

Grazie  
سپاس گزارم  
감사합니다  
Tusind tak  
Dankeschön  
תודה  
Merci  
Ňakujem  
Teşekkür ederim  
Gracias  
Obrigado  
感謝  
Köszönöm  
Terima kasih  
ขอบคุณ  
Tack så mycket  
благодаря  
شكراً  
आप सभी का धन्यवाद  
**thank you**



International Edition

MASIMO 2066  
Apple v. Masimo  
IPR2022-01465

To the many who have helped shape, guide, inspire, and innovate the first 25 years of Masimo,

**thank you.**

## REGULATORY NOTICE

This Annual Report ("Annual Report, International and Investor Edition") presents Masimo features and/or products that are marketed outside of the United States and for the global investor audience.

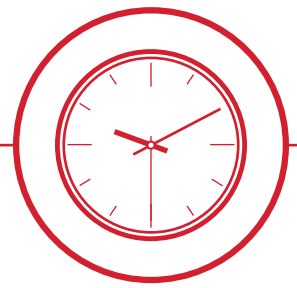
See the "Annual Report, U.S." for Masimo features and/or products that are FDA-cleared for the United States market.

At the time of printing, not all Masimo features and/or products profiled in the "Annual Report, International and Investor Edition" have worldwide regulatory clearances and/or approvals.

For example, the following profiled features and/or products are pending clearances as of February 12, 2015:

- Europe CE Marking: Animal Health products, iSpO<sub>2</sub>, and iSpO<sub>2</sub> Rx for infant & neonatal use and MightySat Rx
- Canada MDL: ISA AX+, ISA OR+, iSpO<sub>2</sub> Rx for infant & neonatal use, Radius-7 and ORI.

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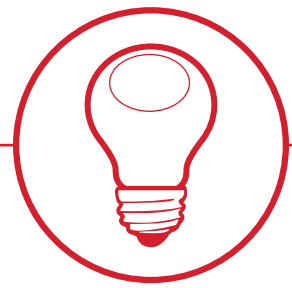
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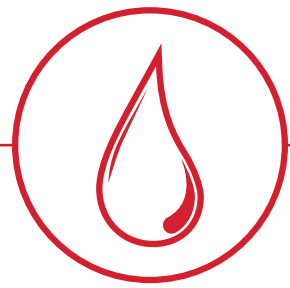
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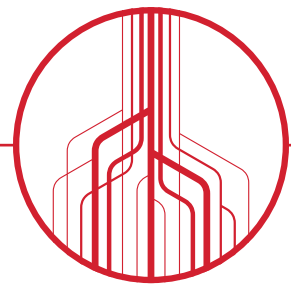
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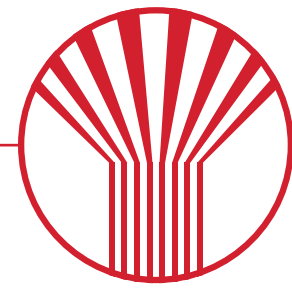
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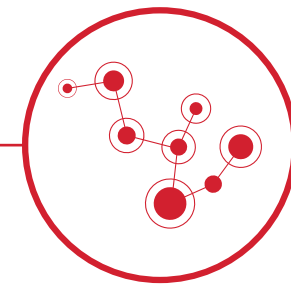
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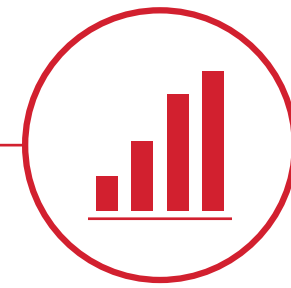
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# THE FIRST 25 YEARS



1989

**Founding of Masimo**  
Company founded by Massi Joe E. Kiani and soon after Mohamed Diab and Mary Kiani joined



1995

**Masimo SET<sup>™</sup> Pulse Oximetry**  
First Measure-through Motion and Low Perfusion<sup>™</sup> pulse oximetry – debuts at the Society for Technology in Anesthesia<sup>™</sup> and wins Excellence in Technology Innovation Award



1995

**High-Fidelity Pleth Waveform**  
First true diagnostic-quality pleth waveform



1995

**MS-1<sup>™</sup> Board**  
First commercially available SET<sup>™</sup> OEM board

PI

1995

**Perfusion Index**  
First accurate quantification of amplitude of the pleth waveform to 0.02%



1996

**LNOP<sup>®</sup> Sensors**  
High signal-to-noise ratio sensor with non-absorbent material, rejuvenating adhesive, and replaceable tapes – minimizing waste

First Implementation with Masimo SET<sup>®</sup>

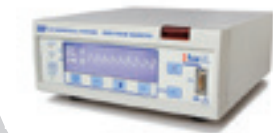
1996

**Kontron Multi-parameter**  
First Masimo SET<sup>™</sup> multi-parameter implementation

First Standalone with Masimo SET<sup>®</sup>

1997

**NEC**  
First Masimo SET<sup>™</sup> standalone device implementation



1998

**IVY Biomedical 2000**  
First Masimo SET<sup>™</sup> standalone device implementation in the U.S.

Breakthrough Study

1998

Breakthrough study shows **Masimo LNOP<sup>®</sup> sensors** last nearly twice as long as the market-leading adhesive disposable sensors

Thomas A et al. *Respir Care*. 1998;43(10):860.

SmarTone

1998

**SmarTone™**  
Ability to maintain saturation tones with variable pitch during low signal-to-noise conditions



1998

**SofTouch™**  
First Masimo sensor designed for sensitive skin of neonates



1998

**Datascopes**  
Datascopes, along with other OEMs, brings commercialization of Masimo SET™ in to their patient monitors

Measure-through Motion  
510(k)

1998

First FDA 510(k) clearance for Measure-through Motion pulse oximetry

Measure-through Low Perfusion  
510(k)

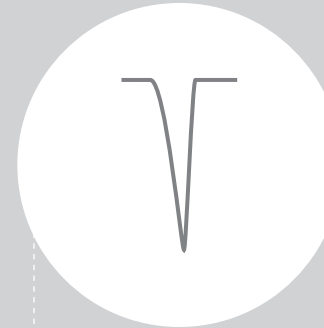
1999

First FDA 510(k) clearance for Measure-through Low Perfusion pulse oximetry



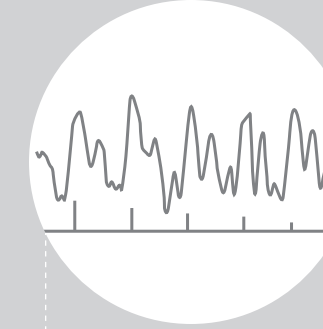
2000

**Radical® Pulse Oximeter**  
First 3-in-1 pulse oximeter standalone device for bedside monitoring with detachable handheld unit for portable monitoring, SatShare® interface to upgrade conventional pulse oximetry in multi-parameter patient monitors to Masimo SET™, and first monitor to have an automated rotational screen



2000

**FastSat®**  
Enabling accurate tracking of rapid saturation changes



2000

**Signal IQ®**  
First to quantify measurement quality and give clinicians a way to know when to have confidence in the SpO2 values during motion and low perfusion



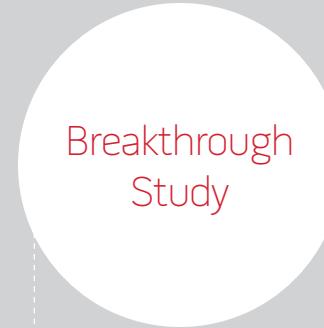
2000

**FastStart™**  
SpO2 value in less than 10 seconds from the time the instrument is turned on

Award-winning Breakthrough Study

2000

Study shows **Masimo SET™** helps increase caregiver efficiency  
Durbin C.G. et al. Anesthesiology. 2000; 93(3A): A-556.



2002

Study shows **Masimo SET™** helps wean patients from the ventilator faster, reduce FiO2 levels, and reduce arterial blood gas measurements  
Durbin C.G. et al. Crit Care Med. 2002 Aug;30(8):1735-40.

Breakthrough Study

2002

Breakthrough study shows Masimo SET™ linked to reduced medical errors in critical care medicine

Hay W.W. et al. *J Perinatol*. 2002 Jul-Aug;22(5):360-6.

Breakthrough Study

2003

Breakthrough study shows Masimo SET™ linked to reduced retinopathy of prematurity in neonatal patients

Chow L.C. et al. *Pediatrics*. 2003 Feb;111(2):339-45.

APOD

2003

Adaptive Probe Off Detection® (APOD™)

Reducing false display of values by 83% when the probe is not on the patient, compared to competing pulse oximeters



2004

Rad-5™ Handheld Pulse Oximeter

First handheld incorporating Masimo SET™



2004

LNCS™ Sensors

Low noise cable sensor design



2004

Newborn Sensor

First sensor designed for newborn monitoring during resuscitation



2005

Blue™ Sensor

First sensor for accurate measurements in cyanotic infants and children

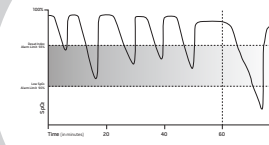


Masimo rainbow

2005

rainbow™ SET in MX-1™ Board

First noninvasive blood constituent platform



2005

3D Desat Index Alarm™

First alarm to alert clinicians to patterns of transient desaturation that may predict respiratory depression

SpCO

2005

SpCO™

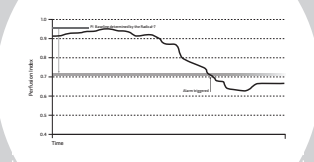
First noninvasive carboxyhemoglobin measurement



2005

Rad-5™

First handheld capable of noninvasively measuring carbon monoxide levels in the blood



2005

3D Perfusion Index Delta Alarm™

First alarm to alert clinicians of changing peripheral perfusion status that may indicate worsening condition



2005

**Radical-7**  
First bedside rainbow SET<sup>™</sup>  
Pulse CO-Oximeter<sup>®</sup>



Breakthrough  
Study

2005

Breakthrough study shows  
assessment with **Masimo  
SET<sup>™</sup>** improves screening  
for congenital heart  
disease in newborns  
  
de-Wahl Granelli A, et al. *Acta  
Paediatr.* 2005 Nov;94(11):1590-  
1596.



2006

**SpMet<sup>™</sup>**  
First noninvasive  
methemoglobin  
measurement



PVI

2007

**Pleth Variability  
Index (PVI)**  
First noninvasive  
and continuous fluid  
responsiveness  
measurement



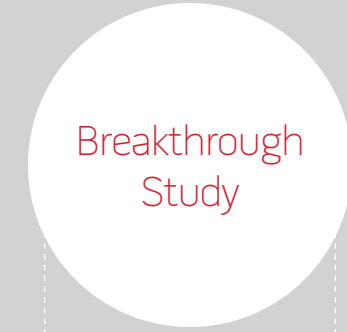
2007

**Patient SafetyNet<sup>™</sup>**  
First remote notification  
system capable of rainbow<sup>®</sup>  
measurements – with  
optional central monitoring  
based on 802.11 ABG



2008

**National Fire Protection  
Association Standard**  
NFPA 1584 releases  
fire rehab standards  
and includes carbon  
monoxide assessment  
during fire rehab



Breakthrough  
Study

2008

Breakthrough study  
shows **PVI<sup>®</sup>** predicts  
fluid responsiveness  
during surgery  
  
Cannesson M, et al. *Br J Anaesth.*  
2008 Aug;101(2):200-6.



SpHb

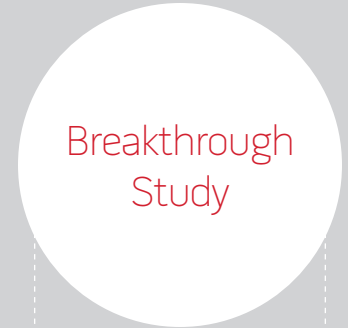
2008

**SpHb<sup>®</sup>**  
First noninvasive  
and continuous  
total hemoglobin  
measurement



2008

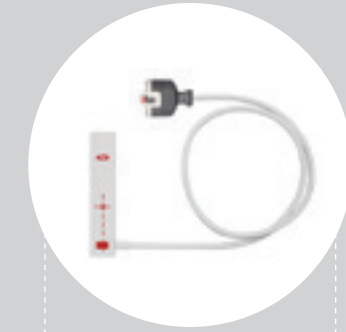
**Rad-87<sup>™</sup>**  
First Pulse CO-Oximeter  
with integrated 802.11  
ABG wireless radio



Breakthrough  
Study

2008

Breakthrough study  
shows **SpCO<sup>®</sup>** identifies  
unsuspected CO poisoning  
in the ER  
  
Suner S, et al. *J Emerg Med.* 2008  
May;34(4):441-50.



2008

**NeoPt-500**  
First sensor for extremely  
low birth weight babies



2009

**rainbow ReSposable<sup>®</sup>  
Sensor System**  
featuring performance  
of adhesive sensors with  
Green Designed In<sup>™</sup>, which  
reduces both landfill and  
carbon footprint

RRa

2009

**rainbow® Acoustic Monitoring (RAM™)**

First noninvasive and continuous respiration rate (RRa) monitor with acoustic sensor

Fluid Management Study

2010

Study shows **PVI** helps clinicians improve fluid management and decrease lactate levels in surgical patients

Forget P, et al. *Anesth Analg*. 2010 Oct;111(4):910-4.

Breakthrough Study

2010

Study shows **Masimo SET™** and **Masimo Patient SafetyNet** improve outcomes in adults on the med-surg unit – fewer rapid response activations, ICU transfers, and ICU days

Taenzer A.H., et al. *Anesthesiology*. 2010 Feb;112(2):282-7.

Breakthrough Study

2010

Study shows **PVI** helps assess which patients will become hemodynamically unstable with the addition of PEEP

Desebbe O et al. *Anesth Analg*. 2010;110:792-798.



2010

**Masimo Foundation for Ethics, Innovation, and Competition in Healthcare** created with a \$10 million gift



2010

**Radical-7**  
Featuring touch screen display, wireless capability, and external display functionality



2010

**Pronto® and Pronto-7™**  
First noninvasive spot checking of hemoglobin, SpO<sub>2</sub>, pulse rate, and perfusion index

Adaptive Threshold Alarm

2010

**Adaptive Threshold Alarm**  
First dynamic physiologic alarm threshold based on changes from each patient's baseline value

Breakthrough Study

2010

**SpHb**  
Breakthrough study shows SpHb monitoring helps clinicians optimize blood management

Ehrenfeld J.M., et al. *American Society of Anesthesiologists*. 2010;LB05.

RRp

2011

**Respiration Rate from the Pleth (RRp™)**  
First noninvasive and continuous respiration rate measurement from the pulse oximeter signal

Halo Index

2011

**Halo Index™**  
Cumulative trending assessment of the global patient status. Increases in Halo Index suggest physiologic deterioration and may indicate a need for clinicians to more closely assess the patient



2012

**Capnography and Gas Monitoring**  
Masimo begins offering innovative, multispectral technologies for measuring respiratory gases and anesthetic agents



SpfO<sub>2</sub>

2012

**SpfO<sub>2</sub>**  
The first noninvasive fractional oxygen saturation monitor measurement



2013

**Root Patient Monitoring and Connectivity Platform**

First device to integrate:  
> rainbow measurements  
> Iris connectivity for third party devices  
> Masimo Open Connect (MOC-9™) for measurement expansion



2013

**ISA Capnography**

The ISA capnography MOC-9 module for Root features high sidestream performance and offers cost-effective disposables through the innovative Nomoline adapter with extended monitoring time and use of generic cannulas



2014

**Radius-7**

Radius-7 for Root is the first and only wearable, wireless monitor with Masimo's breakthrough rainbow SET technology



2014

**Eve Newborn Screening Application**

Animated tutorial for the Radical-7 specifically designed to help clinicians more effectively and efficiently screen newborns for critical congenital heart disease (CCHD)

ORI

2014

**ORI**

The first noninvasive and continuous parameter to provide insight into oxygen reserve in patient's receiving supplemental oxygen



2013

**iSpO<sub>2</sub> Pulse Oximeter**

The first pulse oximetry for both iOS (Apple) and Android™ mobile devices



2013

**SedLine Brain Function Monitoring**

The SedLine MOC-9 module for Root features 4 simultaneous channels of high-quality EEG data; SedLine provides continuous information about both sides of the brain and provides information about a patient's response to anesthesia



2014

**O<sub>3</sub> Regional Oximetry**

The O<sub>3</sub> Regional Oximetry MOC-9 module for Root features near-infrared spectroscopy (NIRS) and reflectance pulse oximetry to enable simultaneous monitoring of tissue oxygen saturation (rSO<sub>2</sub>) in the brain and arterial blood oxygenation (SpO<sub>2</sub>)



2014

**rainbow DCI-mini**

The first and only reusable spot check hemoglobin sensor for infant and pediatric patients from 3 to 30 kg



2014

**TFA-1**

Single-patient-use forehead sensor for Masimo SET



2015

**MightySat**

First fingertip pulse oximeter with Masimo SET Measure-through Motion and Low Perfusion technology

For sports and aviation use only in the U.S.



# LETTER FROM THE CHAIRMAN & CEO

2014 marked the 25<sup>th</sup> anniversary of Masimo. I would like to thank everyone, from our employees and customers to our investors and advisors, who has helped Masimo achieve its mission of improving patient outcomes and reducing cost of care by taking noninvasive monitoring to new sites and applications.

**We** believe that Masimo SET<sup>®</sup> pulse oximetry now helps clinicians monitor more than 100 million patients a year and is the primary pulse oximetry technology for eight of the top 10 hospitals on the U.S. News & World Report Best Hospitals Honor Roll for 2014-2015. That's a long way from 1989, when we started with a \$40,000 loan on my condominium and the dream that one day we could fulfill our mission, make a contribution to society, reward the investors who believed in us, and achieve financial stability.

Since its introduction, Masimo SET<sup>®</sup> Measure-through Motion and Low Perfusion™ pulse oximetry has helped prevent at least 25,000 potential cases of retinopathy of prematurity (ROP) in newborns worldwide, and has impacted the quality of care for millions of patients of all ages, including babies born with critical congenital heart disease, and adults in post surgical wards.

## MISSION STATEMENT

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

So even as I take humble pride in Masimo's achievements, I can tell you we are all committed to achieving even greater accomplishments in the years to come. This is one reason why we worked so hard to put in place a plan several years ago to produce a product a month during 2014, our 25<sup>th</sup> anniversary. This was more than just flexing our innovation might. By producing clinically significant products at a pace unmatched by anyone else in the medical technology industry, we demonstrated that Masimo is more than capable of addressing

current market needs and, more importantly, anticipating future market expectations. A few of the highlights include:

**1** CE Marking of O3 regional oximetry\* for Root. O3 regional oximetry uses near-infrared spectroscopy (NIRS) through MOC-9 with up to two sensors per MOC-9 module. Each sensor contains four light-emitting diodes (LEDs) and two detectors to continuously and simultaneously measure both organ oxygen saturation (rSO<sub>2</sub>) and arterial blood oxygenation (SpO<sub>2</sub>). Root

\*O3 regional oximetry is pending FDA 510(k). Not available in the U.S.

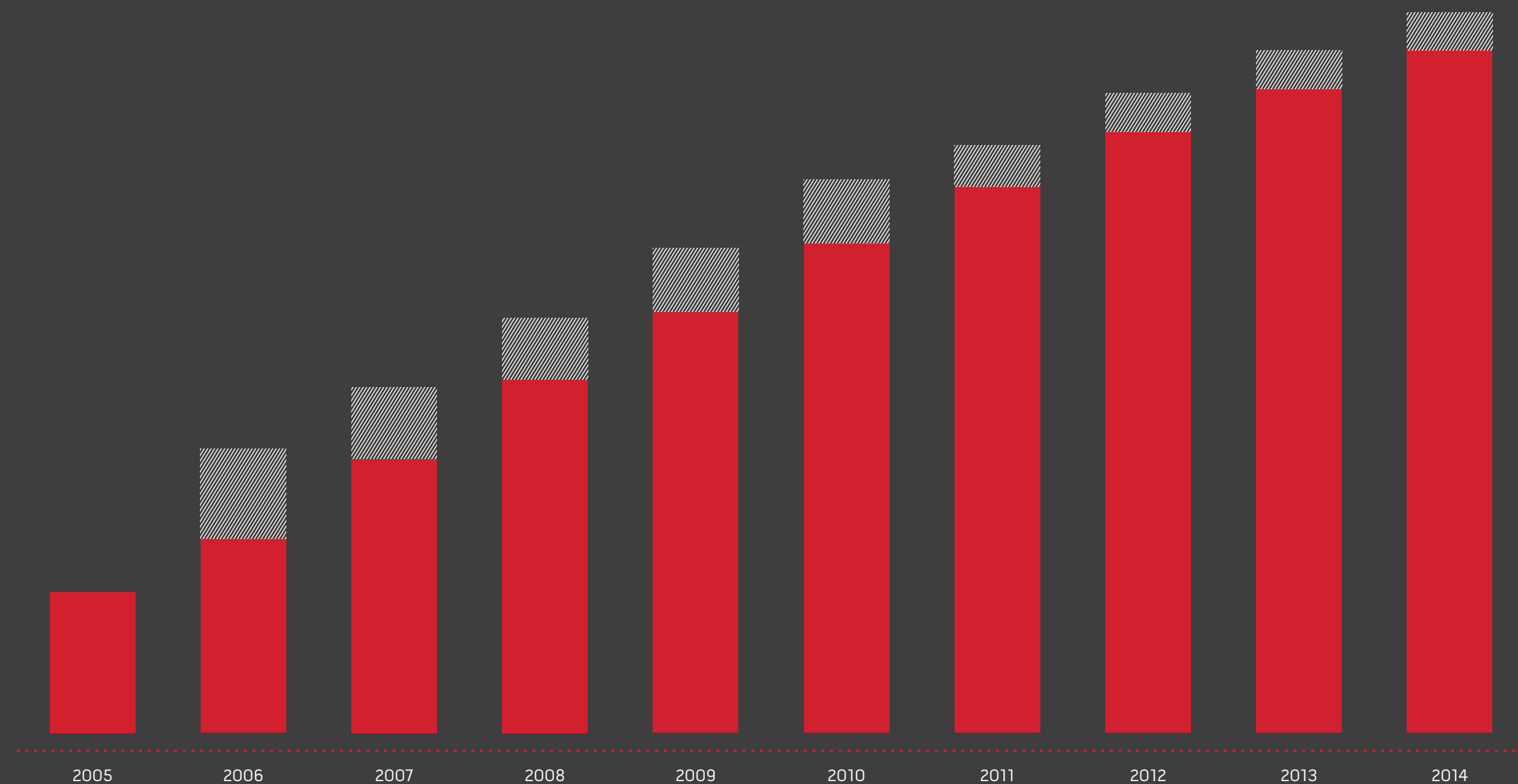


**Joe Kiani**  
Chairman & CEO, Masimo

# REVENUES // 2005-2014

IN MILLIONS OF DOLLARS

■ PRODUCT REVENUES // ▨ ROYALTY REVENUES



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Total Revenues	107.9	224.3	256.3	307.1	349.1	405.4	439.0	493.2	547.2	586.6
Product Revenues	---	155.5	200.2	259.6	300.1	356.4	406.5	464.9	517.4	556.8
Royalty Revenues	---	68.8	56.1	47.5	49.0	49.0	32.5	28.3	29.8	29.8

allows either one or two O3 MOC-9 modules to be connected, enabling monitoring with as few as one and as many as four sensors. Organ Oximetry, also known as regional oximetry and cerebral oximetry, enables the continuous assessment of the oxygenation of the organ beneath the sensor. O3 helps clinicians detect cerebral hypoxemia that pulse oximetry alone can miss. In addition, the Root monitor can automate the differential analysis of regional to central oxygen saturation. O3 monitoring is as simple as applying O3 regional oximetry sensors to the forehead and connecting the O3 MOC-9 module to any Root through one of its three MOC-9 ports.

**2** iSpO2 Pulse Oximeter for Android. With the release of iSpO2 in the popular Android operating system, more consumers than ever have access to Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry – the same technology used in leading hospitals worldwide. iSpO2 provides accurate, real-time oxygen saturation (SpO2), pulse rate (PR), and perfusion index (PI) readings – ideal for anyone who desires access to accurate health data through their mobile devices.

**3** FDA 510(k) clearance of the Root patient monitoring and connectivity platform. Root can be a hub at the bedside, enable Masimo's breakthrough noninvasive measurements to be used by experts and novices with trend and analog views, take advantage of a rich set of additional measurements, and provide other companies a robust platform on which to develop other innovative measurements via MOC-9. High-impact innovations in Root that are now available in the U.S. include:

- > Iris – Built-in connectivity gateway through Iris for verified standalone devices such as IV pumps, ventilators, hospital beds, and other patient monitors to EMR
- > MOC-9 – Flexible measurement expansion through Masimo Open Connect (MOC-9) with MOC-9 modules from Masimo or third-party measurements from other companies to expand the platform's measurements and capabilities. New MOC-9 modules may require new 510(k) clearances
- > Capnography – ISA CO2 sidestream module featuring fast warm-up time and the

innovative and cost-effective Nomoline sampling line

- > Wireless functionality – Capable of transmitting information through Bluetooth and Wi-Fi.

**4** Later, Masimo also announced ISA OR+ multigas monitoring, a Masimo Open Connect (MOC-9) Module for Root. During general anesthesia, the ISA OR+ monitors the inhaled and exhaled concentration of five anesthetic gas agents (Sevoflurane, Isoflurane, Halothane, Desflurane, Enflurane), carbon dioxide (CO2), nitrous oxide (N2O), and oxygen (O2), in addition to respiration rate. When technology modules are connected with Root, multiple additional parameters are available including Masimo SET® pulse oximetry, noninvasive and continuous hemoglobin (SpHb), PVI, SedLine brain function monitoring, and O3 regional oximetry.

**5** Another amazing technology for Root that we're very proud of is Radius-7, the first and only wearable, wireless monitor with Masimo's breakthrough Masimo SET® and rainbow Acoustic Monitoring™ technology,

offering patients continuous monitoring with freedom of movement. Radius-7, which received FDA 510(k) clearance in 2014, can alert clinicians – at the bedside or remotely, through our Patient SafetyNet\* remote monitoring system – of critical changes in a patient's oxygen saturation and pulse rate – even during states of motion and low perfusion – as well as

## 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

\*The use of the trademarks Patient SafetyNet and PSN is under license from University Health System Consortium.





respiration through acoustic respiration rate (RRa). Lightweight at only 0.34 lbs. (155g), the Radius-7 attaches to the patient's arm, allowing untethered monitoring while they are in bed or out. With no need to disconnect and reconnect the cable to get out of bed, the Radius-7 reduces the need for nursing assistance. And the Radius-7's wireless communication functionality – either short-range via Bluetooth back to Root or with upgradeable WiFi+ for long-range communication – ensures the patient can be continuously monitored and connected to caregivers wherever they are in the hospital. Radius-7 allows clinicians to continuously monitor their patients when they are mobile, and studies have shown that patient mobility is a key factor in more rapid patient recovery.<sup>1</sup>

**6** MightySat, the first fingertip pulse oximeter with Masimo SET®. MightySat, for sports and aviation use, is available in three versions – each of which provides oxygen saturation (SpO<sub>2</sub>), pulse rate (PR), and perfusion index (PI) measurements in a compact, battery-powered design with a large

color screen that can be rotated for real-time display of the pleth waveform as well as measurements. Optional Bluetooth wireless functionality enables measurement display via a free, downloadable app on iOS and Android mobile devices as well as the ability to trend and communicate measurements. And for those who want to use their pulse oximeter to evaluate another physiologic dimension, MightySat is the only fingertip pulse oximeter available with the optional Pleth Variability Index (PVI), a measure of the dynamic changes in PI that occur during one or more complete respiratory cycles.<sup>2</sup>

**7** CE Mark of Eve™\*, a newborn screening application for the Radical-7. Masimo gained its first commercial foothold in the NICU, so this new technology holds a special place for us. Eve is an intuitive software feature to help clinicians more effectively screen for critical congenital heart disease (CCHD). Eve automates the screening steps with animated instruction, including sensor application, measurement selection, and screening result determination. Eve owes

its name to the daughter of Annamarie Saarinen, co-founder and CEO of the Newborn Foundation. Eve was diagnosed at 48 hours old with CCHD, and Annamarie has made it her life's mission to make sure all newborns are screened. We hope our Eve software feature will help professionals accomplish their mission to help save the lives of babies and spare families from heartbreaking loss.

**8** Oxygen Reserve Index (ORI™†). With CE Mark and limited market release, ORI became the first noninvasive and continuous parameter of its kind to provide insight into a patient's oxygen reserve when they are receiving supplemental oxygen. With ORI, Masimo's rainbow SET® Pulse CO-Oximeters with the latest MX-5 circuit board can now measure an unprecedented 11 parameters<sup>3</sup> through noninvasive optical rainbow® sensor technology. A clinical study at the University of Texas Southwestern and Children's Medical Center in Dallas evaluating ORI showed that ORI can provide advanced warning of potential hypoxia and may help clinicians optimize oxygenation before and during

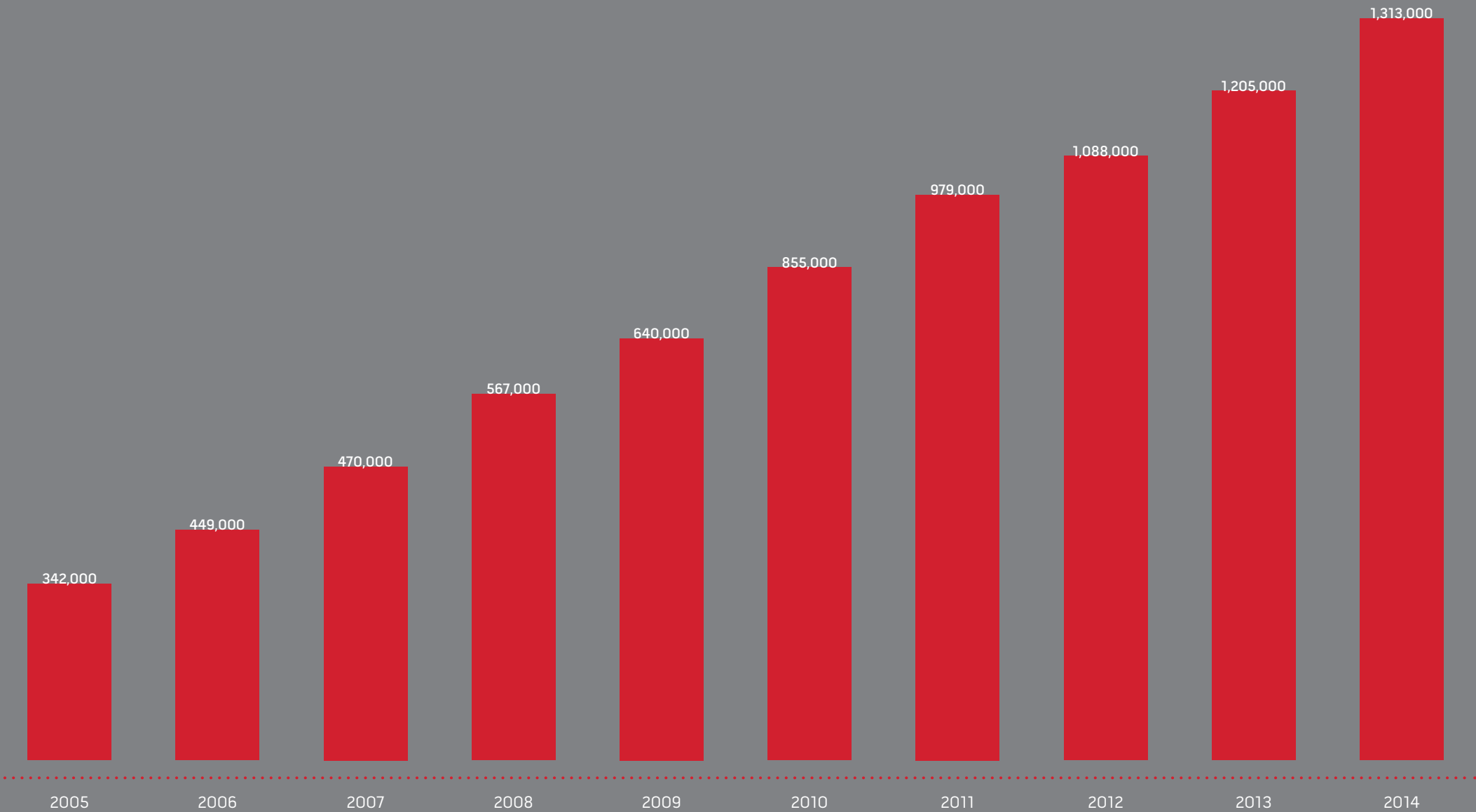
prolonged intubation.<sup>4</sup> The study was among 12 selected from more than 1,000 as one of the Best Abstracts at the American Society of Anesthesiologists (ASA) Annual Meeting in New Orleans, the largest gathering of anesthesiologists in the world.

**9** CE Mark, clearance in Japan, and limited market release of the rainbow® DCI-mini™‡. DCI-mini is the first noninvasive hemoglobin (SpHb) spot-check sensor for infants and small children (weight 3 to 30 kg). Paired with Masimo's handheld Pronto device, the rainbow® DCI-mini sensors are designed to help clinicians quickly and easily spot-check hemoglobin levels. DCI-mini allows clinicians and public health programs around the world to expand hemoglobin assessment to vulnerable populations who need a noninvasive and convenient method. We hope that the new rainbow® DCI-mini will help more infants and small children, along with their moms, around the globe to receive timely assessment and treatment, which will benefit their long-term health, as well as the health of our society.

