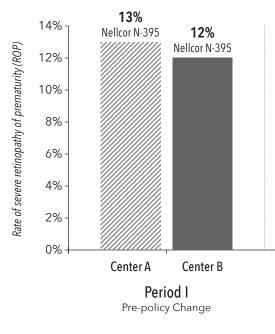
Premature infants requiring neonatal intensive care need enough oxygen to preserve vital or function. However, too much oxygen can caus severe eye damage from retinopathy of prem (ROP). With changes in clinical practice and the







#### Severe Retinopathy of Prematurity Rate

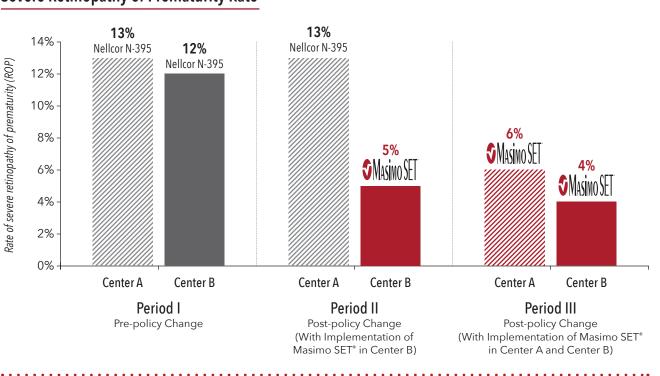


In period one, the baseline rate for severe ROP in two centers, both using Nellcor pulse oximetry, was established. In period two, new practice guidelines were implemented at both centers, however, only Center B switched to Masimo SET\*, which led to a significant reduction in ROP (from 12% to 5%). In period three, Center A also switched to Masimo SET\* and experienced a reduction in ROP from period two (from 13% to 6%).<sup>5</sup>

Incidence in ROP stages 3 to 4 for infants with birthweight of 500 to 1500 g at CSMC and VON for the years 1997 to 2001.

1 Cox PN et al. Anesthesiology. 2007;107:A1540. (abstract). 2 Sola et al. Pediatrics. 2003 Feb;111(2):339-45. 3 Harris BU et al. Pediatr Care Med. 2016 Apr;17(4):315-20. 4 son M et al. Anesthesiology 2007; 107: A204. <sup>s</sup>Castillo A et al. Acta Paediatr. 2011 Feb;100(2):188-92. <sup>s</sup>Sola et al. Pediatrics. 2003 Feb;111(2):339-45

the	addition of <b>Masimo SET</b> <sup>®</sup> pulse oximetry, clinicians have shown a reduction in ROP. <sup>5</sup>
e ensor	In another study, following the implementation of <b>Masimo SET</b> <sup>*</sup> with a new protocol in a single tertiary
ition	neonatal center at Cedars-Sinai Medical Center (CSMC), the incidence in severe ROP decreased
	over a five year period from 12.5% to 2.5% in very low birth weight infants. The changes are compared
е	to the data reported by the Vermont Oxford
rgan	Network (VON), a nonprofit voluntary collaboration
se	of >400 NICUs that maintains a database including
naturity he	>25,000 infants. <sup>6</sup>



# Improving Screening for **Critical Congenital Heart Disease**

In the United States, CCHD screening with motion-tolerant pulse oximetry has been added to the Department of Health and Human Services' Recommended Uniform Screening Panel and is further advocated by several healthcare authorities. With the proven measure through motion low perfusion performance of Masimo SET<sup>®</sup> as an effective CCHD screening tool, we look forward to helping more clinicians care for newborns as awareness in CCHD screening spreads to other parts of the world.

According to the National Institutes of Health (NIH), "Critical congenital heart disease (CCHD) is a term that refers to a group of serious heart defects that are present from birth. These abnormalities result from problems with the formation of one or more parts of the heart during the early stages of embryonic development. CCHD prevents the

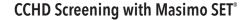
heart from pumping blood effectively or reduces the amount of oxygen in the blood. As a result, organs and tissues throughout the body do not receive enough oxygen, which can lead to organ damage and life-threatening complications."<sup>2</sup> While congenital heart disease affects approximately eight per 1,000 newborns, critical congenital heart

disease has an incidence of approximately 2.5 to 3 per 1,000 live births.<sup>3</sup> CCHD requires intervention soon after birth to prevent significant morbidity or mortality. Some babies with CCHD can appear healthy at first and may be discharged from the hospital before their heart defect is detected, which may lead to cardiogenic shock or death. Later detection of CCHD in infants also increases the risk of brain damage.<sup>4</sup>

#### Screening for CCHD with Masimo SET<sup>®</sup>

In one of the earlier CCHD detection studies with pulse oximetry, Masimo SET<sup>®</sup> and a conventional pulse oximeter were used, but due to a lack of measurements and a high false positive rate the conventional pulse oximeter was abandoned by researchers mid-study.

In a study of 39,821 infants, researchers observed an increase in CCHD detection from 63% with



N = 39,821 BABIES	Physical Exam Alone	Physical Exam + Masimo SET <sup>®</sup> Pulse Oximetry Screening <sup>1</sup>
Sensitivity for CCHD Detection	63%	83%
Specificity for CCHD Detection	98%	99.8%

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%.1

de-Wahl Granelli et al. BMJ. 2009 Jan 8;338:a3037. 2 NIH US National Library of Medicine, Genetics Home Reference (https://ghr.nlm.nih.gov/c heart-disease) <sup>3</sup> Hoffman JL et al. J Am Coll Cardiol. 2002;39(12):1890-1900 <sup>4</sup> 2011 Legislative Report; State of Maryland, Department of Health and Mental Hygiene, State Advisory Council on Hereditary and Congenital Disorders. Recommendations on Implementation of Screening for Critical Congenital Heart Disease in Newborns. Page 7. <sup>5</sup> Granelli et al. Acta Paediatrica 2005;94:1590-1596. <sup>6</sup> Zhao QM et al. Lancet. 2014 Aug 30;384(9945):747-54. <sup>7</sup> Ewer AK et al. Lancet. 2011 Aug 27;378(9793):785-94. <sup>8</sup> Kemper et al. Pediatrics, 2011, October, e4. 9 de-Wahl Granelli et al. Acta Paediatr. 2007;96(2):1455-1459. \* Radical-7 with Eve is not available in the U.S



physical exam alone to 83% with physical exam and the utilization of Masimo SET<sup>®</sup> pulse oximetry.<sup>1</sup>

Similarly, in the largest CCHD screening study to date-including over 122,738 subjects-the combined use of Masimo SET<sup>®</sup> pulse oximetry and clinical assessment increased screening sensitivity from 77% to 93%.6

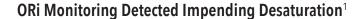
Masimo SET<sup>®</sup> pulse oximeters and sensors were exclusively used in the two studies<sup>1,6,7</sup> (59,876 subjects) that were the basis for the CCHD workgroup recommendation for CCHD screening protocols.<sup>8</sup> Furthermore, investigators observed that the incorporation of cut-off values for perfusion index with routine pulse oximetry may further increase sensitivity in CCHD screening in infants with pathologically low (<0.70) perfusion.<sup>9</sup>

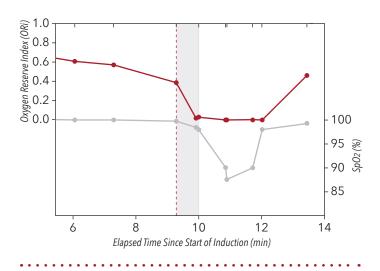
# **Always Moving** Noninvasive Blood Oxygen **Monitoring Forward**

**Extending Noninvasive Blood Oxygen** Monitoring to Moderate Hyperoxia with ORi<sup>™</sup> With the creation of rainbow<sup>®</sup> Pulse CO-Oximetry in 2005, we were able to leverage more light wavelengths to noninvasively measure additional blood constituents that previously required invasive techniques. For example, prior to the introduction of Masimo Oxygen Reserve Index<sup>™</sup> (ORi), there was not a noninvasive method of assessing moderate hyperoxia. When a patient is on supplemental oxygen, SpO2 provides a late indication of oxygenation level. Between invasive samplings, changes in the partial pressure of oxygen (PaO<sub>2</sub>) can often go unnoticed, leading to unexpected hypoxia or unintended hyperoxia. By providing insight into a patient's oxygen status in the moderate hyperoxic range of 100 to 200 mmHq, ORi represents a fundamental step forward in the visibility of a physiologic trait that was until now difficult to measure.

#### Masimo SpfO2<sup>™</sup> Fractional Measurement with rainbow<sup>®</sup>

Masimo SpfO2\* is the first truly fractional noninvasive oxygen saturation measurement, and is made possible, like ORi, through the use of rainbow<sup>®</sup> technology. SpfO2 allows truer arterial oxygenation assessment in patients with





Median alarm occurs 31.5 sec before desaturation.

elevated dyshemoglobins-common throughout the hospital and pre-hospital settings-as compared to functional oxygen saturation (SpO2). As a result, SpfO2 may enable earlier interventions and more timely therapeutic decisions.

#### **Enhancing Comfort and Simplifying** Use with RD SET<sup>™</sup> Sensors

As part of our commitment to improving the core Masimo SET<sup>®</sup> pulse oximetry experience, in 2016 we introduced the RD SET<sup>™</sup> sensor system. In addition to other benefits, RD SET<sup>™</sup> sensors feature small, thin optical components that lie comfortably on and better conform to the patient's hand or foot. Significantly, RD SET sensors have higher accuracy than previous-generation sensors. RD rainbow SET and RD rainbow Lite SET<sup>™</sup> sensors will make similar benefits available to rainbow<sup>®</sup> Pulse CO-Oximetry monitoring.

#### Enhancing Patient Safety with X-Cal<sup>™</sup>

Imitation cables and sensors using components and manufacturing processes that do not meet Masimo quality and performance specificationsspecifications required to provide consistently high SET<sup>®</sup> and rainbow<sup>®</sup> performance during

challenging monitoring conditions-can lead to measurement inaccuracy and patient safety risks. To overcome this, we developed X-Cal technology, which enhances clinical performance, patient safety, and clinician efficiency by allowing the sensor, patient cable, and Masimo technology board, installed in a host multi-parameter patient monitor or Masimo pulse oximeter, to operate as an integrated system. X-Cal alerts users when an imitation or defective cable or sensor, or a sensor or cable that has been used beyond its expected life, needs to be replaced.

#### TFA-1<sup>™</sup> Disposable Forehead Sensor

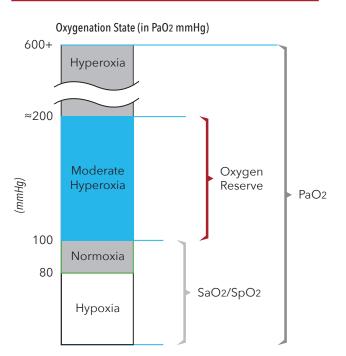
Masimo now offers the TFA-1 transflectance forehead adhesive sensor as an alternative to traditional digit sensors. The forehead provides rapid detection of saturation changes compared to digit sites during low perfusion and also offers easy access during surgery, resuscitation, and in patients with finger deformities or inaccessible digits.

# ORi<sup>™</sup>: First Noninvasive and Continuous Parameter to Provide Early Indication of Impending Hypoxia

Pulse oximetry provides noninvasive and continuous visibility to arterial blood oxygenation in hypoxia (less than normal oxygenation) and normoxia (normal oxygenation). During supplemental oxygen administration, clinicians often use the partial pressure of oxygen (PaO2), which is invasive and intermittent, to monitor levels of hyperoxia (higher than normal oxygenation). Between invasive samplings, changes in PaO2 can go unnoticed and lead to unexpected hypoxia or unintended hyperoxia.

Oxygen Reserve Index (ORi)\* is a relative indicator of the partial pressure of oxygen in arterial blood (PaO2) in the range of 100 to 200 mmHg. ORi is intended to supplement, not replace, SpO2 monitoring and PaO2 measurements. As an "index" parameter with a unit-less scale between 0.00 and 1.00, ORi can be trended and has optional alarms to notify clinicians of changes in a patient's oxygen reserve.

#### PaO2 Range and Available Monitoring Methods





In patients receiving supplemental oxygen, such as those in surgery, under conscious sedation, or in the intensive care unit, ORi may provide an advance warning of an impending hypoxic event. In addition, ORi may provide an indication of a hyperoxic state. In this way, ORi may enable proactive interventions during preoxygenation before intubating and extubating to avoid hypoxia and unintended hyperoxia.

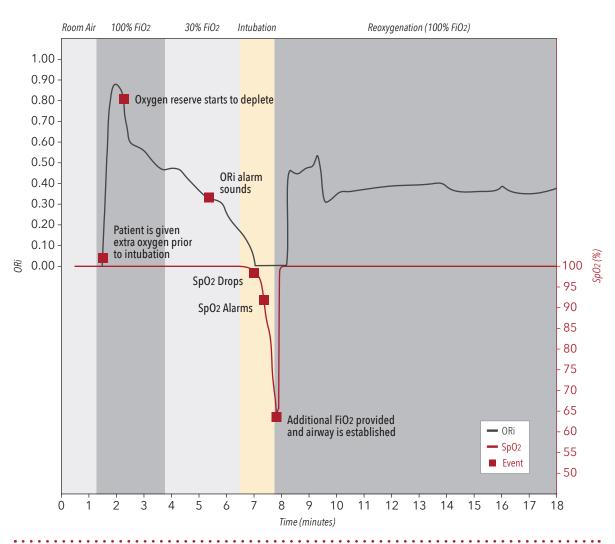
# **Clinical Evidence for** the Utility of Masimo ORi

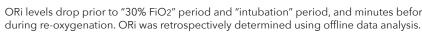
In a prospective study published in Anesthesiology, Dr. Peter Szmuk and colleagues concluded that ORi could provide clinicians with a median of 31.5 seconds advanced warning of impending desaturation in pediatric patients with induced apnea after pre-oxygenation.

The investigators enrolled 33 patients in this study. Eight of these resumed spontaneous ventilation

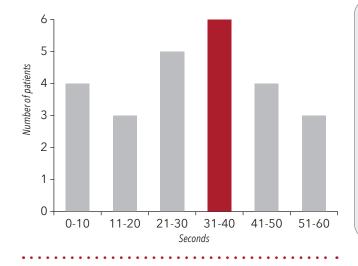
during the study period, leaving 25 apneic patients to evaluate, with an average age of 7.6 years. Data were recorded continuously with a Masimo Radical-7 Pulse CO-Oximeter®. ORi was retrospectively calculated and was not visible to investigators. The amount of early warning time, per patient, observed by the researchers is summarized in the following histogram.

#### **ORi Pediatric Surgical Case Study**





#### **Early Warning Time Distribution (Seconds)**



"In this pilot study, we found that during prolonged apnea in healthy anesthetized children, the ORi detected impending desaturation in median of 31.5 seconds (IQR, 19 to 34.3 seconds) before noticeable changes in SpO2 occurred. Knowing even roughly how much time remains before the rapid desaturation phase begins seems likely to guide proper decisions."

Szmuk et al.

24

ORi levels drop prior to "30% FiO2" period and "intubation" period, and minutes before the SpO2 drop. ORi then rises

### **RD Sensor System**

The RD Sensor System was designed to enhance sensor comfort. The family includes RD SET, RD rainbow Lite SET, and RD rainbow SET.

