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 approvals.

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

- Europe CE Marking: Animal health products, iSp02, and iSPO2 Rx for infant & neonatal use and MightySat Rx
- Canada MDA: iSaaX+, iSaa OR+, iSp02 Rx for infant & neonatal use and MightySat Rx
- Canada MDA: U.S. A. device for adult & neonatal use (RadiiX and oximo)
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THE FIRST 25 YEARS

**1998**
- **SmarTone™** Ability to maintain calibration even with variable pitch during low signal for neonates
- **Max Sensitivity Setting** Enabling reliable measurements in the most challenging conditions of low perfusion
- **DataScope MaxTouch™** First Masimo sensor designed for sensitive skin of neonates

**1998**
- **FastSat™** SpO2 value in less than 10 seconds from the time the instrument is turned on
- **Measure-through Motion 510(k)** First FDA 510(k) clearance for measure-through-motion pulse oximetry
- **Measure-through Low Perfusion 510(k)** First FDA 510(k) clearance for measure-through-low-perfusion pulse oximetry

**1998**
- **First Fda 510(k) clearance** for measure-through-motion pulse oximetry
- **SofTouch™** First Masimo sensor designed for sensitive skin of neonates

**1999**
- **FastStart™** First FDA 510(k) clearance for measure-through motion pulse oximetry
- **Signal IQ™** First to quantify measurement quality and give clinicians a way to know when they can have confidence in the SpO2 values during motion and low perfusion

**2000**
- **FastSat™** SpO2 value in less than 10 seconds from the time the instrument is turned on
- **Radial 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
- **Study shows Masimo SET® helps increase caregiver efficiency**

**2000**
- **Study shows Masimo SET® helps wean patients from the ventilator faster, reduce Fio2 levels, and reduce arterial blood gas measurements**

**2002**
- **Breakthrough Study**
2002
Breakthrough Study
- Masimo SET® linked to reduced medical errors in critical care medicine

2003
Breakthrough Study
- Adaptive Probe Off Detection™ (APOD) reduces the display of false low SpO2 on the patient, improving patient monitoring

2004
- SET® Handheld Pulse Oximeter: First handheld incorporating Masimo SET®
- LNCS® Sensors: Live-rate oximetry sensor design
- Newborn Sensor: First sensor designed for noninvasive monitoring of cyanotic infants and children

2005
- Blue Sensor: First sensor for accurate carboxyhemoglobin measurement in cyanotic infants and children
- SET® in MX-1® Board: First noninvasive blood constituent platform
- 3D Desat Index Alarm™: First alarm to alert clinicians to patterns of transient desaturation that may predict respiratory depression
- SpCO®: First noninvasive carboxyhemoglobin measurement
- SpO2 Baseline Determined by the Radical-7
- PI Delta % Change = 25 (within a 1-hour period)

2006
- SET®: First handheld capable of noninvasively measuring carbon monoxide levels in the blood

2007
- Radical-7: First device to alert clinicians of changing peripheral perfusion status that may indicate worsening condition

2008
- Breakthrough Study
- Rainbow SET® Study shows Masimo SET® linked to reduced medical errors in critical care medicine

THE FIRST 25 YEARS
THE FIRST 25 YEARS

2005
Radical-7 First bedside rainbow SET® Pulse CO-Oximeter

2006
SpMet First noninvasive methemoglobin measurement

2007
PVI First noninvasive and continuous fluid responsiveness measurement

2008
National Fire Protection Association Standard NFPA 1584 releases fire rehab standards and includes carbon monoxide assessment during fire rehab

2008
Breakthrough Study

2008
SpHb First noninvasive and continuous total hemoglobin measurement

2008
Red-87 First pulse oximeter with integrated 802.11 abg wireless radio

2008
Breakthrough Study

2008
SpMet First noninvasive and continuous total hemoglobin measurement

2009
NeeP-500 First sensor for extremely low birth weight babies

2009
Rainbow Resposable® Sensor System featuring performance of adhesive sensors with green Design in™, which reduces both landfill and carbon footprint
The First 25 Years

2009

**Respiration Rate from the Pleth (RRp)**

- First noninvasive and continuous respiration rate monitoring with an acoustic sensor.

2010

**Breakthrough Study**

- Study shows Masimo SET® and Masimo Patient SafetyNet™ improve patient outcomes in anesthesia surgery.

**Fluid Management Study**

- Study shows Prismo® helps optimize fluid management and decrease fluid usage in surgical patients.

2010

**Breakthrough Study**

- Study shows Masimo SET® and Masimo Patient SafetyNet™ improve patient outcomes in anesthesia surgery.