## INSTALLED BASE // 2005-2014

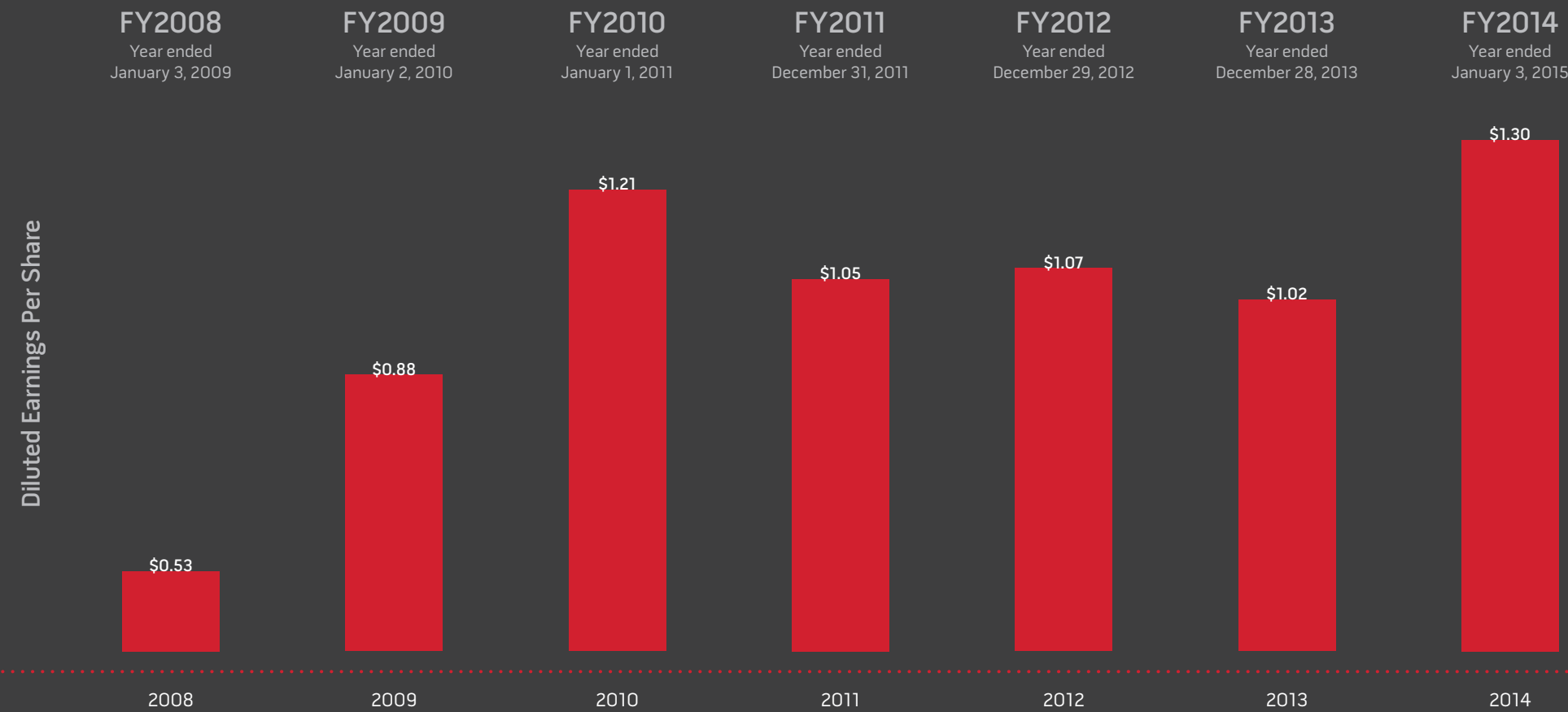
ESTIMATED UNITS

EXCLUDES HANDHELDS



<sup>1</sup> The configuration for long-range communication is not yet released. \* Eve CE Marked. Currently not available in the U.S. † ORI is CE Marked. Currently not available in the U.S. ‡ rainbow® DCI-mini is CE Marked. Currently not available in the U.S. <sup>2</sup> Needham D, Korupolu R, Zanni J, Pradhan P, Colantuoni E, Palmer J, Brower R, Fan E. "Early Physical Medicine and Rehabilitation for Patients With Acute Respiratory Failure: A Quality Improvement Project." *Archives of Physical Medicine and Rehabilitation* Vol 91, Issue 4, PP 536–542, April 2010. <sup>3</sup> The utility of PVI is unknown at this time and requires further clinical studies. Technical factors that may affect PVI include probe position and patient motion. <sup>4</sup> Eleven parameters include: 1) oxygen saturation (SpO<sub>2</sub>); 2) Pulse rate; 3) Perfusion index (PI); 4) Pleth Variability Index (PVI); 5) Respiration Rate from the pleth (RRp); 6) Total hemoglobin (SpHb); 7) Oxygen Content (SpCO); 8) Carboxyhemoglobin (SpCO); 9) Methemoglobin (SpMet); 10) Fractional oxygen saturation (SpFO<sub>2</sub>); 11) Oxygen Reserve Index (ORI). \*Szmuk P, Steiner J, Olomu P, Dela Curuz J, Sessler D. Oxygen Reserve Index - a New, Noninvasive Method of Oxygen Reserve Measurement" Proceedings of the American Society of Anesthesiologists, Oct.14, 2014, New Orleans, BOC12, Room 275-277.

# EARNINGS PER SHARE DATA FOR ANNUAL REPORT // 2008-2014



**10** CE Mark of the TFA-1\* transreflectance forehead adhesive sensor. TFA-1, a single-use sensor for adult and pediatric patients, offers clinicians the power of Masimo SET® pulse oximetry on an alternative monitoring site for rapid detection of oxygen saturation changes during low perfusion. TFA-1 also offers pulse rate, perfusion index, and PVI measurements. TFA-1 gives clinicians yet another way to leverage the breakthrough measurement capability in Masimo SET® pulse oximetry. By continuing to take Masimo's breakthrough technologies to new sites and applications, we are helping improve patient outcomes and safety while reducing cost of care.

**W**hile we are happy that we fulfilled the expectations of everyone who invested in Masimo up until we went public, we are restless in fulfilling the expectations of our investors, post our IPO. I am grateful for the patience that our investors have exhibited while we work through the 10-year plan we established in 2007. The good news for those who remained patient over the past 7 years is that we expect all of the planning and execution of the past 7 years will begin to pay off in not only the lives we improve and save, but the increase we expect in our earnings and hopefully our stock price.

For fiscal year 2014, total revenue rose 7% to \$586.6 million from \$547.2 million the year

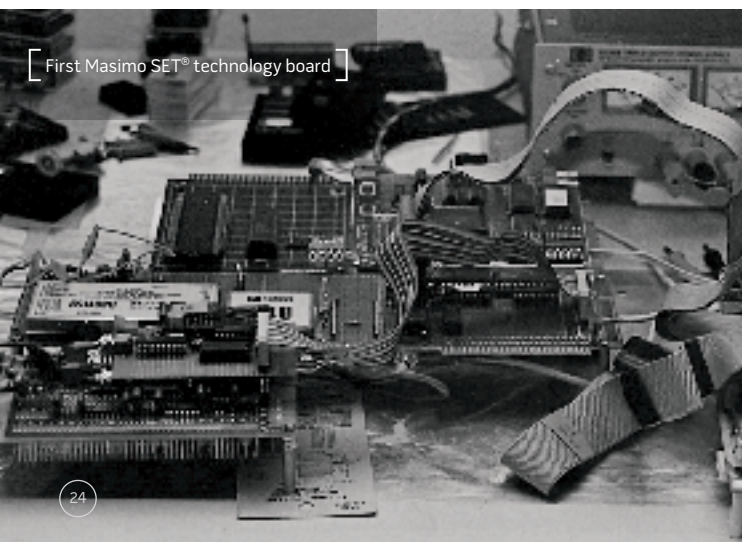
before. That included product revenue of \$556.8, million – up 8% from \$517.4 million. Since 2007, we have focused on building a strong and knowledgeable worldwide sales and marketing organization, capable of expanding both our Masimo SET® and rainbow® businesses. While we continue to make strategic investments in our worldwide organization, we believe that we have now reached the level of staffing needed for our sales, marketing, engineering, and other organizations to support higher product revenue growth.

It is not hubris to envision that within the next 3 years, Masimo will reach new heights with our customers and shareholders, as our

lifescaping breakthrough products become ubiquitous in healthcare settings and beyond. Our technology will expand and evolve to meet the future needs of healthcare, by helping improve surgical and post-surgical outcomes with shorter lengths of stay. By better assessing patients we can help reduce the cost of care.

We've set in motion the "consumerization" of our core technologies with the iSpO2 pulse oximeter for smartphones, and more recently MightySat, the world's first fingertip pulse oximeter with Masimo SET® pulse oximetry. Elite athletes such as an Olympic silver medal cyclist and a four-time free diving champion and Guinness World Record holder

\*TFA-1 is CE Marked. Currently not available in the U.S.





It is humbling and profoundly motivating to think that the technology we have created – and continue to create – is saving and improving lives around the world.

are using our technologies to help improve their training and recovery regimens. Throughout most of Masimo's history, our medical devices have been designed to help patients recuperate. Now, we're also helping healthy people improve their lives.

Since its beginning, Masimo has confronted and overcome obstacles – a real-world David versus Goliath story, only with sequels. It has been a wonderful journey, with many successes and challenges, and undoubtedly many more yet to come. But we stand alert and ready and will not let anything

stop us from getting our breakthrough technologies in the hands of clinicians for the safety and care of patients.

It is humbling and profoundly motivating to think that the technology we have created – and continue to create – is saving and improving lives around the world. This is a great honor, and a great responsibility. On behalf of all of us at Masimo, we look forward to rising to the challenges of this millennium, driven by the mission to improve patient outcomes, while reducing the cost of care by taking noninvasive monitoring to new sites and applications.

**Joe Kiani**  
Chairman & CEO

Joe Kiani and Mohamed Diab solved the "unsolvable" – inventing pulse oximetry that was accurate when patients moved or had low perfusion.



OUR STORY,  
FROM THOSE  
WHO LIVED IT



# The Early Years

as told by Mohamed Diab, Mary Kiani, Walt Weber, Bob Smith, and Ammar Al-Ali

From the 1975 debut of the Nihon Kohden OLV-5100, the world's first pulse oximeter, the science of pulse oximetry was plagued by unreliability when it was needed most – during patient motion and low perfusion. The industry had given up and considered the problem “unsolvable.” Clinicians were forced to live with the results – excessive false alarms, delayed notification due to long averaging times, inaccurate data, and an inability to obtain data on the most critical patients.

When Joe Kiani and Mohamed Diab looked at pulse oximetry signals differently than anyone had before, they created new possibilities. By employing advanced signal processing techniques – including parallel engines and adaptive filters – they believed they could find the true arterial signal that would allow accurate monitoring of arterial oxygen saturation and pulse rate, even during the most challenging conditions. After six years of dedicated and focused research and development, Masimo SET® debuted in 1995 at the Society for Technology in Anesthesia and won the prestigious Excellence in Technology Innovation Award.

## Mohamed Diab

> *At Masimo, we learned from the beginning that if it could be imagined, Mohamed could make it become reality. That's how good he is. From figuring out how to make adaptive filters work in noninvasive monitoring, to figuring out the discrete saturation transform, he has always been a core of technical ability and integrity that allowed our company to attract many other amazing engineers because they love working around Mohamed.*

“WHEN WE STARTED Masimo, medical device manufacturers assumed that ‘motion artifact’, in pulse oximetry was an ‘unsolvable’ problem and that the best a pulse oximeter could do was detect the presence of motion and freeze the number on the screen until the motion subsided. In fact, even the slightest hand motion generates extraneous signals, many times the size of the arterial pulse, and hence it can easily corrupt the measured arterial signal, which causes conventional pulse oximeters to display false low or high SpO<sub>2</sub> and pulse rates – resulting in false alarms as high as 90%. I recall a meeting with Joe Kiani in late 1989 where he told me that if we were to build a successful pulse oximeter company we had to solve two fundamental problems: Motion Artifact and Low Perfusion.

“We started with motion artifact knowing well that adaptive filters were the way to go – but how? No book or paper had a solution for the problem. Our first breakthrough came in May 1990 when we figured out a way to mathematically extract a signal that described the noise using a conventional sensor with only two LEDs. However, that solution required a quiet period, at the beginning, where a clean arterial signal could be sampled. Unsatisfied with that solution, the second breakthrough came when I was on a plane coming back from Syria. I ended up calling it DST, the discrete saturation transform.

“Here’s a simple explanation: Imagine you’re moving to Los Angeles and want to buy a house. You ask what the median price of a home is, but there’s a huge difference in prices in different areas. So, what if someone gives you a map of each city in the area: the median price in Palos Verdes is this, in Beverly Hills it’s this much, in Compton this much, a distribution of prices. You can look at the full picture and more easily see where you can afford to buy. With a conventional pulse oximeter, when you shake your hand, you get a false reading that is kind of the average between the venous and the arterial saturations.

“It’s mixed in-between. If you’re not shaking your hand, then you get a good reading. As the late Dr. Swan characterized it, “Pulse oximetry has been, at best, a fair weather friend.” What DST gives you is a map; it says this is the good number and here are some of the bad numbers. It just breaks things up and shows a total map. That enabled us to extract the correct arterial saturation even under motion conditions, and that’s the power of it. That changed everything for us because we knew that there was at least one solution to the motion artifact problem!

“We solved the low perfusion problem – measuring blood oxygen saturation at extremely low blood flow – by properly designing our hardware and sensors and by using advanced digital signal processing techniques. This enabled us to reliably extract extremely small signals under a wide range of patient conditions.

“By the summer of 1992 Bob Smith, Rex McCarthy and Walt Weber had joined Masimo. They have tremendously contributed to the hardware, software and algorithm development. Bob’s work on a very low-noise platform was crucial in extracting very low signals. Walt and Rex further developed the DST as well as newer techniques for extracting the arterial signal under motion condition. In 1995 Ammar Al-Ali joined us and quickly became the leader of Masimo’s pulse oximetry development with major contributions to the algorithms, software and system design.”

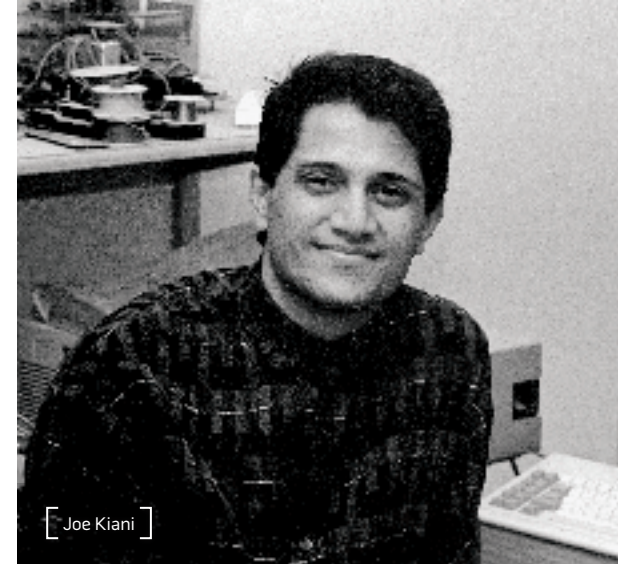
## Mary Kiani

> *Mary was a full-time dentist and recently married, yet she knew her brother was also working a full-time job while trying to build what became Masimo. With no expectations of any stock or value, merely to help out, she drove to the L.A. Public Library to conduct patent searches and to UCSD and UC Irvine to do library searches*

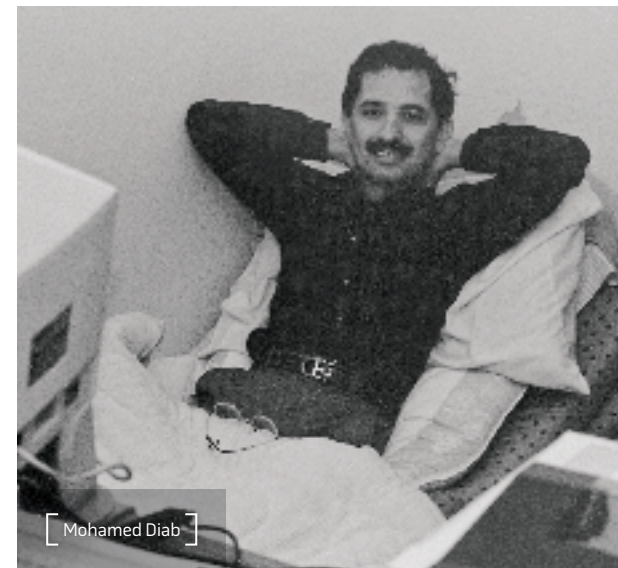
*on physiology that helped us better understand the problems we were facing.*

“WHEN MASIMO STARTED, I wanted to help my brother, because he was working full time and doing Masimo at the same time with no help from anyone. I was a licensed dentist, and working full time at an office in Brea, but my work was at night and Saturdays which gave me all day to help him. I did secretarial duties, answered the phones, and handled the mail, did library searches, whatever was needed. I was also Director of Medical Affairs, being the only degreed person on staff with anything like a physician’s license. I conducted early patent searches at the Los Angeles public library. When professional copies needed to be made of the business plan that Joe had developed or logo graphics for publications, I would go to the printers. I helped our mom cook for the Christmas parties, and to provide food for the investor and director meetings. Basically, I took care of whatever he needed to free him to work on the prototype, develop the business plan, find investors, go to various business conventions, and all other things that he did to make the company happen – which were endless.

“When Masimo first gained ample funding, we had about 60 people on staff. Joe asked me to resign, as he had people who were more qualified to be members of the board of directors of the company by that time. Joe always did what was best for the company. That meant having the right people for the right job at the right time, and I was no longer what the company needed. I was happy to do it, as my intention all along had been to help until I was no longer needed. I had my own career and a growing family. He made sure that I had plenty of shares in our then still-private company. He always took care of people. I didn’t realize what the stock might mean, and I wasn’t the only one who found out about the rewards of helping Joe. A friend of his, Barry Miller, loaned Masimo a top-of-the-line Macintosh computer at a time when we couldn’t easily



[ Joe Kiani ]



[ Mohamed Diab ]



[ Mary Kiani ]





Sales and Engineering "debate" whether product is ready to ship



Bob Smith



Masimo's first incarnation was Vital Signals Inc, or VSI



Walt Weber

afford one, so Joe could do the business plan; because of being so gracious about the computer, Joe gave him 30,000 shares, which later with all the stock splits became much more shares. Barry passed away before Masimo went public, but his wife and daughter made a lot of money with those shares. At the first annual shareholder meeting after 2007, Barry's widow found Joe and said, 'Joe, we felt like Barry sent us money from heaven.' Helping people can pay off in ways you don't expect. It's all about your heart."

### Walt Weber

> When Walt joined our company in the very early days, we had the technology of solving the pulse oximeter motion problem, but implementation of it was unstable. The signal processing portion had to be re-done. Walt figured out how to solve that problem and that allowed us to jump forward with the development of the commercial product. He has continued to be an incredible and honest mathematical sounding board for us ever since.

"I JOINED MASIMO ON MARCH 24, 1992. I had three interviews over a few months. They were looking for somebody to do some signal processing. Mohamed gave me a demo of some of the stuff they were doing on a computer system called the Comdisco, which kind of impressed me. I had another job offer, but I wanted to take the Masimo job because it's what

I wanted to do. What I was doing initially was showing what was achievable by conceptualizing and developing algorithms together with a system for processing data. One of the things that really opened up my eyes, back then, was a journal by the Institute of Electrical and Electronics Engineers on biomedical signal processing. The biomedical signal processing state of the art was primitive compared to the state of other applications of signal processing. I thought, you can really improve biomedical signal processing – because it was really in its infancy – if you remove noise from signals and give a vital sign that's indicative of a noise-free type of environment.

"In the early 90's, journal articles would often cite problems with pulse oximeter devices to include such items as patient motion, low perfusion, ambient light as well as the effects of dyshemoglobins among others. We would use these papers as a basis to create a list of items that we would find solutions to. These were not treated as problems but rather opportunities to improve and create new products.

"I believe that, one of the keys to our success has been Engineering's employee retention. Everything that we have built is based on expertise that has been developed over time. Therefore, part of the team that developed our pulse oximetry products was utilized to develop our rainbow® products. And part of the team that developed our pulse oximetry and rainbow® products were utilized to develop our brain function

monitoring products. This continuity within the company has been rewarding and wonderful to be a part of.

"It's been quite a journey, 25 years now as a company, and it was well worth it. We've shipped over 1 million Signal Extraction Technology® pulse oximeters. We believe over 100 million people are monitored with them each year. Every time someone turns on that pulse oximeter, that thing is running my algorithms. Isn't that cool?"

### Bob Smith

> A great engineer with a heart of gold, Bob came to the company at a time when we didn't know how to make a product. None of us before him had ever built a product – we simply had ideas about how to make technologies better. Bob brought in unbelievably great hardware design skills and created an environment for development of design, keeping track of the details that, at the end of the day, have continually helped our manufacturing people create every generation of our groundbreaking products.

"I JOINED MASIMO IN JUNE OF 1992. What I remember about those early days was there was always a struggle to keep 10 people on the payroll. That was a magic number because if you dropped below 10, it was difficult to get health insurance for everybody. At the same time, we



didn't have a whole lot of money. So we had to make sure that everyone was contributing mightily to the company. There were no sales, no marketing, no FDA submissions. It was all about the engineering and trying to get something together that showed people what we had really did work and was important. It was all about pushing the commercially available electronics to the limit of what was possible, and applying it in new ways. It was all about pushing ourselves beyond what we thought we could do, and being part of something greater than the sum of the individuals."

## Ammar Al-Ali

> *When Ammar arrived, we assigned him a huge challenge that we had not been able to conquer, which was how to make an optical simulator so that we could simulate in the engineering lab very low signals to test out our perfusion capability. No one else had been able to do it. Ammar did it one day on his own hours. Soon after, he became our head of engineering. Sharing Mohamed's brilliance of inventiveness, he also had the discipline of system engineering and managed engineers to help us deliver*

*the first Masimo SET® board to the market. SatShare®, the Radical®, and continual innovations followed. He's been invaluable.*

**"I WAS INTRODUCED TO MASIMO** through Mohamed Diab in 1995. At that time, there was more work than people. I worked with Walt Weber on developing and optimizing algorithms for SpO<sub>2</sub>.

"I came in as a software engineer, and was running the engineering department after about a year and a half. Over the years, I went from Vice-President, to Executive VP, to Chief Technical Officer, and now I'm focused on technical work. I managed our group for 15 years, when Masimo was mostly engineers. We now have more than 120 engineers in our Irvine facility. I've hired a lot of people and I have a rule about it. I look for two properties: (1) high IQ; (2) good attitude. If someone has those two things, you can do anything together.

"The biggest challenge I've faced during the time I've been here was getting all Masimo efforts moving in a unified direction, on a long-term plan. I remember sitting on the

floor one night with Joe and Mohamed at about 10 PM – our normal going home time – talking about plans. Our OEM prototype board, which was running at 4.5 watts at that time and cost us about \$500, ran very hot, and was basically unusable. I told them that the board could be taken down to 100 milliwatts and cost under \$100, and we made a goal.

"But we didn't try to go for that all at once. I developed a step plan so we could use each step as an improvement in technology. The first commercial board, MS-1, was 2.4 watts. The MS-3 was 1 watt. Our MS-5 was 500mw, MS-7 was 250mw, and MS-11 was 125mw. Now we have the MS-2000 family, which is 100mw, and the MS-2040, which is < 45mw. It took us 10 years to get there, but we got several useful boards out of it.

"Now our business is much more complex and there are so many products, it can feel like maybe we're spread too thin. After many successful product introductions, many new technologies that make a difference in people's lives, a strong IP portfolio with 162 patents to my name, and considering where we started from and where we are now, we're doing extremely well."



# The Early Investors

as told by Abbas Bolandgray, Ron Nessim (for Jose Nessim), Harish Patel, Bobby Yazdani, Omid Kordestani, and Robert Feibusch

When Joe Kiani first proposed building an “impossible” pulse oximeter to Mohamed Diab, the idea of leaving a steady job was not too palatable to Mohamed. The company Mohamed worked for, however, was moving to Colorado and Mohamed loved southern California. So he told Joe if he could raise \$75,000 he would work with him. Joe came up with \$50,000 within two months, and Mohamed gave five months’ notice to his employer.

They named their company Vital Signals, Inc.; it was founded February 1989 when Joe Kiani had just turned 24 years old. By the summer of 1989, their first prototype was ready. All of this was possible due to some singularly visionary doctors and engineers.

## Abbas Bolandgray

*> Dr. Bolandgray was our first investor, with a check for \$5,000. A man who would always give his best advice to any young person who would sit and listen, he championed our company when it was only a one-page idea to doctor friends who provided the bulk of the \$80,000 in funds that launched us. Through him came Dr. Jose Nessim and then Dr. Jeremy Swan, both of whom lent us great credibility. He didn't just put in his money – he called everyone that he knew who might help, and help they did.*

“**MY FAMILY AND I** came from Iran to the ‘Land of Opportunity’ – the United States – permanently in 1982. Through mutual friends, I got to know a recently graduated Iranian-American student, Joe Kiani. One day, he came to our house with one piece of paper in his hand, telling me he was going to make a pulse oximeter. I knew he had a degree in electronics, but he did not have much knowledge about medicine. Without hesitation, however, I gave him all the encouragement I could and told him he would make it without any doubt, particularly in the Land of Opportunity.

“Then the critical question came up. He asked me if I could invest in this future company. I gave it a great deal of thought, considering my position at the beginning of our migration (we had arrived below zero financially). I decided to invest very minimally with this young, reliable, intelligent person and told him that I could give him \$5,000.

“Later on, while I was on-call at Cedars-Sinai Medical Center in Los Angeles, I discussed Joe’s venture with a few colleagues and a couple of them invested \$5,000. Dr. Jose Nessim wanted to meet Joe, so I gave him Joe’s phone number. Apparently, Dr. Nessim was a well-known gentleman and influential with people, and he invested \$10,000 at first, and \$130,000 subsequently. Later on, I invested another \$5,000 for a friend who did not want to keep the investment, so I took it and had \$10,000 invested in the company, which gave me 20,000 shares.

“Many years passed and Masimo increased my number of shares three times. I divided the 60,000 shares among my daughters and kept some for myself. More years passed and one day I received a letter from Masimo saying they were paying dividends. Here came \$200,000. In another year’s time, \$100,000. Then another year, and \$90,000. I was quite surprised to count that amount of money!

“About a year ago, I met with Joe and thanked him for his vision, hard work, and persistence and not only for helping others but helping change my humble retirement to a comfortable level.

“As a Farsi expression goes, I told him: ‘If you ever have some shares and don’t know what to do with them and are going to donate them to charity, I know somebody who would like to have a couple more. His name is Abbas Bolandgray and he prays for you.’”

## Ron Nessim (for Jose Nessim)

*> Given his initial skeptical views and negative advice he received from a world-renowned doctor friend, Jose Nessim was a physician who seemed highly unlikely to become a Masimo advocate, much less an investor. But he did both, and much more. Once he was sold on our technology, he became a tireless advisor and champion. At a time when investors wanted 60% of the company for a very small investment and we decided to walk away, Dr. Nessim wrote a check for \$134,000 that allowed us to continue. We are forever grateful.*

“**MY FATHER, JOSE NESSIM**, met Joe Kiani and they really hit it off. Dad was a practicing OB/GYN. He really liked the Masimo pulse oximeter and he really liked Joe, and we invested very early. My father introduced Joe to other people at Cedars-Sinai, the main hospital my Dad was affiliated with, and introduced him to Dr. Jeremy Swan, a famous cardiologist who co-invented the Swan-Ganz heart catheter that revolutionized heart surgery. We have a place in Laguna Beach where Joe would visit talking business. I also remember Joe coming to the house in Beverly Hills and making a presentation as part of raising money early on. My dad was a bit of a risk taker who believed in people and new things, and he would jump on innovative products if they hit him right. With Masimo, that happened repeatedly; he invested several times.

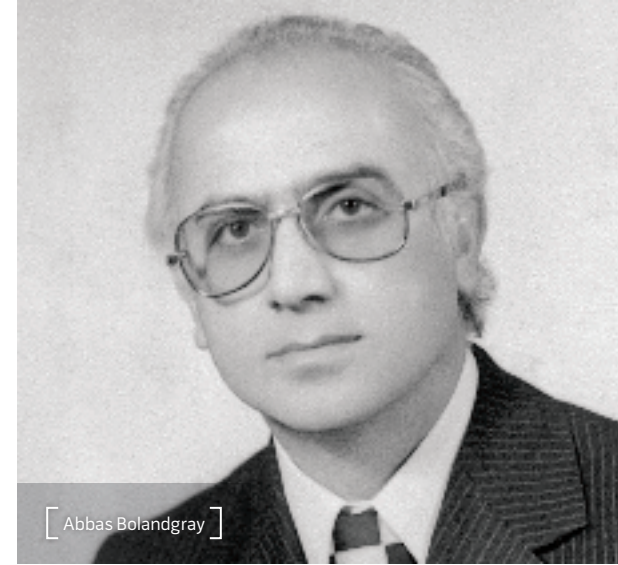
I bought shares, too, early on – 1990, 1991, 1992, 1993. And as happened with many Masimo investors from those early years, the investments paid off very well.”

## Harish Patel

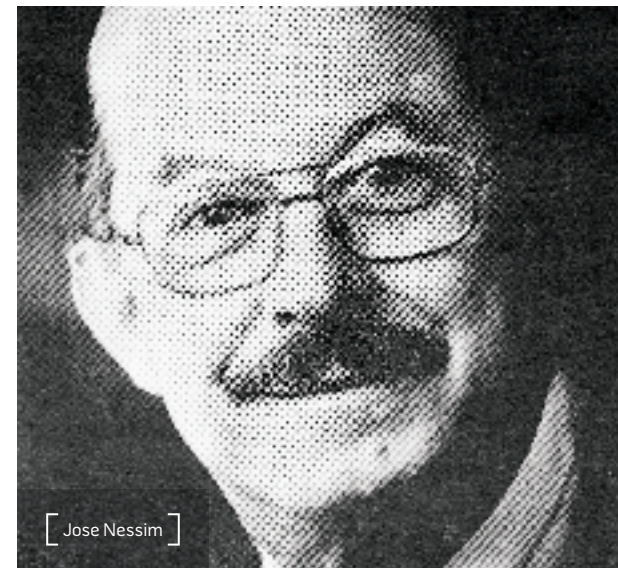
*> As Joe Kiani’s friend and fellow field applications engineer before Masimo began, Harish knew about the idea for the company very early in planning stages. He initially helped by providing an introduction to three doctor friends who contributed \$10,000 each to our initial \$80,000. And all of them, though not related, shared the last name of Patel. Harish remained a great friend of the company, helping us with, among other things, including support from Analog Devices, whose DSP chip we use in our products.*

“**I FIRST MET JOE** in 1988 when we were both working as field application engineers, me at PMI as a Staff FAE for the Southwest region and Joe a FAE at Bell Industries, a distributor of PMI. We hit it off the first time we met and became really good friends. We worked together on many customer design opportunities in Orange County. Joe’s technical strength, willingness to learn, enthusiasm, and great communications skills were highly regarded by our customers and the PMI Southwest sales team.

“About mid-1989, Joe had moved to Anthem, another PMI distributor. We discussed medical and other market opportunities in a meeting, and he said he would like to show me a product he and his friend Mohamed had been working on that had great market potential. We went over to Mohamed’s apartment to see their invention – the pulse oximeter! This product was a 19-inch rack size PC board. Mohamed and Joe gave me a demo. Until then I did not really understand how a pulse oximeter worked, or its life-saving benefits for patients resulting from accurate measurement of blood oxygen levels. I was very impressed with the demo on the kitchen table. I asked Joe, what



[ Abbas Bolandgray ]



[ Jose Nessim ]



[ Harish and Gita Patel ]



would be the next step. He mentioned finishing off some fixes, refining it over the next few months, and finding investors so they could launch, at which time he would leave Anthem.

"Over the next couple of weeks Joe asked me if I would be willing to invest. Regrettably, I could not, as my wife had just started a travel agency which had consumed my savings. But I approached some of my friends and sold the idea to three Indian doctors. These friends asked to see the product and meet Joe. So there was another demo on Mohamed's kitchen table. After a little more convincing, the doctors decided to invest \$10K each. Both Joe and Mo were ecstatic. So was I, as these doctors providing the money were very tough customers and they asked a lot of searching questions!

"In January 1990, Joe called and mentioned he had left Anthem, and that he and Mo had founded VSI (Vital Signals Inc.). He also had secured some office space and a couple of engineers, Bob Smith being one of them. Initially, I had reservations about Joe's very aggressive timeline for going to production with the first pulse oximeter due to various FDA requirements. Still, I had a strong hunch that Joe with his vision, optimism, drive to succeed, and his trust in the people he worked with would allow him to lead a successful company that would be a leader and envy of the medical field.

"I am very proud of Joe, and what he has accomplished, at such a young age. Thank you, Joe and family, for your friendship. On Masimo's 25<sup>th</sup> anniversary, I wish you even more success, health and happiness, and many more anniversaries in the future. Keep up your great work."

## Bobby Yazdani

> Shortly after Masimo began, Bobby, a very good software developer, brought object-oriented software development into Masimo so that we didn't create spaghetti code. He would fly down from the San Francisco Bay Area on weekends and brainstorm with us about software. He introduced us to a big angel investor that invested initially half a million and then later another half million. Bobby helped us bridge between the small family friend investors to venture capitalists. That changed the paradigm.

"I WAS INTRODUCED to Joe Kiani through a common family member, and Joe told me what he was trying to accomplish. At that time I was a new software engineer at Oracle. And I got very interested in the project – I got very interested in the space. I was an early investor and I tried to put Joe and his vision in front of some of the people

that I knew in Silicon Valley. I was based in San Francisco. I introduced Joe to Val Vaden, who brought major financial investment to Masimo.

"In addition to my involvement as a small investor, and in making introductions to Joe, one summer I went to Orange County and helped Joe and Mo with some of the software that they were trying to write for their system. These were very, very early versions of Masimo SET. Mohamed had a two-bedroom apartment, and one of the bedrooms was his lab. I had a software background, so I tried to share some of my experience in terms of production quality software. I advised them on software practices for their devices.