> Orientation of optical components positions sensor cable comfortably on top of hand

> > RD rainbow SET Solib Soller ORi



RD rainbow SET SpHb SpMet

#### Small, Thin Optical Components

- Lightweight, flat sensor with smooth edges lies comfortably on a patient's hand or foot
- Low profile internal components allow the sensor to better conform to the shape of a finger and were designed to put less pressure on the measurement site



**RD SET** • SpO2, PR, Pi, PVi<sup>®</sup>

• SpO2, PR, Pi, PVi, ORi, RPVi™





#### RD rainbow Lite SET

#### **RD** rainbow SET

• SpO2, PR, Pi, PVi, ORi, RPVi, SpHb<sup>®</sup>, SpCO<sup>®</sup>, SpMet<sup>®</sup>, SpfO2, SpOC<sup>™</sup>

# **RD SET**<sup>™</sup> Sensors

RD SET sensors provide higher accuracy than previous-generation sensors, simplify use, and reduce waste.

#### **Designed to Improve Accuracy**

RD SET sensors have higher accuracy than previous generation sensors. The adjacent table shows bias, precision, and A<sub>RMS</sub> (Accuracy Root Mean Square) values measured using the RD SET Adt sensor with Masimo SET<sup>®</sup> Oximetry technology in a Masimo study of healthy volunteers.<sup>1</sup>

Bias	Precision	ARMS <sup>2</sup>
0.47	1.36	1.44

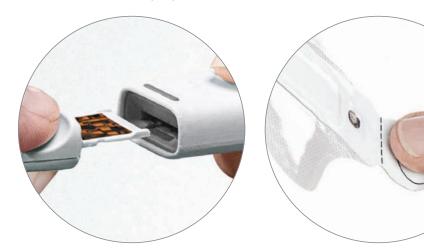
#### Designed to Help Hospitals Meet Green Initiatives 🗘

- Lightweight sensor results in less material waste
- traditional cable-based sensors\*





- Sensor labels and graphics immediately communicate emitter and detector locations and guide proper application for optimal performance and easier removal and re-application
- Quick and intuitive sensor-to-cable connection with tactile and audible feedback ensures proper connection



Masimo SET technology has been validated for no motion accuracy in a human blood study on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory co-oximeter.<sup>2</sup> ARMs accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study. Waste calculated by comparing the sensor and packaging weight of traditional cable based sensors versus Adult RD adhesive sensors. Internal data on file.

• Sleek, recyclable packaging reduces storage space by half

• Up to 84% less waste with Adult RD SET sensors versus



# X-Cal<sup>™</sup> for Enhanced Patient Safety

#### A Systems Approach to Safety

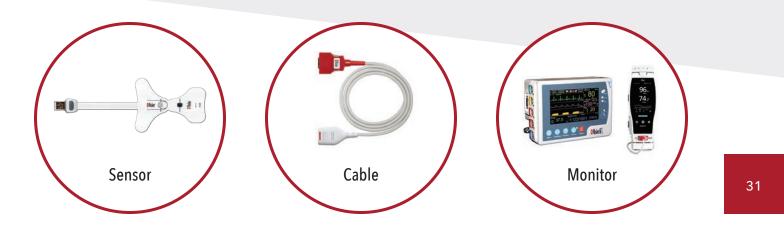
X-Cal technology is designed to enhance clinical performance, patient safety, and clinician efficiency by allowing the sensor, patient cable, and Masimo technology board, installed in a host multi-parameter patient monitor or Masimo pulse oximeter, to operate as an integrated system.

When all three components are genuine and within their useful life, the system works as intended. However, when any one component is compromised, erroneous measurements may occur which can impact patient safety.

#### How X-Cal Works

This system design helps prevent the measurement inaccuracy and patient safety risks that may be caused by violations of the above principles, such as imitation cables and sensors using components and manufacturing processes that do not meet Masimo quality and performance specifications-specifications required to provide consistent high performance during challenging monitoring conditions. When an unreliable or imitation sensor or cable is connected to an X-Calenabled monitor, a message alerts the user that the cable or sensor should be replaced.

To address the reliability risks associated with failures that can occur in cables and sensors used beyond their expected lives, X-Cal technology automatically tracks the aggregate time that individual cables and sensors are used for active patient monitoring. X-Cal detects when a specific cable or sensor has been used beyond its expected life and notifies the user, reducing the likelihood of a sensor failure that could affect patient safety. X-Cal also includes Site ID, which encodes the sensor with a unique identifier upon use. Site ID is designed to help ensure that reprocessed sensors are sourced from hospitals' own supply of genuine Masimo sensors.



66



Setting Our Sights Higher with rainbow<sup>®</sup> Pulse CO-Oximetry:

# Noninvasive Patient Monitoring Movement



# **Building Momentum with** rainbow<sup>®</sup> Pulse CO-Oximetry

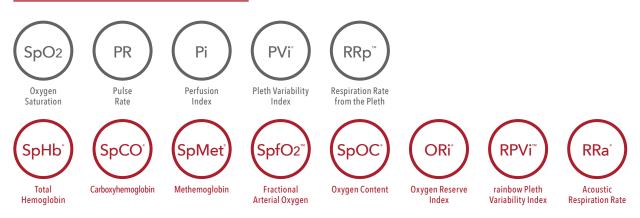
After solving the "unsolvable" problems of motion and low perfusion in pulse oximetry, we set our sights even higher.

By leveraging more wavelengths of light, we created rainbow<sup>®</sup> technology-a suite of noninvasive measurements for total hemoglobin, dyshemoglobins, and other physiologic parameters that previously could only be measured invasively. Our rainbow® technologies now help clinicians keep critical care patients safe; help nurses monitor

postoperative patients' respiration rates; help EMS first responders care for accident victims; and help doctors screen for anemia.

rainbow<sup>®</sup> uses more than seven wavelengths of light to acquire blood constituent data based on light absorption. Advanced signal processing algorithms and unique adaptive filters work together to isolate, identify, and quantify various types of hemoglobin. Measurement results are then displayed numerically and graphically as a trend line on select instruments.

#### rainbow SET measurements include:





concentration (SpHb) and fractional arterial oxygen saturation (SpfO2) 



Utilizing more than seven wavelengths of light and breakthrough signal processing, Masimo's rainbow\* Pulse CO-Oximeters can measure and display oxygen content (SpOC), along with total hemoglobin

# **Real-time Visibility of** Hemoglobin Status Between **Invasive Blood Samples**

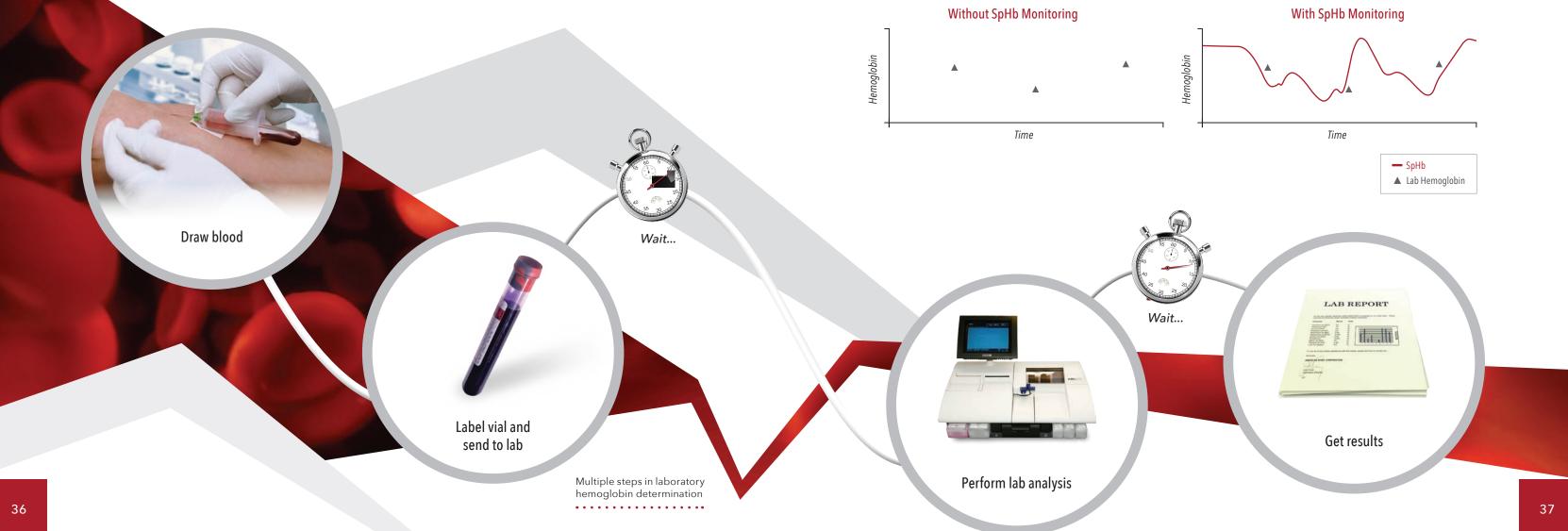
#### **Limitations of Traditional Blood Sampling Methods**

• Without SpHb, clinicians are only limited to invasive blood samples, which provide intermittent and delayed laboratory hemoglobin results

#### Helping Clinicians Make More Informed And Timely Transfusion Decisions

Continuous hemoglobin monitoring provides real-time visibility to changes-or lack of changesin hemoglobin between invasive blood samples.

SpHb trend monitoring may provide additional insight between invasive blood samples when:



• The SpHb trend is stable and the clinician may otherwise think hemoglobin is dropping

• The SpHb trend is rising and the clinician may otherwise think hemoglobin is not rising

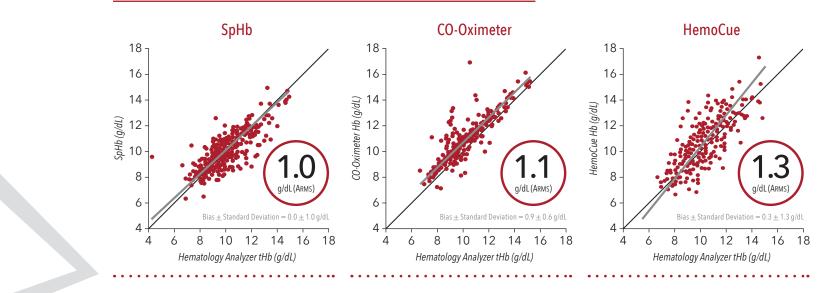
• The SpHb trend is dropping and the clinician may otherwise think hemoglobin is stable

# Accuracy of Masimo SpHb **Compared to Common Invasive Methodologies**

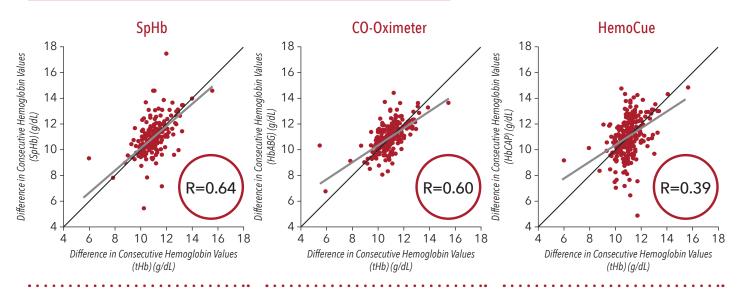
While hemoglobin is one of the most common laboratory tests performed, most clinicians are unaware of the variation that should be expected when comparing hemoglobin measurements-from various devices. This is because clinicians do not typically measure hemoglobin more than once in the same patient at the same time. Variation is caused by physiology, blood sampling technique, device methodology, and individual device calibration.<sup>1</sup>

The results of a study conducted in a surgical intensive care unit illustrate the variation that can be expected between hemoglobin devices. 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<sup>2</sup> when all three methods were compared to the central laboratory hemoglobin analyzer, both in single-measurement comparisons as well as trended-measurement comparisons. Some independent researchers have conducted their own testing and obtained similar results to the presented cases, while other researchers have reported larger, or in some cases smaller, differences when comparing SpHb measurements to laboratory measurements.



#### Trended Hemoglobin Measurement Comparison Between Three Devices and the Central Laboratory Hematology Analyzer<sup>2,3</sup>



<sup>1</sup> Berkow L. J Clin Monit Comput. 2013 Mar 26. PMID: 23529342.<sup>2</sup> Frasca D et al. Critical Care 2012, 16 (Suppl 1):P433 (doi: 10.1186/cc11040).<sup>3</sup> ARMS was calculated as defined by the ISO 80601-2-61. Published clinical studies on the accuracy of Masimo SpHb can be found on our website at: http://www.masimo.com/cpub/clinical-evidence.htm



Single Hemoglobin Measurement Comparison Between Three Devices and the Central Laboratory Hematology Analyzer<sup>2,3</sup>

# Risk and Costs of Red Blood Cell Transfusions

With noninvasive and continuous total hemoglobin (SpHb), Masimo may help clinician decision-making regarding one of the most common, costly, and critical problems in healthcare.<sup>1-3</sup>

Blood transfusions are one of the more common procedures in hospitals today.<sup>2</sup> The Joint Commission has noted that, "while blood transfusions can be lifesaving, they also carry risks that range from mild complications to death."<sup>4</sup> The Joint Commission and the American Medical Association have listed transfusions among their top five "overuse intervention targets."<sup>4</sup> Several clinical studies and meta-analyses also have suggested clinical risk associated with inappropriate transfusions, and some suggest that restrictive blood transfusion practices may improve clinical outcomes.<sup>5-7</sup> Also, given the costs associated with acquiring, storing, and administering blood, a reduction in unneeded transfusions may have an economic benefit.<sup>3</sup> For these reasons, and others, many institutions are adopting patient blood management protocols and programs.<sup>8</sup>

<sup>1</sup>Ehrenfeld JM et al. *J Blood Disorders Transf.* 2014. 5:237. doi:10.4172/2155-9864.1000237. <sup>2</sup>ACMS data pull: ICD 99<sup>3</sup> Shander A et al. *Transfusion*. 2010;50(4):753-765.<sup>4</sup> Proceedings from the National Summit on Overuse September 24, 2012 <sup>5</sup> Rohdes et al. *JAMA*, 5/2014 <sup>6</sup> Salpeter et al. *American Journal of Medicine* 2014<sup>7</sup> Villanueva et al. *N Engl J Med* 2013;368:11-21.<sup>8</sup> SABM PBM Directory http://www.sabm.org/programsbystate



and with the

 $0 \cdot 0 \cdot 0$ 

# SpHb May Help Clinicians Reduce **Blood Transfusions in Both Low** and High Blood Loss Surgery

A randomized trial of 327 patients undergoing elective orthopedic surgery conducted at Massachusetts General Hospital (MGH) found that the use of continuous noninvasive hemoglobin monitoring reduced the rate of transfusions when compared to standard care without continuous noninvasive hemoglobin monitoring. Patients undergoing elective orthopedic surgery were randomized to receive standard care alone or

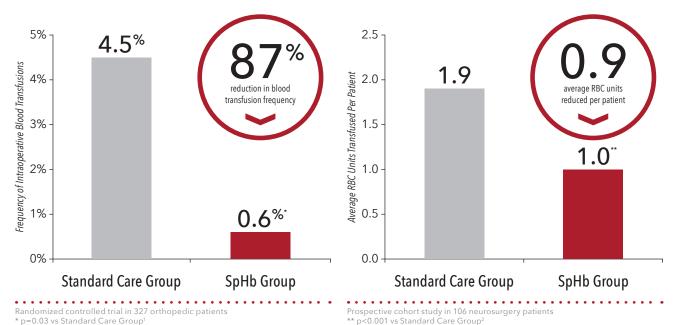
standard care with SpHb monitoring. The researchers concluded, "We believe that the availability of SpHb decreases inappropriate transfusion."1

A prospective cohort study of 106 neurosurgical patients found that adding SpHb monitoring to standard of care blood management resulted in decreased blood utilization in high blood loss neurosurgery, while also facilitating earlier transfusions.<sup>2</sup>

#### In Two Studies, SpHb was Shown to Help Clinicians Reduce Blood Transfusions in Both Low & High Blood Loss Surgery

SpHb Helped Clinicians Reduce Transfusion Frequency in Lower Blood Loss Surgery<sup>1</sup>

SpHb Helped Clinicians Reduce the Amount of Blood Transfused in Higher Blood Loss Surgery<sup>2</sup>



Patients were enrolled into either a Control Group SpHb Helped Clinicians Decrease the Time to or an intervention group (SpHb Group) where the Control Group received intraoperative hemoglobin monitoring by intermittent blood sampling. In 60 each group, if researchers noted SpHb trended 50.2 downward, below 10g/dL, a red blood cell 48 transfusion was started and continued until SpHb minutes reduction in time to transfuse trended upward, above 10g/dL. The blood sampling technique was the same for patients in both the 36 control and the test group. Arterial blood was drawn from a 20 gauge radial artery cannula into 2mL 24 ethylenediaminetetraacetic acid collection tubes, thoroughly mixed, then sent immediately to the 9.2 12 central lab for analysis by a hematology analyzer. The reference laboratory device used for hemoglobin measurements in the study was a Coulter GEN-S Hematology Analyzer. The transfusion threshold of Standard Care Group SpHb Group 10g/dL was predetermined by the study protocol and may not be appropriate for all patients. Clinical Prospective cohort study in 106 neurosurgery patients \*\*\* p<0.001 vs Standard Care Group<sup>2</sup> decisions regarding red blood cell transfusions should be based on the clinician's judgment considering among other factors: patient condition, continuous SpHb monitoring, and laboratory diagnostic tests using blood samples.