**Breakthrough Study**

- Study shows Primo® and Primo-7 ® achieve breakthrough in monitoring hemoglobin, pulse rate, and perfusion index.

2010

**Radical-7**

- Redefining touch screen display, connectivity, and external display functionality.

**Adaptive Threshold Alarm**

- First dynamic physiologic alarm thresholded on changes from each patient’s baseline value.

2011

**Halo Index**

- Cumulative trending assessment of the global patient status.

2012

**Capnography and Gas Monitoring**

- Masimo begins offering innovative, multispectral technologies for measuring respiratory gases and anesthetic agents.
THE FIRST 25 YEARS

2012

SpfO2™
The first noninvasive fractional oxygen saturation monitor

2013

SpfO2 Pulse Oximeter
The first pulse oximeter for both iOS and Android mobile devices

2014

SpfO2™
The first noninvasive fractional oxygen saturation monitor

2013

Ox®, Brain Function Monitoring
The SaLO2 Regional Oximetry module for Root features high sensitivity and high-quality data; Ox® provides information about patient response to anesthesia

2013

1st Patient Monitoring and Connectivity Platform
First device to integrate
- SaLO2, measurements
- ir™ connectivity for third-party devices
- Moxi Open Connectivity™ (MOC™) for measurement expansion

2013

ISA® Capnography
The ISA capnography MOC-9 module for Root features high performance and affordable cost-effective disposables through the innovative ISA™-mini with extended monitoring time and use of generic cannulas

2014

Radion 7™
The first lightweight, wireless, wearable monitor with Moxi Onboard™ technology

2014

ORI™
The first noninvasive and continuous parameter to provide insight into oxygen reserve in patients receiving supplemental oxygen

2014

Eve™ Newborn Screening Application
An animated tutorial for the Radical-7 specifically designed to help clinicians more effectively and efficiently screen newborns for critical congenital heart disease (CHD)

2014

TFa-1™
Single-patient-use forehead sensor for Masimo SET®

2015

MightySat™
The first fingertip pulse oximeter with Masimo SET® technology for sports and aviation use only in the U.S.
1918

1918

We believe that Masimo SET® 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 in the U.S. News & World Report Best Hospitals Honor Roll for the years 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® 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.

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 25th 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:

- 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 (rSo2) and arterial blood oxygenation (SpO2). Root...

LETTER FROM THE CHAIRMAN & CEO

2014 marked the 25th 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.

MISSION STATEMENT

Improve patient outcomes and reduce the cost of care by taking noninvasive monitoring to new sites and applications.
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 hypoxia 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. (O3) Pulse Oximeter for Android. With the release of O3P 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. O3P 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 device.

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 Narmoline sampling line
- Wireless functionality – Capable of transmitting information through Bluetooth and Wi-Fi

4. Later, Masimo also announced O3 DRY+ multigas monitoring, a Masimo open connect (Moc-9) Module for Root. During general anesthesia, the O3 DRY+ 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 patients’ oxygen saturation and pulse rate – even during states of motion and low perfusion – as well as

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**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**

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*The use of the trademarks Patient SafetyNet and PSN is under license from university Health System consortium.
6 MightySat, the first finger-tip pulse oximeter with Masimo SET®. MightySat, the first finger-tip pulse oximeter with Masimo SET®

7 The Rainbows have a compact, battery-powered design with a large display of the pleth waveform as well as 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 finger-tip pulse oximeter available with the optional/Perf variability index (PVi), a measure of the dynamic changes in Pi that occur during one or more complete respiratory cycles.

8 Oxygen Reserve Index (oRi™†). With ce Mark and limited market release, o Ri has the configuration for long-range communication is not yet released. * The protocol for respiration rate from the pleth (RRp); 6) total hemoglobin (SpHb); 7) oxygen content (Sp oc); 8) carboxyhemoglobin (SpHb); 9) carbon dioxide saturation (Spf co2); 10) oxygen Reserve Index (oRi). 4 Szmuk P, Steiner J, o lomu 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, bo c12, Room 275-277.

9 The device, the rainbow® Dci-mini sensors are designed to help clinicians quickly and easily trend spot-check hemoglobin levels. Dci-mini allows clinicians to help save the lives of babies and their mothers, around the globe to receive timely assessment and treatment, which will benefit their long-term health, as well as the health of their society.

10 The study was among 10 selected from more than 100 abstracts 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.
ce Mark of the TFA-1* transflectance forehead adhesive sensor. TFA-1 is 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 PVDF 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.

While 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. We are 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—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—a 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 lifesaving breakthrough products become ubiquitous in healthcare settings and beyond. Our technology will expand and evolve to meet the future needs of humanity 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
Joe Kiani and Mohamed Diab solved the “unsolvable” — inventing pulse oximetry that was accurate when patients moved or had low perfusion.