"Since that time, Joe has been a great friend and he supported me with my company, Saba, when I founded it and when we took it public. He helped me as a board member of my company and gave me a lot of advice as I was developing Saba and also through its growth years. He helped me build my business. Joe is a high integrity guy, and he's very humble. Nothing gets to his head, and he's no different than he was 20-some years ago. The industry really hasn't changed him much, in terms of his empathy for people. I think of Joe's vision of how ultimately technology can evolve this category of life science. It's a lot of hard work

that has gone into making Masimo what it is today. I think Joe has demonstrated that ultimately by having a vision, putting your energy and your hard work behind it, and remaining a high integrity individual who always tries to do the right thing for other people, you can do very well."

## Omid Kordestani

> Introduced to us by Bobby Yazdani (who was a childhood friend), Omid brought a savvy aspect to our company in the way of advice, along with his own investment. He had been involved in several high-flying startups that failed, but those failures didn't faze him, he would go on to become the first business person hired by a new company called Google. Omid offered to help any way he could, and described Joe as the epitome of what a CEO should be like. He pushed Masimo to major investors.

"AT A COMMENCEMENT SPEECH at my undergraduate school, I had the privilege of imparting some of my life lessons to the graduating class of 2007 at San Jose State University. The key theme of my talk was the 'immigrant attitude' and how I believe it can be a key ingredient for success for everyone. I talked about the singular focus to succeed and breaking through any and all barriers that one

may confront in life, with a positive attitude and a winning spirit. Joe Kiani and the story of Masimo embody all the the traits that I talked proudly about that day.

"I had the pleasure of being a small contributor to Masimo's success through a chance introduction from a close friend of mine who I went to school with from first grade in Iran. Bobby Yazdani was an advisor and friend of Joe. In the early days of Masimo, Bobby invited me to make a small investment in the company and become a friend of Joe and Masimo and the journey they were about to embark on. At the time, I was busy growing this small startup called Google that I had joined as its first business executive and employee number 11! I had invited my friend Bobby to make an investment in Google and he invited me to do the same in Masimo. The relationship evolved from there and I introduced my Stanford Business School classmate Val Vaden, who was a successful investor and VC, to Masimo. Val in turn invested in Masimo at a critical time in Masimo's evolution... and the rest is history!

"Great individuals with a heart of gold, a great smile, and winning immigrant attitude like Joe Kiani, make the world a better place! I am proud and honored to have a small part in their success."

## Robert Feibusch

> Bob had been a successful entrepreneur, sold his company for \$100 million, and then set up a small investment group with a friend of his who had been his board member. When an associate made him aware of Masimo, Bob not only invested an initial \$500,000, he became a mentor to Joe. Bob and his partner spent a lot of time providing advice any time Joe needed to visit them. They helped 26 year-old Joe in thinking through company planning, and even helped out in meetings with OEM customers.

"I BELIEVE WE WERE THE FIRST non-private financial investor in Masimo. At the time I met Joe, we were active investors. Val Vaden was working at our company and introduced us to Joe and Mohamed through a mutual friend. I remember very clearly our first meeting with them. They put their first prototype on my finger to demonstrate how it worked. Well, it didn't! During the test Joe couldn't even get a signal and I thought he was going to panic. Then he said to Val, 'Well of course it couldn't work. Bob is obviously a regular venture capitalist; he has no heart.' We all cracked up, and to my great pleasure, I invested anyway. Years later, I told Joe that I decided I had to invest in him. It's how you overcome those obstacles and deal with them that matters most."



[ Manizheh Kiani ]



Pre-thanksgiving lunch catered by Manizheh Kiani, Joe's Mother



[ Bobby Yazdani ]



[ Omid Kordestani ]



[ Mohamed Diab ]

# Early Advocates

as told by the late Jeremy Swan, Steve Barker, Mitchell Goldstein, Peter Cox, and Augusto Sola

Starting with a relatively small amount of financing, and no marketing department, the creation of Masimo was a continuous uphill climb. When they invented SET® – Signal Extraction Pulse Oximetry Technology – in 1989, they managed to separate the arterial signal from the non-arterial noise (e.g. venous blood movement during motion). This gave the company the first and only pulse oximetry technology scientifically and clinically proven to be accurate during challenging conditions of patient motion and low perfusion. Great news, but how do you sell a pulse oximeter in a market dominated by one company? Simple – you get the thought leaders in medicine to review it, hoping that you can prove you’ve built a much better technology as promised. That approach takes courage because bad results from respected medical authorities can result in the demise of a fledgling company with limited assets. Approaching the problem fearlessly, Joe Kiani and his team sought out tough but highly respected experts to study and test Masimo products. Speaking to the true quality of their innovative technology, Masimo won the day and in some cases, saved precious young lives.

## Jeremy Swan

> H.J.C. “Jeremy” Swan (June 1, 1922 – February 7, 2005) was an Irish cardiologist who was a president of the American College of Cardiology, and Chairman Emeritus of Cedars-Sinai Medical Center’s Division of Cardiology.

As the co-inventor of the Swan-Ganz catheter, Dr. Swan was a rock star among doctors. When no one knew who Masimo was, his presence made everyone pay attention. With Dr. Swan’s encouragement, Masimo developed Halo Index™, which provides a cumulative trending assessment of the global patient status. Dr. Swan was the founding Chairman of our Scientific Advisory Board and was invaluable to Masimo’s evolution.

When our company was no more than two young engineers in a garage, Dr. Swan generously gave his time and moral support. As the founding Chairman of our Scientific Advisory Board, he made our goals very clear when he urged us to: “deliver the highest fidelity signal possible and let the clinicians decide on how to use the newly available information.” From that time forward, we did just that.

He lived a long and productive life, and was a friend we hated to lose. Dr. Swan made great medical contributions and triggered other developments that helped mankind. It was wonderful for us all to have lived in a time that Dr. Swan was among us.

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

**Jeremy Swan, MD**

Former Chairman of Masimo’s Scientific Advisory Board and Chairman, Emeritus Cedars-Sinai Medical Center’s Division of Cardiology

## Steve Barker

> Dr. Barker had done more studies on pulse oximetry than anyone when he came to our attention. He always published the truth. In fact, his study on the first company that made reflectance pulse oximetry showed its limitations and put that company out of business. That’s when we knew he was the clinician-researcher that we wanted to have studying our pulse oximetry technology. When Joe walked him through how Discrete Saturation Transform worked, because he’s an engineer as well as a doctor, he loved it. He never asked for any money for any study he did. If it weren’t for Steve Barker, clinical people might never have believed in us. Now we’re very proud to say he’s the chairman of our Scientific Advisory Board.

“I CONSULTED ONCE FOR A START-UP COMPANY called Sentinel. They were the first company that commercially marketed reflectance pulse oximetry, with a sticky pulse oximeter probe that you slapped on the forehead. It measured reflected light rather than transmitted light. I did some work with them, including a small clinical trial, and I finally said, ‘Look, I have to be honest with you guys. It doesn’t really work, and here’s why.’ It had a very high failure rate due to venous pulsation in the forehead with a patient in the supine or trendelenburg position. They were very nice people, but I published a study that basically put their company out of business. So, when Joe Kiani came to me for advice, he knew that just because I like the people that have asked me to do a study, it didn’t mean I would change my standards. In fact, years later, he told me that is exactly the reason he came to me. I had proven that I would be scientifically honest. When I did my first study, I couldn’t believe the results, so I wanted to find out why it worked. When Joe explained the technology, I said, ‘That’s incredible, why didn’t I think of that?’

“Sometimes the truth hurts, but it’s the best course. I was an expert witness in the first Nellcor patent-infringement trial. I was on the witness stand being cross-examined by the Nellcor attorney. I had been talking about how in our clinical study we found that Nellcor pulse oximeters failed quite often during motion. The guy said, ‘Well tell me, isn’t the Nellcor pulse oximeter correct some of the time?’ Without hesitating, I replied, ‘Yes, and a broken clock is right twice a day.’ I could hear the titters from the jury.

“When I met Joe he was just a kid, about 23 or 24. I sometimes think of him as an adopted son; he’s about the same age as my oldest child. He called me when he and his partner were starting this new company, called Masi-something. I had published a number of pulse oximetry papers and consulted with companies like Datascope, Novamatrix, and even Nellcor. I believed in his product early on and helped with studies. I watched the company grow from the startup in Joe’s apartment to what it is today. Through it all, he has kept that wonderful, child-like curiosity about him, which I often tell him, don’t ever lose. That constant curiosity and the desire to always make things better – that’s what has made Masimo different. They’re always exploring new technologies. They’re constantly looking at new stuff and when I give him my own ideas – and I come up with a lot of hare-brained ideas – they always listen and some of them actually get developed. For example, I was pushing Masimo for years to look into multi-wavelength pulse oximetry. Now they have become the pioneers and dominating force in that whole market. They’re the only company today that makes a multi-wavelength pulse oximeter that can not only measure carboxyhemoglobin and methemoglobin but now it can even measure total hemoglobin.

“I often remind Joe that Masimo is the embodiment of the American Dream, and I kid him about it, too. But his story truly is



Dr. Steve Barker



Dr. Jeremy Swan and Joe Kiani



Party for shipment of first Masimo SET® board

MASIMO 2066  
Apple v. Masimo  
IPR2022-01465



Dr. Mitchell Goldstein

the American Dream. He started with new ideas and brains, skill and a lot of determination, and then guided it forward to where it is today – a thriving, leading company with a bright future ahead.”

## Mitchell Goldstein

> When Joe gave Dr. Goldstein a demo of our pulse oximeter, he was so impressed by its ability to read through motion, he called every doctor and nurse in the hospital to come see it, and they were all just blown away by it. One day, he called about saving baby Joshua Diaz's life and that story became the lead in the New York Times exposé on Group Purchasing Organizations. Mitch testified at the Senate hearing about GPOs despite pressures that he not, and has always been one of our greatest friends.

**"IN 1995, I WAS ON CALL** when I heard from the emergency room. I was told, 'We've got a baby here who doesn't look so great, and we'd like to send him up to you in the NICU.' I was told he was a few weeks old, was breathing kind of hard, and he looked kind of blue. Five minutes later, he was there in the NICU, and he looked in extremis. We started doing everything we could. We placed a breathing tube with no response. We had the baby on an N200 pulse oximeter that could not obtain a signal. The baby was not moving. We had an electrical tracing of the heart rate, but the nurses and the respiratory therapist thought it was obvious that the baby was going to die. They asked me to stop. We sent off a blood gas but the lab was a half an hour prospect because it was downstairs in the basement. A respiratory therapist had to come get the blood, go downstairs, run the tests, and then run it back to us so that we could confirm the reading. So I told the parents,

I have this new oximeter that we've been trialing. It is not FDA-approved. We've been using it to read saturations at times when we wouldn't otherwise be able to get a reading.' The dad consented for the baby to be on study. This was Masimo technology. Within moments, I had a saturation that improved from initially 10-15% as we continued our therapy. If we hadn't had that oximeter, we would have stopped. This baby was Joshua Diaz, the first life saved with Masimo technology. In addition to being featured in the New York Times article, Joshua was invited to the Society of Critical Care Medicine meeting to see Joe receive the Technology Excellence award, the same technology that saved his life. Without Masimo, Joshua would have been dead before he was even a month old."

## Peter Cox

> After a completely unnecessary death due to poor monitoring at Toronto's Hospital for Sick Children in the mid-1990s, Dr. Cox and a hospital team searched everywhere for the most reliable pulse oximetry and contacted Masimo. He tested the equipment personally, fought to replace the hospital's Philips equipment with GE who had integrated Masimo SET® (they'd been with Philips for 30 years), completed the first installation of continuous Masimo monitoring on any general floor, and has been a huge advocate ever since.

**"AN INQUEST IN 1999** set our team at the Hospital for Sick Children, Toronto, Canada on a plan to monitor every bedside in the hospital. I first met Joe Kiani in 1999, and then again a couple of times in 2000. We were searching for an integrated monitoring system that was both centralized and could be spread out through the institution. There were a number of monitors on the market

at that time. There was: Ohmeda; Nellcor; and HP (the bedside monitoring system we were using), which eventually was acquired by Philips. None of these companies would agree to include the Masimo technology. It was clear to us in the pediatric world that our patients needed a robust, read through-motion system that was able to accurately measure saturations below 95% (we deal with a large congenital heart disease population). And, through testing in our own institution, Masimo was the only one that met those criteria. To get Masimo technology, we had to change the patient monitoring company we used. I believe we were one of the first institutions to implement standardized monitoring across the institution. We adopted Masimo technology hospital-wide and we've been satisfied with our choice ever since."

## Augusto Sola

> Joe met Dr. Sola for the first time after he read the The New York Times article on the GPOs that came out in 2002. He had a hypothesis that the high levels of oxygen given to premature babies and the back and forth jockeying of levels was contributing to retinopathy of prematurity (ROP). He was right. To test his hypothesis, he needed a pulse oximeter that was accurate even during motion and low perfusion. Masimo, of course, was it. He fought to get Masimo pulse oximetry into use at the Neonatal Intensive Care Unit (NICU) and lost his job over it. Eventually, he won the war, his ground-breaking study proved that proper titration of oxygen using Masimo's pulse oximetry can reduce ROP dramatically, and Dr. Sola's work has saved thousands of babies from blindness.

**"WHEN I WAS A CLINICAL DIRECTOR** at the University of California San Francisco, I was offered the position of Professor of Pediatrics at

UCLA and division director at Cedars-Sinai. When I arrived there in 1997, I was interested in improving neonatal outcomes based on data and implementation of actions into clinical practice. When reviewing data I was struck by several issues, one of them being ROP. The available data could not be accurate. So I started to look deeper into that area, while building a new NICU and asking for newer equipment.

"At that time, I read two abstracts of pulse oximetry technology, one by Dr. Steven Barker. All of the technology existing then had a lot of false alarms and nurses were very frequently turning them off. I read these abstracts, and I started to contact people. With some difficulty I was able to get the Masimo technology into that hospital, and we also changed the clinical protocols using SpO2 from the minute after birth.

"After two or three years, we published the first prospective paper on SpO2 targeting, which was a breakthrough. We showed for the first time that with the breakthrough accuracy of SET pulse oximetry even during motion and with good protocols, many more babies with birth weight under 1,500 grams could go home without severe retinopathy, and they and their families could lead normal lives without the emotional and economic burden of a life with blindness. That was a lifesaver. But this was not only an individual issue for babies and families. It was also a large societal contribution made by the then new Masimo technology leading to a significant decrease in health care costs related to the care of blinded individuals for life.

"According to Lao Tse, gratitude is the memory of the heart. It is with heartfelt memory that I thank and congratulate everyone who made that advancement possible."



Dr. Augusto Sola



Dr. Peter Cox testing Masimo pulse oximeter while breathing nitrogen



10th anniversary party



Reception desk at Madero office

# The Venture Capitalists

as told by Jack Lasersohn, Robert Coleman, Jonathan Osgood, Jim Scopa, and Lawrence Saper

When Masimo SET® technology was first perfected, Joe, Mohamed, and the team naturally wanted to get the technology in use for patients ASAP. They calculated that to do that, they should license their invention to market leader Nellcor or another company. They also discussed creating a standalone device, but other ideas came from the first major investors, who came to Masimo by way of Silicon Valley. The route to Robert Feibusch, Jack Lasersohn, and other venture capitalists over the years turned a small path into a medical technology super company. One investor wanted Joe and Mohamed to merely create ideas and license them. Others wanted to replace Joe as CEO – the reasoning being that almost no one was good at both innovating new products and running a company, too. The investors who lasted and profited the most, however, saw kindred spirits in Joe Kiani and Mohamed Diab, people who like themselves were willing to risk it all to make a major difference in the quality of life and health in the world.

## Jack Lasersohn

> Jack came to us as a co-investor with Warburg Pincus in the mid-1990s. He was one of the smartest people who had ever come in contact with Masimo. At one point, he led a charge to take over the company but once he had a change of heart, he became one of the biggest contributors to the board and a great company friend. When we were having a tough time with the patent litigation, he spent many days helping us strategize and has been offering great advice for decades.

“OUR COMPANY THE VERTICAL GROUP is one of the leading medical device venture capitalists. There’s a myth that VCs make financing decisions on the basis of personalities, the people running things. While it is true that we always try to get the best management team, it’s actually a myth that venture capitalists make personalities the #1 item. The important factor is usually the strength of the technological idea. The reason for the myth is that usually most of the people who start companies are not the people who are going to be able to run them when they get larger. And the reality is that the management is often changed from the first time you make an investment in the company to the time it goes from a few people to be 50 to 100 people.

“In my career, I have usually had the greatest success with companies with a great technological idea that’s been well executed. There have only been two exceptions to that rule, where I have invested even when I did not think the business was a great idea, but where I thought the entrepreneur was so extraordinary that I wanted to back him no matter what. Masimo was one of those cases. When I met Joe Kiani and Mohamed Diab, I thought that this was one of the most extraordinary entrepreneurial teams of my career. Their business idea, however, was to try to solve an almost impossible technological problem and then compete head to head with a monopolist – Nellcor – and I thought that was really a terrible business plan. I told Joe, ‘I really hate this idea. I wish I could convince you to do something more reasonable, but I’m going to back you anyway because I think you and Mohamed are two of the most talented young guys I’ve met in my life.’ That’s how I came to invest in Masimo. Sometimes you just need to have guts and go with your instincts about people. Obviously, that bet paid off.”

## Robert Coleman

> A born entrepreneur, Bob had been CEO of another company, sold it, and became very wealthy. He was asked to join the Masimo board at a time when the board kept second-guessing everything Joe was doing. Bob had so much credibility he was able to convince other members of the board to let Joe run the company as he saw fit. When Warburg Pincus tried to take over, Bob found the way out of that. With great comprehensive advice for years, he has always been a wonderful support.

“IN 1996 EDWARD CAHILL, who has now been a fellow Masimo board member for 15 years, told me he had received a copy of a fundraising document from Joe Kiani. He asked me if I would mind traveling to California to meet with Joe and advise him on the merits of a Masimo investment. I had just completed 21 years as a medical device CEO at the time, and I had just sold a company called MediSense to Abbott Laboratories. Joe and I formed a relationship and in 1997, I joined the board. I’ve been a member ever since. Before Masimo became public, Joe and I went off to a trade show event in Hawaii. We were sitting at a shrimp shack getting lunch at a rustic place in Oahu. Joe looked at me and said, ‘Bob, what’s it going to be like to run a public company?’

“I said, Joe, I have just recently finished a tour of doing that myself. First of all, I would rather own the shrimp shack, broken down picnic tables, and some chickens scratching on the ground underneath the tables. And the second thing I have to tell you, as CEO of a public company, is you’d better start thinking about what it might feel like to be the only fire hydrant in a town full of dogs.’ That said, the biggest hurdle that an emerging company has to overcome is what I call the One Trick Pony Syndrome. That is when you have your bright ideas, you get a company going, and then the company

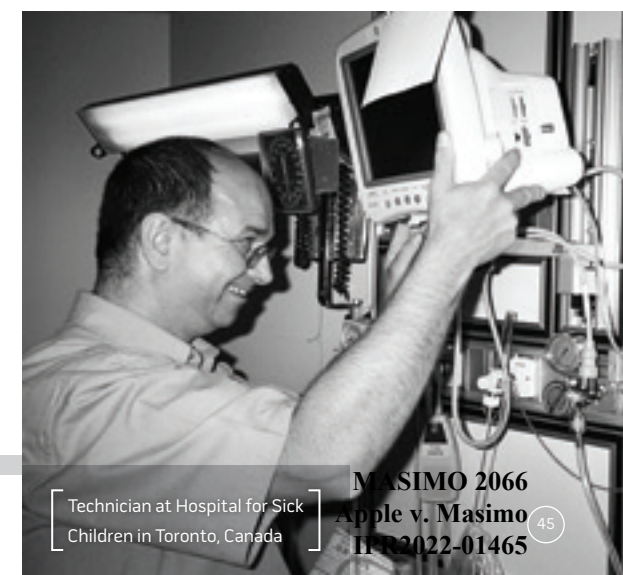
loses its innovative energy and momentum. I think that is the silent battle. When all is said and done, Masimo’s biggest victory may actually be its constant stream of innovation. And then, there are the unstated scenarios of having management leadership – specifically, Joe – that manages to stay ahead of all the growth challenges. Masimo has done that.”

## Jonathan Osgood

> Jon Osgood had a huge brand name as an analyst in the days of our initial attempt at going public in 1996. When market situations proved to be less than fruitful for an initial public offering, he led us into private deals that helped us raise tens of millions, crucial dollars to help us go from an R&D company to a fully commercial one. He was always a staunch supporter, and much appreciated.

“WHEN I WAS INTRODUCED, I was head of the Healthcare Research Group at Alex. Brown & Sons, Inc., and I was also the research analyst responsible for the medical technology industry. My partner in Alex. Brown’s investment banking division, Donald Notman, had discovered Masimo and Joe Kiani and thought it was a promising company. Masimo was looking to raise a private round of financing and wanted Alex. Brown to act as agent. But for Alex. Brown to sign on, both investment banking and research had to agree to do the deal, and that required customary due diligence and meeting the company. Joe and the company left an indelible impression with me.

“The only time that Joe and his team’s schedule aligned with mine was an evening in Chicago. I was flying in from a week in Europe, and Joe was flying from Southern California. I arrived on time in the evening, but I soon learned that Joe’s flight was delayed. And





the delay kept getting longer. At about 7:00 PM Chicago time Joe's flight had still not taken off from Orange County, and I called Joe to tell him that we should postpone. It was the equivalent of about 1:00 AM for me, having just been in Europe. I was tired, and I was sure Joe would rather just go home and reschedule. But Joe, in that calm, smooth voice, assured me that the time wasn't a problem, that nothing was more important than this meeting, and that the pilot had assured him that they would fly.

"I hung up, and went to bed, sure that he would never make it to Chicago, or if so, we'd meet in the morning. About 2:00 AM I was jarred awake by a loud knocking on my hotel door. A thin, very young, dark-haired guy stood at the door smiling at me. I thought it was someone from room service who had gotten the wrong room. But I soon realized that I was standing face-to-face with Joe Kiani, who was there to have our meeting. I was incredulous, and a bit sour for being wakened at 2:00 in the morning. For the next three hours Joe talked passionately about Masimo, its technology, and his strategy for competing with Nellcor. By the time he was finished, the sun was coming up and he had me convinced that Masimo would be successful and worth backing. Joe's persistence, passion, patience and salesmanship were all displayed at that meeting and in the hours that led up to it. I knew we had a winner because I knew Joe would never give up, ever."

## Jim Scopa

> *Jim Scopa was the banker whose involvement with Masimo blended in beautifully with the advice we got from Jonathan Osgood. Jim became a great friend and assisted us with great financial advice at every step of the way. Eventually, he became a venture capitalist so we couldn't work with him as a banker any more, but the total support he gave us in every way possible will never be forgotten.*

"WHILE I WAS AT the former Alex. Brown, we made a valiant attempt to take Masimo public in June of 1996. The window closed before we could get there. Given what happened in the market after that to early medical device company valuations, the company was probably better off private. Even though we couldn't get the company public, we immediately went into a private placement process and generated \$10 or \$15 million. It was 11 years from the time that the company first attempted to go public in 1996 to when it actually did in 2007. That is probably a record. Usually, such efforts die a natural death in that amount of time. And it was unclear how the company would best get to market with its technology. Nevertheless, I would say we raised something like \$50 million for the company privately over time.

"We made another attempt in 2001 to get the company public, but it just wasn't to be. The market went south on us again, as part of the dotcom bust. By the time Masimo went public in 2007, I had already changed careers and come to MPM Capital to do venture capital. So when Masimo's initial public offering ultimately happened, I felt like a proud father, but I wasn't there at the birth. Nevertheless, as everybody is aware, that IPO turned out to be more than a 10X return for the investors we brought in, and for some, an approximately 200X return, even before the legal settlement with Tyco/Nellcor. So it was a happy day and well worth the wait."

## Lawrence Saper

> *As founder and CEO of Datascope, Larry seemed angry at our first meeting because he wished he had learned about Masimo sooner. He loved what we were doing. When none of the major OEMs in the U.S. were putting Masimo in their products due to GPO/Nellcor blockage, Larry put Masimo into his products and by promoting that action, basically forced all other OEMs to sign up. Later, he made a major investment in our company at a very crucial time, making him one of our favorite people, ever.*

"MY COMPANY, Datascope, had the objective of having a comprehensive physiological monitoring apparatus. The variable of pulse oximetry, measuring a concentration of oxygen in a patient's blood, was an essential component in making up a complete physiological profile. At some point, we considered do we make it ourselves, or do we see what's out there. I clearly wanted to see what was out there, and the best thing that we found was Masimo. I discovered that my motivation for getting into business and the way I do business was very consistent with that of Joe Kiani. We both pretty much look at the world – the technology world, the business world – in the same way.

"I take a measure of a person depending on a number of elements. I get a picture of somebody: either I like them or am neutral or I dislike them. It's rare that I dislike someone, but it's also rare that I find someone who's working for the same reasons as I do. And who talks straight, thinks straight, and has a sense of humor, which Joe Kiani has. We looked outside and discovered Joe's pulse oximetry abstract, which was very good for us, so we made an OEM deal where we bought instrumentation from Joe's company and incorporated it in various forms in our monitoring apparatus. Later, Masimo had developed to a point where Joe needed capital, and we invested. It was unique for us because we never did that before or since. We were never in the business of lending people money."



[ Lawrence Saper ]



[ Forbes names Masimo one of the best small public companies in America in 2011 ]



# Taking on the GPOs

as told by Seth Bloom, Sen. Herb Kohl, and Walt Bogdanich

By 2002, Masimo was engaged in a legal battle with pulse oximetry industry leader Nellcor. Despite occasional breakthroughs like Cook County Hospital in Chicago, that the famed ER TV show was about which completed a system-wide conversion to Masimo SET®, the company was in essence shut out of 95% of American hospitals due to the monopolistic practices of dominant companies like Nellcor with Group Purchasing Organizations who got paid by them. When Nellcor not only manipulated GPOs to keep Masimo out of the U.S. hospitals, but also attempted to co-opt Masimo technology, there was no choice but legal action. To break up the group purchasing organization oppression of small innovative companies trying to break in with better technology, government intervention was necessary. That came about via a Senate panel chaired by Sen. Herb Kohl of Wisconsin and Sen. Mike DeWine of Ohio, bolstered by a series of New York Times articles, the first one titled “MEDICINE’S MIDDLEMEN; Questions Raised of Conflicts At 2 Hospital Buying Groups.” That piece began with the story of how baby Joshua Diaz was saved in the hospital as a newborn due to use of a Masimo monitor. Walt Bogdanich, the Times reporter, wrote about Joe Kiani, “he still cannot sell his oximeter, regardless of the price, to many American hospitals, even though medical experts say it helps the most fragile of patients – premature infants.” The articles were devastating indictments of the GPO payoff schemes and monopolies, and after reviewing the situation and hearing voluminous testimony, Sen. Kohl’s committee drafted legislation and persuaded the offending GPOs to voluntarily change their ways. Subsequently, Masimo received its first contract with Premier (one of the two major GPOs), and other med tech innovators soon found entrée to American hospitals to be much easier.

> **OUR CRUSADING HEROES:** *Masimo had technology that was 30 to 100 times better than any other pulse oximeter available, yet we could not sell it to hospitals in the U.S. due to the GPO monopoly. So we concentrated on small NICUs and non-GPO based hospitals, which were few. Then we noticed that Medical Device Manufacturers Association (MDMA), a new group representing medical companies, publicly said there was a problem with this whole GPO setup. That led us to Seth Bloom, an aide to Senator Herb Kohl, who was conducting his own relentless investigation.*

*MDMA told us we had to come to Washington to visit Sen. Kohl’s people, specifically Seth, a true idealist. Sen. Kohl was wealthy and didn’t need to raise money to become elected. He held hearings on the issue and thanks to him and Seth, we were able to sell our products in the U.S. and save countless lives and the eyesight of thousands of premature babies. We all owe Seth and Sen. Kohl copious thanks.*

*When we contacted 60 Minutes about our issues, they gave us Walt Bogdanich’s name. Walt, while previously at ABC News, broke the controversial story about tobacco companies manipulating nicotine to make cigarettes more addictive. Walt said the story was so big he was willing to go to The New York Times with it. Since a 15 minute segment wouldn’t do it justice, he got an agreement from them to do a whole series on the GPOs if Joe was willing to step up and speak up, and he certainly did. About a year and a half after Joe assisted Walt on his investigation, the story was shelved in the wake of 9/11, but when the story finally launched in March 2002, it helped change the healthcare industry for the better.*

## Seth Bloom

“**THE GROUP PURCHASING ORGANIZATION ISSUE** and how innovative medical devices were being prevented from reaching patients first came to my attention at the end of December 2000. There was a meeting, I believe, sponsored by the Medical Device Manufacturers Association. There was a group of maybe 10 or 15 people around the table in my office and I was in a sort of shock about the situation. It caught my attention in particular because it affected patient health and safety. I couldn’t imagine a more important competition issue. After having this meeting, I brought it up with Sen. Kohl, whom I worked for at the time, and who was the senior Democrat on the Antitrust Subcommittee. I didn’t meet Joe Kiani until sometime in 2001.

“When the New York Times stories on GPOs appeared in 2002, we were already planning our hearing where Joe testified, but the first Times story definitely attracted Sen. Kohl’s attention. He was appalled by the kinds of things the paper was writing about. The Senator felt the most effective use of the bully pulpit of a Congressional hearing was to get the GPOs, and their trade association, to agree to change their ways voluntarily. Joe’s testimony was vitally important at the first hearing.

“Those testifying all told the same story – how the GPO system prevented crucial, in many cases potentially life-saving, devices from reaching patients and helped entrench the market positions of the large vendors.

“This hearing led to the GPOs establishing codes of conduct, which they did only after Sen. Kohl turned the spotlight on them and we threatened legislation to remedy the situation. Among other things, the leading GPOs and their trade association agreed to end some of their worse practices – for example, ethical abuses and conflicts of interests where GPO executives would have investments in companies that obtained GPO contracts. And many of GPO-negotiated contracts were five to seven years. The GPOs agreed, for clinical preference products, to limit the length of the contract to three years, which obviously gives competitors a better shot at getting in. And they agreed to end exclusive, sole source and bundling contracts for medical devices. Sen. Kohl was very directly involved in negotiating with the two largest GPOs to get them to use these voluntary codes of conduct. It was quite an achievement. We had our first hearing in 2002 in the spring.

“By the summer of 2003, we had these agreements in place. So that was a major accomplishment of these hearings.”

## Sen. Herb Kohl

“**I WAS VERY IMPRESSED** by Masimo and its CEO, Joe Kiani. In my view, Masimo was exactly the kind of company we

wanted to encourage, an upstart company, founded by immigrants, taking on the industry’s incumbents with a better product. And this product was a basic medical device key to helping prevent blindness in premature babies. I was quite disturbed to learn that hospital GPOs, acting at the behest of dominant suppliers, were effectively preventing Masimo’s devices from reaching physicians and patients. That patients – particularly premature babies – could be denied access to these critical devices was shocking to me. The experience of Masimo and other similarly situated medical device manufacturers led me to conclude that something had to be done to end the stranglehold on the market of the large incumbent suppliers resulting from the GPO system.

“I recall that Mitchell Goldstein, a physician from a Southern California hospital, offered compelling testimony at our first hearing in 2002 about being denied access to Masimo’s devices, and the dangers that posed to his patients, including premature infants.

“Our interest in the GPO system was to insure that patients received access to the best medical devices at the best prices. While we did not get involved in this issue to benefit any one company or group of companies – we were just acting to promote competition and help patients get access to needed medical devices – Joe Kiani’s testimony was crucial to our efforts. I recall how sincere he was in seeking reforms and how courageous he was in coming to testify. His testimony exposed the shortcomings of the GPO system, and yet he testified next to representatives of the very GPOs from whom

he needed to obtain contracts. I don’t know whether we could have achieved the reforms to the GPO system that we got the GPOs to agree to without Mr. Kiani’s testimony.”

## Walt Bogdanich

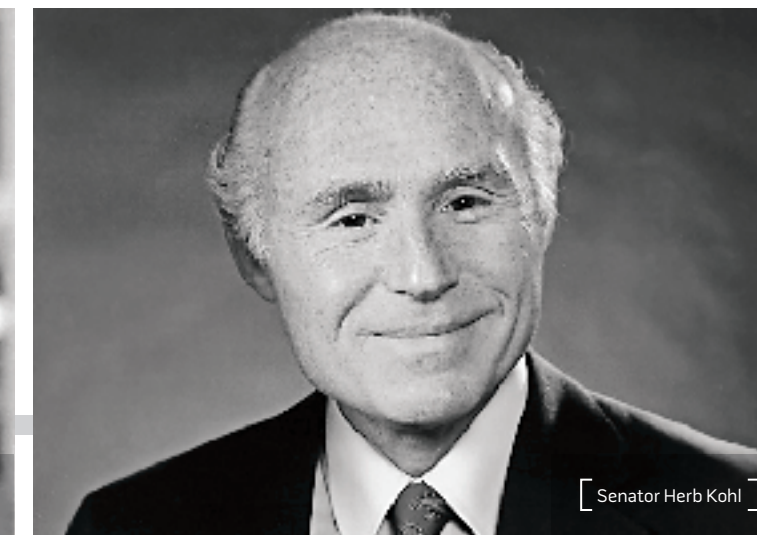
“**I HAVE A CLOSE FRIEND** who worked in the medical device arena and he had complained many times about the outsized influence of Group Purchase Organizations. I always thought of GPOs as inherently good. The story he told me painted a very different picture of them.

“I can recall with great clarity my first meeting with Joe Kiani. We were sitting and talking at a nice New York restaurant. For some reason, I remember the sun streaming in through the window. I had heard the outlines of Joe’s story, but I needed him to fill in the blanks. I also needed to assess his credibility in person. Needless to say, he passed with flying colors.

“The GPO story was a difficult one to tell. And, to be absolutely honest, our editors did not immediately see the value in spending a great deal of time learning about the dark side of GPOs. But we kept at it. We followed the money and it led us to an incredibly important series of discoveries. The result was a compelling series about the hidden hand of GPOs in the marketplace. The best part of that series – hands down – was the opening anecdote which dealt with Joe’s product. Without that, I’m not sure anyone would have read beyond the first few paragraphs.”