Compared to the Control Group, the SpHb Group demonstrated:<sup>2</sup>

- Fewer units of blood transfused
- 1.0 (SpHb) vs 1.9 (Control) units for all patients - 2.3 (SpHb) vs 3.9 (Control) units in patients receiving transfusion
- Fewer patients receiving more than 3 units - 32% (SpHb) vs 73% (Control)
- A shorter time to transfusion after the need was established
- 9.2 (SpHb) vs 50.2 (Control) min

<sup>1</sup> Ehrenfeld JM et al. J Blood Disorders Transf. 2014. 5:237. doi:10.4172/2155-9864.1000237. <sup>2</sup> Awada WN et al. J Clin Monit Comput. 2015 Feb 4. SpHb is not intended to replace lab testing but it can provide immediate and additional information to aid patient assessmen

# Transfusion, When Transfusion was Truly Indicated<sup>2</sup>

The investigators concluded, "Adding SpHb monitoring to standard of care blood management resulted in decreased blood utilization in high blood loss neurosurgery, while facilitating earlier transfusions."

# Risk and Cost of Internal Bleeding

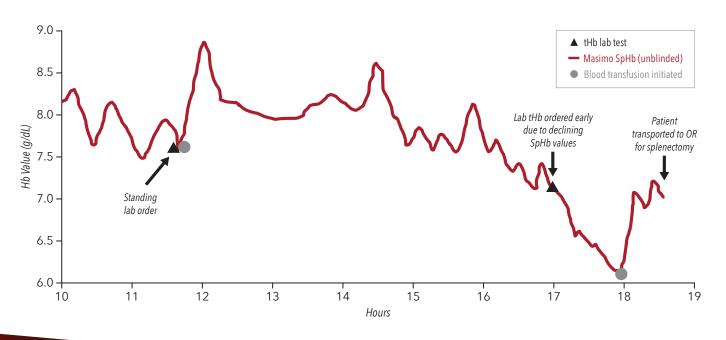
In addition to assisting with transfusion management, Masimo SpHb may help clinicians inside and outside the operating room identify changes in hemoglobin continuously.

Bleeding is considered a significant risk factor for patients, and late detection further increases risk and cost.<sup>1</sup>

Low hemoglobin is usually a reliable indicator that the patient is bleeding. However, current

invasive blood monitoring methods are often intermittent and delayed.<sup>2</sup> A declining SpHb trend may allow clinicians to identify falling hemoglobin levels and allow clinicians to intervene sooner.

#### **Example of How SpHb Monitoring Can Help Identify Internal Bleeding<sup>3</sup>**



<sup>1</sup> Herwaldt LA. *Infect Control Hosp Epidemiol*. 2003; 24(1):44-50. <sup>2</sup> Bruns B et al. *J Trauma*. 2007; 63(2):312-5. <sup>3</sup> McEvoy M et al. *Am J Crit Care*. November 2013 vol. 22 no. 6 eS1-eS13. doi:10.4037/ajcc2013729.



# **Recent Study Investigates** the Impact of SpHb & PVi on **Anesthesia-Related Mortality**

In a recent study conducted at Hospital Dupuytren (part of the Centre Hospitalier Universitaire of Limoges, France), Professor Nathalie Nathan and colleagues concluded that monitoring with SpHb and PVi, as part of a vascular filling protocol in surgical patients, "allowed earlier transfusion and reduces mortality at a scale of a whole hospital with different clinical practices (and practitioners) and unselected patients."1

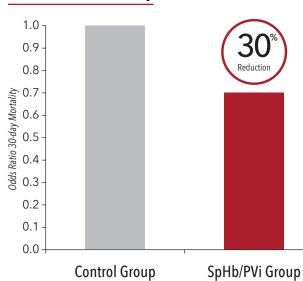
The study included 18,867 patients, of whom 3,450 underwent SpHb and PVi monitoring via Masimo Radical-7 Pulse CO-Oximeters, which were installed in all operating rooms, recovery rooms, and intensive care units, along with Masimo Patient SafetyNet<sup>™\*</sup>. Patients in the monitoring group received vascular filling with crystalloids or blood, according to the clinical algorithm. Demographic, anesthesia, surgical, and transfusion data were collected in electronic medical records using

Patient SafetyNet. The researchers compared the percentage of patients in the monitored group who received transfusions within the first postoperative 48 hours to the percentage in the non-monitored group. They also compared mortality rates for each group at 30 days following surgery.

The researchers found that the patients in the group monitored with SpHb and PVi had a 30% reduction in mortality at 30 days in comparison to the control

group. While the proportion of patients receiving transfusions and the number of units transfused within 48 hours were not significantly different between the two groups, non-cardiac surgical patients in the monitored group were transfused sooner in the operative or recovery room.





46

. . . . . . . . . . . . . . . .

Nathan N et al. Impact of Continuous Perioperative SpHb Monitor Proceedings from the 2016 ASA Annual Meeting, Chicago. Abstract #A1103. \*The use of the trademark SafetyNet is under license from University HealthSystem Consortium

# Quick and Noninvasive Hemoglobin and Oxygen Saturation Measurements

Rad-67<sup>™</sup> Pulse CO-Oximeter features rainbow SET technology for noninvasive spot-checking of total hemoglobin (SpHb), oxygen saturation (SpO2), pulse rate (PR), and perfusion index (Pi).

#### A Remarkable Device for a Variety of Clinical Settings

The Rad-67 Pulse CO-Oximeter offers noninvasive hemoglobin and oxygen saturation measurements. The portable Rad-67–approximately 9" x 4" x 1" and weighing just 20 ounces–puts the power of noninvasive hemoglobin spot-check in clinicians' hands in a variety of care environments including hospitals, clinics, and emergency medical services.

#### Next Generation SpHb Spot-check\*

New software in Rad-67 offers several enhancements when used in conjunction with

the new reusable **rainbow**<sup>®</sup> DCI-mini sensor. Next Generation SpHb technology offers improved motion tolerance, SpHb results display in as few as 30 seconds, enhanced field performance in the range of 6 to 11 g/dL, and is comparable to certain portable invasive point-of-care devices.

SpHb is not intended to replace lab testing, but it can provide immediate and additional information to aid patient assessment.

#### Next Generation SpHb Accuracy Compared to Invasive Methods

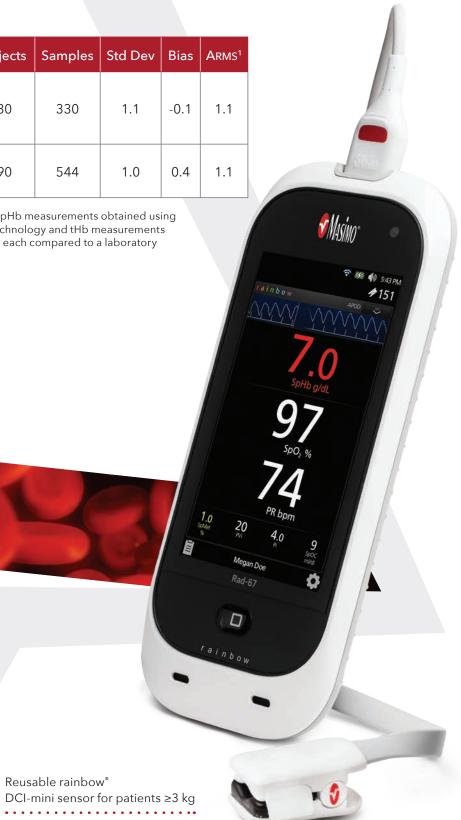
The data in this section describes the accuracy of SpHb measurements in the range of 8-17 g/dL by a Rad-67 and a HemoCue analyzer each compared to a laboratory reference device.

ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within ± ARMS of the reference measurements in a controlled study. 'Next generation SpHb, Rad-67, and rainbow DCI mini Sensor are not available in the U.S. "Data on file. Masimo SpHb and HemoCue accuracy was determined by testing on healthy adult, pediatric, and patient volunteers with light to dark skin pigmentation at clinical sites against an automated Beckman Coulter laboratory hematology analyzer. Masimo study. Data collected at six different centers on healthy and sick subjects.

#### Performance Summary\*\*

Device	Subjects	Sample
Invasive Point-of-care Device vs Laboratory Hematology Analyzers	330	330
SpHb vs Laboratory Hematology Analyzers	290	544

The table represents the accuracy of SpHb measurements obtained using Rad-67 with Next Generation SpHb Technology and tHb measurements using an invasive point-of-care device, each compared to a laboratory reference device.





# Limitations of Existing Methods to Support Fluid Management

Fluid administration is one of the most common hospital interventions. Although it is critical for improving patient status and enabling end organ preservation, unnecessary fluid administration is associated with increased morbidity and mortality.<sup>1</sup>

Clinicians commonly use intravenous fluid administration in the operating room and intensive care unit to attempt to improve blood flow, or cardiac output. However, administering either too little or too much fluid can increase patient risk. Therefore, experts recommend the use of "dynamic" parameters that measure physiologic variation over the respiratory cycle.<sup>2</sup> A meta-analysis of 31 randomized controlled trials showed that goal-directed fluid management, using parameters such as stroke volume variation (SVV) and pulse pressure variation (PPV), reduced surgical complications by 32%.<sup>3</sup> While studies have shown these dynamic parameters to be beneficial, most are invasive, difficult to use, and costly.

#### A Noninvasive Fluid Monitoring Option

Masimo SET<sup>®</sup> pulse oximetry technology has the unique ability to also provide a dynamic variable, called Pleth Variability Index (PVi). PVi is a measure of the dynamic changes in Perfusion Index (Pi) that occur during the respiratory cycle. The calculation is made by measuring changes in Pi over a time interval during which one or more complete respiratory cycles have occurred. Pleth Variability Index (PVi) may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions. PVi is displayed on the same monitor and obtained with the same sensors as are used for Masimo SET<sup>®</sup> pulse oximetry and rainbow<sup>®</sup> monitoring.

<sup>1</sup>Bundgaard-Nielsen M et al. *Acta Anaesthesiol Scand*. 2007; 51(3):331-40. <sup>2</sup>Vallet B et al. *SFAR*. 2013. <sup>3</sup>Grocott et al. *Br J Anaesth*. 2013.



# Inclusion of PVi in **Intraoperative Clinical Guidelines and Pathways**

The positive and expanding evidence for PVi has led to its inclusion in guidelines and best practices for fluid management.

In a study of colorectal surgery patients managed with the Enhanced Recovery After Surgery (ERAS) protocol, PVi was integrated into the fluid therapy bundle to reduce lactate levels, while the median length of stay was reduced by 2.1 days.<sup>1</sup>

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.<sup>2</sup>

In 2013, the French Society for Anaesthesia and Intensive Care (SFAR ) added PVi to its guidelines for optimal hemodynamic management of surgical patients.<sup>3</sup>

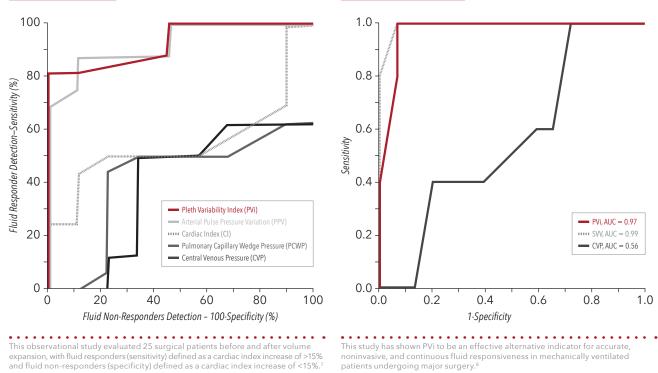
#### The Power of PVi and SpHb Together

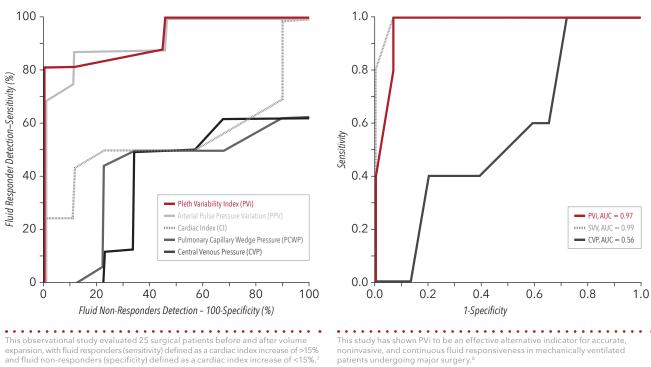
While PVi and SpHb can help improve the quality of care when used individually, the integrative power of these parameters, brought together by Radical-7 and Root, can provide additional clinical insight.

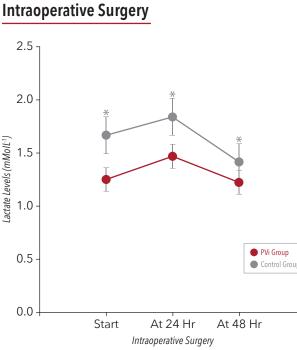
Research suggests that the titration of excess fluid could lead to hemodilution which could subsequently increase the risk of complications, such as tissue edema and cardiopulmonary complications.<sup>4</sup> Additionally, the administration of excess blood could lead to high hematocrit or hemoconcentration, which increases risks for morbidities such as venous thrombosis.<sup>5</sup>

By using SpHb and PVi together, it is possible to monitor both total hemoglobin and a patient's fluid responsiveness on a single monitor. This visibility can help clinicians view the changes of these parameters in response to changing patient condition, or in response to an intervention such as a transfusion, in real time. In a clinical study in which investigators monitored patients with Masimo's SpHb and PVi, the result was a decrease in mortality of 25%.<sup>6</sup>









This randomized study of 82 abdominal surgery patients found that PVi-based, goal-directed fluid management reduced the volume of intraoperative fluid infused and reduced intraoperative and postoperative lactate levels.<sup>9</sup>



#### **Financial Benefits of Using Enhanced Recovery** After Surgery (ERAS) Protocol Including PVi for **Goal-Directed Therapy**

Outcome	Conventional Approach without PVi	ERAS Approach with PVi
30-day hospital costs	\$18,017	\$15,150
Median length of stay	5 days	3 days

Most recently, and as part of a multi-modal perioperative management approach called ERAS, PVi was shown to help reduce 30-day hospital costs by \$2,867 per patient and reduce median length of stay by 2 days.1

Thiele RH et al. Journal of the American College of Surgeons (2015), doi: Initiale Art et al. Sournal of the American Conlege of Surgeons (2015), doi: 10.1016/j.jamcollsurg.2014.12.042\_<sup>2</sup> http://www.ntac.nbs.uk/NewsAndEvents/ IOFM\_Technology\_Adoption\_Pack\_Published.aspx. <sup>3</sup>Vallet B et al. SFAR. 2013. <sup>4</sup> Chappell et al. Crit Care, 2014, 18:538. 5 Schreijer et al. Haematologica. 2010 Feb, 95(2). <sup>6</sup>Ponsonnard et al. Proceedings of the European Society of Anaesthesiology Annual Congress (Euroaneasthesia), 2015, Poster Abstract.<sup>7</sup> Cannesson M et al. Br J Anaesth 2008;101(2):200-6. <sup>8</sup>Zimmermann M et al. Eur J Anaesthesiol. 2010 Jun;27(6):555-61. Forget P et al. Anesth Analg 2010; 111(4):910-4.