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
OUR STORY, FROM THOSE WHO LIVED IT
The Early Years

Mhamdiab

>> As Mhamdiab, we learned from the beginning that it [would] create the tool that we had the ability to find that signal, if it couldn’t be found. We also discovered it [that] the pulse oximeter [could] only deliver it at a certain time when the arterial signal was present. 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 motion artifact, an inability to obtain data on the most critical patients.

> 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 SpO2 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 a clean sheet of paper,’ I remember Joe saying. ‘We knew we could do this. We knew we could make a better device. We just had to figure out how to remove 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. Unfastened from that solid, the second breakthrough came when we were on a plane coming back from Sydney. I read up a little on DST, the discrete saturation transform.’

> ‘Tight, mixed in between. If you’re not shaking your hand, then you get a reading with no baseline. As the Dr. St. Louis characterized it, “Pulse oximetry has been at best, a fair weather friend.” What DST gives you is a map. It’s the top 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 more than one solution to the motion artifact problem!’

> “We solved the low perfusion problem – measuring blood oxygen saturation with blood flow low – by properly designing our hardware and sensors and using advanced digital signal processing techniques. This enabled us to reliably extract extremely small signals under a wide range of patient conditions. In 1995 at AAA, Al joined us and quickly became the leader of Masimo’s pulse oximetry development with major contributions to the algorithm, software and system design.”

Mary Kiani

>> Mary was a full-time dentist and married man, yet she knew her brother was also needing a future job while trying to build what became Masimo. With no expectations of any stock or value, she asked her brother if there was anything 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 got going, all people were well intentioned who helped, but Masimo was also fortunate to have 60 people on staff. ‘Joe asked me to reign his, to be the people who were more qualified to be members of the board of directors of the company at that time. Joe did a great job and I am proud of what he has done. But I think that it is very important that people keep in mind that there are always going to be challenges. If you are not shaking your hand, then you get a reading with no baseline. I was a licensed dentist, and working full-time at an office in Beverly Hills, but my work was at night and Saturdays, which helped me to help the company because I was happy to do it. I was also Director of Medical Affairs, being the only person at Masimo who had a clinical background in Anesthesia and who was the one who got the patents approved.’

‘When Poccis Started,’ I wanted to help my brother, because he was working full time and doing Masimo on the same time with no help from anyone. I was a licensed dentist, and working full-time at an office in Beverly Hills, but my work was at night and Saturdays, which helped me to help the company because I was happy to do it. I was also Director of Medical Affairs, being the only person at Masimo who had a clinical background in Anesthesia and who was the one who got the patents approved.’
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 called 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.

>i believe that, one of the keys to our success has been engineering 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. i'm proud of Masimo's 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 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.

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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. 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

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In the early 90s, journal articles would often cite problems with pulse oximeter devices to include such items as patient motion, poor 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.

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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 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 been unable 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 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. Selling the RedOne and continual innovations followed. It’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 SpO2.

"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 think that the board could be taken down to 100 milliwatts and cost under $50, 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 500 milliwatts, and MS-7 was 250 milliwatts. Then we began developing the MS-2000 family, which is 100 milliwatts, and the MS-2040, which is <45 milliwatts. 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.”
Dr. Bolandgray was our first investor, with a check for $5,000. He didn’t just put in his money – he called everyone that he knew who might help, and help they did. Through him came Dr. Jose Nessim and then Dr. Jeremy Swan, both of whom lent us great credibility. 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 also for helping change my retirement to a comfortable level.

"As an Italian expression goes, I told him: 'You have now some shares and don’t know what to do with them and you are going to donate them to charity, I know someone who would like to have a couple more. His name is Abbas Bolandgray, let’s pray for you.'"

**Ron Namss (for Joe Namss)**

**MY FAMILY:** I grew up in the Land of Opportunity, the United States, permanently in 1984. Through mutual friends, I got to know a recently graduated Iranian-American student, Joe Kiani. One day he came to our house with a 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, I gave him all the encouragement I could and told him he would make it without any doubt. In particular, in the Land of Opportunity.

"Then the critical question came up. I asked if I could invest in this future company. I gave a great deal of thought, considering my position at the beginning of our migration..."

I invested very early with this young, rich, intelligent person and told him that I could give him $50,000! 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 $1,000. Dr. Jose Nessim was so much into the oximeter, he gave me no two-phase number. Apparently Dr. Nessim was a well-known gentleman and influential with people, and he invested $25,000; and so, $25,000 subsequently. Later on, I invested another $5,000 for a friend who didn’t want to take the investment, so I took it and had $30,000 invested in the company, which gave me 20,000 shares.