[ Seth Bloom ]



[ Senator Herb Kohl ]



[ Walt Bogdanich ]

# The Legal Warriors

as told by Joe Re and Steve Jensen

As 2004 began, the patent trial was on everyone's mind, but despite advancing in the marketplace, Masimo was \$5,000,000 in debt to its law firm, Knobbe, Martens, Olson & Bear. Attorney Steve Jensen believed in the Masimo mission and urged his partners to continue with the case, fearing that if the company did not win, it could literally mean a great many unnecessary deaths in the future. The Knobbe firm assembled a small army of personnel on a floor of a hotel in downtown Los Angeles. Mohamed Diab thought it looked like a war room, with an IT specialist, computers everywhere, and Steve Jensen writing the trial strategy like a field general. To reassure his clients, attorney Joe Re told Masimo that it had many legal "smoking guns" with which to go after Nellcor and its parent company at the time, Mallinckrodt, while in most trials of this kind, there was only one. This was a prescient comment. On Friday, March 26, 2004, the 27-day trial was over and Masimo won to the tune of \$270 million overall, with a 14.8 percent royalty to be paid to Masimo by Nellcor each year for use of Masimo technology. Everyone at Masimo was hugely relieved, but it was too early to celebrate; with appeals, it might be years to collect. Through appeals and another trial, however, Masimo persisted, and Nellcor lost. A med tech David had brought down a med tech Goliath, and Masimo showed the world that "right is might" and no just fight was impossible to win, if you had enough determination, persistence, and truth on your side.

**> OUR LEGAL TEAM:** As a lawyer, we think of Joe Re as bigger than life. He's King Kong. He doesn't leave anything behind. Together with Steve Jensen, they formed a simply unstoppable team. During our patent litigation, Steve was detail oriented, found all the facts, did all the discovery work, and came up with the legal strategy along with Joe. And when Joe Re went in front of that jury and displayed his mastery, our ultimate success was assured, no matter how much trepidation we had going in and during the trial.

The patent trial victory was cleansing and healing and the wonderful result was heavily dependent on Steve, who was literally tireless. He would work all night leading up to and during the weeks of the trial. At 4:00 or 5:00 in the morning he'd hand off the questions that Joe would ask the witnesses the next day. And then Steve would go take an hour nap, shower up and come back to court with us. He lost 30 pounds during that 4- to 5-week period, and he and Joe won us our life as a company.

## Joe Re

**"WHAT AN HONOR** it was for me and my partners at Knobbe to present the Masimo story to eight strangers, a jury. As each day passed during that six-week patent infringement trial, the contrast between Masimo and Nellcor became more and more evident. While Nellcor was struggling to preserve its market dominance, Masimo was fighting to introduce its SET® technology to improve healthcare for everyone.

"The trial revealed that Nellcor's executives had been telling Joe Kiani that his dream of expanding pulse oximetry was unrealistic, that he should pursue something else, or maybe get some experience as a VP first.

"When Masimo offered its technology for Nellcor to introduce, Nellcor's pride got in the way. Its executives could not stomach that two young engineers, Joe Kiani and Mohamed Diab, solved problems that had long plagued the pulse-oximetry industry. Nellcor refused to agree to implement Masimo's technology immediately because it wanted to keep SET®, which they referred to as that 'killer app,' on the shelf until its own sensor patents expired, regardless of how that plan would harm patients. Guided by his self-determination and integrity, Joe had Masimo introduce its SET® technology on its own.



Joe Re

"As the truth prevailed, the jury easily saw the stark difference between the two companies, one focused on themselves, and the other focused on the patient."

## Steve Jensen

**"WHEN THE NELLCOR PATENT LAWSUIT** was filed, Masimo was a very small company and not yet profitable. Nellcor had a large legal team. Masimo did not have the funds to keep up and just got further and further in debt to my law firm. At one point, the debt owed to my firm was so significantly impacting the firm's financial situation that my partners wanted me to withdraw from the case.

"I didn't want to withdraw, and believed we would win the case. I believed that patient care would forever suffer if Masimo's technology did not make it to the market. And if we didn't win this patent case, I didn't believe Masimo's revolutionary technology would ever make it to patients in a meaningful way because the much larger competitor was infringing its patents.

"For patients to benefit, Masimo needed to be able to protect its innovations. And if I withdrew, I think that may have been the end of Masimo.

"The first bank wire Masimo received after we won was over \$300 million, and Masimo's revolutionary technology began to be adopted rapidly."



Steve Jensen

# International Advocates

as told by Katsuyuki Miyasaka, Christian Poets, and Atsuhiko Sakamoto

Masimo's international reach was expanded in February of 1998 with deals with Datascope Corp. and Invivo Research. Datascope put the company in front of a worldwide market when it agreed to integrate Masimo SET® into its monitors. But before that, Japanese companies, NEC Medical and Atom, had agreed to introduce Masimo to Japan, and a UK company, Kontron, agreed to do so in Europe. This was quickly followed by GS Electromedical, a German company whose primary products were defibrillators and monitors used in emergency medical applications. Gunter Stemple, President of GS Electromedical, called Masimo technology a "quantum leap in performance and reliability," which was quite a recommendation for the rest of the European market. With the Group Purchasing Organization structure in the U.S. hindering market expansion for so long, Masimo's necessary outreach to international markets turned into a blessing long-term, and some special champions of our work made a big difference with their support, encouragement, and advice.

## Katsuyuki Miyasaka

> *Dr. Miyasaka was an anesthesiologist in the National Children's Hospital in Japan. He did original studies for us in Japan when NEC was implementing Masimo SET® into their products. His data gave us a clue that eventually helped us figure out how to make a pulse oximeter that was good even on cyanotic patients. Even better, he pushed us to complete rainbow®, which was major, by telling Joe over dinner, "If you don't do it, no one else will!"*

"MY INTEREST IN PULSE OXIMETRY began over 30 years ago, particularly regarding its use in clinical settings for neonates, and in pediatric anesthesia and critical care. I was one of the first to promote the use of pulse oximetry in Japan through my involvement in conferences on oximetry use and publication of scientific and clinical papers from the late 1980s. My scientific and clinical association with Masimo started in 1993 when Mr. Joe Kiani visited Japan, from which time I became involved in Masimo pulse oximeter product development. Clinical data from physicians in the field provided important feedback to Masimo and led to suggestions for product improvement.

"There was little interest in pulse oximeter use at the beginning because in adult anesthesia the monitor always showed 100%, but the situation was quite different in pediatrics as patients were always labile and fragile.

"My focus on such issues as the influence of venous pulsation on motion artifact during poor perfusion in pediatric patients and the use of clinical data analysis contributed to the improvement of Masimo SET® technology. The reduction of false alarms due to motion artifact was of utmost importance in establishing clinician acceptance of pulse oximetry. I believe its use in adult medicine was based in part upon its success in pediatric medicine. I find many other issues, such as the importance of noninvasive measurement of hemoglobin and dyshemoglobins, to be of great interest.

"As a physician researcher specializing in pediatric anesthesia and critical care, I have been aware of the importance of pulse oximetry in pediatric anesthesia and NICUs and have tried to deepen understanding of the issues involved through clinical studies that provide information to the medical community, both in Japan and overseas. I look forward to further development of products by Masimo in the future."

## Christian Poets

> *Christian rolled up his sleeves, tested our product (when it was in a little blue box) on babies in his care, collected a lot of great data, and challenged us to make it better. He urged us to*

*improve pulse rate algorithm, and we did. Because of his help, data prodding, and then his publications, he showed our competitor's product not only gave false readings but they also missed true alarms. None of this ever showed us as perfect but all of a sudden we were seen as much better than whatever was out there.*

"I WAS CONTACTED in late 1993 by Trevor Jones, a senior manager from a British Monitor company, Kontron (Watford, UK). They had supported us by designing a transcutaneous PO2 monitor for home use in infants (to notify parents of severe hypoxemia potentially leading to sudden infant death syndrome (SIDS)). We had chosen transcutaneous monitoring because pulse oximetry was nowhere near suitable as a home monitor at that time. Trevor told me he had had contacts with a person called Joe Kiani, who had developed a new, motion resistant pulse oximeter, and asked whether I was interested in meeting this guy – which I certainly was, as I had never liked the idea of using transcutaneous oxygen monitors in the home environment, and was thus keen to meet somebody who promised he had solved its main problem, i.e., motion artifact!

"Joe walked into my office a few weeks later, and was proud to present me his pulse oximeter. However, when I tested this device in our patients on the neonatal intensive care unit, I saw its potential, but in my opinion, there were still far too many false alarms due to motion. I told him that, and he asked me whether I would be willing to record saturation data in some really difficult infants on our NICU (with a lot of motion, but also recurrent true hypoxemia), which I was. Masimo sent equipment, and I then started

these recordings (including the raw red-to-infrared data), which apparently helped the Masimo team a great deal to improve their software. I did this because I saw the potential: there was never any money involved.

"What struck me already during our first encounter was Joe's determination to really improve pulse oximetry, not just to make money. He was burning to make a potentially extremely helpful technology better, more user-friendly and reliable, and he could accept/respond to critique. I gave him a really hard time in 1993, when he was so proud about his new invention, and it was certainly not easy for him to swallow my rather blunt statement: 'It's better than what I have seen from your competitors, but not what I expect from a really good device.' He did not ignore my critique, but took it as a challenge that ultimately helped Masimo to become better."

## Atsuhiko Sakamoto

> *Dr. Sakamoto met Joe Kiani in Tokyo in 2007 and provided Joe with information about the style of Japanese medical practice and about the Japanese medical business. Dr. Sakamoto also helped study noninvasive hemoglobin and rainbow acoustic monitoring as the head of the Masimo Japan Working Group (MJWG) and has been instrumental in helping us better shape our products for assisting patients in Japan.*

"IN JAPAN, since 2008, I have been a leader in reviewing over 1,000 clinical data on SpHb® while collaborating with

15+ key medical institutes. I organized an SpHb study group called MJWG with 35+ key teaching hospitals on the subject of SpHb. MJWG shares its clinical study data with those key teaching hospitals, and this collaboration has contributed to a greatly improved product. MJWG not only contributed to various clinical studies on SpHb, but also to the penetration of Masimo SpHb into the Japanese market. We consider this to be a great asset to the health of our country's people.

"I also have a strong interest in enhancing patient safety. For that purpose, I am working on a project for our hospital to improve patient respiratory management. I find Masimo RRA® and SpO2 greatly contributes to increasing patient safety at clinical sites.

"Our hospital resources, rather than being abundant, are limited. Therefore, it is important for us to know how to manage patient safety in critical care and in the general ward with our limited number of medical staff. Just applying a monitor to a patient on the general ward is not enough. Vital signs should be monitored continuously and collected in real time and should be closely observed and analyzed at a Central Station for the best patient care.

"The greatest importance is how quickly our staff members grasp a patient's medical condition and how quickly we can take necessary actions for a patient. I am assured that Masimo products with SpO2, RRA, Hb, and a central monitoring system maximizing our hospital LAN network system are powerful tools for our medical staff to increase patient safety throughout our hospital."



The Kianis with \_\_\_\_\_ and Dr. Katsuyuki Miyasaka



Dr. Christian Poets



Joe Kiani and Dr. Atsuhiko Sakamoto

# The Researchers

Masimo has been fortunate to build partnerships with some of the most renowned researchers in the world. These collaborations are based on the fundamental desire to improve patients' lives more significantly. In recognition of these individuals for their commitment to evidence-based research, and hence to the evolution of noninvasive monitoring technologies, we have provided highlights of their individual contributions.

## Nitin Kumudchandra Shah

> Professor of Anesthesiology at Loma Linda University;  
Chief of Surgical ICU at Long Beach VAHS

**DR. SHAH'S** 1997 study was the first to show that Masimo SET® pulse oximetry had higher sensitivity and specificity than competitive pulse oximetry during motion and low perfusion conditions. Dr. Shah went on to complete several additional studies with similar results, including a 2010 study that showed Masimo SET® continued to have higher sensitivity and specificity than to the latest generation of competitive pulse oximetry.

## Charles G. Durbin

> Professor of Anesthesiology and Surgery,  
University of Virginia Health System

**DR. DURBIN'S** 2000 study in post-coronary artery bypass graft (CABG) surgery found that when comparing Masimo SET® vs. non-Masimo SET® pulse oximetry, ICU clinicians weaned patients from their ventilator faster while administering fewer arterial blood gas draws.

## David Drover

> Associate Professor of Anesthesiology, Perioperative and Pain Medicine,  
Stanford University Medical Center

**DR. DROVER'S** 2002 study was the first to show that SedLine® brain function monitoring with Patient State Index resulted in faster emergence and recovery from propofol-alfentanil-nitrous oxide anesthesia, compared to standard practice without brain function monitoring.

## William W. Hay, Jr.

> Scientific Director of the Perinatal Research Center;  
Director, Neonatal Clinical Research Center;  
Scientific Director, Perinatal Research Center,  
University of Colorado, Denver;  
Professor of Pediatrics (Neonatology)

**IN ADDITION** to Dr. Hay's clinical research in early postnatal intravenous nutrition of the extremely low birth weight infant, he is a global expert in the research of neonatal applications of pulse oximetry in newborn infants. In 2002, Dr. Hay's research showed significantly fewer false SpO<sub>2</sub> and PR alarms when using Masimo SET® pulse oximetry versus conventional and new-generation pulse oximeters in the NICU.

## Maxime Cannesson

> Associate Professor of Clinical Anesthesiology,  
University of California, Irvine, CA

**IN 2008**, Dr. Cannesson was the first researcher to show that Masimo's noninvasive pleth variability index (PVI®) was significantly better than traditional measures used to help clinicians assess fluid responsiveness in mechanically ventilated patients during general anaesthesia. After Dr. Cannesson's study, over ten studies have been published on PVI showing similar results as well as the impact of PVI on goal-directed fluid management decisions and patient risk.

In addition, PVI has now been recommended in both France and the United Kingdom for use during surgery to perform goal-directed fluid management.

## Andreas H. Taenzer

> Associate Professor of Anesthesiology and Pediatrics,  
Director, Pediatric Acute Pain Service,  
Dartmouth-Hitchcock Medical Center;  
Director of the Dartmouth Patient Deterioration  
Prediction Laboratory (DP2L)

**DR. TAENZER'S** 2010 study with Masimo SET® pulse oximetry and Patient SafetyNet™ was the first to show that pulse oximetry and remote monitoring could reduce rescue activations and ICU transfers in post-surgical patients. After Dr. Taenzer's study, the Anesthesia Patient Safety Foundation and Joint Commission recommended that all patients on opioids be continuously monitored with pulse oximetry.

## Jesse Ehrenfeld

> Associate Professor of Anesthesiology,  
Surgery, and Biomedical Informatics;  
Director of the Anesthesiology &  
Perioperative Informatics Research Division;  
Director of the Center for Evidence-Based Anesthesia,  
Medical Director for Perioperative Quality

**DR. EHRENFELD'S** 2010 study in patients undergoing orthopedic

surgery was the first to show that using noninvasive and continuous hemoglobin (SpHb) monitoring helped clinicians reduce the frequency of intraoperative red blood cell transfusions and the average units of blood transfused per patient.

## Michael A.E. Ramsay

> Chairman, Department of Anesthesiology,  
Baylor University Medical Center;  
President, Baylor Research Institute

**DR. RAMSAY'S** 2013 study was the first to show that acoustic respiration rate (RRa) detected the cessation of breathing faster than traditional capnography, providing a well-tolerated solution for patients at risk of respiratory depression.

## Dominik Roth

> Medical University of Vienna,  
Department of Emergency Medicine

**DR. ROTH'S** 2014 study showed that adding noninvasive carboxyhemoglobin (SpCO®) assessment to the standard emergency department assessment revealed nearly twice as many more cases of carbon monoxide poisoning being detected than reported previously. CO poisoning accounts for an estimated 50,000 ED visits in the U.S. annually. Dr. Roth's study means that an additional 34,500 patients may have carbon monoxide poisoning, but are undiagnosed.



Dr. Nitin Kumudchandra Shah



Dr. Charles G. Durbin



Dr. David Drover



Dr. William W. Hay, Jr.



Dr. Maxime Cannesson



Dr. Andreas H. Taenzer



Dr. Jesse Ehrenfeld



Dr. Michael A. E. Ramsay



MASIMO 2066  
Apple v. Masimo  
TPR2022-01465  
Dr. Dominik Roth

# The Masimo Foundation

as told by Jim Bergman

The Masimo Foundation for Ethics, Innovation and Competition in Healthcare is a non-profit organization we formed to facilitate our corporate philanthropy. During the first quarter of 2010, we provided a monetary gift and an in-kind contribution of pulse oximetry equipment and supplies to support the Foundation's efforts. Our \$10 million gift to the Foundation represented a portion of the multi-million dollar payment received in January 2010 from the antitrust victory against Nellcor/Tyco Healthcare. The Foundation's established purpose was to encourage and promote various activities, programs, and research opportunities designed to improve patient safety and deliver advanced healthcare to people worldwide that may not otherwise have access to lifesaving technologies.

In addition, the Foundation is meant to support third-party research, development initiatives, and clinical studies designed to expand the healthcare industry's ability to provide better and more cost-effective solutions and protocols for healthcare delivery throughout the world. Finally, the Foundation is intended to provide special attention to those causes whose ultimate goals are ethical – focused on doing the right thing for the right reasons – and designed to create healthy competition, which Masimo believes is the ultimate answer to lower health care costs in the U.S. and throughout the world. The Masimo Foundation is dedicated to improving patient care through philanthropic programs and research initiatives that foster an environment of robust and honest competition, and enhance caregiver access to cost-effective and innovative healthcare solutions. The Masimo Foundation is also a family affair with Sarah, Mrs. Joe Kiani, serving on the board.

As we look back over the past quarter century and consider our struggles along the way, we feel particularly blessed to have made it this far because there were many times when the future seemed shaky, as the following story from a Masimo Foundation board member illustrates.

## Jim Bergman

> *When we walked away from our first venture capital deal, Jim Bergman's firm was one of the companies involved. Despite our departure, Jim came forward and said he and his firm really like us and wanted to invest. He felt that Masimo's valuation was six times higher than investors offered less than a year before. He not only became our first real venture capital investor, he has always reminded us about fairness. He was our very first choice to be involved with the Masimo Foundation, and is still onboard.*

**"RIGHT AFTER WE** had raised several million dollars in a round of investment, a couple of new people joined the Board of Directors. This created a board of four outsiders and three insiders, and there were three outside people who wanted to bring in a new CEO. They wanted to move Joe over to marketing manager or engineering manager. We had a vote, it was 4 to 3, and thank goodness, we didn't do it. I mean, had I voted the other way, Joe wouldn't be the CEO.

"When we were battling Nellcor, normally, the little guy never can outlast the big guy, in terms of spending money. We probably spent \$15 million. For a company that was not making much money, that was a lot of money to spend, but we somehow persevered. In my experience in venture capital, I don't think I've ever seen or been aware of anyone winning that big a lawsuit when it was sort of David vs Goliath.

"Masimo is the great story of the American dream, two hardworking young guys who went to San Diego State rather than Harvard or Yale or even Stanford or UCLA and came up with

a great idea and just managed to persevere basically through everything with the guts to keep trudging ahead, and they finally won. And I can't say there's any better story that I can think of than that.

"For over 30 years, I was a General Partner of firms that provided capital and management assistance to emerging companies primarily in high technology, particularly those technologies associated with electronics, communications, biotechnology and health care. I've served on the Boards of more than thirty-five companies, and I was a director of the National Venture Capital Association from 1985 to 1990.

"But my real love is the charitable sector. I've been on the boards of Micro Finance banks and organizations in Africa and have served on numerous other church and charitable boards and committees. My wife and I have taken more than forty field trips to Developing World countries with World Vision, Church Resource Ministries, Opportunity International, and other organizations.

"Because I love helping others, I feel perfectly at home being on the Board of the Masimo Foundation, whose humanitarian outreach and scope has been worldwide in its emphasis since the organization's beginning. Here's to another quarter century of success!"



Rescue medical team  
in Haiti using donated  
Masimo technology



The Kiani family at fundraiser  
for Juvenile Diabetes Research  
Fund (JDRF) with the Mayor of  
Irvine, Steven Choi

# The Patient Safety Movement

as told by President William Jefferson Clinton

## President William Jefferson Clinton

> In the summer of 2012, Joe Kiani spent over a week with President Clinton in Africa. It was part of a commitment Joe had made to help the President with his work for the Clinton Global Initiative (CGI). They became friends, and Joe told President Clinton something that was fascinating but horrifying – that three million people die worldwide every year from deaths that are preventable. More than 200,000 of those deaths occur in the U.S. The two agreed that the goal of healthcare in the new millennium should be more than simply providing people access to healthcare, but also advancing a healthcare system that assures patient safety and dignity.

“I’ve been impressed by Joe’s commitment to end all deaths due to preventable medical circumstances. I believe that the goal of the Patient Safety Movement can be accomplished--and because it can it has to be done.

“I know big goals can be achieved. Since 2005, members of the Clinton Global Initiative, with their thousands of Commitments to Action, have had a positive impact on more than 400 million people in 180 countries. Being a CGI member entails making a commitment and doing your best to keep it. The CGI staff works year round to help our members develop and keep their commitments. They draw upon each other’s strengths and create new partnerships to put their ideas into action. We call it ‘mobilizing for impact.’

“This is exactly what Joe Kiani has demonstrated in building Masimo, and in creating the Patient Safety Movement. On their 25th anniversary, I’d like to congratulate Joe and the people at Masimo for helping us achieve a healthier world, and commit to doing my part until the goal of zero preventable deaths becomes a reality.”



[ Joe Kiani and President Clinton ]



[ President Clinton as keynote speaker at inaugural Patient Safety Summit ]



[ President Clinton in Africa on tour ]

# In Memoriam

It is never easy to say goodbye to a Masimo team member, and doubly difficult when someone from the Masimo family passes. Thankfully, there have not been many such instances over the quarter century of our existence, but we would like to remember here some people who gave us great service and fond memories in their time with us all.

Scott Barnhouse

Philip Bonwell

Jeffery Dempsey Jr.

Patricia Jasion

Joseph Mueller

Cynthia Nelson

Sue Nevill

Jennifer Nibarger

Ashley Chuck Smith

James Van Slochteren

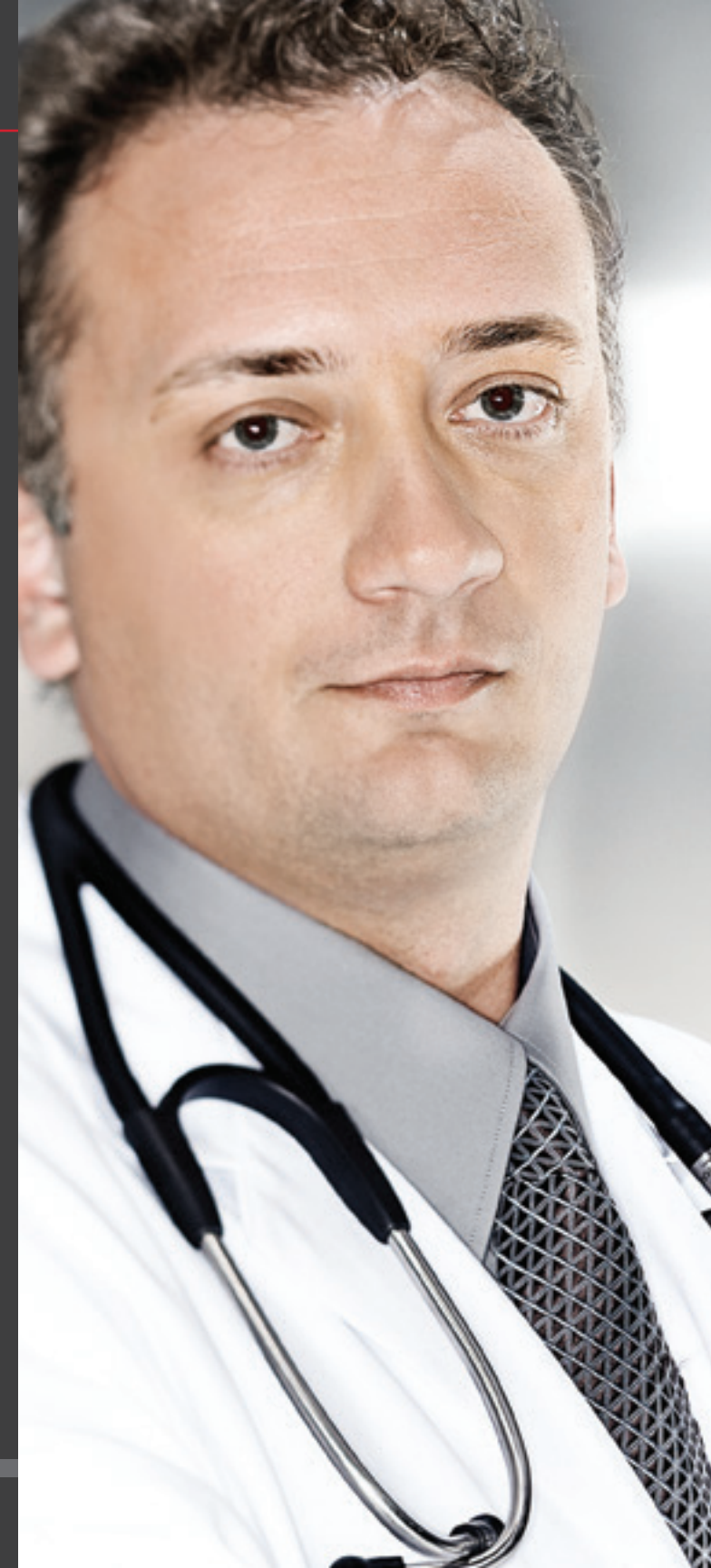
Sari Wheaton



[ Masimo team on 20-year anniversary ]



# SOLVING THE UNSOLVABLE







# SIGNAL EXTRACTION TECHNOLOGY<sup>®</sup>

Twenty-five years ago, two young engineers asked why pulse oximetry wouldn't work during patient motion and low perfusion. In doing so, they started a revolution in patient monitoring.

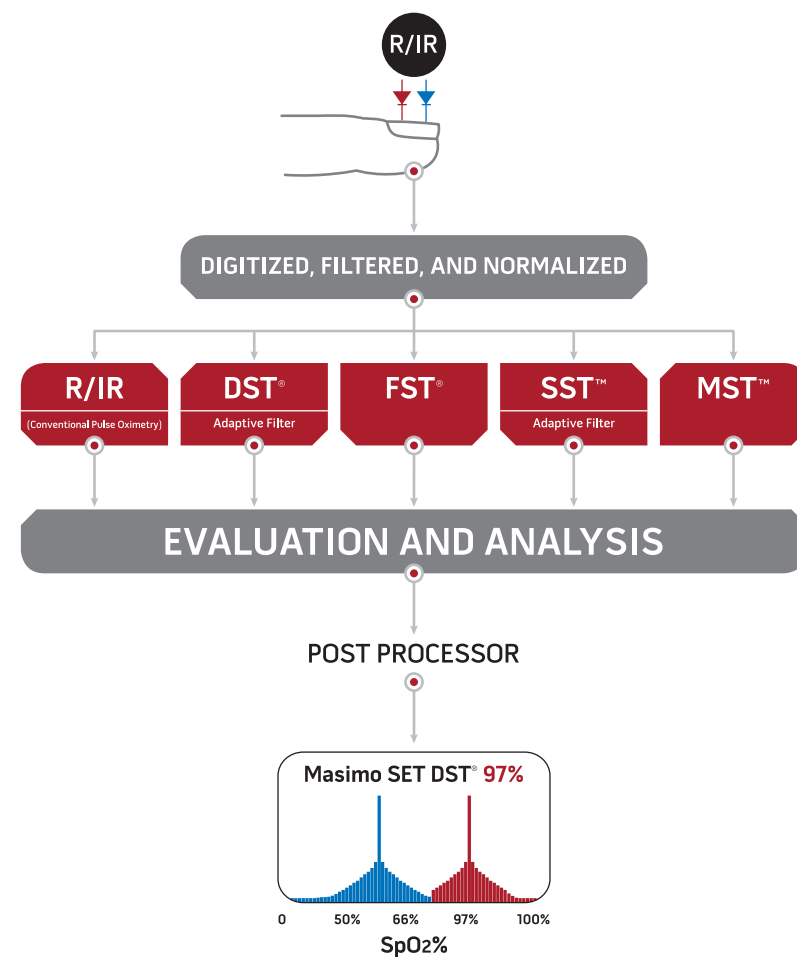
## OVERCOMING THE LIMITATIONS OF CONVENTIONAL PULSE OXIMETRY

Pulse oximetry had always been unreliable when it was needed most – during patient motion and low perfusion. The industry considered the problem “unsolvable” and clinicians were forced to live with the consequences – excessive false alarms, delayed notification due to long averaging times, inaccurate data, and an inability to obtain data on the most critical patients. Something had to change.

Conventional pulse oximetry works under the assumption that by looking at only the

pulse and normalizing the pulsating signal over the non-pulsating signal, oxygen saturation (SpO<sub>2</sub>) can be obtained. Although this was a big step forward in pulse oximetry's evolution, this core assumption has major flaw – it assumes that the *only* pulsating component is arterial blood.

Unfortunately for conventional pulse oximetry, venous blood moves every time the patient moves or breathes. This causes conventional pulse oximeters to display false low or high SpO<sub>2</sub> readings and pulse rates – causing false alarm rates as high as 90% in ICUs and recovery rooms.



Conventional pulse oximetry uses the standard red over infrared algorithm to provide SpO<sub>2</sub>, while Masimo SET<sup>®</sup> uses that conventional algorithm but has added four other algorithms that all run in parallel. These algorithms allow the distinction between arterial and venous signal during motion and low perfusion by identifying and isolating the non-arterial and venous noise SpO<sub>2</sub> (left peak shown in blue) from the true arterial SpO<sub>2</sub> components (right peak shown in red) in the signal. The plot peak on the right is then chosen as the SpO<sub>2</sub> value, since the physiologically higher SpO<sub>2</sub> value within the measuring site will always be arterial signal.



# UNLEASHING BREAKTHROUGH PERFORMANCE



Joe Kiani and Mohamed Diab approached pulse oximetry from a completely different perspective.

In doing so, they opened up a whole set of exciting new possibilities. Masimo SET® acknowledges that both the arterial and venous blood can move and uses parallel signal processing engines – DST®, FST®, SST™, and

MST™ – to separate the arterial signal from sources of noise (including the venous signal) to measure SpO<sub>2</sub> and pulse rate accurately, even during the so-called challenging conditions of motion and low perfusion.

### VALIDATED BY INDEPENDENT AND OBJECTIVE RESEARCH

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

After six years of dedicated and focused research and development, Masimo SET® debuted in 1995 at the Society for Technology in Anesthesia and won the prestigious Excellence in Technology Innovation Award.

Thereafter, skeptical clinicians around the world sought actively to compare Masimo SET® to pulse oximetry technologies offered by other companies. But in study after study, the breakthrough signal processing

of Masimo SET® consistently resulted in significantly fewer false alarms and improved detection of true alarms. With Masimo SET®, clinical studies have shown false alarms can be reduced by over 95%, while true alarm

detection was shown to be over 97% – even during motion and low perfusion.<sup>1</sup>

<sup>1</sup>Shah N., Ragaswamy H.B., Govindugari K., Estanol L. *J Clin Anesth.* 2012 Aug;24(5):385-91.

## MISSED TRUE ALARMS AND SENSITIVITY DURING CHALLENGING CONDITIONS

//// MISSED TRUE ALARMS // ■ SENSITIVITY

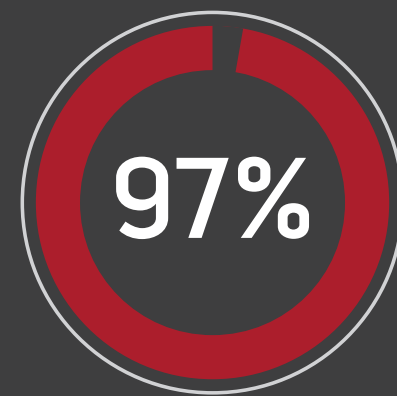


Nellcor N-600



Masimo SET®

In this hospital-based study, investigators measured SpO<sub>2</sub> in 10 subjects during motion and low perfusion conditions and calculated the false alarm rate during 120 full oxygenation events (specificity) and true alarm rates during 40 de-oxygenated events (sensitivity).<sup>1</sup>



Sensitivity

## FALSE ALARM RATES AND SPECIFICITY DURING CHALLENGING CONDITIONS

//// FALSE ALARMS // ■ SPECIFICITY

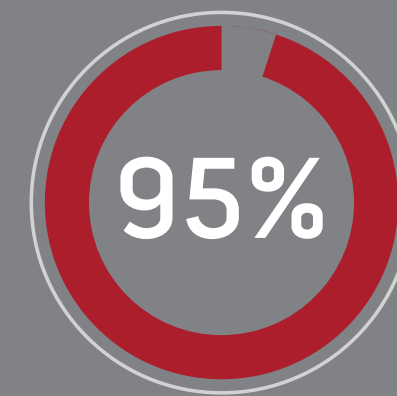


Nellcor N-600



Masimo SET®

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Specificity

# INDUSTRY-LEADING PULSE OXIMETRY SOLUTION



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

## THE CHOICE OF CLINICIANS IN THE WORLD'S LEADING HOSPITALS

Because of its unmatched reliability during challenging conditions of motion and low perfusion,<sup>1</sup> clinicians at thousands of hospitals around the world count on Masimo SET® every day to help them care for patients. And while many leading hospitals have already integrated Masimo SET®, more are converting every day.