# Helping First Responders Monitor CO Levels and Screen for Elevated CO Levels

#### Deadly Exposure Revealed with SpCO

Our original rainbow<sup>®</sup> measurement, SpCO, measures carboxyhemoglobin, which forms in red blood cells upon contact with carbon monoxide (CO). This is particularly useful for patients who show no symptoms, but may have been exposed to dangerously high levels of CO. Evidence has indicated that noninvasive SpCO monitoring may lead to the identification of elevated CO levels that might otherwise go undetected in front-line settings. SpCO is intended to be used to monitor CO levels in the blood. SpCO monitoring is not intended to replace laboratory blood testing and not to be used as the sole basis for making diagnosis or treatment decisions related to carbon monoxide poisoning. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

Results from several clinical studies conducted on emergency room patients demonstrate that SpCO technology may be a valuable tool in screening a large number of patients for possible CO exposure,<sup>1,2</sup> supporting the possible use of SpCO as an efficient and rapid tool in first-line screening.<sup>3</sup> A recent study at the Medical University of Vienna assessed 32,396 emergency room patients with noninvasive SpCO. Of the 32 patients with a diagnosis of CO poisoning, 22 (69%) would not have been identified without obtaining an SpCO measurement.<sup>4</sup>

#### Saving Lives Every Day

SpCO helps paramedics and emergency medical technicians identify and assess CO levels in the blood. Just one severe CO exposure event nearly doubles the risk of premature death, and consistent CO exposure may cause long-term heart and brain damage.<sup>5,6</sup>

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, leading to poor decision making and increasing

<sup>1</sup> Suner S. et al. *J Emerg Med.* 2008 May;34(4):441-50. <sup>2</sup> Roth D et al. *Ann Emerg Med.* 2011 Jul;58 (1): 74-9. <sup>3</sup> Sebbane M et al. *Respir Care.* 19 March 2013. <sup>4</sup> Roth Det al. *Int J Clin Pract.* 2014 Apr 2. <sup>5</sup> Hampson NB et al. *Crit Care Med.* 2009; 37(6):1941-47. <sup>6</sup> Bledsoe BE. *J Emerg Med Svcs.* 2007l 32:54-59. <sup>7</sup> Jakubowski G. FireRescue Magazine. 22(11):52-55, 2004. <sup>8</sup>Bledsoe BE. FireRescue Magazine. September 2005.

the risk of heart disease or stroke-two conditions that account for nearly 50% of on-duty firefighter deaths.<sup>7,8</sup> As a result of factors such as these, industry-leading organizations have lined up to support CO education. The National Fire Protection Association (NFPA) released an updated Fire Rehabilitation Standard (NFPA 1584) which requires that firefighters exposed to smoke at incident scenes and during training be assessed for elevated carbon monoxide (CO) levels on the scene.



# Immediate Capnography at the Point of Patient Contact

Ø

#### EMMA<sup>™</sup> (Emergency Mainstream Analyzer)

EMMA is a compact, portable, lightweight mainstream capnograph that requires minimal warm-up time, with full accuracy in 15 seconds. Capnographs measure carbon dioxide (CO2) concentration in expired gases. Their primary use is short-term monitoring of end-tidal CO2 levels and respiration rate in adults, pediatric, and infant patients. They are used during anesthesia, emergency care, and intensive care, where capnography is often used to confirm endotracheal intubation and to monitor assisted ventilation performance. The continuous capnograph allows clinicians to confirm effective resuscitation, to assess the depth and effectiveness of compressions, and to recognize the return of spontaneous circulation.<sup>1,2</sup>

3

<sup>1</sup>Neumar RW et al. Circulation. 2010;122:S729-S767.<sup>2</sup>2010 American Heart Association



# **Helping Clinicians Monitor** Methemoglobin Levels

#### Acquired Methemoglobinemia

Many drugs commonly used in hospitals-such as lidocaine, benzocaine, dapsone, and nitrates-may cause a dangerous reaction known as acquired methemoglobinemia. Methemoglobinemia is a blood disorder in which an abnormal amount of methemoglobin, a form of hemoglobin,

is produced. With methemoglobinemia, the hemoglobin can carry oxygen but is unable to release it effectively to body tissues. While methemoglobinemia can occur in all care areas and patients, it is often unrecognized and undiagnosed.<sup>1</sup> If not identified and treated, it may result in avoidable injury or death.

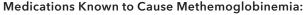
#### Masimo SpMet May Be Valuable in Methemoglobinemia Assessment

Masimo noninvasive methemoglobin (SpMet) helps clinicians monitor for methemoglobin in care areas where the drugs that cause methemoglobinemia are most common, such as procedure labs and the operating room. This enables them to quickly adjust

#### Prevalence of Methemoglobinemia

Number of Methemoglobinemia Cases	Patient Ages	Care Areas	Fatalities
138 (2.5 cases per hospital per month)	4 days to 86 years	Surgery, intensive care, outpatient clinics, pediatrics, emergency department, cardiac catheterization lab	1 fatality 3 near fatalities

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.<sup>1</sup>



Benzocaine, Cetacaine, Chloroquine, Dapsone, EMLA topical, Flutamide, Lidocaine, Metoclopramide, Nitrates, Nitric oxide, Nitroglycerin, Nitroprusside, Nitrous oxide, Phenazopyridine (Pyridium), Prilocaine, Primaquine, Riluzole, Silver nitrate, Sodium nitrate, Sulfonamides 



drug regimens and initiate potentially life-saving treatment.<sup>2</sup> SpMet monitoring is not intended to replace laboratory blood testing and not to be used as the sole basis for making diagnosis or treatment decisions related to methemoglobinemia. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

# Protecting More Patients by Monitoring Every Breath

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

#### rainbow Acoustic Monitoring®

Continuous monitoring of respiration rate is especially important for post-surgical patients receiving patient-controlled analgesia for pain management. The Anesthesia Patient Safety Foundation (APSF) and The Joint Commission recommend continuous oxygenation and ventilation monitoring for all patients receiving opioid-based pain medications.<sup>1,2</sup> Conscious sedation can induce respiratory depression and place patients at considerable risk of serious injury or death.<sup>3</sup> However, current methods for respiration rate monitoring may be limited by patient tolerance.<sup>3,4</sup> While Masimo offers capnography solutions, rainbow Acoustic Monitoring may be better suited for postsurgical monitoring and conscious sedation.

#### Ability to Detect Respiratory Pause

RESPIRATION RATE METHOD	Oridion Capnostream SARA v4.5	Masimo rainbow Acoustic Monitoring v7804
<b>Sensitivity</b> (respiratory pause detected when actual respiratory pause occurs)	62%	81%

Retrospective analysis of 33 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.<sup>3</sup>

rainbow Acoustic Monitoring provides noninvasive and continuous respiration rate, Acoustic Respiration Rate (RRa), an accurate, easy-to-use, and reliable monitoring solution that also enjoys higher patient compliance.<sup>5,6</sup> RRa may facilitate earlier detection of respiratory compromise and patient distress, offering a breakthrough in patient safety for post-surgical patients and for procedures requiring conscious sedation.<sup>6</sup>

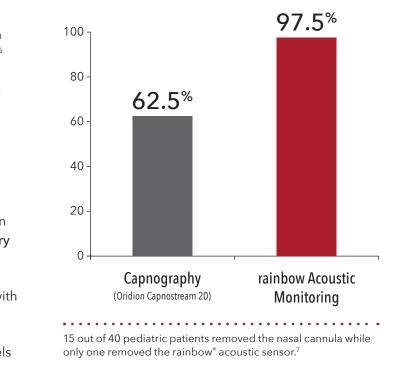
#### Monitoring More Patients More Safely than Ever Before

When rainbow Acoustic Monitoring is used in conjunction with **rainbow**<sup>®</sup> **Pulse CO-Oximetry** and the Patient SafetyNet system, clinicians can track key oxygenation indicators with industry-leading Masimo SpO2; ventilation with breakthrough acoustic respiration rate (RRa); circulation with Masimo Measure-through Motion pulse rate (PR); and hemoglobin levels with Masimo's continuous and noninvasive hemoglobin (SpHb).

RAS-45 Respiratory Acoustic Sensor

<sup>1</sup>Stoelting RK et al. APSF Newsletter. 2011. (www.apsf.org).<sup>2</sup> The Joint Commission Sentinel Event Alert. Issue 49, August 8, 2012. http://www. jointcommission.org/assets/11/8/SEA\_49\_opioids\_8\_2\_12\_ final.pdf <sup>3</sup>Ramsay M et al. Anesth Analg. 2013. <sup>4</sup>Applegate RA et al. Anesth Analg. 2016;122(4):1070-8. <sup>5</sup>Macknet MR et al. Anesthesiology. 2007;107:A84. (abstract) <sup>6</sup>Goudra BG et al. Open J Anesthesiol. 2013; 3:74-79. <sup>7</sup>Patino M et al. Paediatr Anaesth. 2013 Sep 3

#### **Patient Tolerance**





# Rad-97<sup>™</sup> and Rad-67: Our Next Generation of Compact Portable Patient Monitors

Rad-97 is our newest patient monitoring and connectivity device.\* Highly configurable and adaptable for use in a wide variety of care areas, Rad-97 utilizes our breakthrough **rainbow SET** measurement platform with future options to add capnography or noninvasive blood pressure and temperature, or even a camera module to enhance the way the device works for you.

The touchscreen interface is sleek, responsive, and highly intuitive. Rad-97's customizable display provides clinicians with pertinent data at a glance, offering a more complete picture of the patient's physiological status. Additionally, the device settings can be configured to suit a variety of clinical environments, workflows, clinician preferences, and patient-specific needs.

\*Rad-97 and Rad-67 are not available in the U.S.





Innovating Patient Monitoring and Connectivity Solutions

# Moving Hospital Rooms to the Future



### The Root of Patient Care

All of our innovations are designed for one purpose-to enable clinicians to get to the root of better care for their patients

Root is a powerful patient monitoring and connectivity platform that augments our breakthrough rainbow<sup>®</sup> and SET<sup>®</sup> measurements with multiple additional parameters-including SedLine<sup>®</sup> brain function monitoring, O3<sup>®</sup> regional oximetry, and capnography and gas monitoring.

Root includes a dock for the Radical-7 or Radius-7°, an intuitive display, and Iris<sup>®</sup> connectivity ports for third-party devices such as infusion pumps, ventilators, and anesthesia machines. Root integrates multiple streams of data and simplifies patient care workflows, helping caregivers make quicker patient assessments, earlier intervention, and better clinical decisions throughout the continuum of care.

100

15

20

www.www.

74

4.0

#### Intuitive Multi-touch Navigation

Root is as easy to use and configure as the smartphone in your pocket. With a simple tap, swipe, or drag-and-drop, screen views and parameter sizing can be customized to suit a given care area, workflow, clinician preference, or patient-specific need. This allows Root to be used across a wide variety of environments with disparate clinical and operational requirementsfrom the operating room, to the intensive care unit, to medical-surgical units.



#### Versatile, High-visibility Display

Root displays Masimo's breakthrough noninvasive measurements with a docked Radical-7 handheld or paired Radius-7 patient-worn monitor. The brilliant, high-resolution, adaptive display is designed to aid clinicians' rapid assessment of patient status in three distinct ways:

1. Trend view in which each measurement value is displayed alongside its graphical trend

Analog view

- 2. Analog view in which virtual gauges show measurement values in relation to alarm ranges
- 3. Alarm status visualizer in which a three-dimensional, anatomical image associates device measurements with alarm status

#### Alarm Status Visualizer



with a simple tap, swipe,







# Kite<sup>°</sup>: Flexible, Versatile, **Clinician-centric**

#### IV pumps, pulse oximeters, lab and radiology results, and myriad other sources. In high acuity departments, such as the ED, where comprehensive,

#### Expanding the Visibility of Patient Data with Masimo Kite®

Kite provides a supplemental display of the patient data from Masimo devices and connected MOC-9<sup>™</sup> modules, including SedLine brain function monitoring, O3 regional oximetry, and NomoLine capnography, through connection to a compatible smart device, such as an LCD television. How the patient data is displayed can be configured differently than on the monitoring device itself. By customizing what can be displayed, Kite allows clinicians to focus on the most pertinent data for each stage of a patient's care, empowering clinicians to make more informed decisions. In addition, Kite also visually projects patient alarms

from the monitoring device, providing quick notification of changes in a patient's physiological status. With its ability to project the most needed data, with powerful customization possibilities, Kite allows all clinicians in a busy operating room, cardiac theater, or other venue to have better visibility of the patient data they need.

#### Next Generation Data Aggregation and Display with Masimo UniView<sup>™\*</sup>

Building on the projection and customization capabilities of Kite, UniView will take the aggregation and customizable display of patient data to a new level. Through a wired or wireless connection to Masimo Iris Gateway<sup>™</sup>, which gathers data from multiple Masimo and 3<sup>rd</sup> party devices and sources, UniView will be able to project integrated, near real-time information about the patient from all connected systems in the hospital. UniView will provide a central, convenient, and

customizable display of data from ventilators,

rainbow

clearly organized, and timely data are key to making the best clinical decisions and providing the best patient care, UniView may make all the difference.



# MyView<sup>™</sup>: Clinician-centric Monitoring

#### MyView empowers clinicians to see things their way.

The level and types 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 at all times. 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 every time. MyView technology-a feature of 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, patients, and their families each want to see. While a physician may want to see all parameters and waveforms, a medical assistant may only want to see a few parameters and no waveforms. If no clinician is in the room, the patient and family members 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.





MyView in Patient SafetyNet automatically senses when a clinician approaches and highlights their patients for easy viewing . . . . . . . . . .

RM312B RM313A RM313B RM314A RM314B RM315A RM317A RM315B RM315C RM315D 14 RM317B RM319B RM318A RM318B **RM319A** 5 RM320A RM320B RM322A RM322C RM325A 🏝 🕹 9:46:03<sub>4</sub> Misino

Feel Better So We Can... Play!