"About mid-1989, Joe had moved to Anthem, another PMI distributor. Joe and I hit it off the first time we met and became really good friends. He was a bit of a risk taker who believed in people and new things, and making a presentation as part of raising money early on. I was very impressed with the demo on the kitchen table. I asked Joe, what was this product..."

"The father of my children, Joe Kiani and another really nice off. Dad was a practicing OB/GYN. He really liked the Masimo pulse oximeter and really liked Joe, and I invested very early. My father introduced Joe to other people at Cedars Sinai, the main hospital, and Dad was all sold on it, and introduced me to Dr. Joe Kiani. My father was a famous cardiologist who co-invented the Starr-Edwards heart catheter that revolutionized heart surgery..."

I bought a place in Laguna Beach where Joe would still visiting business. I also remember he coming to the house in Beverly Hills and making a representation as part of raising money early on. My dad was still a little taken with Masimo people and new things, and we would jump from one product to the next. Afterwards, with Masimo, that happened repeatedly, he invested several times.

I bought shares, too, early on – 1985, 1992, 1993. As happened with many Masimo investors from those early years, the investments paid off very well."
would be the next step. He mentioned finishing off some fixes, getting things ready for our first demo, and making arrangements for the small group to come down to the lab. After a little more convincing, the doctors decided to invest $1500 each. Both Joe and I were ecstatic. So was Joe. I think this was the first time the family friend investors to venture capitalists. I had my business 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. The relationship evolved from there and the relationship with the first pulse oximeter due to various FD and quality requirements. Still, I had a strong hunch that Joe would lead a successful company with his high integrity and great management style.

In January 1990, Joe called and mentioned he had left Anthem, and that he had founded Bedside 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 FD and quality requirements. Still, I had a strong hunch that Joe would lead a successful company with his high integrity and great management style.

“Since that time, Joe has been very interested in the space. I was an early investor and tried to meet Joe. So there was another demo on Mohamed’s kitchen table. After a little more convincing, the doctors decided to invest $1500 each. Both Joe and I were ecstatic. So was Joe. I think this was the first time the family friend investors to venture capitalists. I had my business 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. The relationship evolved from there and the relationship with the first pulse oximeter due to various FD and quality requirements. Still, I had a strong hunch that Joe would lead a successful company with his high integrity and great management style.

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sought out tough but highly respected experts to study and test masimo products. With limited assets, approaching the problem fearlessly, Joe Kiani and his team from respected medical authorities can result in the demise of a fledgling company. Leaders in medicine to review it, hoping that you can prove you’ve built a much oximeter in a market dominated by one company? Simple – you get the thought of patient motion and low perfusion. Great news, but how do you sell a pulse scientifically and clinically proven to be accurate during challenging conditions (motion). This gave the company the first and only pulse oximetry technology 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.

The creation of masimo was a continuous uphill climb. When they invented set® – starting with a relatively small amount of financing, and no marketing department, and in some cases, saved precious young lives.

Speaking to the true quality of their innovative technology, masimo won the day.

Jeremy Swan, MD
[Dr. Jeremy Swan is an affiliate professor of physiology at the University of Southern California and the founder of Masimo, Inc.]

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

Steve Barker
[Dr. Steve Barker is a member of Masimo’s scientific advisory board.]

“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 taking an oath about a clinical study we found the Nellcor pulse oximeters failed to maintain during motion. The guy said: ‘Well tell me, tell me, the Nellcor pulse oximeter correct some of the time?’ Without hesitating, I replied, ‘Yes, and someone’s risk is right now at risk.”
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, and after a few weeks of testing, he was there in the NICU, and he looked kind of blue. Five minutes later, he was there in the hospital. I first met Joe Kiani in 1999, and then again a couple of times over the years. I heard from the emergency room when I heard from the emergency room.

When Joe gave Dr. Goldstein a demo of our pulse oximeter, he was just blown away by it. He called me back soon after and said, ‘I think we should buy it!’ And then guided it forward to where it is today—a thriving, leading company with a sight for the future.’”

Mitchell Goldstein

“IN ‘95, I WAS ON CALL when I heard from the emergency room. I was told that the baby didn’t have a heart rate, and 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 too far away. When the baby was on an N200 breathing tube with no response. We had the baby on an N200 pulse oximeter that couldn’t obtain a signal. The baby was not breathing. We measured the electrical reading 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 half an hour away because it was downstairs in the basement. A respiratory therapist had to come upstairs to 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 FDA-approved. We’ve been using it to get real saturations at times when we wouldn’t otherwise see a reading. The dad consented for the baby to be on this oximeter study. This was Masimo technology.”