Leading hospitals and clinicians choose Masimo SET® to help them deliver effective and efficient patient care. With fewer false alarms,<sup>2</sup> clinicians can focus on the patients who need the most attention. With more accurate measurements,<sup>1</sup> clinicians can more tightly control oxygenation levels. And with

timelier detection of true events, clinicians can intervene earlier for better patient outcomes and improved patient safety.<sup>1</sup>

## INTEGRATED IN MORE INDUSTRY-LEADING PRODUCTS THAN ANY OTHER PULSE OXIMETRY TECHNOLOGY

Masimo SET® is integrated in more industry-leading multiparameter monitors than any other pulse oximetry technology – more than 100 monitors from 50 leading brands. In many of these monitors, Masimo SET® is the only pulse oximetry technology offered. In addition, more and more of our original equipment manufacturer (OEM) partners are enhancing the capabilities of their monitoring solutions by integrating our rainbow® technology.

<sup>1</sup>Shah N et al. *J Clin Anesth*. 2012 Aug;24(5):385-91. <sup>2</sup>Barker SJ. *Anesth Analg*. 2002 Oct;95(4):967-72.

Leading hospitals and clinicians choose Masimo SET® to help them deliver effective and efficient patient care.



Physio-Control® with rainbow®



ZOLL® with rainbow®



GE® with Masimo SET, rainbow® integration underway



MS-2040™ Very low power SET® OEM Board

Masimo SET® is integrated in more industry-leading products than any other pulse oximetry technology



Dräger® with rainbow®



Philips® with Masimo SET, rainbow® integration underway



MS-2013™ Low power SET® OEM Board

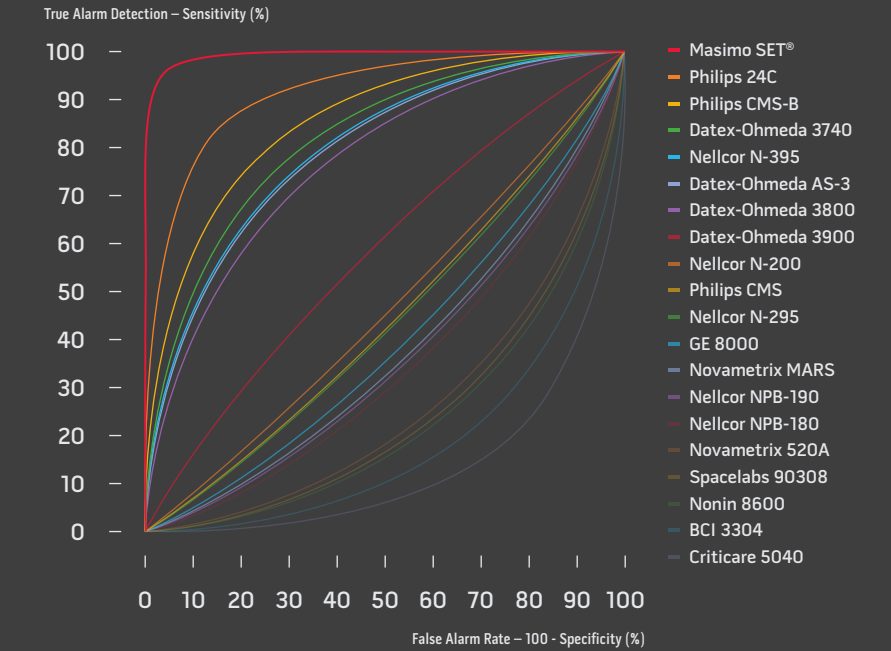


MX-5™ Low power rainbow® OEM Board



Welch Allyn® with rainbow®

# PERFORMANCE DURING MOTION AND LOW PERFUSION



A total of 70 volunteers were tested with motorized hand motions. Each motion was studied during both room air breathing and hypoxemia. Pulse oximeters on the stationary hand were used to provide control measurements for comparison. Sensitivity was defined as ability to detect a true SpO<sub>2</sub> <90%. Specificity was defined as the ability to detect a true SpO<sub>2</sub> >90%.<sup>2</sup>

"Masimo SET® is advantageous because even though it significantly reduces false alarms, it doesn't do that by ignoring physiological changes."

Christian Poets, MD  
Director, Neonatal Intensive Care Medical School, Hanover, Germany

# HELPING CLINICIANS SCREEN FOR CRITICAL CONGENITAL HEART DISEASE AND PRESERVE BABIES' EYESIGHT



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

## ENABLING NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DISEASE

The breakthrough performance of Masimo SET® is often most appreciated by clinicians caring for fragile newborns. Up to 30% of all congenital heart disease (CHD) deaths occurring in the first year of life are unrecognized at post-natal discharge. Masimo SET® pulse oximetry has been shown to reliably assist clinicians in screening for critical congenital heart disease

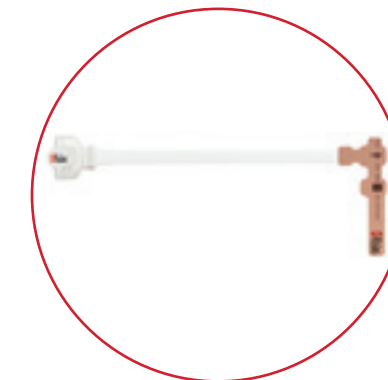
(CCHD),<sup>1,2</sup> spurring the US Secretary of Health and Human Services to add "motion-tolerant" pulse oximetry to the Recommended Uniform Screening Panel for newborns.<sup>3</sup> Masimo SET® pulse oximeters and sensors meet the recommended criteria for newborn screening, were exclusively used in the two studies that were the basis for the CCHD workgroup decision to recommend newborn screening, and were the first to receive FDA 510(k) clearance with labeling for CCHD screening.

<sup>1</sup>Ewer AK et al. *Lancet*. 2011 Aug 27;378(9793):785-94. <sup>2</sup>de-Wahl Granelli AD et al. *BMJ*. 2009;338. <sup>3</sup>Secretary of Health & Human Services letter to the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), dated September 21, 2011. <sup>4</sup>Castillo A et al. *Acta Paediatr*. 2011 Feb;100(2):188-92. <sup>5</sup>Cox PN et al. *Anesthesiology*. 2007;107:A1540. (abstract).



## HELPING CLINICIANS REDUCE RETINOPATHY OF PREMATURITY

Premature infants requiring neonatal intensive care need enough oxygen to preserve vital organ function, but too much oxygen can cause severe eye damage from retinopathy of prematurity (ROP). Masimo SET® is the only pulse oximetry shown to help clinicians dramatically reduce ROP.<sup>4</sup>



## BETTER CARE FOR CYANOTIC PATIENTS

In cyanotic infants, Masimo SET® with the Blue Sensor is the only pulse oximeter shown to enable accurate maintenance of targeted oxygen saturation levels.<sup>5</sup> And for very low birth-weight babies, only the Masimo NeoPt-500 Sensors are designed for both size and performance in infants as small as 500 grams.



## OPTIMAL NEWBORN RESUSCITATION

Every second matters during newborn resuscitation. The Masimo Newborn Sensor ensures the fastest response time with maximum sensitivity – allowing clinicians to focus on real-time patient management instead of the device. In addition, Masimo SET® is being used by hospitals to supplement the standard APGAR score to assess general newborn health.

## NEWBORN SCREENING WITH MASIMO SET®<sup>2</sup>

N = 39,821 BABIES

	Physical Exam Alone	Physical Exam + Masimo SET® Pulse Oximetry Screening <sup>2</sup>
Sensitivity for CCHD Detection	63%	83%
Specificity for CCHD Detection	98%	99.8%

SpO<sub>2</sub> 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 SpO<sub>2</sub> measurement was <90%; 2) if in three repeat measurements, both preductal and postductal SpO<sub>2</sub> were <95%, or the difference between the two measurements was >3%.

## REDUCTION OF ROP WITH MASIMO SET®<sup>5</sup>

SEVERE RETINOPATHY OF PREMATURITY (ROP) RATE

Center	Period 1 (pre-policy change)	Period 2 (post-policy change)	Period 3 (post-policy change)
A	12% with Nellcor	5% with Masimo	4% with Masimo
B	13% with Nellcor	13% with Nellcor	6% with Masimo

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



Masimo's latest innovation in pulse oximetry, Eve,\* is an intuitive application that transforms the Radical-7® into a simple yet powerful newborn screening tool designed for improved accuracy and efficiency.

\* Eve is pending CE Mark. Not currently available in the U.S.



# ADDRESSING THE NUMBER ONE TECHNOLOGY HAZARD IN HOSPITALS TODAY—ALARMS

## CORE TECHNOLOGY ADVANTAGES OF MASIMO SET®

The Joint Commission, the ECRI Institute, the Anesthesia Patient Safety Foundation, and numerous other leading industry bodies have repeatedly cited alarm fatigue among the most pressing patient safety hazards.<sup>1-3</sup> Conventional approaches to alarm management were developed mainly to address the problems of conventional pulse oximetry's inability to measure through motion. Fixed alarm thresholds and delays sometimes reduce non actionable alarms, but with potentially delayed notification of

significant events. Masimo SET® broke through past barriers and reduced false alarms by over 95%. In an area like the ICU where up to 90% of all alarms used to be false, Masimo has helped reduce the false alarm incidence to just 5%.<sup>4</sup>

## AUTOMATED, PATIENT-CENTRIC APPROACH WITH ADAPTIVE THRESHOLD ALARM\*

We designed Adaptive Threshold Alarm to help clinicians manage the frequency of alarms, improving on the limited

alarm paradigms of the past to notify clinicians when significant changes in physiology have occurred.

Adaptive Threshold Alarm helps clinicians reduce alarms and reduces the time required to set patient-specific alarms by automatically adjusting the audible alarm to the patient's baseline (Figure 1).

\*Adaptive Threshold Alarm is CE Marked. Currently not available in the U.S.

Figure 1: Adaptive Threshold Alarm Example



# PROVIDING EARLIER NOTIFICATION OF POTENTIAL RISK WITH ADVANCED ALARMS



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

- > **3D Desat Index Alarm™** helps clinicians detect multiple transient desaturation events that may identify patients at risk for respiratory failure.<sup>5</sup>
  - Low SpO2 alarm limits are typically set too low to spot multiple transient desaturations that could indicate patient distress. 3D Desat Index Delta Alarm signals after five desaturations below 93% over a period of 60 minutes or less (Figure 2).
- > **3D Perfusion Index Delta Alarm** helps clinicians quickly detect critical changes in peripheral perfusion.<sup>6,7</sup>
  - Changes in peripheral perfusion can reflect significant underlying cardiovascular changes. 3D Perfusion Index Delta Alarm notifies clinicians when there is a 25% change in Perfusion Index (PI) within a period of 60 minutes or less (Figure 3).

Figure 2: 3D Desat Index Alarm Example

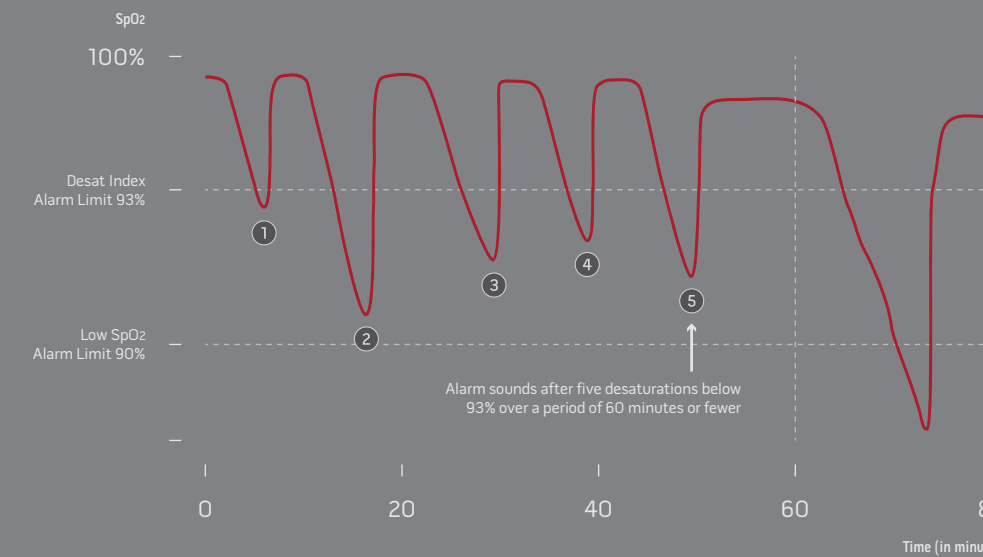
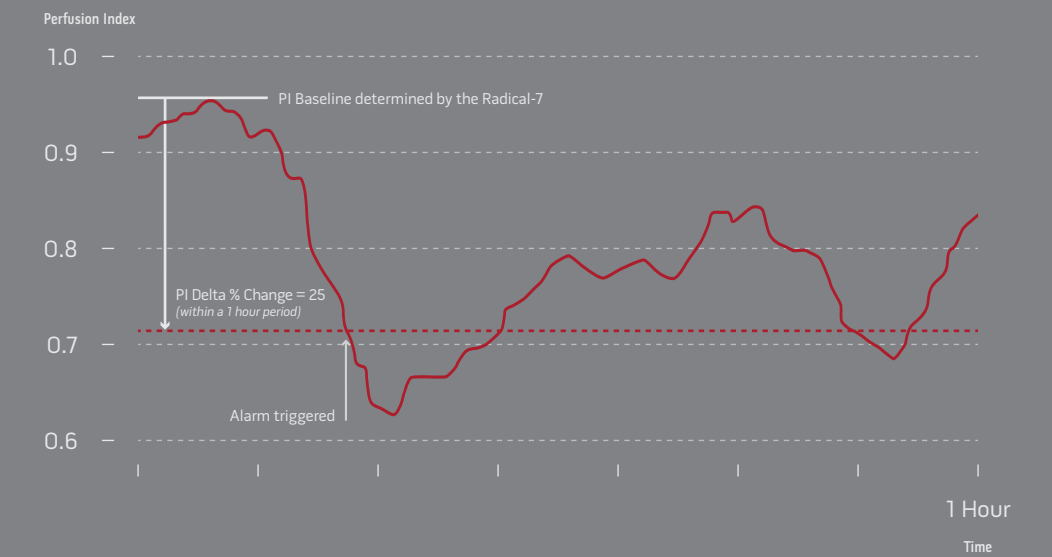


Figure 3: 3D PI Delta Alarm Example



<sup>1</sup> The Joint Commission Sentinel Event Alert. 2012;49. <sup>2</sup> ECRI Institute. 2012. <sup>3</sup> Stoelting RK et al. *APSF*. 2011. <sup>4</sup> Shah N et al. *J Clin Anesthesiology*. 2012. <sup>5</sup> Wong MW et al. *J Trauma Inj Infect Crit Care*. 2004; 56(2):356-362. <sup>6</sup> De Felice et al. *Pediatr Crit Care Med*. 2008;(9)2:203-208. <sup>7</sup> Ginasar et al. *Acta Anaesthesiol Scand*. 2009; 53:1018-1026.

# ADVANCING PULSE OXIMETRY

Masimo's newest innovations demonstrate that our commitment to pulse oximetry technology has never been stronger.

## FIRST EVER NONINVASIVE FRACTIONAL SPO<sub>2</sub> MEASUREMENT

Until now, pulse oximeters could only measure and display functional oxygen saturation (SpO<sub>2</sub>). So, when patients had elevated carboxyhemoglobin (from carbon monoxide poisoning) and/or elevated methemoglobin (adverse reaction to more than 30 common drugs used in hospitals, like caines, nitrates, and Dapsone), the displayed functional oxygen saturation overstated the actual oxygen saturation value.

Masimo SpfO<sub>2</sub><sup>™</sup>\* is the first truly fractional, noninvasive oxygen saturation measurement. SpfO<sub>2</sub> allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins – common throughout the hospital and pre-hospital settings – as compared to functional oxygen saturation (SpO<sub>2</sub>). As a result, SpfO<sub>2</sub> should enable earlier interventions and more timely therapeutic decisions. For example, in a patient who is a smoker with an SpO<sub>2</sub> of 97%, carboxyhemoglobin level of 12%, and methemoglobin of 1%, if SpfO<sub>2</sub> were available, it would be displayed at 84%. It is well accepted that clinicians would frequently make different diagnostic and therapeutic decisions at an oxygenation of 84% versus 97%.

## TFA-1<sup>™</sup> DISPOSABLE FOREHEAD SENSOR\*

Expanding its versatility of sensors, Masimo now offers the TFA-1 transreflectance 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 offers easy access during surgery, resuscitation, and in patients with finger deformities or when the digit is not accessible.



Utilizing more than seven wavelengths of light and breakthrough signal processing, Masimo rainbow<sup>®</sup> Pulse CO-Oximetry can measure and display oxygen content (SpOC<sup>™</sup>), along with its components, hemoglobin and fractional arterial oxygen saturation (SpfO<sub>2</sub>).



# X-CAL<sup>™</sup> TECHNOLOGY FOR ENHANCED PATIENT SAFETY

## X-CAL TECHNOLOGY FOR ENHANCED PATIENT SAFETY AND IMPROVED CLINICIAN EFFICIENCY

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

X-Cal is designed to address three common factors that can impact measurement accuracy and patient safety due to

poor quality and performance of system components:

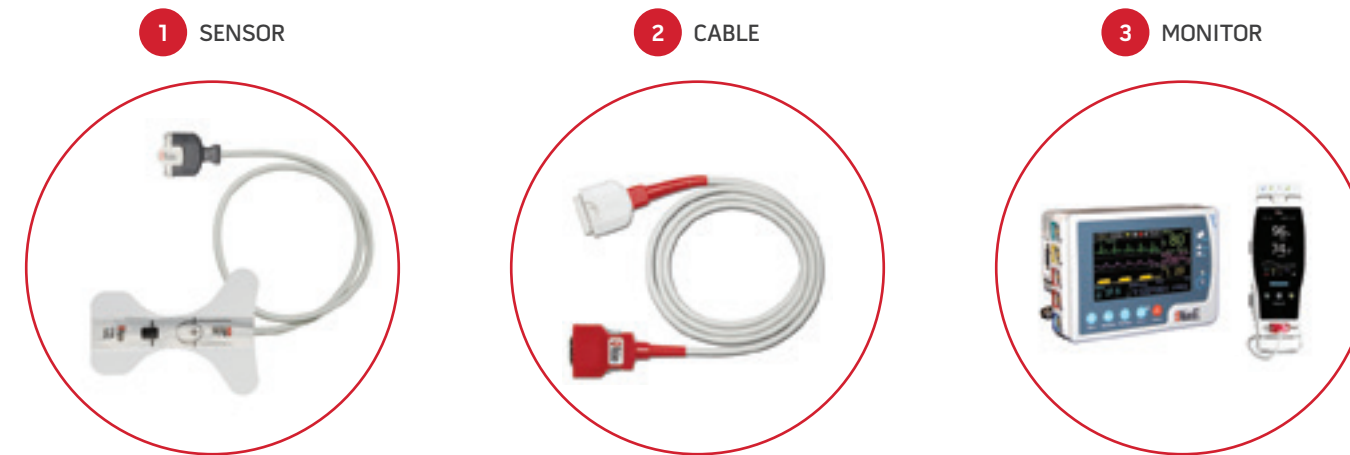
- 1) Imitation Masimo sensors and cables
- 2) Cables and sensors used far beyond their expected life
- 3) Third-party reprocessed pulse oximetry sensors

## HOW X-CAL WORKS

X-Cal is seamlessly integrated into Masimo sensors, cables and circuit boards and is provided at no additional cost to end-users. X-Cal can detect imitation cables and sensors and measures the active patient monitoring time of each

cable and sensor. Monitors equipped with X-Cal-enabled circuit boards will not function with imitation cables and sensors and will display a message to replace cables and sensors that have been used beyond their useful life.

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



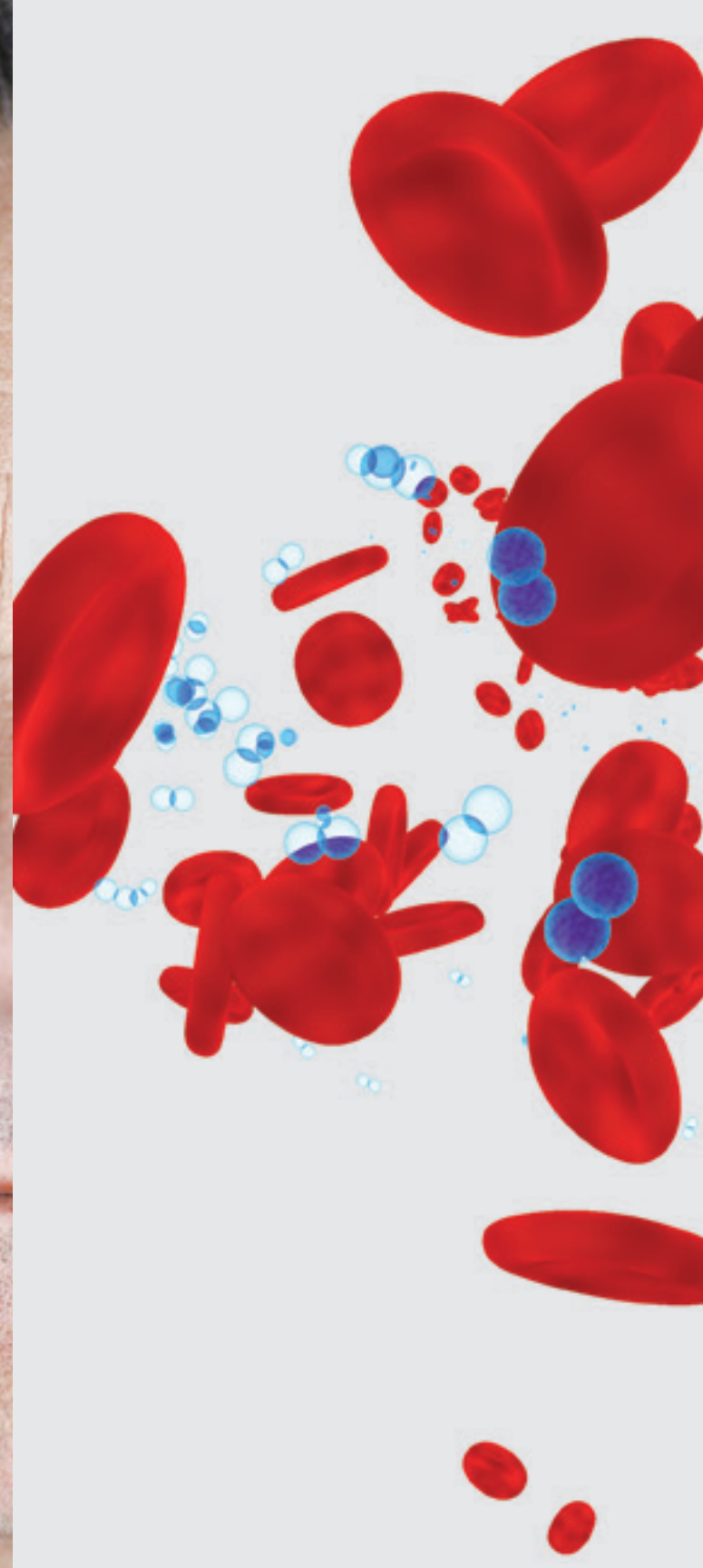
Patient Monitor or Masimo Oximeter

Masimo SET<sup>®</sup> Measure-through Motion and Low Perfusion<sup>™</sup> pulse oximetry has three system components: 1) The sensor that connects to the patient; 2) The patient cable that connects the sensor to the Masimo circuit board in the monitor; 3) The Masimo circuit board (SET<sup>®</sup> SpO<sub>2</sub> or rainbow<sup>®</sup> Pulse CO-Oximetry) installed in a multiparameter patient monitor or Masimo pulse oximeter.





SEE MORE  
DO MORE





# HELPING CLINICIANS OPTIMIZE BLOOD MANAGEMENT

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

## RISKS AND COSTS OF RED BLOOD CELL TRANSFUSIONS

Red blood cell (RBC) transfusion is one of the most frequent procedures performed in U.S. hospitals, with one in ten inpatients receiving one or more blood units.<sup>1</sup> While blood loss during surgery is a known risk factor, RBC transfusion overuse can increase patient risk and the cost of care.<sup>2</sup> Meta-analysis of pooled results from multiple observational studies, each of which adjusts for risks between patients, shows that patients receiving RBC transfusions have a 69% higher mortality, 88% higher infection rate, and 250% higher rate of acute respiratory distress syndrome (ARDS).<sup>2</sup> Multiple randomized controlled trials indicate that restrictive transfusion practices – those

in which significantly lower hemoglobin triggers are used to determine need for transfusion – are safe.<sup>3</sup> In addition, the cost of each RBC unit is estimated between \$522 and \$1,183 per unit, without including morbidity-associated costs.<sup>4</sup> Beyond the cost of transfusion, each RBC unit transfused is associated with increased cost of care and transfusions that occur at higher hemoglobin levels increase the cost of care more than those given at lower hemoglobin levels.<sup>5</sup> With the growing recognition of the need to reduce transfusions, noninvasive and continuous hemoglobin (SpHb) can be a key tool to help clinicians overcome the limitations of existing approaches, although SpHb monitoring is not intended to replace blood draws.

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

**Dr. Aryeh Shander**

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

<sup>1</sup>AHRQ. Inpatient Sample, 1997-2007. <sup>2</sup>Marik PE et al. *Crit Care Med.* 2008;36(9):2667-74. <sup>3</sup>Carson et al. *Cochrane Database Syst Rev.* 2012 Apr 18;4:CD002042. <sup>4</sup>Shander A et al. *Transfusion.* 2010;50(4):753-765. <sup>5</sup>Murphy G J et al. *Circulation.* 2007;116:2544-2552. Prior to using this device, the user should read and understand the Operator's Manual and Directions for Use. Laboratory diagnostic tests using blood samples should be conducted prior to clinical decision making to completely understand the patient's condition. Comparisons between SpHb measurements and laboratory diagnostic hemoglobin measurements may be affected by sample type, collection technique, physiological, and other factors.



# OVERUSE OF BLOOD TRANSFUSIONS



## GROWING RECOGNITION OF THE NEED TO REDUCE TRANSFUSIONS

Many transfusions are unnecessary. A systematic, expert review of 494 studies for positive impact on health outcomes showed that 59% of RBC transfusions are "inappropriate."<sup>1</sup> Given the risks and costs of RBC transfusions, there is a growing recognition of the need to implement strategies to reduce RBC transfusions. The Joint Commission has introduced Patient Blood Management Measures that encourage hospitals to evaluate appropriateness of transfusions as a continuous quality indicator.<sup>2</sup> The American Medical Association and The Joint Commission also recently identified RBC transfusions as one of the top five overused procedures in medicine, defining overuse as "circumstances where the likelihood of benefit is negligible or zero, and the patient is exposed to the risk of harm."<sup>3</sup>

## LIMITATIONS WITH EXISTING APPROACHES TO ASSESS TRANSFUSION NEED

The most universally available information about whether a transfusion is needed during surgery is estimated blood loss, which is often overstated. Visible blood and fluid loss appears to indicate how much blood has been lost, but in a recent study at Duke University, anesthesiologists estimated blood loss at 40% more than it actually was.<sup>4</sup> The implication is that the need for transfusion may appear to exist, when in fact it does not.

## HOW SpHb MONITORING HELPS WITH TRANSFUSION DECISIONS

Masimo's SpHb measures hemoglobin noninvasively and continuously. The noninvasive aspect makes the technology easy to apply to the patient, and the continuous aspect

assists in better decision-making. While SpHb monitoring is not intended to replace blood draws, it nonetheless identifies significant changes in hemoglobin trends and lack of significant changes in hemoglobin between invasive blood sampling and laboratory analysis.<sup>5</sup>

Continuous hemoglobin means clinicians have real-time visibility to the directional trend of hemoglobin – whether it is stable, rising, or falling. This can help clinicians avoid unnecessary transfusions when the SpHb trend is stable even though the clinician may otherwise perceive hemoglobin to be dropping. Likewise, when the SpHb trend is rising but the clinician may otherwise believe that it's not rising fast enough. Inside and outside the operating room, a declining SpHb trend may also allow clinicians to identify internal bleeding and permit earlier interventions.

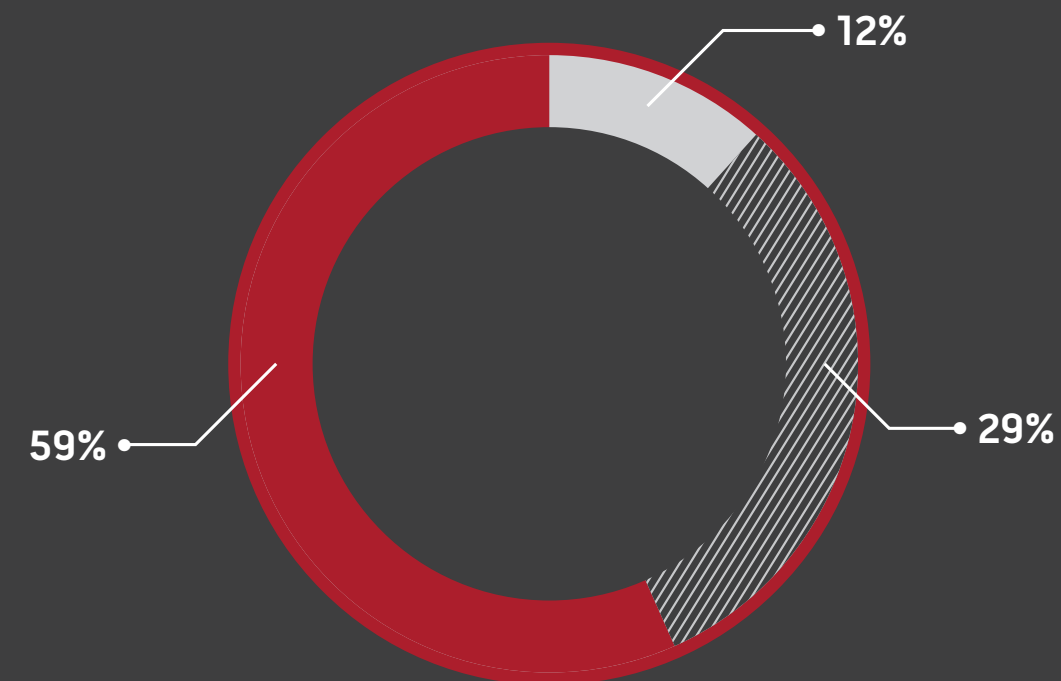
A systematic, expert review of 494 studies for positive impact on health outcomes showed that 59% of RBC transfusions are "inappropriate."



<sup>1</sup>Shander et al. *TransMed Rev.* 2011; 232-246. <sup>2</sup>Joint Commission Perspectives. *The Joint Commission Continues to Study Overuse Issues.* Volume 32, (Radical-7) Number 5, 2012: 4-8(5). <sup>3</sup>[http://www.jointcommission.org/patient\\_blood\\_management\\_performance\\_measures\\_project/](http://www.jointcommission.org/patient_blood_management_performance_measures_project/) <sup>4</sup>Hill SJ et al. *ASA.* 2011 (abstract). <sup>5</sup>Frasca D et al. *Crit Care Med.* 39(10); 2011; 2277-2282.

# APPROPRIATE USE OF TRANSFUSION

■ INAPPROPRIATE // ■ APPROPRIATE // ▨ UNCERTAIN

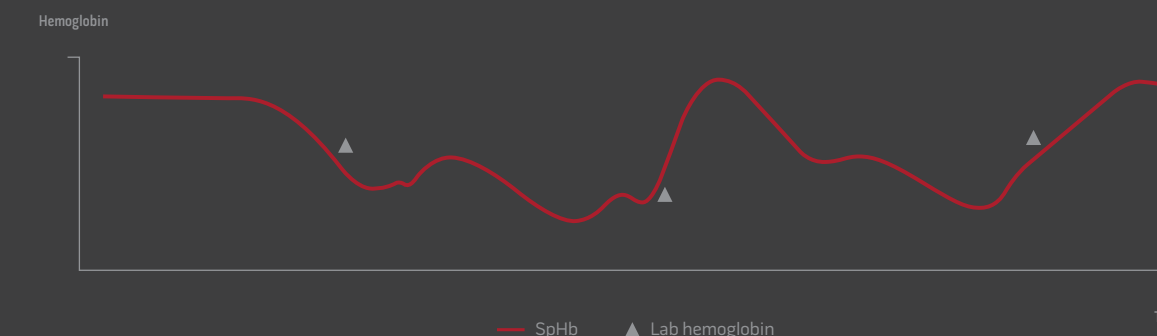


The American Medical Association and The Joint Commission also recently identified RBC transfusions as one of the top five overused procedures in medicine, defining overuse as "circumstances where the likelihood of benefit is negligible or zero, and the patient is exposed to the risk of harm."<sup>3</sup>

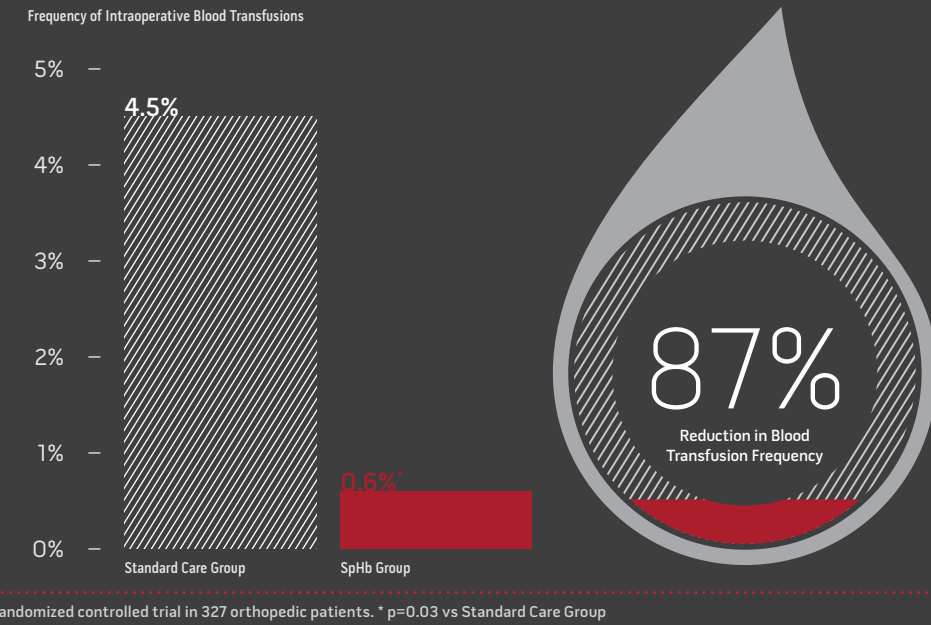
494 studies were evaluated by an expert panel in a systematic method to assess appropriateness of RBC transfusion, revealing a significant opportunity to reduce unnecessary transfusions.<sup>1</sup>

Continuous hemoglobin trending between invasive blood sampling provides a real-time indication of whether:

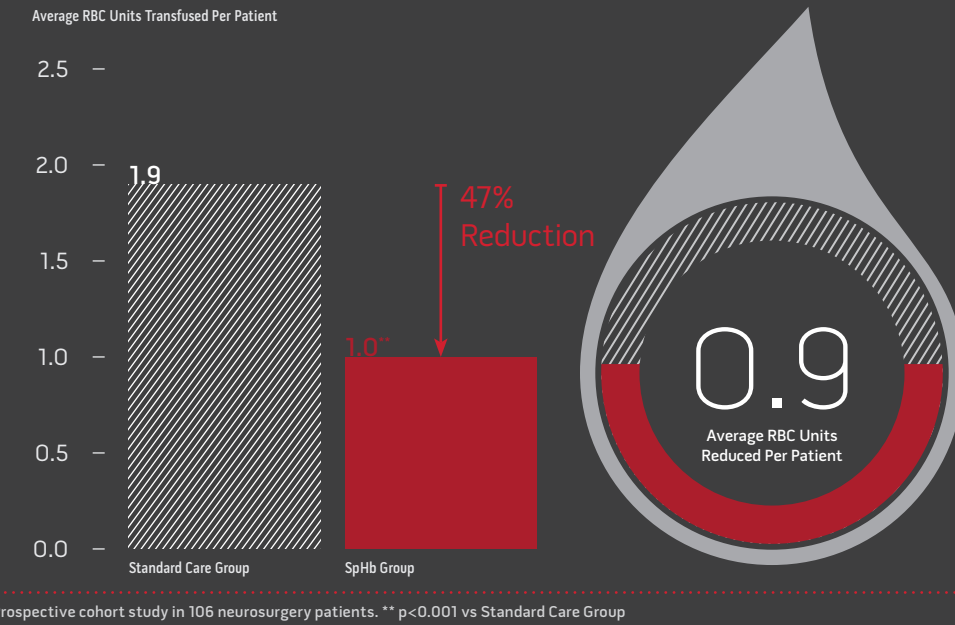
- > hemoglobin is stable when it may appear to be dropping
- > rising when it may not appear to be rising
- > or dropping when it appears to be stable.