Clinician-centric view with the use of a presence tag or smartphone allows caregivers to see the customized information most important to them as they approach a patient

94 92 13 11.5 96 85 13 10.7 94 96 13 11.5 96 88 13 10.5 96 85 14 10.7 96 88 13 10.5 96 88 15 10.8 95 94 13 11. 87 14 10.8





When no clinician is present, 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 members while limiting unnecessary concerns and questions. When a clinician enters the room, MyView recognizes them and displays that clinician's preferred view 

### Root with Iris<sup>®</sup>: Keeping Clinicians, Patients, and Data Connected

#### Iris Connectivity

Despite advances in medical technology, the lack of device interoperability is a serious patient safety risk. Existing approaches for device interoperability require separate hardware, software, and network infrastructure which can clutter the patient room, burden IT management, and increase the complexity and cost of care. Root with Iris is an important part of Masimo's goal of bridging medical device data silos, acting as a built-in connectivity hub that can integrate multiple standalone devices. Device connectivity with Iris is designed to leverage existing network infrastructure and reduce costs, while enhancing workflows and decision support. Via Iris Gateway and Patient SafetyNet, Root with Iris can be used to connect isolated devices to hospital EMR systems in high-acuity settings like the OR and the ICU or in lowacuity settings like the general ward.

#### Iris Gateway and Patient SafetyNet

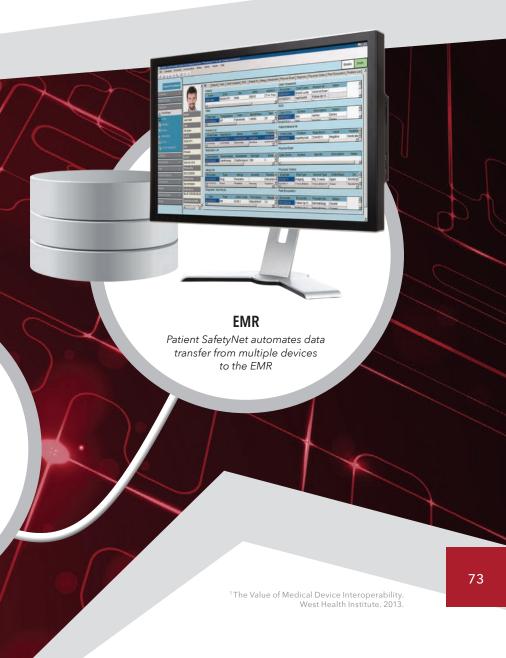
Data generated from medical devices typically remain captive within each device and may not be captured in patient records. Iris Gateway provides a timely and cost-effective solution by connecting to existing medical devices, such as Root with Iris, and performing the required translations to move data from devices into the EMR. When medical device data is readily available in the EMR, clinicians have a more complete, more timely

Automatic data transfer from medical devices to the EMR could improve productivity and reduce the likelihood of transcription errors'

Root + 3<sup>rd</sup> Party Standalone Devices Root's built-in Iris ports act as a

Root's built-in Iris ports act as a connectivity hub for 3<sup>rd</sup> party standalone devices

Patient SafetyNet Patient SafetyNet converts all Masimo and 3<sup>rd</sup> party standalone device data into HL7 picture of the patient. In addition to automated documentation of patient data from multiple devices in the EMR, Patient SafetyNet further enhances connectivity by allowing patient data to be remotely viewed at central stations and alarms and alerts to be remotely transmitted to clinicians. Together, Root with Iris, Iris Gateway, and Patient SafetyNet are helping to connect clinicians, patients, and their data more closely than ever.



## Root with Radius-7<sup>™</sup>: The Power of Masimo Measurements in a Patient-worn Monitor

#### **Designed for Monitoring Mobile Patients**

Studies have shown that patient mobility is a key factor in more rapid patient recovery.<sup>1</sup> Radius-7 allows clinicians to continuously monitor their patients while they are mobile.

Root with Radius-7 can alert clinicians to critical changes in a patient's oxygen saturation, pulse rate,

respiration rate, and other key measurements at the bedside or remotely, through Patient SafetyNet. Radius-7's wireless communication functionalityeither short range via Bluetooth® to Root or with upgradeable WiFi for longer-range communication-ensures patients can be continuously monitored and connected to caregivers while they are ambulating.



#### First and Only Wearable rainbow<sup>®</sup> Monitor

Radius-7 is the only wearable wireless device to enable continuous noninvasive monitoring of 10 rainbow SET parameters:

- Oxygen saturation (SpO2), pulse rate and perfusion index (Pi) via Masimo SET<sup>®</sup> pulse oximetry, shown to reduce false alarms and increase detection of true alarms during patient motion and low perfusion
- Respiration rate with either rainbow Acoustic Monitoring (for increased patient tolerance versus capnography) or respiration rate from the pleth (RRp)\*
- Noninvasive and continuous monitoring of a patient's hemoglobin concentration with SpHb, carboxyhemoglobin with SpCO; methemoglobin concentration with SpMet; oxygen content with SpOC; and Pleth Variability Index (PVi).



40 140

75

18.0.0.0.0.0.0.0

1.0.0.0.0.0.0.0.0000 ..........

## Root with Noninvasive Blood Pressure and Temperature

With the addition of blood pressure and temperature monitoring capabilities, Root is now available as a powerful and versatile vital signs monitor.

Root with integrated noninvasive blood pressure and temperature (NIBPT) can enhance nursing workflows and help ensure correct patient data management. When used in conjunction with Patient SafetyNet or Iris Gateway, Root with NIBPT can be interfaced directly to hospital admit, discharge, transfer (ADT), and charting systems. This allows nurses to use a USB barcode scanner attached to Root to scan patient wristbands for simple, easy patient association, directly at the point of care.

Once the patient association is complete, all measurements are sent directly to the patient's chart with no additional steps required by the clinician. In addition to transmitting and charting data measured by Root NIBPT, the system is also able to intake information from third-party devices via its Iris ports, enabling information from these devices to be charted as well. The system comes with user-configured software that prompts clinicians to associate patients so that data can be charted and stored when measured, and disassociate patients when measurements are complete, ensuring that correct patient data goes to each chart.

#### Early Warning Score

A recent Root software upgrade adds the capability to automatically calculate an Early Warning Score (EWS), based on existing device measurements and additional clinician input, that represents the potential degree of patient deterioration. As with other patient data, the EWS, which must be clinician-initiated, can be pushed to the Electronic Medical Record (EMR) directly when Root is connected to Patient SafetyNet or Iris Gateway.





## MOC-9<sup>™</sup>: Flexible **Measurement Expansion With** Masimo Open Connect<sup>™</sup>

Masimo offers other companies the opportunity to develop and commercialize their innovations and deliver them to market 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, Masimo capnography and gas monitoring, and O3 regional oximetry are all provided as MOC-9 modules.

Designed to Stimulate Third-party Innovation MOC-9 is designed to spur third-party development of additional measurements.

D

MOC-9"

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 provides an open invitation to other companies, large and small, to develop and commercialize their innovations and deliver them to market via the Root platform. We anticipate a new ecosystem of third-party measurements springing from Root, seeding whole new fields of innovation in patient monitoring.

D

6

MOC-9 modules expand Root's capability via third-party development of additional measurements



97 ···

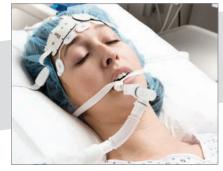
15:

SedLine brain function monitoring is a "plug and play" MOC-9 module . . . . . . . . . . . . . . . . . . .

			<b>S</b> Masimo	
	ADL	11 🗰 🖇 🗢 🕷 📰	1≸% 1\$41 <b>♦</b> 0) 1:27 AM	
Line Mm www	way marked	whenner	monthing	
30 mm/sec	- M. ale	Jun man		
1		$\sim$	26 50	
my 5	m	L.	36	
			15	
Sanda La	a da	in the second	and Shifting	
		a which the	ASTA	
BATELY MENT CONTRACTOR	the section of the section of the section of the	02:25:13	ASYM L42 02:30:13	
mark a hand	randweighting ran	mphone we we	Monthly With a	
9.28999999	an vitre serveriai nee	dianan in 1962 in 1962 i	-40	
		m		
			h	
mar	Angland		$\mathbf{U}$	
O showe Forehead Right	30 AUC	30 <sup>(spo</sup> )	-/50 %/SO2	
O Alasse Forehead Right	30 AUC	30 (%00)		
O shade Forehead Right		·····	<b>6</b> 5	
0 Abase Forehead Right	22 AUC	معة 30 معنا 32 معنا 32	50 NITSO2 655 50 NITSO2	
Forehead Right	22 AUC	32 (SPO2	65 50 11/502	
0 Abase Forehead Right	22 AUC	32 (SPO2	65 	
0 Abase Forehead Right	22 AUC	32 (spo) - MAEL-15-10 - 571	65 	
0 Abase Forehead Right	22 AUC	32 (540)2	65 	



**S**Masimo



O3 regional oximetry is a "plug and play" MOC-9 module . . . . . . . . . .

# Root with SedLine<sup>™</sup> 2.0 **Brain Function Monitoring**

Four simultaneous channels of EEG data provide continuous information about a patient's response to anesthesia.

Patients respond differently to anesthetics, which can mean over- or under-administration during surgery and conscious sedation procedures. SedLine brain function monitoring provides continuous information about a patient's response to anesthesia. With four channels of high-fidelity EEG data, SedLine enables monitoring of both sides of the brain simultaneously. The Density Spectral Array (DSA) enables immediate recognition of asymmetrical activity, identification of the specific frequency in which most EEG activity is occurring, and an easy-to-see display of burst suppression events.

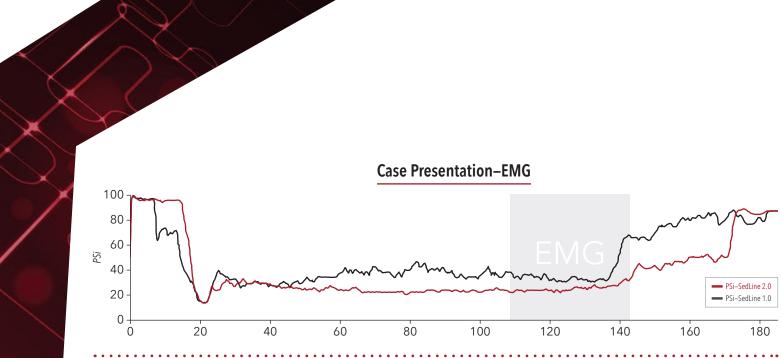
Use of SedLine with its Patient State Index (PSi) has been shown to help clinicians manage patients to significantly faster emergence from anesthesia and recovery.<sup>1</sup>

#### SedLine 2.0

Our latest brain function monitoring innovation was developed to display a PSi value that reflects the patient's anesthetic state during challenging brain function monitoring situations. SedLine 2.0 utilizes Masimo's Parallel Signal Processing Engines to compute an EEG-derived parameter (PSi) that is less influenced by electromyography (EMG). SedLine 2.0 also utilizes Masimo's Adaptive Signal Processing with bandindependent features to search across many EEG frequency bands and thus offer improved PSi performance in cases of low power EEG.







The above case demonstrates the improvement to PSi in SedLine 2.0 in reducing EMG bias in comparison to a legacy algorithm.



<sup>1</sup> Drover DR et al. Acta Anesthesiology. 2002; 97:82-89. SedLine 2.0 is not available in the U.S.

## Root with O3 Regional Oximetry

O3 regional oximetry uses near-infrared spectroscopy (NIRS) to monitor oxygen saturation (rSO2) in the brain.

#### The Root of Better Brain Oxygenation Monitoring

Regional oximetry, also referred to as tissue or cerebral oximetry, may help clinicians monitor cerebral oxygenation in situations in which pulse oximetry alone may not be fully indicative of the oxygen in the brain.

In a study on 27 subjects published in *Anesthesia and Analgesia*, researchers compared cerebral oxygen saturation measurements obtained from O3 with saturations obtained from blood samples (SavO2) through induced hypoxia.<sup>1</sup> O3 regional oximetry provided absolute root-mean-squared error of 4% and relative root-mean-squared error of 2.1%.<sup>1</sup> This study did not require that end tidal carbon dioxide (EtCO<sub>2</sub>) levels be fixed in the study protocol, allowing the O3 measurement to be responsive to changes in tissue oxygen saturation due to changes in CO<sub>2</sub> in the blood. Follow-up studies with O3 extended the subject pool to 74 subjects and demonstrated that O3 maintained its absolute and relative accuracy.<sup>2</sup>

#### A Powerful Combination

The combination of O3's accurate regional oximetry measurements and SedLine brain function monitoring provides clinicians with even more information about the brain's response to anesthesia on the same monitoring platform.

### **O3** Regional Oximetry Specifications

	Adult	Pediatric
Body Weight	> 40 kgs	< 40 kgs
Trending Regional Oxygen Saturation (rSO2) Accuracy	3%	3%
Absolute Regional Oxygen Saturation (rSO2) Accuracy	4%	_

O3 regional oximetry is a "plug and play" MOC-9 module

**S**Masino



<sup>1</sup>Redford D et al. Anesth Analg. 2014 Dec;119(6):1315-9. <sup>2</sup>Masimo FDA submission data on file.



83

## Root with Capnography and Gas Monitoring

Changes in expired respiratory gas can be an early indicator of an adverse respiratory event. Capnography can help clinicians quickly spot hypoventilation, hyperventilation, airway obstruction, and other potentially life-threatening conditions.<sup>1</sup>

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. Root with capnography and gas monitoring complements our breakthrough noninvasive portfolio with innovative, multispectral technologies for measuring respiratory gases and inhaled anesthetic agents. The solutions range

from integrated OEM solutions to an external "plug in and measure" gas analyzer, to handheld devices. With multiple measurements delivered through either mainstream or sidestream options, clinicians can now benefit from end-tidal CO2, FiCO<sub>2</sub>, RR, N<sub>2</sub>O, O<sub>2</sub>, and inhalation anesthetic agent monitoring in a range of hospital environments-from the operating room, to intensive care, to the general wards.

> ISA<sup>™</sup> CO2 with NomoLine<sup>™</sup> attached to the back of Root enables capnography and gas monitoring to be quickly disconnected from and re-deployed to any available Root . . . . . . . . . . . .

Masim



84



Capnography and Gas Monitoring are "plug and play" MOC-9 modules 





# Solutions for a Variety of **Capnography Applications**

Traditional capnography solutions utilize compounds such as Nafion<sup>®</sup> to attract and trap water which enters the sampling line due to condensation of the expired patient gas. The Nafion portion of the sampling line absorbs water before it enters the gas analyzer and is the most costly per-patient component of the sampling line. These components, however, continuously absorb water, which can occlude the patient sampling line, causing readings to degrade over time or potentially result in no readings at all.

#### NomoLine No Moisture Sampling Line

NomoLine technology eliminates common problems associated with conventional sidestream gas analysis. Incorporating a special polymer and a hydrophobic bacterial filter, NomoLine technology allows water in the sampling line to evaporate into the surrounding air. This enables

> Single-patient-use cannula and NomoLine adapter

a single NomoLine to last much longer than conventional capnography sampling line solutions, without affecting functionality of the ISA module. NomoLine's innovative design also allows multipatient use as a "resposable" solution, along with the use of generic cannulas.

#### ISA-A High Performance Sidestream Analyzer

Using state-of-the-art spectrometer technology that utilizes nine different wavelengths of light and powerful signal processing algorithms, the ISA sidestream analyzer provides clinicians with capnography and gas measurements. Crisp waveforms help depict the clinical situation from the operating room to the general wards. Additionally, with virtually no warm-up time and full accuracy performance in ten seconds, ISA saves time in critical situations. ISA is factorycalibrated and does not require field calibration, minimizing hospital-level maintenance. ISA sidestream analyzers are available as standalone or easy-to-integrate OEM modules.

#### IRMA<sup>™</sup>–A Complete Monitor in a Probe

With its compact size and microprocessor technology, the versatile IRMA mainstream analyzer weighs less than one ounce and fits in the palm of your hand.

IRMA AX+ EtCO2, RR, N2O, Inhalation Anesthetic

Agent Identification

mann manna

97

1 (0)

**IRMA CO2** . . . . . . . . . EtCO2, FiCO2, RR

. . . . . . . .