When I heard from the emergency room, 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.”

Augusto Sola

“I have a good friend who is a neonatologist in São Paulo. Colombia is close to us in the South America, and he was interested in improving neonatal outcomes based on data and implementation of actions into clinical practice. When reviewing data, a lot of fellows and nurses were very frequently turning off oximeters, 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.

When two or three years after, we published the first prospective paper on SpO2 targeting, which was a breakthrough. We showed that first time that with the breakthrough accuracy of SET pulse oximetry, women during delivery with good SpO2, many more babies with birth weight under 1,500 grams could go home without severe retinopathy, and they and their families could look into the future with the emotional and economic burden of life with blindness. That was a revolution. But this was not only an individual issue for babies and families. It was also a social and cultural change 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 Luiz Toc, one of the authors of the study, it is with heartfelt memory that I think and congratulate everyone who made that advancement possible.”
Jack Laserson

Jack became us as 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 every point, he said he’d like to take over the company but said he’d change his mind. He became one of the greatest contributors to the board and great company friend. When we were having touchy feelings with the patent litigation, he spent many days helping us strategize and I’ve been offering great advice for decades.

"OUR COMPANY: THE VERTICAL GROUP is one of the leading medical device venture capital investors. Driven by a strong belief in technology as a tool to help transform healthcare, we invest in high-growth companies that have the potential to redefine the way people live, work, and play. Our team has extensive experience in the healthcare industry, including operations, sales, marketing, and more. We believe in creating long-term relationships with our portfolio companies and helping them succeed, no matter what it takes. We are committed to supporting our portfolio companies in every way we can and believe in the power of teamwork to achieve great things.

In my career, I have always used the greatest successes with companies with a great technological idea. I think that's the most important element. When you do have exceptions to that rule, where I have invested even when I didn't think the business was a great idea, the reason for the myth is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea. The reason for the myth is usually the most important factor is usually the strength of the technological idea.

Robert Coleman

Robert, entrepreneur, had been CEO of another company, sold, and become very wealthy. He asked Jack and me to join the Masimo board of directors when the board kept second-guessing everything. He was doing it not because he was able to crow about other members of the board to Joe on the company as the war rages. When Warburg Pincus tried to take over, Bob found he was out of that. With great experience being on the board of the most successful technology companies, he had always been a valuable supporter.

"1996: EDWARD CHAI, who had now become a fellow Masimo board member for 15 years, told me he had received a copy of a fundraising document from John Laserson and we arranged to get a lawyer for another of the merits of a Masimo investment. I had just completed 27 years as a medical device CEO at the time, and I’d just sold a company called Med Gnosis to Abbott Laboratories. Joe and I formed a relationship and in 1997, I joined the board. I’ve been a mentor ever since. Before the sale to Abbott, you know, you have to be at a trade show event in Hawaii. We were sitting at a shrimp shack getting all in a nautical place in Dubai. We were so worried and said, ‘Well, what’s it going to be to run a public company?’

I said, ‘Joe, I have just recently finished a. In the middle of it, all of a sudden, I was the only shrimp shack, broken down picnic tables, and some chairs chattering on the sand underneath the tables. And the second thing I had is that we have to be better than the other shrimp shack. I have just finished a time that is far greater for the shrimp shack to come.’

"When I was introduced, I was head of the healthcare research group at Alex. Brown & Sons, Inc., and I also owned the healthcare practice. Masimo was looking to raise a private round of financing and wanted Alex. Brown to act as agent. But Alex. Brown to sign us, 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 had an incredible impression with me.

"The only time that Joe and I flew to two steps at a time with everyone was an evening in Chicago. I was flying in from Europe in a week, and Joe was flying in from Southern California. I was scheduled to leave in the evening, but I soon learned that Joe and I flight was delayed. And
celebrating one
1:00 aM for me, having just been in europe. i was tired, and i was to tell him that we should postpone. it was the equivalent of about
flight had still not taken off from orange county, and i called Joe
the delay kept getting longer. at about 7:00 PM chicago time Joe's
chicago, or if so, we'd meet in the morning. about 2:00 aM i was jarred
"i hung up, and went to bed, sure that he would never make it to
nothing was more important than this meeting, and that the pilot
calm, smooth voice, assured me that the time wasn't a problem, that sure Joe would rather just go home and reschedule. but Joe, in that
had a winner because i knew Joe would never give up, ever.