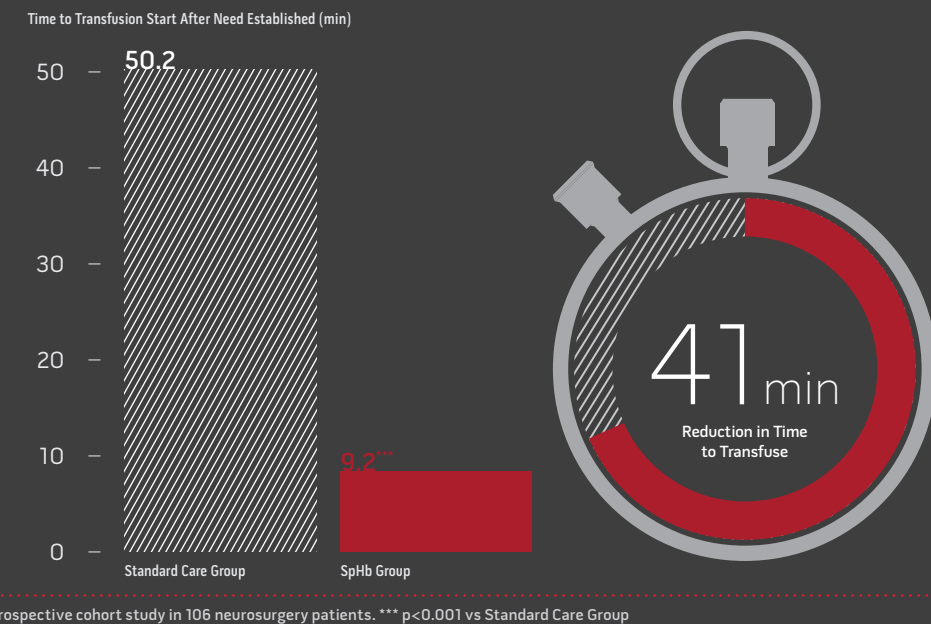
## SpHb Helped Clinicians Reduce Transfusion Frequency in Lower Blood Loss Surgery<sup>1</sup>



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



## SpHb Helped Clinicians Decrease the Time to Transfusion, When a Transfusion is Truly Indicated<sup>2</sup>



## Range of Potential Blood Cost Savings Per Patient with SpHb Monitoring<sup>3</sup>

Range of RBC Transfusion Cost Estimates	PROJECTED SpHb SAVINGS	
	Low Blood Loss Surgery <sup>1</sup>	High Blood Loss Surgery <sup>2</sup>
\$522	\$47	\$470
\$1,183	\$106	\$1,065

<sup>1</sup>Ehrenfeld JM et al. ASA. 2010. LB05. (abstract). <sup>2</sup>Awada WN et al. *J Clin Monit Comput.* 2015 Feb 4. [Epub ahead of print] PubMed PMID: 25649717. <sup>3</sup>Shander et al. *Transfusion.* 2010;50(4):753-765.

## REDUCING BLOOD TRANSFUSIONS AND COST



### CLINICAL EVIDENCE THAT SpHb MONITORING HELPS REDUCE TRANSFUSIONS

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

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

SpHb monitoring has also been shown in a prospective cohort study in higher blood loss surgery (neurosurgery)

to reduce the percent of patients receiving three or more RBC units from 73% to 32% and reduce the average number of RBC units transfused by 47% (from 1.9 to 1.0 units per patient).<sup>2</sup> In this study, the researchers also showed that with SpHb monitoring, patients who needed RBC units received them sooner by 41 minutes on average.

### PROJECTED COST SAVINGS FROM SpHb MONITORING TO REDUCE TRANSFUSIONS

To project the potential savings from SpHb monitoring, we can simply multiply the range of published cost estimates for RBC transfusions (\$522 to \$1,183) by the expected reduction in RBC transfusions per patient.<sup>3</sup>

In lower blood loss surgery, the 0.09 lower RBC units per patient with SpHb monitoring is projected to reduce RBC costs by \$47 to \$106 per patient monitored.<sup>1</sup> In higher blood loss surgery, the 0.90 lower RBC units per patient with SpHb monitoring is projected to reduce RBC costs by \$470 to \$1,065 per patient monitored.<sup>2</sup> These estimates do not take into account the expense of SpHb monitors or sensors, or the other costs associated with over-transfusion or delayed interventions.

## RISK AND COST OF UNDETECTED BLEEDING



In addition to assisting with transfusion management, continuous SpHb can also help clinicians inside and outside the operating room identify changes in hemoglobin that may be associated with internal bleeding.

Bleeding affects up to 35% of patients in surgery, intensive care, and obstetric care areas.<sup>1</sup> Bleeding is considered a significant risk factor for patients, and late detection further increases risk and cost.<sup>2</sup> Surveys show that the majority of U.S. hospitals have multiple patients per year with serious injury or death due to late detection of bleeding.<sup>3</sup>

### LIMITATIONS OF CURRENT APPROACHES TO DETECT BLEEDING

A significant number of injuries or deaths due to bleeding are preventable. Prevention requires identifying that a patient has experienced significant bleeding and then intervening to stop the bleeding and improve the patient's condition. Identifying bleeding is challenging because even during surgery and

childbirth, clinical estimation of blood loss is inaccurate and changes in standard vital signs can occur long after the bleeding has begun. Low hemoglobin identifies bleeding over 90% of the time, but is only assessed intermittently and requires a blood draw and laboratory analysis.<sup>4</sup> In some parts of the world, laboratory testing is simply not available.

By measuring hemoglobin continuously, clinicians can become aware of real-time drops in hemoglobin that may be indicative of bleeding. Identification of low or falling hemoglobin levels allows interventions that may prevent preventable death and disability. SpHb monitoring is not intended to replace blood draws.

<sup>1</sup>Hebert PC. *Crit Care*. 1999; 3(2):57-63. <sup>2</sup>Herwaldt LA. *Infect Control Hosp Epidemiol*. 2003; 24(1):44-50. <sup>3</sup>HRA Research of Hospital Executive. 2012. <sup>4</sup>Bruns B et al. *J Trauma*. 2007; 63(2):312-5.



## POTENTIAL FOR EARLIER IDENTIFICATION OF FALLING HEMOGLOBIN VALUES

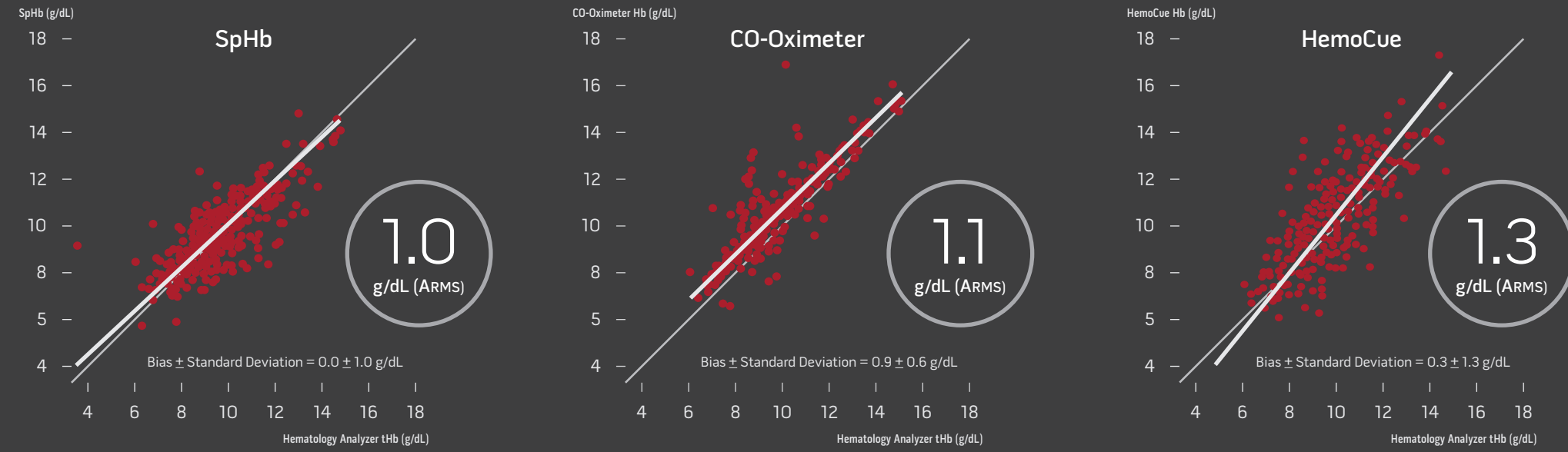


“Masimo SpHb helped prevent a potentially life-threatening event. I am now using it for all my major craniofacial procedures and can’t see doing a surgery without it.”

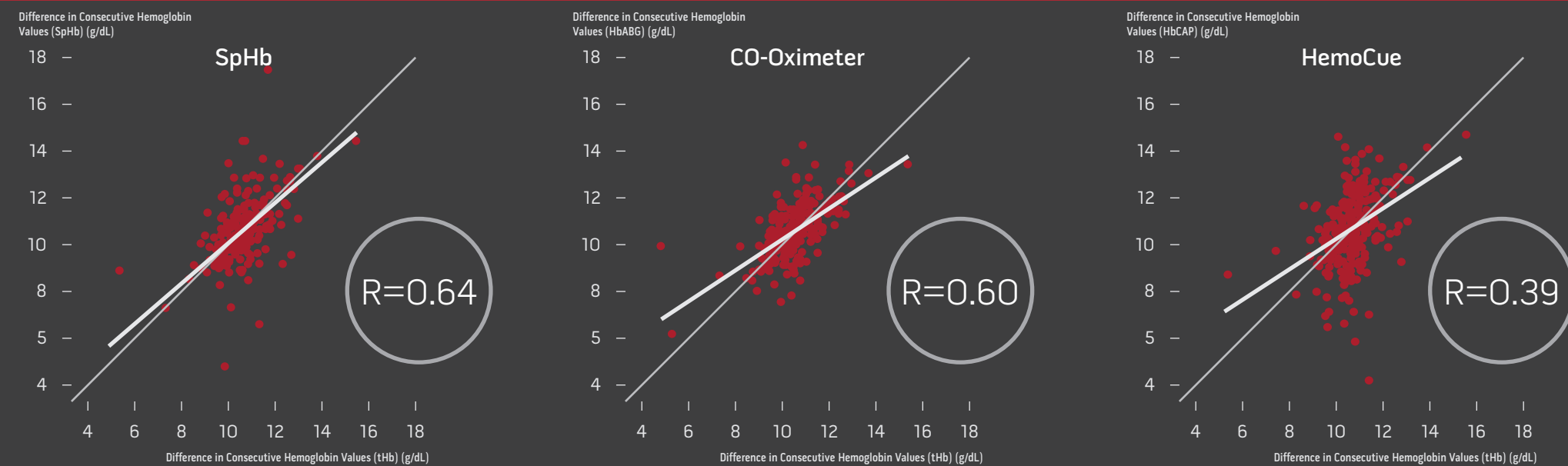
**Jeffrey Fearon, MD**

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

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



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



## ACCURACY OF NONINVASIVE AND CONTINUOUS HEMOGLOBIN MONITORING COMPARED TO COMMON INVASIVE METHODOLOGIES



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

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

In this study, the absolute accuracy and trending accuracy of SpHb was similar to the two widely used invasive methods<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. Only SpHb provides hemoglobin noninvasively and continuously – for real-time visibility to hemoglobin changes, or lack of changes, in-between invasive blood sampling and laboratory analysis.

The results of an independent study conducted in a surgical intensive care unit illustrate the variation that can be expected between hemoglobin device methods. A total of 471 hemoglobin measurements were evaluated from 62 patients.



<sup>1</sup> Berkow L. *J Clin Monit Comput.* 2013 Mar 26. <sup>2</sup> Frasca D et al. *Crit Care Med.* 2011 Oct;39(10):2277-82. <sup>3</sup> ARMS was calculated as defined by the ISO 80601-2-61. Some independent researchers have conducted their own testing and obtained similar results, while other researchers have reported larger differences when comparing SpHb measurements to laboratory measurements.

# AIDING CLINICIAN ASSESSMENT OF FLUID RESPONSIVENESS AND FLUID MANAGEMENT WITH PVI®



Fluid administration is one of the most common hospital interventions. Although it is critical to improving patient status and enabling end organ preservation, unnecessary fluid administration is associated with increased morbidity and mortality.<sup>1</sup> While commonly used, traditional “static” measurements such as central venous pressure are not reliable to predict whether a patient will respond to volume administration with an increase in blood flow (stroke volume or cardiac output) and therefore are not effective to guide fluid management decisions.

## CLINICAL AND FINANCIAL BENEFITS OF DYNAMIC MONITORING TECHNOLOGIES

New “dynamic” monitoring technologies that measure stroke volume variation (SVV), pulse pressure variation (PPV), or stroke volume response (ΔSV) are effective at predicting fluid responsiveness and enabling goal-directed fluid management. A meta-analysis of 32 randomized controlled trials showed that goal-directed fluid management with dynamic monitoring technologies reduces surgical complications by 32% and shortens length of stay by 1.2 days.<sup>3</sup> Depending on the morbidity rate of the patient population, goal-directed fluid management with dynamic monitoring technologies is estimated to save between \$808 to \$7,000 per patient.<sup>4</sup> While these technologies have been shown to improve clinical and cost outcomes, they are invasive and/or complicated and therefore are underutilized and still only justified for the highest risk patients.<sup>5,6,7</sup> As a result, many patients who could benefit from goal-directed fluid management are not receiving it.

## HELPING ASSESS FLUID RESPONSIVENESS WITH PVI

Masimo SET® pulse oximetry technology has the unique ability to also provide a dynamic fluid responsiveness variable called pleth variability index (PVI) that is similar to SVV and PPV but PVI is noninvasive. PVI is displayed on the same monitor and obtained with the same sensors as are used for Masimo SET® pulse oximetry or rainbow® monitoring – with no incremental procedural cost. PVI has been shown to help clinicians assess fluid responsiveness in mechanically ventilated patients under general anesthesia during surgery,<sup>8,9,10,11</sup> in the ICU in adults and children,<sup>12,13</sup> and in septic patients in early stages of shock in the emergency department.<sup>14</sup>

## HELPING IMPROVE FLUID MANAGEMENT WITH PVI

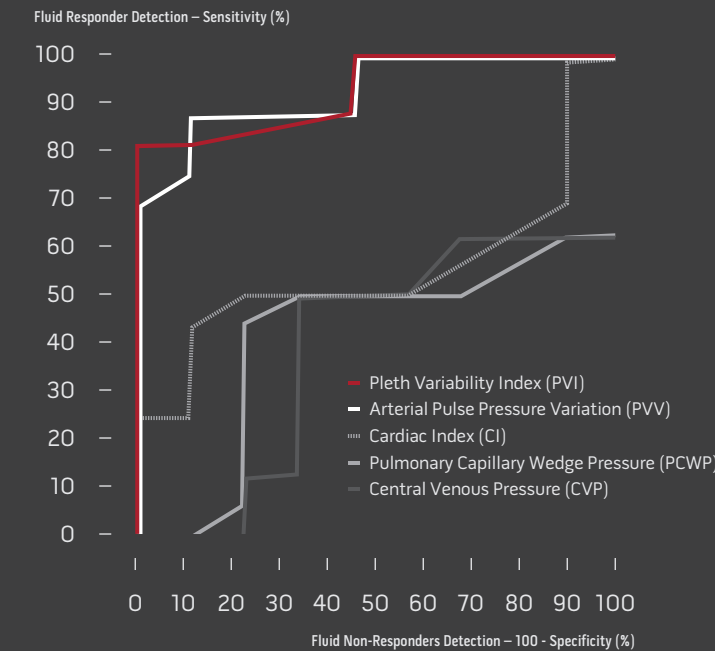
PVI has also been shown to improve fluid management compared to standard care in two randomized controlled trials, reducing intraoperative fluid infused and intraoperative and postoperative lactate levels.<sup>15,16</sup> In addition, compared to goal-directed therapy with invasive dynamic monitoring technologies (PPV and ΔSV), goal-directed therapy with PVI showed similar fluid management

decisions and patient outcomes in two randomized controlled trials.<sup>17,18</sup> In a study of colorectal surgery patients managed with the Enhanced Recovery After Surgery (ERAS) protocol including goal-directed fluid therapy guided by PVI, 30-day hospital costs were reduced by \$2,867 and median length of stay was reduced by 2 days.<sup>19</sup> Also, PVI has also been shown to help assess which patients will become hemodynamically unstable with the addition of Positive End Expiratory Pressure (PEEP), which may allow clinicians to more carefully select ventilator settings and monitor effects more closely.<sup>20</sup>

## INCLUSION IN FLUID MANAGEMENT GUIDELINES

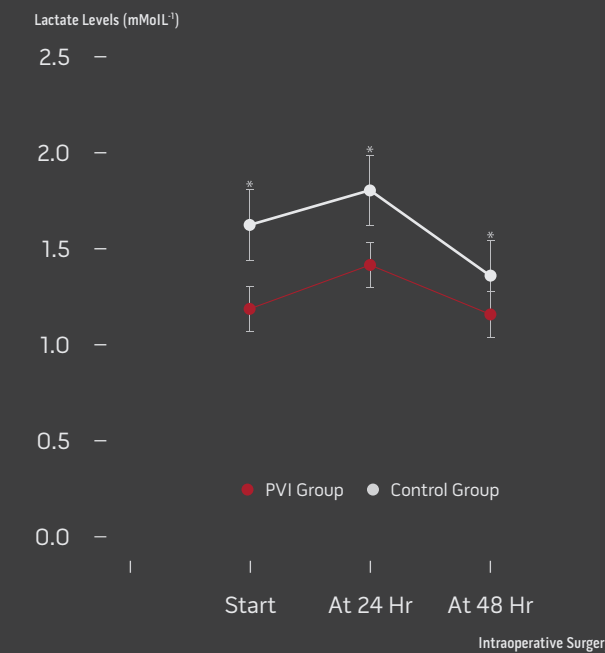
The positive and expanding evidence for PVI has led to its inclusion in guidelines and best practices for fluid management. In 2012, the United Kingdom's National Health Service (NHS) included PVI in its Intra-Operative Fluid Management Pack, which serves as a guide for hospitals implementing fluid responsiveness monitoring to improve patient outcomes.<sup>21</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>22</sup>

## Operating Room<sup>8</sup>



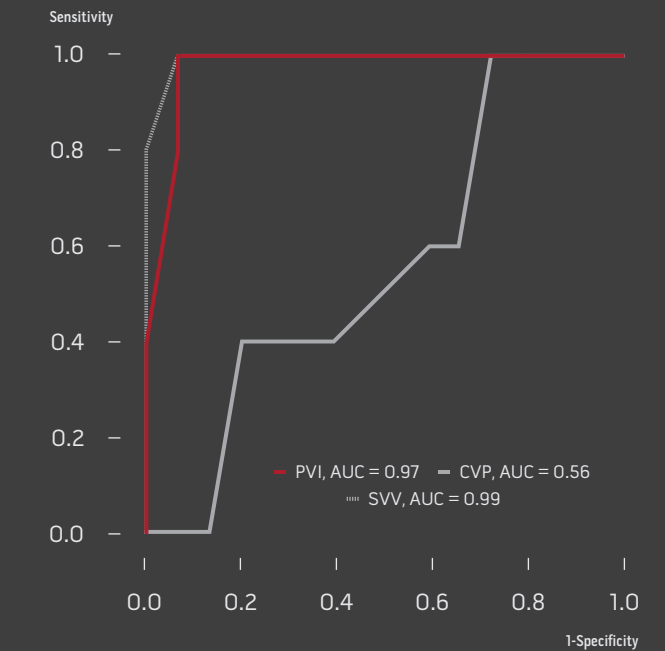
Masimo PVI has been shown to help clinicians assess fluid responsiveness as reliably as new invasive parameters, and better than traditional invasive parameters.

This observational study evaluated 25 surgical patients before and after volume expansion, with fluid responders (sensitivity) defined as a cardiac index increase of >15% and fluid non-responders (specificity) defined as a cardiac index increase of <15%.



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 post-operative lactate levels.<sup>9</sup>

## Intensive Care Unit<sup>9</sup>



This study has shown PVI to be an effective alternative indicator for accurate, noninvasive, and continuous fluid responsiveness in mechanically ventilated patients undergoing major surgery.

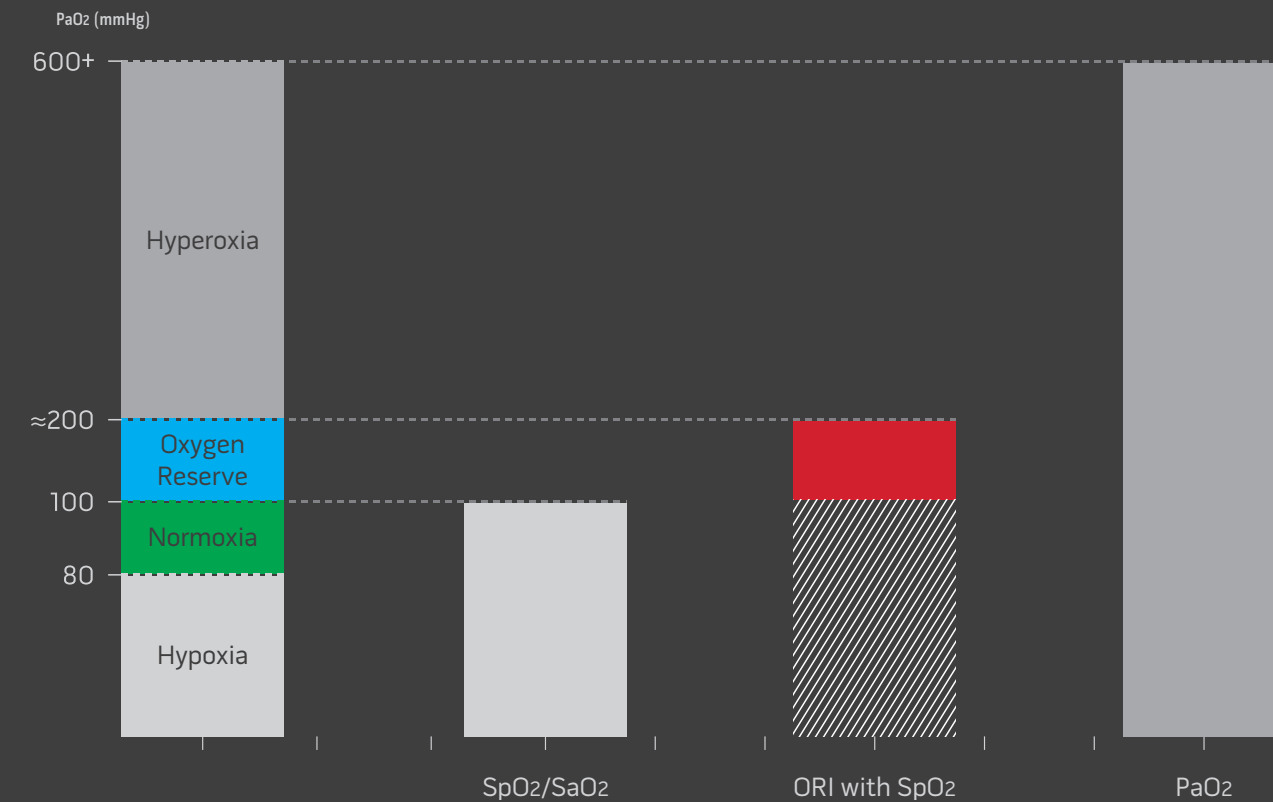
## Financial Benefits of Using Enhanced Recovery After Surgery (ERAS) Protocol Including PVI for Goal-Directed Therapy

Outcome	Conventional Approach without PVI	Enhanced Recovery After Surgery 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 Enhanced Recovery After Surgery (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.

<sup>1</sup> Bundgaard-Nielsen M et al. *Acta Anaesthesiol Scand*. 2007; 51(3):331-40. <sup>2</sup> Michard F et al. *Chest*. 2002. <sup>3</sup> Grocott et al. *Br J Anaesth*. 2013; 111(2):196. <sup>4</sup> Benes J et al. *Critical Care*. 2010; 14:R118. <sup>5</sup> Miller T et al. *ASA*. 2013. #4293. <sup>6</sup> Gan TJ et al. *JARS*. 2013. <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. <sup>9</sup> Fu Q et al. *Biosci Trends*. 2012 Feb;6(1):38-43. <sup>10</sup> Haas S et al. *J Anesth*. 2012 Oct;26(5):696-701. <sup>11</sup> Loupec T et al. *Crit Care Med*. 2011;39(2):294-299. <sup>12</sup> Byon HJ et al. *BJA*. 2012 Dec;DOI 10.1093/bja/ae5467. <sup>13</sup> Feissel M et al. *J Crit Care*. 2013 May 14. <sup>14</sup> Forget P et al. *Anesth Analg*. 2010;111(4):910-4. <sup>15</sup> Yu Y et al. *J Clin Monit Comput*. 2014 Feb 21. <sup>16</sup> Delaporte A et al. *ESA*. 4AP3-9. 2014. <sup>17</sup> Bahlmann H et al. *ESA*. 3AP5-5. 2014. <sup>18</sup> Thiele RH et al. *Journal of the American College of Surgeons* (2015), doi: 10.1016/j.jamcollsurg.2014.12.042. <sup>19</sup> Desebbe O et al. *Anesth Analg*. 2010;110:792-798. <sup>20</sup> [http://www.ntac.nhs.uk/NewsAndEvents/IOFM\\_Technology\\_Adoption\\_Pack\\_Published.aspx](http://www.ntac.nhs.uk/NewsAndEvents/IOFM_Technology_Adoption_Pack_Published.aspx). <sup>21</sup> Vallet B et al. *SFAR*. 2013.

## PaO<sub>2</sub> RANGE AND AVAILABLE MONITORING METHODS



In utilizing ORI the researchers noted mean of 40 sec advance alarm before SpO<sub>2</sub> reached 98% and about 52 seconds advance alarm before the patients reached 90% SpO<sub>2</sub>.

Oxygen Reserve Index: A New Noninvasive Method of Oxygen Reserve Measurement.  
Szmuk P, Steiner J., Olomu P., Dela Cruz B.S., Sessler D.  
Proceedings of the American Society of Anesthesiologists, October 14, 2014. New Orleans; BOC12.



## FIRST NONINVASIVE & CONTINUOUS PARAMETER TO PROVIDE INSIGHT INTO OXYGEN RESERVE IN PATIENTS RECEIVING SUPPLEMENTAL OXYGEN



Pulse oximetry (SpO<sub>2</sub>) 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 (PaO<sub>2</sub>), which is invasive and intermittent, to monitor levels of hyperoxia (higher than normal oxygenation). Between invasive sampling, changes in PaO<sub>2</sub> can go unnoticed and lead to unexpected hypoxia or unintended hyperoxia.

Oxygen Reserve Index (ORI™) provides real-time visibility to oxygenation status in moderate hyperoxic range (PaO<sub>2</sub> of

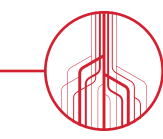
approximately 100 to 200mmHg). ORI is intended to supplement, not replace, SpO<sub>2</sub> monitoring and PaO<sub>2</sub> measurements. As an "index" parameter with a unit-less scale between 0.00 and 1.00, ORI can be trended and has optional alarms to notify clinicians of changes in a patient's oxygen reserve.

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



# AT THE ROOT OF TRANSFORMING PATIENT CARE





# WHY ROOT?

From Masimo's inception, the root of our inspiration has been unwavering – patients, their families, and their caregivers.

This inspiration guides us every time we set out to solve a previously "unsolvable" problem, in every new measurement we create, and in every new software, hardware, or systems innovation we have developed. All our innovations are designed for one purpose – to enable clinicians to get to the root of better care for their patients. That's why we called our latest innovation Root.®

Root is a powerful new patient monitoring and connectivity platform that enhances our breakthrough rainbow® and SET® measurements with multiple additional parameters – including SedLine® brain function monitoring, O3™ regional oximetry,\* and capnography and gas monitoring – in an integrated, clinician-centric platform.

Root includes a dock for the Radical-7® or Radius-7,™ an instantly interpretable display, and Iris™ connectivity ports for third-party devices such as IV pumps and ventilators. Root integrates multiple streams of data and simplifies patient care workflows, empowering caregivers to help make quicker patient assessments, earlier interventions, and better clinical decisions throughout the continuum of care.

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

**Dr. Keith Ruskin**  
Professor of Anesthesiology at Yale-New Haven Hospital in New Haven, CT

\* O3 regional oximetry is CE Marked. Currently not available in the U.S.





## GETTING TO THE ROOT OF ROOT®



### INSTANTLY INTERPRETABLE, HIGH-VISIBILITY DISPLAY

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

-  > "Trend" view in which each measurement value is displayed alongside its graphical trend
-  > "Analog" view for quick assessment through gauges showing measurement values in relation to alarm ranges

When docked with Root, the Radical-7's screen can transform into an alarm status visualizer, with a three-dimensional, anatomical image that associates device measurements with alarm status.



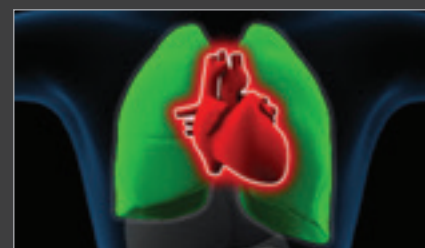
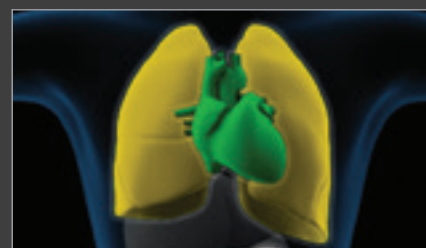
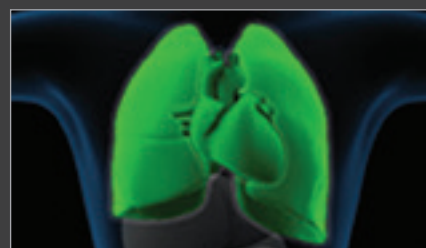
### INTUITIVE TOUCHSCREEN NAVIGATION FOR EASY AND ADAPTABLE USE IN ANY HOSPITAL ENVIRONMENT

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



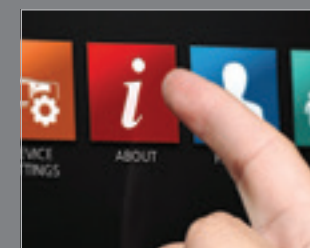
## ALARM STATUS VISUALIZER

A three-dimensional, anatomical image that associates device measurements with alarm status.

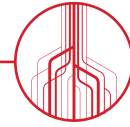


## EASILY CUSTOMIZABLE TOUCHSCREEN

Screen views and parameter sizing are easily customized with a simple tap, swipe, pinch, or drag-and-drop.



# THE POWER OF MASIMO BREAKTHROUGH MEASUREMENTS IN A PATIENT-WORN MONITOR



Untethered, continuous monitoring with Radius-7™ allows patient mobility without the hassle of disconnecting and reconnecting from traditional monitoring devices.