ISA OR+ EtCO2, RR, N2O, O2, Inhalation Anesthetic Agent Identification

ISA AX+ . . . . . . . . EtCO2, RR, N2O, Inhalation Anesthetic Agent Identification

ISA CO<sub>2</sub> . . . . . . . . EtCO2, FiCO2, RR



# Reducing the Cost of Care with Masimo Technologies

At Masimo, we focus not only on improving outcomes but on reducing the cost of carewhich benefits hospitals, clinicians, and patients.

Use of Masimo noninvasive technologies and monitoring systems, including SET pulse oximetry, Patient SafetyNet, PVi, and SpHb, has been shown to reduce costs in a variety of healthcare settings.

### **SET Pulse Oximetry and Patient SafetyNet**

Estimated Potential Cost Savings with SET Pulse Oximetry and Patient SafetyNet				
With Masimo SET <sup>®</sup>				
Reduction in Arterial Blood Gas Testing <sup>1,2</sup> (Masimo SET <sup>®</sup> compared to conventional pulse oximetry)	\$77,520*			
Reduction in Ventilator Time <sup>1-4</sup> (Masimo SET <sup>®</sup> compared to conventional pulse oximetry)	\$266,450 <sup>*</sup>			
False Alarm Distraction Productivity Savings <sup>5</sup> (Masimo SET <sup>*</sup> compared to conventional pulse oximetry)	\$180,180 <sup>*</sup>			
Reductions in ICU Transfers in 36-Bed Step-down Unit Due To Continuous Surveillance Monitoring with Patient SafetyNet, Including SET Pulse Oximetry <sup>6,7</sup>	\$1,479,012			
Total Annual Projected Cost Savings	\$2,003,162			

\*Study results were applied to a 250-bed hospital model.

"Implementation of surveillance with pulse oximetry was associated with a reduced need for patient rescue and intensive care unit transfer."6

> Andreas Taenzer, MD Dartmouth-Hitchcock Medical Center, United States

### **PVi and SpHb**

**Estimated Potential Cost Savings** with an ERAS Protocol

With Masimo PVi Cost savings when using PVi as part of Perioperative Enhanced Recovery Protocol<sup>8</sup>

Cost Savings per patient in Enhanced Recovery Group

Total Annual Projected Cost Savings in ERAS Group\*\*

> **Estimated Potential Cost Savings** with SpHb During High Blood Loss Surgery

With Masimo SpHb Cost savings when using SpHb during high blood loss surgery in a 250-bed hospital with 2,500 surgeries

Estimated Potential Reduction in RBC units<sup>9†</sup>

Total Annual Projected Cost Savings

**Total Potential Annualized Cost Savings** SET Pulse Oximetry + Patient SafetyNet + PVi + SpHb = \$3,164,890<sup>¥</sup>

Durbin CG Jr et al. Crit Care Med. 2002 Aug;30(8):1735-40.<sup>2</sup> Patel DS et al. Advance for Resp Care Managers 2000: 9(9):86. 3 Dasta JF et al. Crit Care Med. 2005 Jun;33(6):1266-71. 4 Wunsch H et al. Crit Care Med. 2013 Dec:41(12):2712-9. <sup>5</sup>Shah N et al. J Clin Anesth. 2012:24(5):385-91. <sup>6</sup>Taenzer AH et al. Anesthesiology 2010:112(2):282-287. <sup>7</sup> Taenzer AH et al. APSF Newsletter 2012. <sup>8</sup> Thiele RH, et al. J Am Coll Surg. 2015 Apr;220(4):430-43. <sup>9</sup> Awada WN et al. J Clin Monit Comput. 2015 Dec;29(6):733-40. 10 Shander A et al. Transfusion. 2010;50(4):753-765.

\$7,129

\$777,061

473

\$384,667

"Using a multidisciplinary approach, we successfully implemented an ER [Enhanced Recovery] pathway that led to substantial reduction in LOS, complications and costs, while improving patient satisfaction."8

> Robert H. Thiele, MD The University of Virginia, United States

"Total annual blood costs are largely driven by transfusion rate, which includes such factors as the proportion of surgical patients transfused and number of RBC units per patient transfused. Reducing either or both factors has the potential to reduce costs dramatically."10

Aryeh Shander, MD Englewood Hospital, United States

\*\* Direct costs associated with enhanced recovery protocol included. <sup>+</sup>Cost Savings at \$853 per unit RBC<sup>10</sup> with a 21% prevalence rate for high blood loss surgeries. <sup>‡</sup>Includes sensor costs. <sup>¥</sup>Not all savings may be realized

### Helping Improve **Outcomes on the Wards** With 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.<sup>1</sup>

Patient SafetyNet-built on Masimo SET<sup>®</sup> pulse oximetry with rainbow Acoustic Monitoring or standard capnography–offers a clinically proven, cost-effective solution for continuous post-operative monitoring with high nursing satisfaction and patient compliance.

#### **Reducing Rescues and ICU Transfers**

Clinicians understand the risks of not continuously monitoring patients on the general wards. However, excessive false alarms due to patient motion often preclude continuous monitoring in these care areas.

In the last decade, Masimo SET<sup>®</sup> 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<sup>™</sup> performance. However, in a landmark study published in Anesthesiology in 2010, researchers found that continuously monitoring patients on a post-surgical floor at Dartmouth-Hitchcock Medical Center using Patient SafetyNet with Masimo bedside devices resulted in a 65% reduction of rapid response team activations and a 48% reduction in transfers back to the ICU. In addition, the reduction in ICU transfers over the initial 11-month period led to a cost savings of \$1.48 million.<sup>2</sup>

Following the initial implementation and positive results in one post-surgical ward, Patient SafetyNet with Masimo bedside devices was expanded to cover more than 200 inpatient beds in all medical and surgical units. In subsequent articles published in Anesthesia Patient Safety Foundation Newsletter in 2012 and The Joint Commission Journal on Quality and Patient Safety in 2016, researchers

Significant reductions in rapid response team activations and ICU transfers were observed in an 11-month evaluation of Patient SafetyNet on a post-surgical unit. Rescue events decreased 65%, from 3.4 to 1.2 per 1,000 patient discharges, and ICU transfers decreased 48%. from 5.6 to 2.9 per 1,000 patient days. The financial impact resulted in annual opportunity cost savings of \$1.48 million.<sup>2</sup> Results drove expansion of the use of Patient SafetyNet to other care areas; after 10 years, the hospital had maintained a 50% reduction in unplanned transfers and 60% reduction in rescue events, despite increases in patient acuity and occupancy.<sup>3,4</sup>

showed that Patient SafetyNet enabled the facility, over a five-year period, to achieve their goal of zero preventable deaths or brain damage due to opioids,<sup>3</sup> and, over a ten-year period, maintain a 50% reduction in unplanned transfers and 60% reduction in rescue events, despite increases in patient acuity and occupancy.<sup>4</sup>

Just as pulse oximetry has become a standard of care in the OR, PACU, and ICU, we believe that Measurethrough Motion and Low Perfusion pulse oximetry will become a standard of care on general wards.

Newsletter. Spring-Summer 2012. 4 McGrath SP et al. The Joint Commission Journal on Quality and Patient Safety. 2016 Jul;42(7):293-302.



#### Proven Cost-effectiveness

As a result of the study, Dartmouth-Hitchcock Medical Center saved \$1.48 million annually, showing that implementing Masimo SET<sup>®</sup> and Patient SafetyNet to more safely monitor postsurgical patients can also have a significant impact on a hospital's bottom line, by increasing ICU bed availability and reducing the costs associated with emergency rescue events. With both clinical and financial rationales now in place, hospitals are increasingly implementing general ward monitoring with Masimo technologies.

## Halo Index<sup>™</sup>: Better View of Overall Patient **Physiological Status**

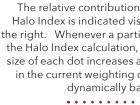
#### Halo Index<sup>™\*</sup> Mimics an Expert Clinician

Halo Index is a new indicator for cumulative trending assessment of global patient status. Physiologic deterioration often occurs long before a crisis event and manifests through subtle and often undetected changes across multiple physiologic parameters. Masimo designed Halo Index to mimic the systematic approach that expert clinicians use in assessing patient physiologic deterioration: analyzing patient history and extracting key vital sign parameter characteristics to assess global

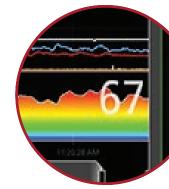
patient status. Halo Index currently uses available Masimo parameters but is scalable to include additional information from the patient data repository. Each parameter's significance is weighted and combined into the Halo Index-a single displayed number with a range from 0 to 100 that provides a cumulative trending assessment of global patient status. An increase in a patient's Halo Index would suggest physiologic deterioration and might indicate the need for clinicians to more closely assess the patient.

Patient SafetyNet can display actual parameter values (below) or color-coded alarm states (right), which allows more patients to be viewed simultaneously on screen 









The relative contribution of each parameter to a patient's Halo Index is indicated visually by a white dot, as shown to the right. Whenever a particular parameter is being used in the Halo Index calculation, the dot appears beneath it. The size of each dot increases and decreases to reflect changes in the current weighting of each parameter, which adjusts dynamically based upon available clinical data. 

. . .



00 65pO2	109 BPM	29 <sub>RRa</sub>	40 <sub>Halo</sub>	RM314A 99 %SpO <sub>2</sub> RM315D	68 <sup>BPM</sup>	18 RRa	27 <sub>Halo</sub>	RM3148 97 %SpO2	74 <sup>врм</sup>	15 RRa	67 <sub>Halo</sub>
98 \$\$p02	78 <sup>врм</sup>	14 RRa	16 <sub>Halo</sub>	100 %5pO2	72 BPM	16 <sub>RRa</sub>	20 <sub>Halo</sub>	82 %5p02	115 BPM	18 RRa	70 Halo
99 SpO2	87 <sup>ВРМ</sup>	16 RRa	24 <sub>Halo</sub>	89 %SpO2	114 врм	20 <sub>RRa</sub>	66 <sub>Halo</sub>	98 %SpO2	69 <sup>BPM</sup>	9 RRa	38 Halo
00 Sp0,	61 <sup>врм</sup>	10 RRa	19 <sub>Halo</sub>	97 %\$p0,	54 <sup>BPM</sup>	11 RRa	15 <sub>Halo</sub>	94 %\$p0,	98 BPM	20 RRa	42 Halo
										anitos	HALO
BPM		PI	PVI		RR	SpHb		SpMet	нарсо	Sţ	юc
17 <sup>46</sup>	1444-1.14	Alhay.	huuuh Pannen	in the second	anddaud Antelany Antelany Antelany	en de la company	Harrister M	M <sup>4</sup> kunip Maning	ni,	Andre	hund hald Anna hald
	14 Harden Hard Harden Harden		luusudi Philippin I				United the	N <sup>44</sup> ki mariya 			n/Hunsteid 1977
			Aprianta Physiother 1103	eri Hayara Hayara An o So		1101	Uninder Maria	When the second			
	HANLUU	sino	6,001	kytensika Pipera i k	он с 		U.,	M. M			-, <sup>14</sup>   
			1/e3	4.2 0 10							

In this example, a rising Halo Index indicates a declining patient condition while displaying parameter trends and their relative contributions to the Halo Index . . . . . . . . . . . . . . . . . . .

Taking Noninvasive Monitoring to New Sites and Applications™

# Through Our Movements, We Are Doing What is Best for Patient Care



### Impact Beyond the Hospital

Masimo technologies are increasingly being used to enhance the quality of patient care outside the hospital.

105-

#### A New Level of Care in the Home

The new Rad-9<sup>™</sup> bedside pulse oximeter will be easily customizable to suit the needs of the home user. With an intuitive touchscreen interface, device settings can be quickly and easily managed. To ensure safety, the "Home" mode setting will lock out non-clinicians from inadvertently changing alarm settings. Rad-9 will be able to trend and store parametric data for up to 96 hours at a two-second sampling rate and offer the ability to transfer data wirelessly via Bluetooth or WiFi, supporting burgeoning telehealth initiatives.

Rad-9's wireless connectivity options allow the device to communicate with connected devices, such as glucometers and weight scales, and can allow the data from the connected device to be

54.3

transmitted remotely. Rad-9 will be available for use on home and enterprise networks to connect to remote monitoring systems, including Patient SafetyNet. Additional devices can be simultaneously attached to Rad-9 using the Iris hub.

#### Adding a Safety Net to 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 expose patients to increased risk of adverse events.<sup>1</sup> When ventilated patients are moved to long-term care or assisted-living environments, Rad-9 will provide continuous monitoring during transportation to help clinicians manage adverse

respiratory events. The integration of Masimo SET\* bedside pulse oximeters and Patient SafetyNet remote monitoring and notification systems has enabled a considerable reduction in rapid response activations as well as emergency "transfer-outs."<sup>2</sup>

#### 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<sup>®</sup> technology is integrated in leading sleep lab monitoring systems, enabling clinicians and patients to benefit from its reliability in this challenging environment.<sup>3</sup>

Both Rad-9 and Rad-97 will be available with an optional camera, which can be used in conjunction with Masimo Patient SafetyNet. The camera will provide a high resolution, high-frame rate video feed, as well as audio, to the Patient SafetyNet view-station. When used at home, camera-equipped Rad-9 and Rad-97 will allow patients and clinicians to interact remotely, making it well-suited as a point-of-care device for potential telehealth applications.

Bouadma L et al. Crit Care Med. 2015 Sep;43(9):1798-806. <sup>2</sup>Taenzer et al. Anesth 2010;112(2):282-287. <sup>3</sup>Brouillette et al. Anesth Anala, 2002:94:S47-S53, 4 Coulthard P. Evid Based Dent 2006;7(4):90-1. \* Kim YH et al. *Dig Endosc*. 2014 May;26(3):417 23. <sup>6</sup> Liao W et al. *J Int Med Res*. 2012;40(4):1371-80. Rad-9 is urrently not available and the Rad-97 is not available in the U.S

Rad-9 includes built-in wireless connectivity, via WiFi and Bluetooth®. Using Bluetooth or a wired USB connection, Rad-9 can connect to nearby devices, such as glucometers and weight scales, and can allow the data from the connected device to be transmitted remotely. 

#### **Outpatient Clinical Procedures**

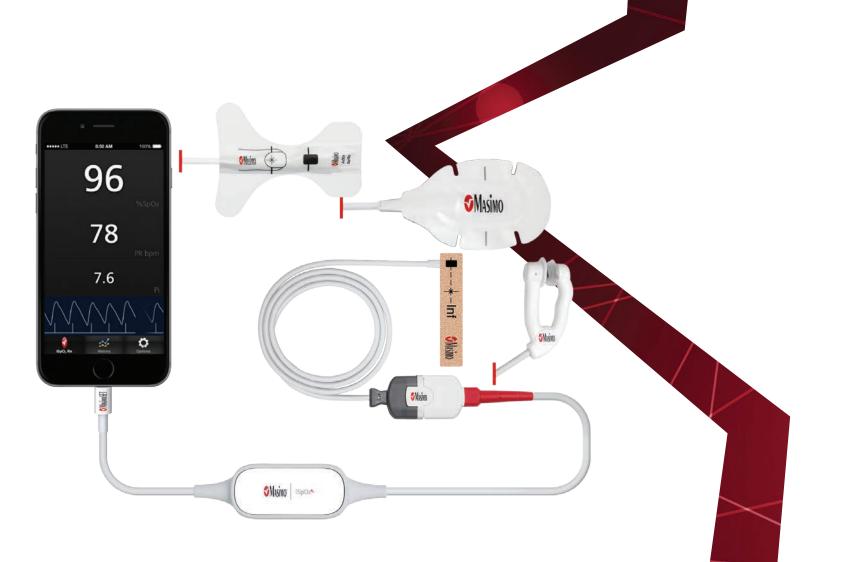
There are many clinical procedures that require light or conscious sedation. Under conscious sedation, patients may have an unexpected reaction to a drug or may inadvertently be oversedated. Both conditions may not be detected without a monitoring system. For dentistry, clinicians can monitor a patient's SpO2 to ensure adequate breathing throughout the procedure.<sup>4</sup> Masimo SET<sup>®</sup> has also been shown to be useful during other outpatient procedures such as colonoscopies and bronchoscopies.<sup>5,6</sup>

## Gearing Up for the mHealth Revolution

Masimo is well positioned for a future when mobile and medical device technologies converge.