displayed at that meeting and in the hours that led up to it. i knew we
backing. Joe's persistence, passion, patience and salesmanship were all
he had me convinced that Masimo would be successful and worth
Nellcor. by the time he was finished, the sun was coming up and
about Masimo, its technology, and his strategy for competing with
were 11 years from the time that the company first attempted to
private placement process and generated $10 or $15 million. it
the company was probably better off private. even though we
to take Masimo public in June of 1996. the window

while i waS aT

couldn't work with him as a banker any more, but the total support he
every step of the way. Eventually, he became a venture capitalist so we
in beautifully with the advice we got from Jonathan Osgood. Jim
Jim Scopa was the banker whose involvement with Masimo blended
in, and for some, an approximately 200X return, even before the
out to be more than a 10X return for the investors we brought
ultimately happened, i felt like a proud father, but i wasn't there at the birth. Nevertheless, as everybody is aware, that IPO turned
ultimately happened, i felt like a proud father, but i wasn't there
2007, i had already changed careers and come to MPM c apital
part of the dotcom bust. b y the time Masimo went public in

one of our favorite people, ever.

major investment in our company at a very crucial time, making him
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while i waS aT

legal settlement with tyco/Nellcor. So it was a happy day and well
worth the wait.

Lawrence Saper

At Bender and CDS of Datascope, Larry owned angry at our first
meeting because he hated what he had learned about Masimo sooner.
He loved what we were doing when we made our first major FDA
in the U.S. were putting Masimo in their products due to GPO/Nellcor.
Technology, Larry put Masimo into his products and by convincing 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.

"We made another attempt in 2007 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.

"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

give us in every way possible will never be forgotten.

Jim Scopa

Jim Scopa was the banker whose involvement with Alex. Brown
in beautiful with the advice we got from Jonathan Osgood. Jim
became a great friend and assisted 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 support he

 had a winner because i knew Joe would never give up, ever.

...
The小组在审议的过程中提出了许多改进意见，其中包括：

- 改进药品供应链管理，提高效率和灵活性。
- 加强对医院采购行为的监管，防止垄断行为。
- 推动产品创新，提高医疗设备的质量和效果。

这些改进意见得到了许多医疗设备公司的支持，他们认为这些改进将有助于提高医疗质量，同时也有助于降低成本。

此外，小组还提出了许多具体的建议，包括：

- 对医院采购行为进行透明化，公开招标流程。
- 对药品价格进行监管，防止过度定价。
- 加强对药品安全的监管，防止不合格产品流入市场。

这些建议得到了许多医院和医疗设备公司的支持，他们认为这些改进将有助于提高医疗质量，同时也有助于降低成本。
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.

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 the 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 their ‘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.

“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.

“Set® technology is expensive, and we had to compete with far more resources. In the end, Nellcor lost, and the jury made a huge, great decision.”

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. Financial situation that my partners wanted me to withdraw from the case.

“I didn’t want to withdraw, and believe we would win the case. I believed that patient care would suffer if Nellcor’s technology did not make it to the market. And I believe we won this case. Nellcor’s revolutionary technology would never 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 withdraw, 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.”
International Advocates

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

Katsuyuki Miyasaka

Dr. Miyasaka was an anesthesiologist in the National Children’s Hospital in Japan. He did his care, collected a lot of great data, and challenged us to make it better. He urged us to improve pulse oximetry, and, as a result of his help, we developed a Blinded statement: ‘it’s better than what I have seen from your competitors’ which apparently helped the Masimo team a great deal to improve their software. I did this because I saw the potential that 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 it was certainly not easy for him to swallow my rather blunt statement: ‘It’s better than what I have seen from your competitors.’ I took this as a real challenge that ultimately helped Masimo to become better.’

Atsuhiro Sakamoto

Christian rolled up his sleeves, tested our product (when it was in a little blue box) on babies and was good even on cyanotic patients. Even better, he pushed us to complete rainbow®, which was good even on cyanotic patients, which apparently helped the Masimo team a great deal to improve their software. I did this because I saw the potential that was never any money involved. My focus on such an issue as the influence of venous pulsation on motion artifact during pulse oximetry in pediatric patients and the use of clinical data contributed to the improvement of Masimo S Et® technology. The reduction of blood shunts due to motion artifact was of utmost importance in establishing clinician acceptance of pulse oximetry. I believe it’s necessary to perform sufficient safety and reliability analyses for an acceptable clinical device. I find many other issues, such as the importance of noninvasive measurement of hemoglobin and deoxyhemoglobin, 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 PICUs 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

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 deoxyhemoglobin, to be of great interest.

Michael Masimo was an anesthesiologist at the National Children’s Hospital in Japan. I did my care, collected a lot of great data, and challenged us to make it better. He urged us to improve pulse oximetry, and, as a result of his help, we developed a Blinded statement: ‘it’s better than what I have seen from your competitors’ which apparently helped the Masimo team a great deal to improve their software. I did this because I saw the potential that 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 it was certainly not easy for him to swallow my rather blunt statement: ‘It’s better than what I have seen from your competitors.’ I took this as a real challenge that ultimately helped Masimo to become better.’