## THE MOBILITY OF PATIENT MONITORING AND ASSESSMENT

Studies have shown that patient mobility is a key factor in more rapid patient recovery.<sup>1</sup> However, continuously monitoring mobile patients presents challenges. Radius-7\* is the first rainbow SET® noninvasive wearable, wireless monitor for the Root Patient Monitoring Platform. Radius-7 is designed to allow patient mobility along with continuous monitoring, enabling early identification of clinical deterioration.

## OPTIMIZE WORKFLOWS AND EFFICIENCIES

Radius-7 is designed to promote greater patient comfort and independence while reducing nurse time to disconnect the monitor each time the patient moves. Radius-7 utilizes a standard wireless short-range communication to Root via secured Bluetooth with upgradeability to WiFi† for direct communication throughout the hospital to the Patient SafetyNet™ remote monitoring system.

## UNLOCK BREAKTHROUGH RAINBOW SET® MEASUREMENTS

Radius-7 is the first and only wearable, wireless monitor to leverage breakthrough Masimo rainbow SET® technology to enable the continuous monitoring of:

- > Oxygen saturation (SpO<sub>2</sub>) and pulse rate monitoring with Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry for reliable detection of desaturation and accurate pulse rate while dramatically reducing false alarms<sup>2,3</sup>
- > Respiration rate monitoring through either rainbow Acoustic Monitoring™ for acoustic respiration rate (RRa®) or through the plethysmograph waveform (RRp™\*) to identify respiratory depression or tachypnea<sup>3</sup>
- > Noninvasive and continuous hemoglobin (SpHb) monitoring with rainbow® Pulse CO-Oximetry may help clinicians detect bleeding earlier, avoid unnecessary blood draws, and optimize transfusion decisions.



One Radius-7 battery charges while the other is being worn by the patient, making battery exchange quick and convenient.



<sup>1</sup> Needham D, et al. *Archives of Physical Medicine and Rehabilitation*. Vol 91, Issue 4, PP 536–542, April 2010. <sup>2</sup> Taenzer A.H, et al. *Anesthesiology*, 2010 Feb;112(2):282-7. <sup>3</sup> Pyke Joshua et al. *Patient Safety & Quality Healthcare*, May/June 2009. \*Radius-7 and RRp are CE Marked. Currently not available in the U.S. † The configuration for long-range communication is not yet released. ‡ The use of the trademarks Patient SafetyNet and PSN is under license from University Health System Consortium.

# FLEXIBLE MEASUREMENT EXPANSION IN ROOT WITH MASIMO OPEN CONNECT



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

### EXPANDING MASIMO MEASUREMENTS

Root offers expanded measurement capability through software upgrades and Masimo Open Connect™ (MOC-9™) modules. SedLine brain function monitoring monitoring, Masimo capnography and gas monitoring, and O3 regional oximetry are all provided as MOC-9 modules.



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



### DESIGNED TO STIMULATE THIRD-PARTY INNOVATION\*

MOC-9 is designed to spur third-party development of additional measurements by companies other than Masimo. Market barriers and development costs often keep small, innovative companies from delivering products to the clinicians and patients who need them most. With Root, Masimo is providing an open invitation to other companies, from small to large, to develop and commercialize their innovations and deliver them to market via the Root platform. We anticipate a whole new ecosystem of third-party measurements to spring from Root – seeding whole new fields of innovation in patient monitoring.

\*Root with third party expandability and O3 are CE Marked. Currently not available in the U.S.

# ROOT WITH BRAIN FUNCTION MONITORING



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

### THE ROOT OF BETTER DATA

Patients respond differently to anesthetics, which can mean over- or under-administration during surgery and conscious sedation procedures. SedLine brain function monitoring provides continuous information about a patient's response to anesthesia. 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 easy-to-see display of burst suppression events.

### FACILITATING INDIVIDUALIZED TITRATION

SedLine enables individualized titration of sedation and faster emergence, while offering reliable monitoring during challenging conditions such as electrocautery.

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



<sup>1</sup>Drover DR et al. *Acta Anesthesiology*. 2002; 97:82-89.

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

**David Drover, MD**  
Stanford University Hospital, Stanford, CA





## ROOT WITH REGIONAL OXIMETRY\*



O3™ regional oximetry uses near-infrared spectroscopy (NIRS) and reflectance pulse oximetry to enable simultaneous monitoring of tissue oxygen saturation (rSO<sub>2</sub>) in the brain and arterial blood oxygenation (SpO<sub>2</sub>).

### THE ROOT OF BETTER BRAIN OXYGENATION MONITORING

Regional oximetry – also known as tissue oximetry or cerebral oximetry – enables continuous assessment of the oxygenation of the tissue beneath the sensor. O3 helps clinicians detect regional hypoxemia that pulse oximetry alone can miss.<sup>1</sup> For this important reason, more and more anesthesiologists and perfusionists are

utilizing regional oximetry during surgery to better monitor cerebral oxygenation.

### A POWERFUL COMBINATION

O3's combination of highly accurate regional oximetry measurements and onboard pulse oximetry enables continuous assessment of deviations between rSO<sub>2</sub> and SpO<sub>2</sub>, taken from either the O3 sensor or from the Radical-7 docked in Root.<sup>2</sup>

"Masimo O3 Regional Oximetry will have the unique ability to measure both rSO<sub>2</sub> and Masimo SET® SpO<sub>2</sub> pulse oximetry simultaneously from the same forehead sensor. This may provide the anesthesiologist or perfusionist for the first time with a differential analysis of regional to central oxygen saturation monitoring that could help the clinician in maintaining brain oxygenation and safe cerebral perfusion during cardiac procedures."

**Michael A.E. Ramsay, MD**

Chief of the Department of Anesthesiology and Pain Management, Baylor University Medical Center, Dallas

<sup>1</sup> Redford D et al. Absolute and Trend Accuracy of Masimo O3 regional oximetry in Healthy Volunteers During Controlled Hypoxia 2014 STA Annual Meeting, January 15-18, Orlando, FL, Abs#46. <sup>2</sup> If regulatory approval has been obtained in your country and Root has the relevant software update. \* O3 regional oximetry is CE Marked. Currently not available in the U.S.

## O3 MONITORING

Every Root offers plug and play monitoring with all MOC-9 modules.



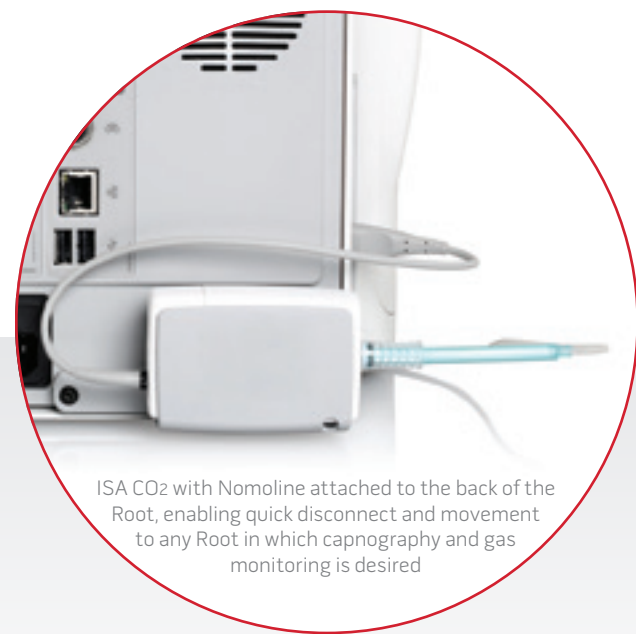
# ROOT WITH CAPNOGRAPHY AND GAS MONITORING



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

Root with capnography and gas monitoring complements our breakthrough noninvasive portfolio with innovative, multispectral technologies for measuring respiratory gases and inhalation anesthetic agents. The solutions range from integrated OEM solutions to external "plug-in and measure" gas analyzers to handheld devices. With multiple

measurements delivered through either mainstream or sidestream options, Masimo customers can now benefit from end-tidal CO<sub>2</sub>, 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 medical-surgical floors.



ISA CO<sub>2</sub> with Nomoline attached to the back of the Root, enabling quick disconnect and movement to any Root in which capnography and gas monitoring is desired



## 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, the Nomoline allows water in the sampling line to evaporate into the surrounding air, while leaving oxygen, carbon dioxide, and anesthetic gases unaffected. Specially designed for low-flow applications and functional in any orientation, Nomoline technology can be used in any clinical application for all types of patients from neonates to adults. Nomoline is designed to extend the product life in single-use applications, such as high humidity environments. Nomoline's innovative design also allows multi-patient use as a responsible solution, along with the use of generic cannulas.



Single-patient-use cannula and Nomoline adapter



Single-patient-use cannula and multi-patient-use Nomoline adapter

## ISA™ – HIGH PERFORMANCE IN A SIDESTREAM ANALYZER

Enabled by state-of-the-art spectrometer technology that utilizes nine different wavelengths of light and powerful signal processing algorithms, ISA provides the clinician with precise capnography and gas measurements with crisp waveforms that help depict the clinical situation for adults and neonates, from the operating room to the general floor. Additionally with virtually no warm-up time and full accuracy performance in ten seconds ISA saves time in critical situations. ISA is factory calibrated and does not require field calibration, minimizing maintenance efforts for hospital Biomedical Engineering departments. ISA sidestream analyzers are available as standalone or easy-to-integrate OEM modules.

## IRMA™ – A COMPLETE MONITOR IN A PROBE

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



IRMA AX+  
EtCO<sub>2</sub>, RR, N<sub>2</sub>O, Inhalation Anesthetic Agent Identification



IRMA CO<sub>2</sub>  
EtCO<sub>2</sub>, FICO<sub>2</sub>, RR

ISA OR+  
EtCO<sub>2</sub>, RR, N<sub>2</sub>O, O<sub>2</sub>, Inhalation Anesthetic Agent Identification



ISA CO<sub>2</sub>  
EtCO<sub>2</sub>, FICO<sub>2</sub>, RR

ISA AX+  
EtCO<sub>2</sub>, RR, N<sub>2</sub>O, Inhalation Anesthetic Agent Identification

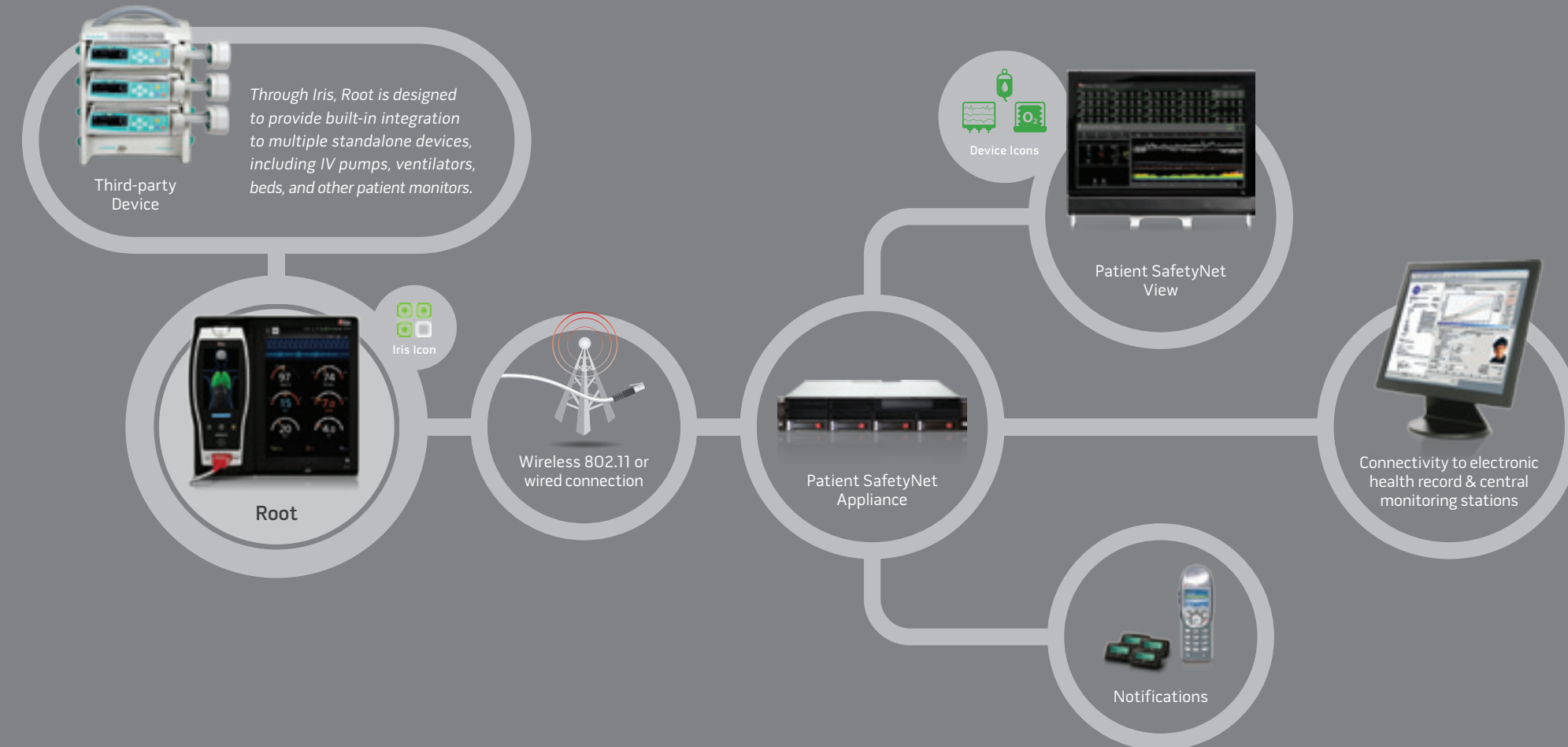
# KEEPING CLINICIANS AND PATIENTS CONNECTED

## KEEPING CLINICIANS AND PATIENTS CONNECTED

New standards for hospitals require meaningful use of the electronic health record (EHR) by charting changes in vital signs as well as documentation of interventions. Masimo enables automatic recording and transmission of key data into the EHR so

clinicians spend their time caring for patients, not recording data. Masimo's pulse oximeters also feature a built-in wireless radio for communication through a hospital's wireless network—with seamless integration to the EHR. Patient SafetyNet incorporates the Masimo Adaptive Connectivity Engine (ACE), which enables

two-way, HL7-based connectivity to the EHR. ACE significantly reduces the time and complexity to integrate and validate custom HL7 implementations, and demonstrates Masimo's commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture.



# INTEGRATING MEASUREMENTS TO ENABLE MEANINGFUL USE OF HEALTH INFORMATION TECHNOLOGY



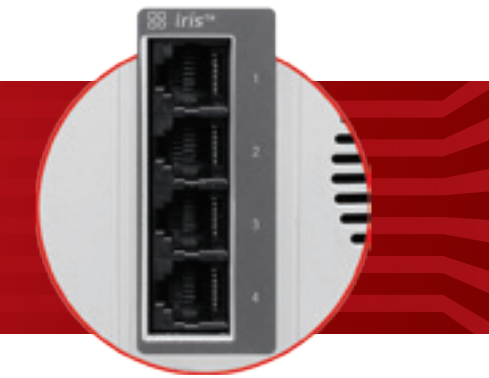
Today's challenging hospital environment subjects clinicians to mountains of information and multiplying documentation requirements. Masimo simplifies and automates this process, streamlining workflows and improving patient safety by empowering clinicians to focus on patients rather than technology.

## IRIS™ INTEGRATION PLATFORM\*

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

be remotely viewed with Patient SafetyNet, transmitted through notification systems or to electronic health record (EHR) systems to facilitate better patient care and meaningful use, and eventually displayed on Root at the point of care to facilitate decision support.

Iris offers a built-in connectivity gateway that can integrate multiple standalone devices.



room, burden IT management, and increase the complexity and cost of care. Root with Iris offers a built-in connectivity gateway that can integrate multiple standalone devices such as IV pumps, ventilators, beds, and other patient monitors. Iris allows device information to

be remotely viewed with Patient SafetyNet, transmitted through notification systems or to electronic health record (EHR) systems to facilitate better patient care and meaningful use, and eventually displayed on Root at the point of care to facilitate decision support.



\* Iris is CE Marked. Currently not available in the U.S.



# ENHANCING PATIENT SAFETY THROUGHOUT THE HOSPITAL





# HELPING PROTECT PATIENTS FROM HIDDEN DANGERS WITH SpMet®



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

## ADDRESSING THE RISK OF DANGEROUS DRUG REACTIONS

Many drugs commonly used in hospitals – such as lidocaine, benzocaine, dapsone, and nitrates – cause a dangerous reaction known as acquired methemoglobinemia

that reduces the delivery of oxygen to the tissues. While methemoglobinemia can occur in all care areas and patients, it is often unrecognized and undiagnosed. If not detected and treated immediately, it can result in avoidable injury or death.

Masimo noninvasive methemoglobin (SpMet) helps clinicians assess for methemoglobinemia, facilitating earlier detection and immediate treatment to reduce patient risk



## ENABLING QUICK TREATMENT WITH SpMet

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

<sup>1</sup>Ash-Bernal RA et al. *Medicine*. 2004;83:265-273.

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

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

## MEDICATIONS KNOWN TO CAUSE METHEMOGLOBINEMIA

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

## PREVALENCE OF METHEMOGLOBINEMIA

Number of Methemoglobinemia Cases	Patient Age	Care Areas	Fatalities
138 <i>(2.5 cases per hospital per month)</i>	4 days to 86 days	Surgery, intensive care, outpatient clinics, pediatrics, emergency department, cardiac cath 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>

## PROTECTING MORE PATIENTS BY MONITORING EVERY BREATH

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

rainbow Acoustic Monitoring™ noninvasively and continuously measures respiration rate using an innovative adhesive cloth sensor with an integrated acoustic transducer that is easily and comfortably applied to the patient's neck.



### 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 in all patients receiving opioid-based pain medications.<sup>1</sup> Conscious sedation can induce respiratory depression and place patients at considerable risk of serious injury or death. However, current methods for respiration rate monitoring are limited by patient tolerance.

While we offer standard capnography solutions, we believe rainbow Acoustic Monitoring™ is better suited for post-surgical monitoring and conscious sedation.

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

### ALLOWING MORE PATIENTS TO BE MONITORED, MORE SAFELY THAN EVER BEFORE

When rainbow Acoustic Monitoring™ is used in conjunction with rainbow® Pulse CO-Oximetry and the Patient SafetyNet system, clinicians can follow key indicators of oxygenation with industry-leading Masimo SpO<sub>2</sub>; 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) – enabling clinicians to monitor more patients, more safely than ever before.



## ABILITY TO DETECT RESPIRATORY PAUSE<sup>3</sup>

RESPIRATION RATE METHOD

	Oridion Capnostream SARA v4.5	Masimo rainbow Acoustic Monitoring™ v7804
<b>Sensitivity</b> <i>(respiratory pause detected when actual respiratory pause occurs)</i>	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.

## PATIENT TOLERANCE<sup>4</sup>

62.5%

Capnography  
(Oridion Capnostream 20)

97.5%

rainbow Acoustic Monitoring™

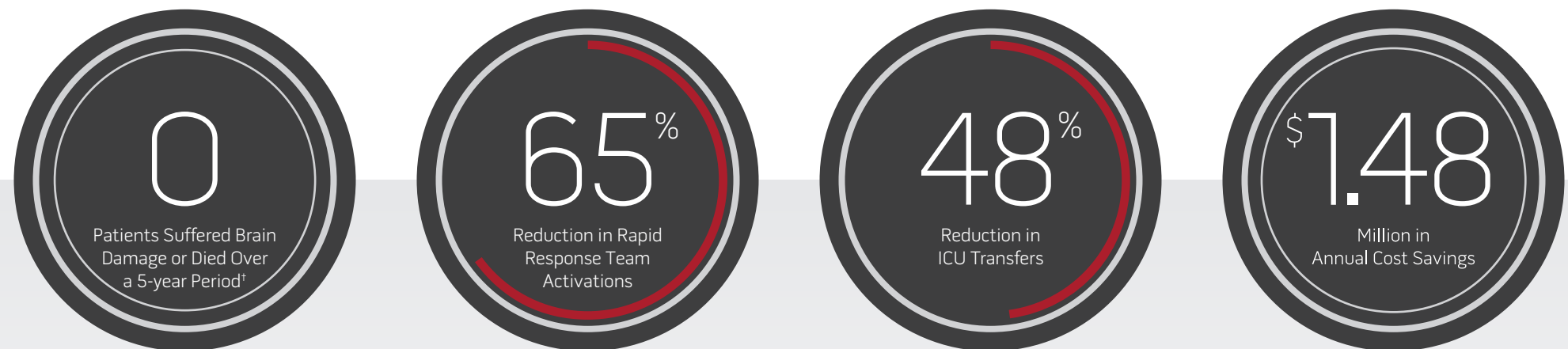
Fifteen of 40 pediatric patients removed the nasal cannula while only one removed rainbow® acoustic sensor.

<sup>1</sup> Stoelting RK et al. APSF Newsletter. 2011. (www.apsf.org). <sup>2</sup> Macknet MR et al. Anesthesiology. 2007;107:A84. (abstract). <sup>3</sup> Ramsay M et al. Anesth Analg. 2013;DOI: 10.1213/ANE.0b013e318290c798. <sup>4</sup> Patino M et al. Paediatr Anaesth. 2013 Dec;23(12):1166-73.

# HELPING IMPROVE OUTCOMES ON MEDICAL-SURGICAL FLOORS WITH MASIMO PATIENT SAFETYNET



In August 2012, The Joint Commission Sentinel Event Alert on the safe use of opioids in hospitals recommended implementation of better dosing along with continuous oxygenation and ventilation monitoring (instead of spot checks) in post-surgical patients.<sup>1</sup> Patient SafetyNet – combined with Masimo SET<sup>®</sup> pulse oximetry and rainbow Acoustic Monitoring<sup>™</sup> or standard capnography – offers a clinically proven, cost-effective approach to continuous postoperative monitoring with high nursing satisfaction and patient compliance.



## REDUCING RESCUES AND ICU TRANSFERS

For many years, clinicians have understood the risks of not continuously monitoring patients on the general floor. However, excessive false alarms due to patient motion made improving the safety of these patients an elusive goal. In the last decade, Masimo SET<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, a landmark study in 2010 showed that Masimo SET<sup>®</sup> also improves clinical outcomes in adults. After implementing Masimo

SET<sup>®</sup> and Patient SafetyNet remote monitoring and wireless notification system in a post-surgical floor where only intermittent spot-checking was used before, Dartmouth-Hitchcock Medical Center reduced rapid response activations by 65% and ICU transfers by 48%,<sup>2</sup> and saved \$1.48 million annually. In addition, there were zero brain-damaged patients over a 5-year period.<sup>3</sup> Just as pulse oximetry has become a standard of care in the OR, PACU, and ICU, we now believe that Measure-through Motion and Low Perfusion<sup>™</sup> pulse oximetry will become a standard of care on the general floor. With Masimo technologies on

the general floor, clinicians can be confident their patients are being watched even when they aren't at the bedside, while families can be assured their loved ones are receiving maximum protection.

## PROVEN COST-EFFECTIVENESS

When translated into financial impact, the Dartmouth-Hitchcock study showed that implementing Masimo SET<sup>®</sup> and Patient SafetyNet to more safely monitor post-surgical patients could also have a significant impact on the hospital's bottom line by increasing ICU bed availability and

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 after implementation. The financial impact resulted in annual opportunity cost savings of \$1.48 million. Results drove expansion of the use of Patient SafetyNet to other care areas.<sup>2,3</sup>

reducing costs associated with emergency rescue events.<sup>3</sup> With both the clinical and financial rationale now in place, hospitals are increasingly implementing general floor monitoring with Masimo technologies.



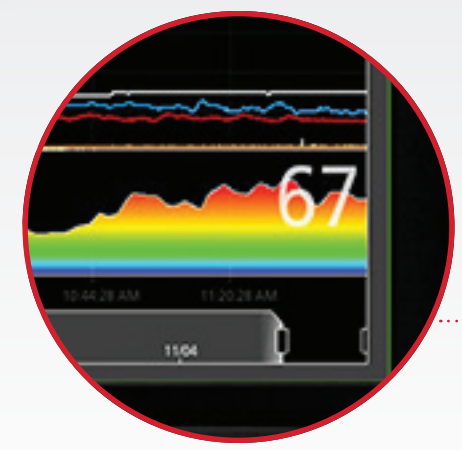
## HALO INDEX<sup>™</sup> ENABLES ASSESSMENT OF PATIENT STATUS

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

<sup>1</sup>The Joint Commission Sentinel Event Alert, 2012;49. <sup>2</sup>Taenzer AH et al. *Anesthesiology*. 2010;112(2):282-287. <sup>3</sup>Taenzer AH et al. *Anesthesia Patient Safety Foundation Newsletter*. Spring-Summer 2012. <sup>\*</sup>Halo Index is CE Marked. Currently not available in the U.S.



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



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

<sup>1</sup>Since expansion, no patients suffered irreversible, severe brain damage or died as a result of respiratory depression from opioids over a 5-year period.

# CLINICIAN-CENTRIC MONITORING WITH MYVIEW™



MyView empowers clinicians to see things their way.

The level of information required can change dramatically by clinician and care area, but medical devices historically function in a static manner with the same parameters, waveforms, and trends displayed the same way. While Masimo measurements and display flexibility continue to expand, this doesn't mean that all clinicians need to see all of the information in the same way. MyView technology – featured in Masimo Patient SafetyNet – is being expanded to allow wireless sensing of the device,

clinician, patient, and care area to provide the parameters, waveforms, and trends that clinicians want to see and what their patients and family see. While a physician may want to see all parameters and waveforms, a medical assistant may only want to see Halo Index\* or a few parameters and no waveforms. If no clinician is in the room, the patient and family may be best served with no specific device information, but rather a visual indicator with a green, yellow, or red color indicating device alarm status.

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



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

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

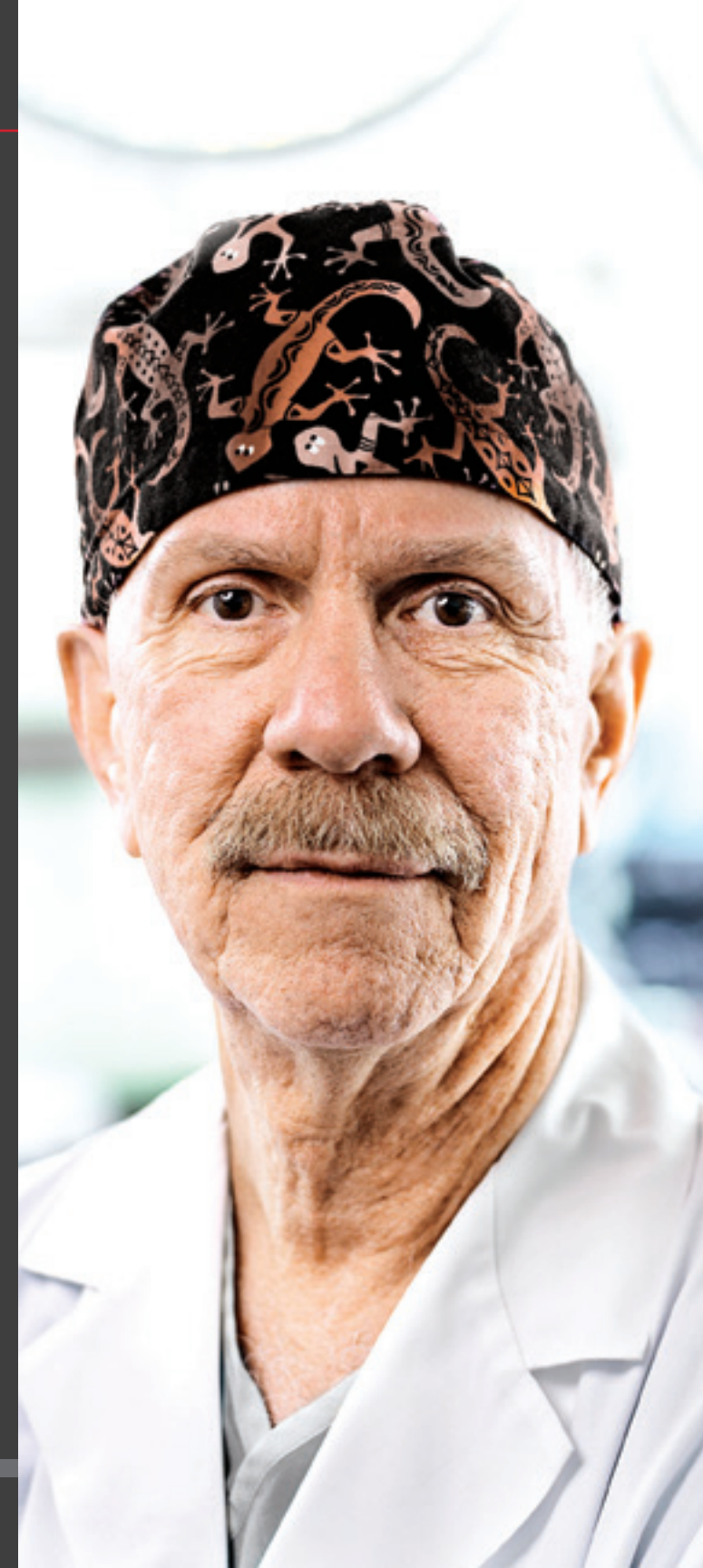


Clinician-centric view with the use of a presence tag or smartphone allows caregivers to see the customized information most important to them upon approach to a patient.

\* Halo Index is CE Marked. Currently not available in the U.S.



# EXPANDING OUR IMPACT BEYOND THE HOSPITAL



## AS HEALTHCARE CONTINUES TO GROW OUTSIDE THE HOSPITAL, SO DO WE

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

### A NEW LEVEL OF CARE IN THE HOME

For pediatric patients requiring continuous monitoring at home, Masimo SET® offers advantages for parents caring for special needs children – dramatically reducing false alarms during motion and low perfusion that can complicate an already difficult situation.

### ADDING A SAFETY NET IN POST-ACUTE CARE

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

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

**Bob Brouillette, MD**  
Montreal Children's Hospital, Montreal, Canada



### RELIABLE SLEEP LAB MONITORING

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



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

**Gene Gantt, RRT**  
Linde Respiratory Support Services



## QUICK AND NONINVASIVE SpHb AND SpO<sub>2</sub> ASSESSMENT



The Pronto-7<sup>®</sup> is designed specifically for faster noninvasive total hemoglobin (SpHb) spot-check testing, along with SpO<sub>2</sub>, pulse rate, and perfusion index.

### A REVOLUTIONARY DEVICE FOR A VARIETY OF CLINICAL SETTINGS

Hemoglobin is one of the most commonly ordered tests in both the hospital and non-hospital setting; however, traditional laboratory testing and processes involve delayed results. The Pronto-7 represents a breakthrough solution for noninvasively measuring hemoglobin and oxygen saturation together, in under a minute.

SpHb is not intended to replace lab testing but it can provide immediate and additional information to aid patient assessment. The palm-sized Pronto-7 – approximately

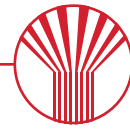
5" x 3" x 1" and weighing just 11 ounces – puts the power of noninvasive hemoglobin spot-check into any clinician's hands in almost any environment, including hospitals, clinics, blood donation centers,\* and emergency medical services.

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

<sup>1</sup> de Benoist B et al. Worldwide prevalence of anemia 1993-2005 WHO Global Database on Anaemia Geneva. World Health Organization. <sup>2</sup> Adams PF et al. Current estimates from the National Health Interview Survey, 1996. Vital Health Stat. 10.1999;1-203. \* Use in blood donation settings is CE Marked. Prior to using this device, the user should read and understand the Operator's Manual and Directions for Use. Laboratory diagnostic tests using blood samples should be conducted prior to clinical decision making to completely understand the patient's condition. Comparisons between SpHb measurements and laboratory diagnostic hemoglobin measurements may be affected by sample type, collection technique, physiological, and other factors.



# IMMEDIATE CAPNOGRAPHY AT THE POINT OF PATIENT CONTACT



## EMMA™ – EMERGENCY MAINSTREAM ANALYZER

Capnographs measure carbon dioxide (CO<sub>2</sub>) concentrations in expired gases. They are used during anesthesia, emergency care, and intensive care—where capnography is often used as a substitute for blood gas measurement or to monitor the performance of assisted ventilation. EMMA is a compact, portable, lightweight mainstream capnograph that requires virtually no warm-up time with full accuracy in 15

seconds. The continuous capnograph allows for confirmation and continuous monitoring of endotracheal tube placement, enables clinicians to assess the depth and effectiveness of compressions, and allows clinicians to recognize return of spontaneous circulation (ROSC).<sup>1</sup> Its primary use is short-term monitoring of end-tidal CO<sub>2</sub> and respiration rate in adults, pediatric, and infant patients.

<sup>1</sup>Neumar RW et al. *Circulation*. 2010;122:S729-S767.



EMMA fits onto a breathing circuit, facilitating CPR



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

**Daniel Davis, MD**

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





## HELPING CLINICIANS IDENTIFY CARBON MONOXIDE POISONING WITH SpCO®

Carbon monoxide (CO) poisoning is the most common cause of poisoning in industrialized countries,<sup>1</sup> but is often misdiagnosed because its symptoms are similar to the flu, and moderate poisoning is possible with no symptoms at all.<sup>2</sup>

### A DEADLY POISON REVEALED WITH SpCO

Our first rainbow® measurement was noninvasive carboxyhemoglobin (SpCO), helping clinicians identify and assess CO levels in the blood. A recent study at Medical University Vienna in Austria assessed 32,396 Emergency Department patients with SpCO by Pulse CO-Oximetry. Of 32 patients with a diagnosis of CO poisoning, 22 (69%) would not have been identified without an elevated SpCO measurement.<sup>2</sup>

In another study, researchers examined data from the Undersea Hyperbaric Medicine Society's CO poisoning surveillance system (supported by the Centers for Disease Control) and found that patients who were initially measured using Pulse CO-Oximetry had an almost one-hour reduction in time from the end of CO exposure to treatment.<sup>3</sup>

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

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



### SAVING LIVES EVERY DAY

In emergency medical services, SpCO is helping protect both victims and first responders from the dangers of CO poisoning. SpCO helps paramedics and emergency medical technicians to identify and assess CO levels in the blood. SpCO is also helping firefighters reduce the risk of CO poisoning that they face every day. Just one severe CO poisoning nearly doubles the risk of premature death, and consistent CO exposure may cause long-term heart and brain damage.<sup>4,5</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 that leads to poor decision making and also increases the risk of heart disease or stroke – two conditions already accounting for nearly 50% of on-duty firefighter deaths.<sup>6</sup> These factors are why industry-leading organizations have lined up to support CO education, and the National Fire Protection Association (NFPA) recently released an updated Fire Rehabilitation Standard (NFPA 1584) requiring firefighters exposed to smoke at incident scenes and during training to be assessed for carbon monoxide (CO) poisoning.