#### iSpO2<sup>®</sup> Rx<sup>\*</sup>-The World's First Pulse Oximeter for iOS and Android Mobile Platforms

Combining a Masimo board-in-cable, reusable or disposable sensor, and an app running on a smartphone or tablet device, iSpO2 Rx features Masimo's proven Measure-through Motion and Low Perfusion pulse oximetry-oxygen saturation (SpO<sub>2</sub>), pulse rate (PR), and perfusion index (Pi).





### MightySat<sup>™</sup> Rx is the First Fingertip Pulse Oximeter with Masimo SET\*

MightySat Rx\* measures SpO2, PR, and Pi in a compact, battery-powered unit with a large color screen that can be rotated for real-time display of the pleth waveform and other measurements. Optional Bluetooth<sup>®</sup> wireless functionality enables measurement display via a free, downloadable app on iOS<sup>®</sup> and Android<sup>™</sup> mobile devices.

The Masimo Professional Health App includes a high resolution plethysmographic waveform, pulse beep audible feature, and trending functionality. The app enables users to view their measurements in real time or over a

trended graphical display on a compatible smart device. The app also interfaces with the Apple Health Kit for iOS users, further expanding its utility. The app empowers clinicians and patients by allowing the captured data to be shared via email.

MightySat Rx is also available with optional Pleth Variability Index (PVi), a measure of the dynamic changes in Pi that occur during the respiratory cycle.

Now with Respiration Rate from the Pleth MightySat Rx now features RRp, a measurement

of respiration rate based on changes in the plethysmographic waveform.

### Better Data = Better Performance<sup>™</sup>

Throughout our history, Masimo devices have mainly been designed to help patients in healthcare settings. Now, we're also helping healthy people live better lives.

We've made medical-grade pulse oximetry technology available in the MightySat<sup>™</sup> fingertip pulse oximeter and iSpO2<sup>®</sup> pulse oximeter for smart devices.

These devices are increasingly being used for general wellness and health applications including sports, fitness, and relaxation management.\* Elite athletes such as Olympic cycling medalist Dotsie Bausch, Ironman<sup>®</sup> champion Heather Jackson, and tennis stars Coco Vandeweghe and Taylor Fritz are using our technologies to enhance their training

100

and recovery regimens. In addition, private pilots are increasingly using our pulse oximeters to accurately measure their oxygen levels, which can fluctuate to very low levels at higher altitudes without supplemental oxygen.

#### The "Quantified Self"

The "quantified self" movement is based on the practice of self-knowledge through self-tracking diet, sleep, activity, and-increasingly-health and wellness. By tracking and comparing data over time, one gains a more comprehensive and objective understanding of one's health and how to actively manage oneself toward an optimal state. Such

self-tracking can be motivated by a simple desire to improve daily function, or for amateur and professional athletes to up their game.

#### The Masimo Advantage

Multiple companies have introduced low-priced health tracking devices, including pulse oximeters, to the consumer market. In some circumstances, these products may provide inaccurate measurements or no measurements at all. With blood oxygen levels, this often occurs when there is low blood flow to the finger (such as when the fingers are cold) or during hand movement (even with minimal motion, such as shaking). In addition, many of the products on the market are of low quality and do not interface with smart devices to store, manage, and share data. With MightySat and iSpO2, the same high-performing Measurethrough Motion and Low Perfusion Masimo SET<sup>®</sup> technology used by leading hospitals is now available for general wellness and health applications. We believe that if

"Masimo MightySat tracks key biometric data that allows me to measure and improve my athletic performance and gauge my recovery."

> ~ Dotsie Bausch . . . . . . . . . . . .

\*For personal us



you're going to quantify yourself, you should have the best, most reliable data available to you. That's what we mean by Better Data = Better Performance and Better Data = Better Health.



Ì

### **Taking Noninvasive Monitoring** to the Animal Kingdom

Masimo Animal Health offers veterinarians the same industry-leading monitoring solutions that have helped so many human patients.

Masimo SET<sup>®</sup> monitors and sensors enhance the accuracy of arterial oxygen saturation (SpO2) and pulse rate (PR) monitoring, particularly during the most challenging conditions of motion and low perfusion. Masimo SET<sup>®</sup> helps veterinarians provide exceptional care-especially when patients are most at risk, during anesthesia-induced operating procedures and post-operative recovery.

#### Innovative Capnography Protects Animals from the Operating Room to Recovery

Over 60% of all post-surgical animal deaths occur in the post-operative setting. More than 70% of these deaths are related to cardiovascular or respiratory problems.<sup>1</sup>

The EMMA capnograph is Masimo's most costeffective method for monitoring end-tidal CO2 and can help identify animals needing intervention during CPR/resuscitation, surgical procedures, and postoperative recovery.<sup>2</sup> This water-resistant, durable capnograph also meets American Animal Hospital Association (AAHA) guidelines for endtidal CO<sub>2</sub> monitoring.<sup>3</sup>



Technology

### Sensor

Masimo provides a full line of reusable sensors for various clinical applications

<sup>1</sup>Hall et al. Veterinary Anaesthesia. 10th ed. London, England: W.B. Saunders;2001:51-53. <sup>2</sup> Brodbelt D et al. Vet Ane and Anal. 2008; 35: 365-373. <sup>3</sup>Bednarski et al. J Am Anim Hosp Assoc 2011; 47:377-385.

Rad-9\*\* . . . . . .

Look for Masimo SET<sup>®</sup>-the market leader in pulse oximetry-for accurate measurements during challenging conditions

\*All accuracy specifications and claims are based on human volunteer studies with sensors placed on specifically determined sites for a given sensor type. Accuracy may vary for SpO2 depending upon species, sensor type, and monitoring site. Refer to operator's manual for complete description, instructions warnings, cautions, and specifications.\*\* Rad-9 is not currently available

## A Revolutionary Patient Safety Movement

We live in turbulent times. Disruption and upheaval are the hallmarks of our age. Some changes are positive-like medical advancements and the drive to empower patients. However, some of the global geopolitical changes are wreaking havoc and suffering on an unprecedented scale-for instance, the Syrian refugee crisis. Masimo is proud to be right in the thick of things, helping out wherever we can.

#### ZERO Preventable Deaths by 2020

In January 2017, the Patient Safety Movement (which the Masimo Foundation founded in 2012 and continues to sponsor) hosted the fifth annual World Patient Safety, Science & Technology Summit in Dana Point, California. President Bill Clinton and Vice President Joe Biden keynoted the event at which hundreds of diverse stakeholders from all parts of the global healthcare ecosystem came together to advance a vital mission—to eliminate preventable patient deaths. The Patient Safety Movement believes that "ZERO preventable deaths by 2020" is not only a worthy goal, but an attainable goal. By fostering and facilitating mass collaboration; by breaking down information silos that exist between hospitals, medical technology companies, the government, and other stakeholders; by promoting the data sharing that can identify at-risk patients before they're in danger; and by providing specific, actionable patient safety solutions (APSS) that healthcare professionals can implement today, we can eliminate preventable patient deaths. It is simply a matter of connecting all the dots.

## Helping Our Neighbors All Over the World

Through our partnerships with the Clinton Global Initiative, the World Health Organization (WHO), Partners in Health, and other organizations, Masimo is proud to contribute to worldwide healthcare improvements, including donating \$5 million in medical equipment to assist Jordan in providing healthcare to over 1 million Syrian and Iraqi refugees.

The wars in Syria and Iraq constitute one of the largest ongoing humanitarian crises in the world Over a million displaced people are now living within Jordan's borders, more than 600,000 of whom are registered with the United Nations Hig Commissioner for Refugees (UNHCR). Managing healthcare is a critical requirement for stability during crises and, while new hospitals are being built near refugee camps, the vast majority of refugees in Jordan reside in existing communitie heightening the demand for health services throughout the country. Masimo was determined to help ease the burden of providing healthcare by donating pulse oximeters and other medical equipment and supplies, along with a long-term



he orld. ng of	commitment to train and provide continued technical support for the Jordanian clinicians who are delivering the front-line care.
s High	Patients in many parts of the developing world
ging	lack access to even basic medical screenings.
ty	Working with WHO, Masimo donated pulse
eing	oximeters for use by front-line health workers in a
f	study in Bangladesh, Ethiopia, India, and Malawi
nities,	which focused on improving access to essential
	treatments for children. Masimo also donated pulse
ined	oximeters to hospitals in Liberia and Sierra Leone
are	as part of a joint effort with Partners in Health to
cal	rebuild the West African healthcare system.
≏rm	

The Appendix
The Movement
Continues



# **Technologies and Products**

### PATIENT SAFETYNET<sup>™</sup> SYSTEM



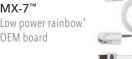
### Patient SafetyNet Remote Monitoring and Notification System

- Direct alarms to nurse via pager
- Open architecture with HL7 interface to hospital EHR
- MyView<sup>™</sup> for clinician-centric monitoring

### **CIRCUIT BOARDS**







MSX™ Very low power SET<sup>®</sup> OEM board



SENSORS



RD rainbow SET™ SpO2, PR, Pi, PVi, SpHb, SpCO, SpMet, SpfO<sub>2</sub>, SpOC, ORi, RPVi



RD rainbow Lite SET<sup>™</sup> SpO<sub>2</sub>, PR, Pi, PVi, ORi, RPVi



SpHb spot-check

### Rad-9<sup>™</sup> Masimo SET<sup>®</sup>

rainbow SET<sup>™</sup> Pulse CO-Oximeter® with rainbow Acoustic and blood pressure monitoring



Specialty Sensors

SpO<sub>2</sub>, PR, Pi, PVi

(Ear, Forehead, Blue, Newborn)



rainbow<sup>®</sup> Sensors SpO<sub>2</sub>, PR, Pi, PVi, SpHb, SpCO, SpMet, SpOC, ORi, RPVi

### **TECHNOLOGIES AND PARAMETERS**

### **S**Masimo SET

#### Masimo SET<sup>®</sup> Pulse Oximetry

Measure-through Motion and Low Perfusion<sup>™</sup> pulse oximetry

- Functional Oxygen Saturation (SpO2)
- Pulse Rate (PR)
- Perfusion Index (Pi) Pleth Variability Index (PVi<sup>®</sup>)
- Respiration Rate from the Pleth (RRp<sup>™</sup>)







Rad-97<sup>™</sup>



CO-Oximeter®

MONITORS

**9** 50

-----

Rad-5®

Masimo SET<sup>®</sup>

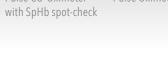
Pronto<sup>®</sup> rainbow SET<sup>™</sup> Pulse CO-Oximeter® with

145 Hb

8

- -Rad-67™

rainbow SET<sup>™</sup> Pulse CO-Oximeter<sup>®</sup> Pulse Oximeter



### **r**ainbow<sup>•</sup>

### rainbow<sup>®</sup> Pulse CO-Oximetry and Acoustic Monitoring

- Noninvasive blood constituent and fluid responsiveness monitoring
- Total Hemoglobin (SpHb<sup>®</sup>)
- Carboxyhemoglobin (SpCO<sup>®</sup>) Methemoglobin (SpMet<sup>®</sup>)
- Fractional Arterial Oxygen
- Saturation (SpfO2<sup>™</sup>)

#### O3 Regional Oximetry

Tissue Oxygen Saturation (rSO2)

#### Brain Function Monitoring

Noninvasive depth of sedation monitoring Patient State Index (PSi)

### Capnography and Gas Monitoring

- End-tidal Carbon Dioxide (EtCO2)
- Fractional Concentration of Inspired Carbon Dioxide (FiCO2)
- Respiration Rate (RR)
- Nitrous Oxide (N2O)
- Oxygen (O2)
- Inhalation Anesthetic Agent Identification (Agent ID)





Oxygen Content (SpOC<sup>®</sup>)

Oxygen Reserve Index<sup>™</sup> (ORi<sup>™</sup>)

Acoustic Respiration Rate<sup>®</sup> (RRa<sup>®</sup>)

• Plus all Masimo SET<sup>®</sup> measurements

• rainbow Pleth Variability Index (RPVi<sup>™</sup>)

Radical-7<sup>®</sup> rainbow SET<sup>™</sup> Pulse CO-Oximeter® with rainbow



Root<sup>®</sup> with NIBPT rainbow SET<sup>™</sup> with rainbow Acoustic and blood pressure monitoring, temperature, MOC-9<sup>™</sup>, Iris<sup>™</sup>





Root with Radius-7<sup>®</sup> rainbow SET<sup>™</sup> with rainbow Acoustic Monitoring, MOC-9, Iris



Acoustic Monitoring

rainbow<sup>®</sup> Acoustic Sensor RRa



O3<sup>™</sup> Sensor RD SedLine® Sensor rSO2, SpO2\* PSi

#### NomoLine™ Sampling line and NomoLine adapter

SAMPLING

II di

LINE



**TECHNOLOGIES** 

**EXTERNAL MEASUREMENT** 

EMMA™ EMMA™ Portable Portable mainstream capnograph capnometer Gas Monitoring

ISA™

Sidestream

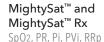
rainbow SET<sup>™</sup> with rainbow Acoustic Monitoring, MOC-9, Iris

IRMA™



SedLine® O3™ Brain Function Regional mainstream Capnography and Capnography and Monitoring Oximetry

iSpO2<sup>®\*\*</sup> and iSpO2<sup>®\*\*</sup> Rx



SpO2, PR, Pi









A 🖬

anna mini

Improving Patient Outcomes and Reducing Cost of Care by Taking Noninvasive Monitoring to New Sites and Applications<sup>®</sup>

> 98 15

74 1<u>3.4</u> 20 1.0





# National and International Awards for Excellence

2015 Life Sciences IP Champion Award



2015 Becker's Hospital Review Top 50 Leaders in Patient Safety

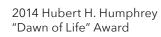
2015 GOLD Medical Design Excellence Award for Root

2014 Zenith Award

ospital Revie

ARC

HOTUCT



2014 Becker's Hospital Review Top 50 Leaders in Patient Safety

2013 Zenith Award at the American Association of Respiratory Care Congress

2013 Best Clinical Application of Technology Award for SpHb

2013 EMS World Top Innovation Award for EMMA

2013 Hot Product Award for EMMA and iSpO2







2011 Zenith Award at the American Association of Respiratory Care Congress

2011 High-Tech Innovation for the Pronto-7



2011 Medical Design Excellence Gold for the Pronto-7





2010 Respiratory Product Best-in-Class Award



2009 Masimo SET<sup>®</sup> and Patient SafetyNet help Dartmouth-Hitchcock Medical Center win the 4<sup>th</sup> Annual Health Devices Achievement Award

2009 Patient Monitoring CEO of the Year





GHX

2009 Best in Class





2005 Innovative Product and Technology

2003 Platform ABBY for Innovations in Healthcare

2003 Technology of the Year in Patient Monitoring



2003 New Standard of Care



2001 Medical Design Excellence



2001 Distinguished Leadership



2001 Innovative Product and Technology



2000 Technology Excellence

2000 Outstanding Medical Device Company

1995 Excellence in Technology Innovation for Measure-through Motion and Low Perfusion<sup>™</sup> Pulse Oximetry

# Select OEM Partners

Masimo SET<sup>\*</sup> is integrated in more than 100 OEM monitors from 50 leading brands-more than any other pulse oximetry technology. In addition, more and more of our OEM partners are enhancing the capabilities of their monitoring solutions by integrating rainbow<sup>\*</sup> technology.