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"We can only do it by giving them a real choice—it’s not just a matter of trying to find the right product, it’s also about finding the right solution for their particular needs. It’s about listening to their concerns and then working together to find the best way forward. My role is to facilitate this process, to bring together experts from different fields, and to help them come up with innovative ideas that can make a real difference. I believe that by doing this, we can drive progress in healthcare and improve the lives of patients everywhere."

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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 patient outcomes 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 Loma Linda VA

Dr. Shah’s 1991 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 2007 study that showed Masimo SET® continued to have higher sensitivity and specificity than the latest generation of competitive pulse oximetry.

Charles G. Durbin

► Associate Professor of Anesthesiology and Surgery, University of Virginia Health System

Dr. Durbin’s 2010 study in pediatric rotary tibial osteotomy grafts revealed 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, Respiratory and Brain Medicines, Stanford University Medical Center

Dr. Drover’s 2002 study was the first to show that SET® and 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 Perioperative Research Center; Director, Neonatal Clinical Research Center; Scientific Director, Perioperative Research Center, University of Colorado, Denver; Professor of Pediatrics (Neonatology)

In ADDITION to Dr. Hay’s clinical research in early postnatal inflammation, detection of sepsis in low birth weight infants, he is a global expert in the research of maternal applications of pulse oximetry in newborn infants. In 2020, Dr. Hay’s research showed significantly fewer false SpO2 and PR alarms when using Masimo SET® pulse oximetry versus conventional and new-generation pulse oximeters in the ICU.

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 (PV1®) was significantly better than traditional measures used to help clinicians assess fluid responsiveness in mechanically ventilated patients during general anesthesia. After Dr. Cannesson’s study, ten studies have been published on PV1 showing similar results as well as the impact of PV1 on goal-directed fluid management decisions and patient risk.

In addition, PV1 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, Department of Anesthesiology & Perioperative Medicine; Director of the Dartmouth Hospital Patient SafetyNet™; Director of the Institute for Patient Safety

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, Department of Emergency Medicine, Dartmouth-Hitchcock Medical Center; Director, Pediatric Acute Pain Service, Department of Anesthesiology & Perioperative Medicine; Director of the Center for Evidence-Based Anesthesia; Medical Director for Perioperative Quality

In 2013, Dr. Ehrenfeld’s 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 intravenous 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 protocol could help clinicians identify many cases of carbon monoxide poisoning that were previously reported as no exposure. 100 poisoning cases for an estimated 50,000 ED visits in the U.S. annually. Dr. Roth’s study means that an additional 24,000 patients may have carbon monoxide poisoning, but are undiagnosed.
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 Masimo patient safety and delivery technology to support various activities designed to improve patient safety and delivery technology to support various activities designed to improve patient safety and delivery technology. 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 healthcare. I’ve served on the boards of more than thirty 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 felt 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, now to another quarter century of success!
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.”
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
SOLVING THE UNSOLVABLE
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.

Conventional pulse oximetry works under the assumption that by looking at only the pulse and normalizing the pulsating signal over the non-pulsating signal, oxygen saturation (Spo2) can be 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 Spo2 readings and pulse rates – causing false alarm rates as high as 90% in ICU and recovery rooms.

Conventional pulse oximetry uses the standard red over infrared algorithm to provide Spo2, while Masimo SET® 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 Spo2 (left peak shown in blue) from the true arterial Spo2 components (right peak shown in red) in the signal. The plot peak on the right is then chosen as the Spo2 value, since the physiologically higher Spo2 value within the measuring site will always be arterial signal.

SIGNAL EXTRACTION TECHNOLOGY®

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

EVALUATION AND ANALYSIS

POST PROCESSOR

0
10
20
30
40
50
60
70
80
90
100

HbO2

Evaluation
PST®

SST®

MST®

DST®

Oxyhemoglobin

Deoxyhemoglobin

Pulse

System

Steady State

Motion

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

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.1

**MISSLED TRUE ALARMS AND SENSITIVITY DURING CHALLENGING CONDITIONS**

<table>
<thead>
<tr>
<th>Device</th>
<th>Sensitivity</th>
<th>Missed True Alarms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nellcor N-600</td>
<td>97%</td>
<td>3%</td>
</tr>
<tr>
<td>Masimo SET®</td>
<td>43%</td>
<td></td>
</tr>
</tbody>
</table>

**FALSE ALARM RATES AND SPECIFICITY DURING CHALLENGING CONDITIONS**

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

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 – DS t®, FS t®, SS t™, and MST® – to separate the arterial signal from sources of noise (including the venous signal) to measure SpO2 and pulse rate accurately, even during the so-called challenging conditions of motion and low perfusion.