<sup>1</sup>Unintentional non-fire-related carbon monoxide exposures - United States, 2001-2003. *MMWR Morb Mortal Wkly Rep.* 2005; 54:36-39. <sup>2</sup>Roth D, et al. *Int J Clin Pract.* 2014; 10.1111/ijcp.12432. <sup>3</sup>Hampson NB. *J Emerg Med.* 2012 May 23. <sup>4</sup>Hampson NB et al. *Crit Care Med.* 2009; 37(6): 1941-47. <sup>5</sup>Bledsoe BE. *JEMS.* 32:54-59, 2007. <sup>6</sup>Bledsoe BE. *FireRescue Magazine.* September 2005.

"There is nothing more important in our profession than firefighter safety. The new 1584 standard builds on the older standard and more comprehensively addresses medical monitoring and carbon monoxide poisoning of the firefighter. I am excited to see this updated standard and that Masimo is at the forefront of making sure firefighters go home at the end of their shifts."

**Gary Ludwig**  
Fire Chief of the Champaign (Ill.) Fire Department

# LEADING THE mHEALTH REVOLUTION



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

### iSpO2® IS THE WORLD'S FIRST PULSE OXIMETER FOR IOS AND ANDROID MOBILE PLATFORMS

Combining a Masimo "board-in-cable," reusable or disposable sensor, and an application running on a smart phone or tablet device, iSpO2\* feature Masimo's proven Measure-through Motion and Low Perfusion™ pulse oximetry – SpO2, pulse rate, and perfusion index.



\*For sports and aviation use only in the U.S.

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

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

Until now no fingertip pulse oximeter has been available with Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry – the same technology used on more than 100 million patients a year in leading hospitals worldwide.

MightySat™\*\* is available in three versions – each of which provides oxygen saturation (SpO2), pulse rate (PR), and perfusion index (PI) measurements in a compact, battery-powered design with a large color screen that can be rotated for real-time display of the pleth waveform as well as measurements. Optional Bluetooth wireless functionality enables measurement display via a free, downloadable app on iOS and Android mobile devices as well as the ability to trend and communicate measurements. And for those who want to use their pulse oximeter to evaluate another physiologic dimension, MightySat is the only fingertip pulse oximeter available with the optional Pleth Variability Index (PVI), a measure of the dynamic changes in the PI that occur during one or more complete respiratory cycles.

\*\*For sports and aviation use only in the U.S.

"I would recommend Masimo's MightySat to anyone interested in health and fitness – understanding what goes on inside your body is paramount to improving performance."

**Stig Severinsen**  
Ph.D. in medicine, four-time World Champion freediver and owner of multiple Guinness World Records, including history's longest breath-hold of 22 minutes



# TAKING NONINVASIVE MONITORING TO ALL CREATURES GREAT AND SMALL



We ramped up our Animal Health business in 2013, offering veterinarians the same industry-leading monitoring solutions that have helped so many human patients.

Masimo SET® monitors and sensors\* greatly enhance the accuracy of arterial oxygen saturation (SpO<sub>2</sub>) and pulse rate (PR) monitoring, particularly in the most challenging conditions of motion and low perfusion.<sup>1</sup> Masimo SET® supports veterinarians in providing the highest level of care – especially when their patients are

at risk – during anesthesia-induced operating procedures and post-operative recovery.

## INNOVATIVE CAPNOGRAPHY PROTECTS PATIENTS FROM THE OPERATING ROOM TO RECOVERY

Up to 60% of all post-surgical animal deaths occur in the post-operative setting. And 74%

Up to 60% of all post-surgical animal deaths occur in the post-operative setting. And 74% of these deaths are related to cardiovascular or respiratory problems.



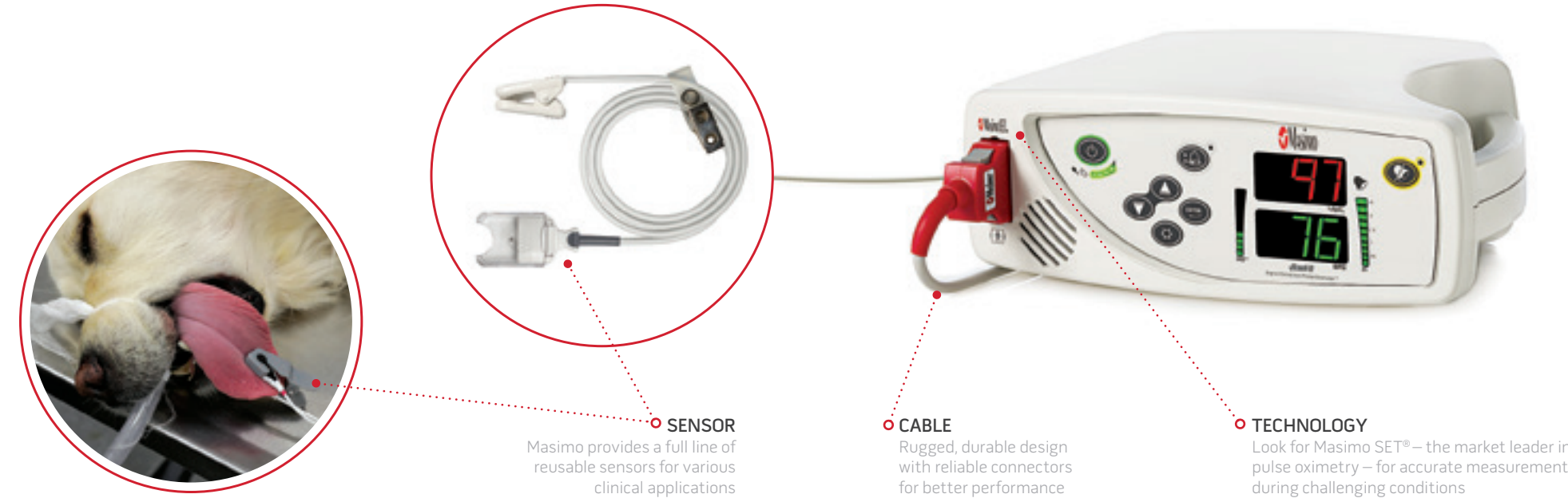
of these deaths are related to cardiovascular or respiratory problems.<sup>2</sup> The EMMA capnograph is Masimo's most cost-effective method for monitoring end-tidal CO<sub>2</sub> and can be used to help identify animals needing an intervention in CPR/resuscitation, during surgical procedures, and in post-operative recovery. The water-resistant durable capnograph also meets American Animal Hospital Association (AAHA) guidelines for end-tidal CO<sub>2</sub> monitoring.

## M-LNCS™ PROVIDES MORE SENSOR OPTIONS THAN ANY SENSOR AND CABLE SYSTEM

With multiple designs to serve the needs of all patient types, M-LNCS sensors offer flexibility for improved patient monitoring from the operating table to the recovery room. The M-LNCS TC-I Tip-Clip Ear Sensor is suited for animals over 30 kg.

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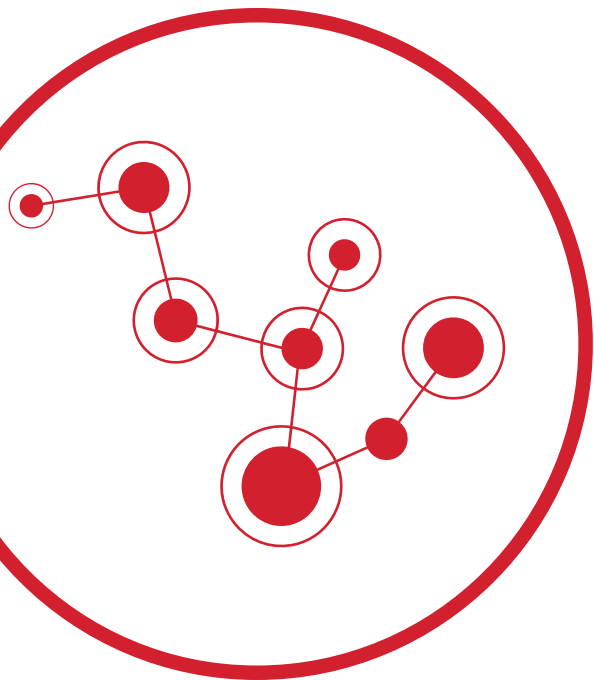
<sup>1</sup>Shah N et al. *J Clin Anesth.* 2012 Aug;24(5):385-91. <sup>2</sup>Brodgelt D et al. *Vet Anesth and Anal.* 2008; 35: 365-373. \* Animal Health products are pending Masimo quality system release.





# LOOKING FORWARD TO THE NEXT 25 YEARS





## PERSPECTIVES ON THE FUTURE FROM THE FOUNDER AND CEO, JOE KIANI

When Masimo was a garage start-up, more than two decades ago, I never imagined it would become a global company with more than half a billion dollars in annual revenues and more than 3,000 employees.

As I reflect on the past 25 years, I am proud of our accomplishments, yet I can't help but think: Maybe I should have dreamed bigger. One of my core values is to never be content with "good enough." I'm always striving to fix my sights higher, to set more challenging goals for my team and myself to accomplish more than before.

It is not hubris to envision that within the next five to 10 years, Masimo technologies will be monitoring more than 200 million patients a year, as our products become ubiquitous in healthcare settings and beyond. Our technology will expand and evolve to meet the future needs of healthcare, by helping improve surgical and post-surgical outcomes with shorter lengths of stay. By better assessing patients we can help reduce the cost of care.

Masimo technologies also will be seen to a greater extent outside clinical settings, as the role of the "empowered patient" evolves. People are becoming more accountable for their own healthcare, driven by policy and technology changes. Fortunately, Masimo is well positioned for a future where healthcare and medical technologies get pushed to home and mobile devices.

Leveraging our well-earned reputation for unprecedented performance and quality, we will be unveiling more consumer and mobile monitoring technologies. Armed with these and other devices, consumers will become more attuned to their physiology. We'll see people playing a larger, more proactive role with their healthcare, rather than merely being passive spectators of their "sick care."

As people increasingly use at-home and mobile devices to monitor themselves, they'll send results to their clinicians from wherever they happen to be. Healthcare of the future will be contextualized by almost constant biofeedback, with wireless networks and consumer devices for health monitoring creating a richer connection between patients and their caregivers.

In keeping with the theme of connectivity and empowerment, we will witness the Root® patient monitoring and connectivity platform continue to evolve and realize its full potential. Root is already available with Masimo SET® pulse oximetry, capnography, noninvasive rainbow® parameters, brain function monitoring, and rainbow Acoustic Monitoring™. Yet Root is designed to expand

Masimo is well positioned for a future where healthcare and medical technologies get pushed to home and mobile devices.

even further with measurements from other potential developers through Masimo Open Connect™ or MOC-9.

Disruptive technologies that improve patient care don't always come from large, well established companies. Yet market barriers and development costs often keep small, innovative companies from delivering their products to the clinicians and patients who need them most. With Root, Masimo is providing an open invitation to other companies, from small to large, to develop and commercialize their innovations through Masimo's "open-innovation" MOC-9 platform.

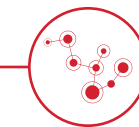
This seemingly incremental functionality – part of a concept I call "microfixing"

or "revolution via evolution" – has the ability to help unleash innovation that will improve patient outcomes and safety, while reducing the cost of care.

I remember others in the medical device industry – I won't name names – literally laughed at me when I proposed this concept. I'm mindful that proprietary mindsets had essentially blocked Masimo from much of the US market years ago. Closed systems that fence off creative, more effective technologies are marked relics.

By doing something like Root, Masimo is lowering the hurdle for innovative technologies to get to the healthcare market, lowering the cost of these monitors, and in the end, saving even more lives.





I'm reminded of the personal computer saga. Before the PC, computers were cold, massive, institutional machines housed in antiseptic rooms where only geniuses or highly specialized technicians were allowed to touch them. With the advent of the PC, computers became something everyone could play with. We see a compelling analogy with our Root platform. The thinking was that someone needed to do for patient monitoring what was done for computing. That is, make it accessible for other developers, create an open architecture to speed innovation, and deliver technologies at a lower cost. That's why we were able to price Root at about the level someone would pay for a PC – a couple thousand dollars instead of \$10,000 or \$15,000 – so it can become truly ubiquitous.

Root also allows us to address interoperability in a more meaningful way. More than a dozen medical devices can be connected to a patient, but those devices are handicapped if they can't communicate with each other. Up to 80% of medical errors in hospitals involve communication problems between healthcare professionals. I believe many of these errors could be avoided if devices could "talk" to each other, and even shut each other off or alarm when a measurement on another product is approaching a dangerous level.

Innovation is key to the future of healthcare. Without innovation, we won't find the cure to cancer or heart disease or Alzheimer's. We won't have the solutions we hope will be there for our kids. However, we need more than technology.

For example, you can dramatically improve patient safety with today's technologies. You don't need new technology to eliminate the 200,000 preventable patient deaths in U.S. hospitals—you need the will.




Restrictive business agreements are a barrier to interoperability and, again, an outdated strategy for med tech companies to make more money. Information-blocking practices harm patients. We can envision a day, hopefully soon, when providers only buy devices that share data, particularly when taxpayer dollars are involved.

Likewise, data accessibility is the companion of device interoperability – and both are essential to create a Patient Data Superhighway. This highway would securely house a patient's complete electronic medical history and would be populated with real-time information from vital-signs monitors, labs and other sources. If we bring monitors,

therapeutic devices, and IT infrastructure all together with intelligent, predictive algorithms in this Patient Data Superhighway, then physicians, along with patients and their families, could be informed of dangerous trends; more lives could be saved; and the process of care could be improved substantially, further reducing cost.

Once again evoking the empowerment of patients, they should also be able to access their own health information from medical devices. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 states that eligible professionals "provide patients with an electronic copy of their health information upon request." It's a laudable

Innovation is key to the future of healthcare. Improving patient safety can be done with today's technologies. You don't need new technology to eliminate the 200,000 preventable patient deaths in U.S. hospitals.



Human warmth, tenderness, and understanding are key ingredients to a more humane and more effective healthcare system.

requirement. But it should be done as a matter of course and should include easy-to-understand data from medical devices.

We know that a lack of meaningful communication and information sharing among medical technologies, clinicians and patients contributes to poor patient outcomes. Patients who know in layman's terms how their devices are programmed, function and interact with their healthcare would be better able to communicate with caregivers. Greater communication throughout the healthcare ecosystem is key. Implicit in that is something that too often is neglected in healthcare discussion and debates. And that is empathy and love. I disagree that empathy and emotion do not have a place in healthcare. Human warmth, tenderness and understanding are key ingredients to a more humane and more effective healthcare system.

Empathy and love are not just for doctors and nurses. Medical technology executives, engineers, health insurance providers, even the orderlies, those who deal with hospital linens, and, of course, patients, need to find room in their hearts for love. The best medical treatment comes when those providing care love what they do and for whom they do it.

If we are to reach a goal of mine – articulated through the Patient Safety Movement Foundation we created in 2012 – to eliminate preventable patient deaths by 2020, then innovative technologies, open engineering architecture, data accessibility and the Patient Data Superhighway, and last but not least, love, will have to become part of our healthcare system of the future.

Masimo is here to help make that happen. That's what I mean by dreaming big.

**Joe Kiani**  
*Chairman & CEO*



# SENIOR MANAGEMENT TEAM

**From left to right:** Tetsuro Maniwa, President, Masimo Japan; Stacey Taggart, President, Europe, Middle East & Africa; Mark de Raad, Executive Vice President & Chief Financial Officer; Paul Jansen, Executive Vice President, Business Development; Jon Coleman, President, Worldwide Sales, Professional Services & Medical Affairs; Rick Fishel, President, Worldwide OEM Business and Blood Management; Joe Kiani, Chief Executive Officer; Yongsam Lee, Executive Vice President, Chief Information Officer; Tom McClenahan, Executive Vice President, General Counsel; Anand Sampath, Executive Vice President, Engineering & Chief Operating Officer; Robert Zyzanski President, Masimo Sweden

**Board of Directors (not pictured):** Joe Kiani, Chairman of the Board of Directors; Steven Barker, MD, PhD; Robert Coleman, PhD; Sanford Fitch; Jack Lasersohn; Craig Reynolds







# APPENDIX

# 6

CONTINENTS  
HAVE MASIMO  
TECHNOLOGIES



OM



CAS

# OEM

Masimo is integrated in more industry-leading products than any other pulse oximetry technology



# TECHNOLOGIES AND PRODUCTS



## MONITORS



**Pronto-7<sup>®</sup>**  
rainbow<sup>®</sup> 4D with SpHb<sup>®</sup> spot-check with wireless communication

**Rad-5v<sup>®</sup>**  
Masimo SET<sup>®</sup>

**Radical-7<sup>®</sup>**  
Complete rainbow<sup>®</sup> Pulse CO-Oximetry, rainbow Acoustic Monitoring™, upgradeable, color touchscreen display, standard wireless radio, MyView™

**Radius-7™**  
Patient-worn monitor

**Root<sup>®</sup>**  
Complete rainbow<sup>®</sup> Pulse CO-Oximetry and rainbow Acoustic Monitoring™, upgradeable, touchscreen, standard wireless radio, MyView™, MOC-9™, Iris™  
Shown with Radius-7™

**Rad-8<sup>®</sup>**  
Masimo SET<sup>®</sup>, LED display

**Rad-57<sup>®</sup>**  
rainbow SET<sup>®</sup> Pulse CO-Oximetry

**Pronto<sup>®</sup>**  
rainbow SET<sup>®</sup> with SpHb<sup>®</sup> spot-check

## EXTERNAL MEASUREMENT TECHNOLOGIES



**iSpO2<sup>®</sup>**  
SpO2, PR, PI

**uSpO2<sup>®</sup>**  
SpO2, PR, PI

**MightySat™**  
SpO2, PR, PI, PVI

**EMMA™**  
Portable mainstream capnometer

**ISA™**  
Sidestream Capnography and Gas Monitoring

**SedLine<sup>®</sup>**  
Brain Function Monitoring

**O3™**  
Regional Oximetry

## PATIENT SAFETYNET™ SYSTEM



**Patient SafetyNet Remote Monitoring and Notification System**

- > Direct alarms to nurse via pager
- > Open architecture with HL7 interface to hospital EHR
- > MyView™ for clinician-centric monitoring
- > IRIS for 3rd party device integration

## TECHNOLOGIES AND PARAMETERS

**Masimo SET**

Measure-through Motion and Low Perfusion™ pulse oximetry

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

**rainbow<sup>®</sup>**

rainbow<sup>®</sup> Pulse CO-Oximetry

Noninvasive blood constituent and fluid responsiveness monitoring

- > Carboxyhemoglobin (SpCO<sup>®</sup>)
- > Methemoglobin (SpMet<sup>®</sup>)
- > Total Hemoglobin (SpHb<sup>®</sup>)
- > Oxygen Content (SpOC<sup>®</sup>)
- > Fractional Oxygen Saturation (SpfO2™)
- > Oxygen Reserve Index (ORI™)
- > Plus all Masimo SET<sup>®</sup> measurements

**rainbow Acoustic Monitoring™**

Noninvasive respiratory monitoring

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

**Brain Function Monitoring**

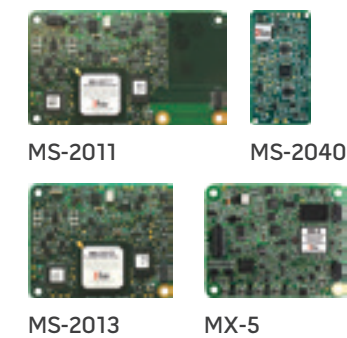
Noninvasive depth of sedation monitoring

- > 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)

## CIRCUIT BOARDS



**MS-2011**

**MS-2040**

**MS-2013**

**MX-5**

## SENSORS



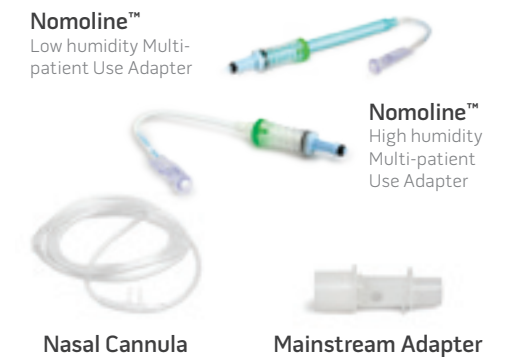
**Masimo SET<sup>®</sup> Sensors**  
SpO2, PR, PI, PVI<sup>®</sup>

**rainbow<sup>®</sup> SET Sensors**  
SpHb<sup>®</sup>, SpOC<sup>®</sup>, SpCO<sup>®</sup>, SpfO2™, SpMet<sup>®</sup>, SpO2, PR, PI, PVI<sup>®</sup>

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

**SedLine<sup>®</sup> Sensor**  
PSI

## CANNULAS AND ADAPTERS



**Nomoline™**  
Low humidity Multi-patient Use Adapter

**Nomoline™**  
High humidity Multi-patient Use Adapter



**Nasal Cannula**

**Mainstream Adapter**

# NATIONAL AND INTERNATIONAL AWARDS FOR EXCELLENCE



 <b>2000</b> Technology Excellence	 <b>2013</b> Best Clinical Application of Technology Award for SpHb	 <b>2014</b> Top 50 Leaders in Patient Safety	 <b>2014</b> Hubert H. Humphrey "Dawn of Life" Award
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<ul style="list-style-type: none"> <li> <b>1995</b> Excellence in Technology Innovation for Measure-through Motion and Low Perfusion Pulse Oximetry</li> <li> <b>2000</b> Outstanding Medical Device Company</li> <li> <b>2001</b> Innovative Product and Technology</li> <li> <b>2001</b> Distinguished Leadership</li> <li> <b>2001</b> Medical Design Excellence</li> <li> <b>2003</b> New Standard of Care</li> <li> <b>2003</b> Technology of the Year in Patient Monitoring</li> <li> <b>2003</b> Platform ABBY for Innovations in Healthcare</li> <li> <b>2005</b> Innovative Product and Technology</li> <li> <b>2006</b> Application of Technology for Noninvasive Methemoglobin and Carboxyhemoglobin Monitoring</li> </ul>	<ul style="list-style-type: none"> <li> <b>2006</b> Medical Design Excellence</li> <li> <b>2007</b> Excellence in Technology Innovation for Noninvasive Total Hemoglobin Monitoring</li> <li> <b>2007</b> Groundbreaking Innovation of rainbow® SET</li> <li> <b>2007</b> Patient Monitoring Technology Leadership of the Year</li> <li> <b>2008</b> Excellence in Medical Technology</li> <li> <b>2008</b> Outstanding Growth</li> <li> <b>2008</b> Outstanding Medical Device Company</li> <li> <b>2008</b> Best in Class</li> <li> <b>2008</b> Zenith Award</li> <li> <b>2009</b> Best in Class</li> </ul>	<ul style="list-style-type: none"> <li> <b>2009</b> Zenith Award</li> <li> <b>2009</b> Patient Monitoring CEO of the Year</li> <li> <b>2009</b> Masimo SET® and Patient SafetyNet help Dartmouth-Hitchcock Medical Center win the 4<sup>th</sup> Annual Health Devices Achievement Award</li> <li> <b>2010</b> Respiratory Product Best-in-Class Award</li> <li> <b>2011</b> Product Design Award for the Pronto-7</li> <li> <b>2011</b> Medical Design Excellence Gold for the Pronto-7</li> <li> <b>2011</b> High-Tech Innovation for the Pronto-7</li> <li> <b>2012</b> National Entrepreneur of the Year Life Sciences Award Winner</li> <li> <b>2012</b> Gold "Stevie" Award for Best New Health Product for the Pronto-7</li> <li> <b>2013</b> Hot Product Award for EMMA and iSpO2</li> </ul>
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# SELECT OEM PARTNERS

Masimo SET® is integrated in more than 100 OEM monitors from 50 leading brands. In addition, more and more of our OEM partners are enhancing the capabilities of their monitoring solutions by integrating rainbow® technology.



**OEM**  
 Masimo is integrated in more industry-leading products than any other pulse oximetry technology

# MASIMO'S GLOBAL REACH



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

## HEADQUARTERS

**HQ CORPORATE HEADQUARTERS**  
52 Discovery  
Irvine, CA 92618  
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Tel: 949 297 7000

## INTERNATIONAL OPERATIONS

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Puits-Godet 10  
2000 Neuchâtel  
Switzerland  
Tel: +41 327201111

## MANUFACTURING CENTERS

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40 Parker  
Irvine, CA 92618  
USA

**MM MEXICO MANUFACTURING**  
Calzada Del Oro No. 2001  
Modulo-6,  
Mexicali, 21395  
Mexico

## COUNTRY OFFICES

### THE AMERICAS

**CA CANADA**  
4878 Levy  
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Edificio Moncayo  
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México, D.F. 06600 México  
Delegación Cuauhtémoc  
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12-14-2016  
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Netherlands  
Tel: +31 135832479

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28760 Tres Cantos  
Madrid  
Spain  
Tel: +34 918049734

### TURKEY

**TU TURKEY**  
Mustafa Kemal Mah.  
2125. Sok  
Kolbay Is Mrk C Blok No:6/10  
Sogutozu  
Ankara  
Turkey  
Tel: +90 312 219 54 38

### UK

**UK UK**  
Unit Q, Loddon  
Matrix House, Basing View  
Basingstoke. Hants.  
RG21 4DZ  
United Kingdom  
Tel: +44 (0)1256 479988

**6**  
CONTINENTS  
HAVE MASIMO  
TECHNOLOGIES

**59**  
OEM PARTNERS  
WORLDWIDE

**134**  
COUNTRIES HAVE  
Masimo SET™

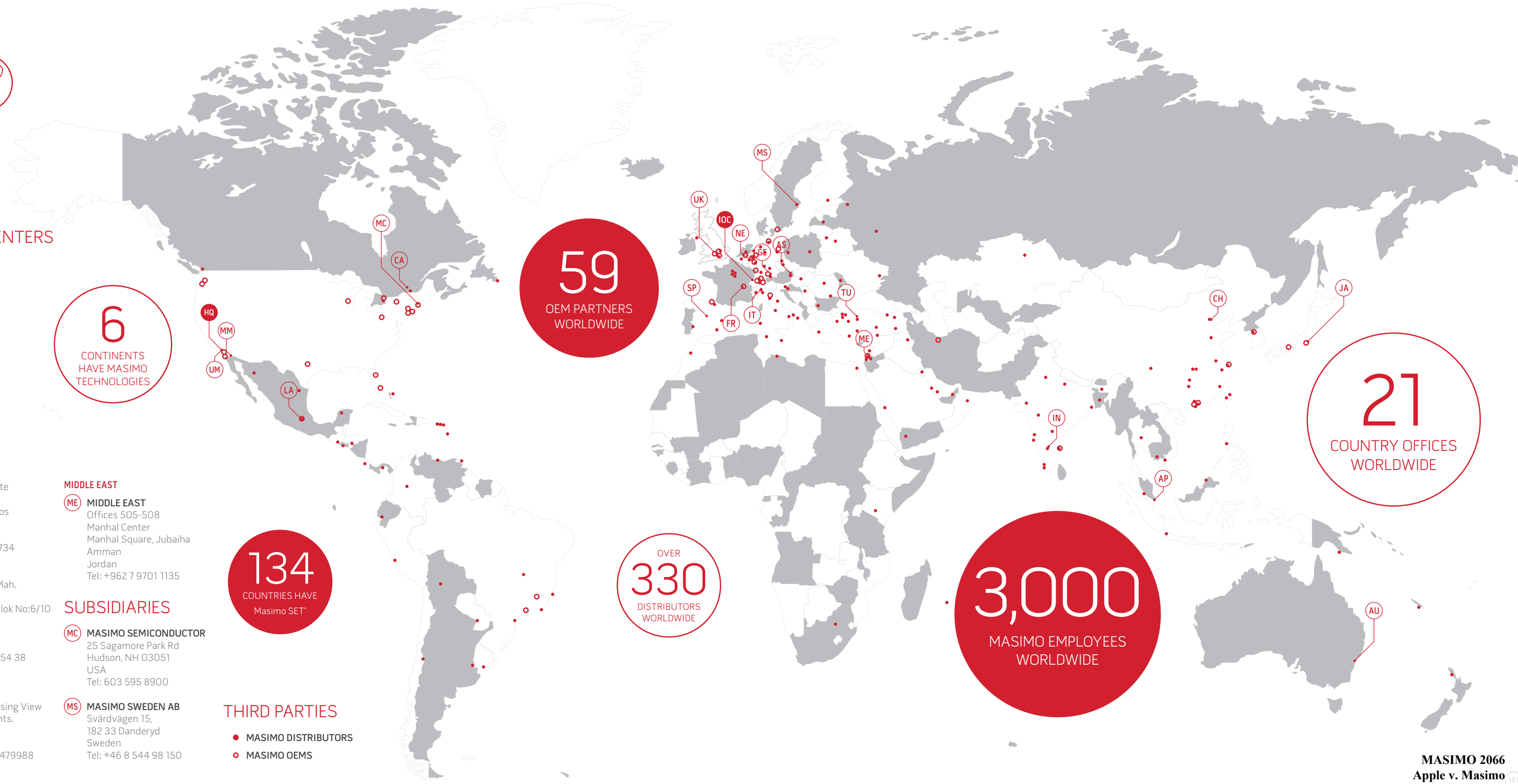
**OVER 330**  
DISTRIBUTORS  
WORLDWIDE

**3,000**  
MASIMO EMPLOYEES  
WORLDWIDE

**21**  
COUNTRY OFFICES  
WORLDWIDE

## THIRD PARTIES

- MASIMO DISTRIBUTORS
- MASIMO OEMS





# 2014 FINANCIALS

## FINANCIAL PERFORMANCE



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

REVENUE	YEAR ENDED:	
	January 3, 2015	December 28, 2013
Product	\$556,764	\$517,429
Royalty	29,879	29,816
Total revenue	586,643	547,245
Cost of goods sold	195,864	188,418
Gross profit	390,779	358,827
Operating expenses:		
Selling, general and administrative	241,016	215,469
Research and development	56,581	55,631
Litigation award and defense costs	(10,331)	8,010
Total operating expenses	287,266	279,110
Operating income	103,513	79,717
Non-operating expense	1,472	3,991
Income before provision for income taxes	102,041	75,726
Provision for income taxes	27,678	20,005
Net income including noncontrolling interest	74,363	55,721
Net income (loss) attributable to noncontrolling interest	1,845	(2,660)
Net income attributable to Masimo Corporation stockholders	\$72,518	\$58,381
Net income per share attributable to Masimo Corporation stockholders:		
Basic	\$1.33	\$1.03
Diluted	\$1.30	\$1.02
Weighted-average shares used in per share calculations:		
Basic	54,708	56,690
Diluted	55,571	57,480



## FORWARD-LOOKING STATEMENTS

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All statements other than statements of historical facts included in this document that address activities, events or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Forward-looking statements include statements which are predictive in nature, which depend upon or refer to future events or conditions, which include words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates” or similar expressions. 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® and Masimo rainbow® SET® products and technologies for substantially all of our revenue; any failure in protecting our intellectual property exposure to competitors’ assertions of intellectual property claims; the highly competitive nature of the markets in which we sell our products and technologies; any failure to continue developing innovative products and technologies; the lack of acceptance of any of our current or future products and technologies; obtaining regulatory approval of our current and future products and technologies; the risk that the implementation of our international realignment will not continue to produce anticipated operational and financial benefits, including a continued lower effective tax rate; the loss of our customers; the failure to retain and recruit senior management; product liability claims exposure; a failure 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 Form 10-Q and Current Reports on Form 8-K, all of which you may obtain for free on the SEC’s website at [www.sec.gov](http://www.sec.gov). Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. 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 the Company’s “annual report to security holders” for purposes of the requirements of the SEC. For a copy of the Company’s annual report to security holders required under Rule 14a-3 of Regulation 14A of the Securities Exchange Act of 1934, as amended, please refer to the Company’s Annual Report on Form 10-K for the fiscal year ended January 3, 2015, which you may obtain for free on the SEC’s website at [www.sec.gov](http://www.sec.gov).



## VENIMUS, VIDIMUS, VICIMUS

Masimo • 52 Discovery • Irvine, CA 92618 • Tel: +41 32 720 1111

© 2015 Masimo. Masimo, SET, rainbow, rainbow Acoustic Monitoring, rainbow 4D, rainbow ReSposable, 3D Desat Index Alarm, Adaptive Probe Off Detection, APOD, Blue, DCI-mini, DOS, DST, E1, EMMA, Eve, FastSat, FST, Halo Index, Iris, IRMA, ISA, iSpO2, iSpO2 Rx, LNCS, LNOP, 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, ORI, Phasein, Pronto, Pronto-7, Pulse CO-Oximetry, Pulse CO-Oximetry, PVI, Rad-5, Rad-57, Rad-5v, Rad-8, Rad-87, Rad-9, Radical, Radical-7, Radius-7, RAM, RAS, Root, ROS, RRa, RRp, SatShare, SedLine, Signal Extraction Technology, Signal I.Q., SmarTone, SofTouch, SpCO, SpfO2, SpHb, SpMet, SpOC, SST, TFA-1, uSpO2, X-Cal, Improve patient outcomes and reduce the cost of care by taking noninvasive monitoring to new sites and new applications, and Closer to the Heart 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.

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**MASIMO 2066**  
**Apple v. Masimo**  
**IPR2022-01465**