# Global Reach

Masimo is committed to improving patient care globally, with over 4,000 talented people worldwide and operations in North America, Europe, Latin America, the Middle East, Asia, and Australia.

**HEADQUARTERS** 

Corporate Headquarters 52 Discovery, Irvine CA 92618 USA Tel: 949 297 7000

#### INTERNATIONAL OPERATIONS

International Headquarters Puits-Godet 10, 2000 Neuchâtel Switzerland Tel: +41 32 720 1111

#### MANUFACTURING CENTERS

U.S. Manufacturing 40 Parker Irvine, CA 92618, USA

25 Sagamore Park Rd Hudson, NH 03051, USA

Mexico Manufacturing Calzada Del Oro No. 2001 Modulo-6, Mexicali, 21395 Mexico

Industrial Vallera de Mexicali S.A. de C.V. Calle José López Portillo, 104-A, Parque Industrial, Código Postal 83455, San Luis Rio Colorado, Sonora, Mexico

Sweden Manufacturing Svärdvägen 15, SE-182 33 Danderyd, Sweden



Asia Pacific 31 Ubi Road 1, #04-05 Singapore 408694 Tel: +65-6521-6700

Australia Suite 3, Bldg. 7 49 Frenchs Forest Rd Frenchs Forest, NSW 2086 Australia Tel: 1-300-MASIMO

Austria Meldemannstr. 18 1200 Wien Austria Tel: +43 (0)1 533 7361

Canada 4878 Rue Levy Street, Suite 200 Saint-Laurent, Québec H4R 2P1 Canada Tel: 888 336 0043

#### China #1004, Hopson Building 13 Deshengmen Wai Street Xicheng District, Beijing 100088 China Tel: +86 (10) 8201-0588

France Espace Europeen Ecully 15 Chemin du Saquin, Bat G 69130 Ecully France Tel: +33 (0) 4 72 17 93 70

Q.

Germany Niederlassung, Deutschland Lindberghstr 11, 82178 Puchheim Germany Tel: +49 89 800 65 899-0

Hong Kong 22/F Unit 6, Tower 1, Millennium City 1 No. 388 Kwun Tong Road Kwun Tong, Kowloon Hong Kong Tel: +852-2326-3011

India 70/2 Miller's Rd Miller's Boulevard, 2<sup>nd</sup> Floor Bangalore 560052 Karnataka State India Tel: + 1 800 425 MASIMO

Italy Via Domenico Scarlatti 30 20124 Milano Italy Tel: +39 02 4507 6308

Japan Shinjuku Front Tower, 24F2-21-1 Kitashinjuku, Shinjuku-ku, Tokyo, 169-0074 Japan Tel: +(81) 3-3868-5201

Korea Platinum Tower 2F Seochodae-ro 398, Seochu-gu Seoul, South Korea Tel: +82 2 597 4900

Latin America/Mexico Paseo de la Reforma 404, Piso 6-602 Edificio Moncayo, Col. Juárez México, D.F. 06600 Delegación Cuauhtémoc Tel: +52 5511-2799

Middle East Jordan Tel: +962 7 9701 1135

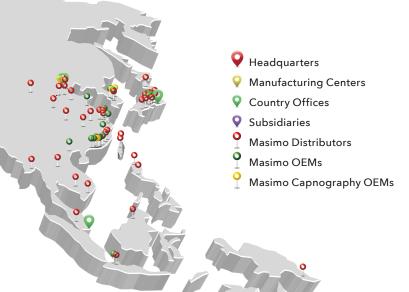
> Netherlands Hart van Brabantlaan 12-14-16 5038 JL Tilburg Netherlands Tel: +31 135 832 479

Saudi Arabia 360 Sulaimaniya Offices Prince Sultan bin abdulaziz St. Al Sulaimaniya District Tel: +966 11 4721113

Spain Ronda de Poniente, 12 2F 28760 Tres Cantos, Madrid Spain Tel: +34 91 8049734

Turkey Mustafa Kemal Mah. 2125. Sok Kolbay Is Merkezi C Blok No. 6/10 Ugur Apt. No. 15/8, Cankaya / Ankara Tel: +90 312 219 54 38

118



Offices 505-508, Manhal Center Manhal Square, Jubaiha, Amman

United Kingdom Matrix House, Basing View Basingstoke-Hampshire RG21 4DZ Tel: +44 (0)1256 479988

#### **SUBSIDIARIES**

Masimo Semiconductor 25 Sagamore Park Rd Hudson, NH 03051, USA Tel: 603 595 8900

Masimo Sweden AB Svärdvägen 15, 182 33 Danderyd, Sweden Tel: +46 8 544 98 150

#### THIRD PARTIES

Masimo Distributors Masimo OEMS Masimo Capnography OEMS 119

# Financial Performance

### Condensed Consolidated Statements of Operations (unaudited, in thousands, except per share amounts)

	TWELVE MO	NTHS ENDED
Revenue:	December 31, 2016	January 2, 2016
Product	\$663,846	\$599,334
Royalty	30,779	30,777
Total revenue	694,625	630,111
Cost of goods sold	230,826	220,128
Gross profit	463,799	409,983
Operating expenses:		
Selling, general and administrative	253,667	252,725
Research and development	59,362	56,617
Litigation settlement, award and/or defense costs	(270,000)	(19,609)
Total operating expenses	43,029	289,733
Operating income	420,770	120,250
Non-operating expense	2,429	3,905
Income before provision for income taxes	418,341	116,345
Provision for income taxes	117,675	34,845
Net income including noncontrolling interest	300,666	81,500
Net loss attributable to noncontrolling interest		(1,800)
Net income attributable to Masimo Corporation stockholders	\$300,666	\$83,300
Net income per share attributable to Masimo Corporation stockholders:		
Basic	\$6.07	\$1.62
Diluted	\$5.65	\$1.55
Weighted-average shares used in per share calculations:		
Basic	49,530	51,311
Diluted	53,195	53,707

#### Condensed Consolidated Balance Sheets (unaudited, in thousands)

#### Assets:

Current assets:		
Cash and cash equivalents	\$305,970	\$132,317
Accounts receivable, net of allowance for doubtful accounts	101,720	80,960
Inventories	72,542	62,038
Prepaid income taxes	981	2,404
Other current assets	26,014	21,423
Total current assets	507,227	299,142
Deferred cost of goods sold	79,948	66,844
Property and equipment, net	135,996	132,466
Intangible assets, net	29,376	27,556
Goodwill	19,780	20,394
Deferred income taxes	38,975	44,320
Other assets	9,223	11,013
Total assets	\$820,525	\$601,735
Liabilities and Equity:	December 31, 2016	January 2, 2016
Current liabilities:		
Accounts payable	\$31,125	\$25,865
Accrued compensation	43,180	38,415
Accrued liabilities	31,476	44,222
Income taxes payable	76,316	2,777
Deferred revenue	38,198	21,280
Current portion of capital lease obligations	71	74
Total current liabilities	220,366	132,633
Deferred revenue	25,336	298
Long-term debt		185,071
Other liabilities	14,587	8,021
Total liabilities	260,289	326,023
Commitments and contingencies		
Equity:		
Masimo Corporation stockholders' equity:		
Preferred stock		
Common stock	50	50
Treasury stock	(404,276)	(340,873)
Additional paid-in capital	382,263	332,417
Accumulated other comprehensive loss	(7,027)	(4,739)
Retained earnings	589,226	288,560
Total Masimo Corporation stockholders' equity	560,236	275,415
Noncontrolling interest	·	297
Total equity	560,236	275,712
	•	

December 31, 2016

January 2, 2016

Current liabilities:
Accounts payable
Accrued compensation
Accrued liabilities
Income taxes payable
Deferred revenue
Current portion of capital lease obligation
Total current liabilities
Deferred revenue
Long-term debt
Other liabilities
Total liabilities
Commitments and contingencies
Equity:
Masimo Corporation stockholders' equity:
Preferred stock
Common stock
Treasury stock
Additional paid-in capital
Accumulated other comprehensive los
Retained earnings
Total Masimo Corporation stockholders' eq
Noncontrolling interest
Total equity
Total liabilities and equity

121

# Financial Performance

### Condensed Consolidated Statements of Cash Flows (unaudited, in thousands)

(unaudited, in ti	100301103/	

	TWELVE MONTHS ENDED		
sh Flows from Operating Activities:	December 31, 2016	January 2, 2016	
Net income including noncontrolling interest	\$300,666	\$81,500	
Adjustments to reconcile net income including noncontrolling interest to net cash provided by operating activities:			
Depreciation and amortization	16,817	15,684	
Share-based compensation	12,503	10,825	
Loss on disposal of property, equipment and intangibles	658	306	
Provision for doubtful accounts	259	342	
Gain on deconsolidation of variable interest entity	(273)		
Benefit from deferred income taxes	5,405	(1,974	
Changes in operating assets and liabilities:			
Increase in accounts receivable	(21,243)	(9,900	
(Increase) decrease in inventories	(10,831)	7,505	
Increase in deferred cost of goods sold	(8,251)	(78	
Decrease (increase) in prepaid income taxes	1,355	(1,992	
Increase in other assets	(7,314)	(3,012	
Increase (decrease) in accounts payable	7,816	(4,319	
Decrease in accounts payable to related party	(1,092)		
Increase in accrued compensation	5,675	5,334	
(Decrease) increase in accrued liabilities	(7,605)	19,902	
Increase in income taxes payable	73,755	1,316	
Increase in deferred revenue	41,900	58	
Increase (decrease) in other liabilities	6,642	(4,587	
cash provided by operating activities	\$416,842	\$117,212	

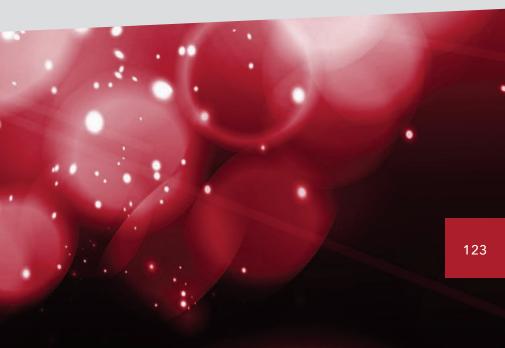
Condensed Consolidated Statements of Cash Flows (unaudited, in thousands)

### Ca

Cash Flows from Investing Activities:	December 31, 2016	January 2, 2016
Purchases of property and equipment	(\$19,707)	(\$50,393)
Increase in intangible assets	(4,644)	(4,201)
Reduction in cash resulting from deconsolidation of variable interest entity	(763)	
Net cash used in investing activities	(25,114)	(54,594)
Cash Flows from Financing Activities:		
Borrowings under revolving line of credit	45,000	130,000
Repayments under revolving line of credit	(230,000)	(70,000)
Debt issuance costs	(621)	
Repayments on capital lease obligations	(75)	(80)
Proceeds from issuance of common stock	37,290	28,285
Payroll tax withholdings on behalf of employee for stock options		(472)
Repurchases of common stock	(68,218)	(150,152)
Net equity issuances (repurchases) by noncontrolling interest		346
Net cash used in financing activities	(216,624)	(62,073)
Effect of foreign currency exchange rates on cash	(1,451)	(2,681)
Net increase (decrease) in cash and cash equivalents	173,653	(2,136)
Cash and cash equivalents at beginning of period	132,317	134,453
Cash and cash equivalents at end of period	\$305,970	\$132,317

#### C

#### TWELVE MONTHS ENDED



### Forward-looking Statements

All statements other than statements of historical facts included in this annual report that address activities, events or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Forward-looking statements include statements which are predictive in nature, which depend upon or refer to future events or conditions, or which include words such as "expects," "anticipates," "intends," "plans," "believes," "estimates" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions.

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: actual foreign currency exchange rates; our dependence on Masimo SET<sup>\*</sup> and Masimo rainbow SET<sup>™</sup> products and technologies for substantially all of our revenue; our ability to protect and enforce our intellectual property rights; potential exposure to competitors' assertions of intellectual property claims; the highly competitive nature of the markets in which we sell our products and technologies; our ability 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;

5

the loss of our customers; our ability to retain and recruit senior management; product liability claims exposure; our ability to obtain expected returns from the amount of intangible assets we have recorded; the maintenance of our brand; the amount and type of equity awards that we may grant to employees and service providers in the future; our ongoing litigation and related matters; 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, Quarterly Reports on Form 10-Q

124



and Current Reports on Form 8-K, all of which you may obtain for free on the SEC's website at www.sec.gov. Although we believe that the expectations reflected in our forwardlooking statements are reasonable, we do not know whether our expectations will prove correct. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, even if subsequently made available by us on our website or otherwise. We do not undertake any obligation to update, amend or clarify these forward-looking statements, whether as a result of new information, future events or

otherwise, except as may be required under applicable securities laws.

#### NOTE REGARDING THIS ANNUAL REPORT

Please note that this annual report does not constitute our "annual report to security holders" for purposes of the requirements of the SEC. For a copy of our 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which you may obtain for free on the SEC 's website at www.sec.gov.





#### Masimo • 52 Discovery • Irvine, CA 92618 • Tel: 949 297 7000

© 2017 Masimo, Masimo, SET, rainbow, rainbow Acoustic Monitoring, rainbow 4D, rainbow ReSposable, rainbow SET, RD rainbow SET, RD rainbow Lite SET, RD SET, 3D Desat Index Alarm, Adaptive Probe Off Detection, APOD, Blue, DCI, DOS, DST, EMMA, Eve, FastSat, FST, Halo Index, Iris, Iris Gateway, IRMA, ISA, iSpO2, Kite, LNCS, LNOP, Masimo Animal Health, Masimo Open Connect, Masimo Patient SafetyNet, Measure-through Motion and Low Perfusion, MightySat, M-LNCS, MOC-9, MS-1, MS-2011, MS-2013, MS-2040, MST, MX-1, MX-3, MX-5, MyView, NomoLine, O3, Oxygen Reserve Index, ORi, Pronto, Pronto-7, Pulse CO-Oximeter, PVi, Rad-57, Rad-67, Rad-9, Rad-97, Radical-7, Radius-7, RAM, Root, ROS, RRa, RRp, SatShare, SedLine, Signal Extraction Technology, Signal I.Q., SpCO, SpfO2, SpHb, SpMet, SpOC, SST, TFA-1, TF-1, UniView, uSpO2, X-Cal, and Improve patient outcomes and reduce the cost of care by taking noninvasive monitoring to new sites and new applications, are trademarks, registered trademarks, or service marks of Masimo Corporation.

All rights reserved. Apple, iPhone, iPad, iPod, and iPod touch are registered trademarks of Apple Inc. registered in the U.S. and other countries. IOS is a trademark or registered trademark of Cisco in the U.S. and other countries and is used under license. Android is a trademark of Google Inc. All other products, logos, or company names mentioned herein may be trademarks and/or registered trademarks of their respective companies.

#### REGULATORY NOTICE

This "Annual Report, International Edition" presents Masimo features and/or products that have obtained CE Mark-unless otherwise noted. Not all features and/or products have U.S. FDA 510(k) clearance. See the "Annual Report, U.S. Edition" for Masimo features and/or products that are cleared for the United States market. Outside the United States, please consult local Masimo representatives for the commercially available products in specific regions/countries with the appropriate regulatory approvals/clearances.

60073/PLM-10610B-0617