**UNLEASHING BREAKTHROUGH PERFORMANCE**

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The choice of clinicians in the world’s leading hospitals
Because of its unmatched reliability during challenging conditions of motion and low perfusion, clinicians at thousands of institutions around the world count on Masimo Set® every day to help them care for patients. And while 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, clinicians can intervene earlier to improve patient outcomes and improve patient safety.1

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.

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"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

A total of 70 volunteers were tested with respiratory hand motions. Each oximeter was characterized at rapid breathing (50 breaths per minute) and hypoxia (SpO₂ 90%). Sensitivity was defined as the ability to detect a true SpO₂ < 90%.

Specificity was defined as the ability to detect a true SpO₂ > 90%.

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

**NEWBORN SCREENING WITH MASIMO SET**

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

HELPING CLINICIANS SCREEN 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 (CCHD) deaths occurring in the first year of life are unrecognized at postnatal discharge. Masimo SET® pulse oximetry has been shown to initially alert clinicians to screening for critical congenital heart disease (CCHD) by the US Secretary of Health and Human Services to add Motion-Tolerant pulse oximetry to the Recommended Uniform Screening Panel for newborns. Masimo SET® pulse oximeters and sensors meet the recommended criteria for newborn screening, were exclusively used in the two studies that were the basis for the US CCHD workgroup decision to recommend newborn screening, and were the first to receive FDA 510(k) clearance with labeling for CCHD screening.

HELPING CLINICIANS REDUCE RETINOPATHY OF PREMATUREITY

Premature infants requiring severe 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.

REDUCTION OF ROP WITH MASIMO SET

**SEVERE RETINOPATHY OF PREMATURITY (ROP) RATE**

<table>
<thead>
<tr>
<th>Center</th>
<th>Period 1 (per 1,000 babies)</th>
<th>Period 2 (per 1,000 babies)</th>
<th>Period 3 (per 1,000 babies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>12% with Nellcor</td>
<td>5% with Masimo</td>
<td>4% with Masimo</td>
</tr>
<tr>
<td>B</td>
<td>13% with Nellcor</td>
<td>13% with Masimo</td>
<td>6% with Masimo</td>
</tr>
</tbody>
</table>

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In period one, the baseline rate for severe ROP in two centers, both using Nellcor pulse oximeters, 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%).

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.

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 in hospitals to supplement the standard Apgar score to assess general newborn health.

Masimo SET® is pending CE Mark. Not currently available in the U.S.
**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. 1-3 Conventional approaches to alarm management were developed primarily 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® helped reduce both past false alarms by over 50%. 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 1%. 

**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.

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. 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 1%.

**3D Desat Index Alarm** helps clinicians detect multiple transient desaturation events that may indicate patient distress. 5 A low Spo2 alarm limit is 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. 6, 7 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).

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

**ADAPTED THRESHOLD ALARM**

When standard Spo2 and pulse rate alarms can sometimes provide a signal of deteriorating patient conditions, Masimo advanced 3D alarms give you another dimension of advanced notification of parameter conditions that may precede clinically 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 1%.

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**PROVIDING EARLIER NOTIFICATION OF POTENTIAL RISK WITH ADVANCED ALARMS**

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**Figure 1: Adaptive Threshold Alarm Example**

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

**Figure 2: 3D Desat Index Alarm Example**

3D Desat Index Alarm helps clinicians detect multiple transient desaturation events that may indicate patient distress. 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).

**Figure 3: 3D PI Delta Alarm Example**

3D Perfusion Index Delta Alarm helps clinicians quickly detect critical changes in peripheral perfusion. 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).
Masimo's newest innovations demonstrate that our commitment to pulse oximetry technology has never been stronger.

**FIRST EVER NONINVASIVE FRACTIONAL SPO2 MEASUREMENT**

Utilizing more than seven wavelengths of light and breakthrough signal processing, Masimo rainbow® Pulse co-oximeters can measure and display oxygen content (SpO2™), along with its components, hemoglobin and fractional arterial oxygen saturation (SpfO2). This is the first truly fractional, noninvasive oxygen saturation measurement (SpfO2). SpfO2 allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins – common throughout the hospital and pre-hospital settings – as compared to functional oxygen saturation (SpO2). As a result, SpfO2 helps enable earlier interventions and more timely therapeutic decisions. For example, in a patient who is a smoker with an SpO2 of 97%, carboxyhemoglobin level of 12%, and methemoglobin of 1%, if SpfO2 were available, it would be displayed at 84%. It is well accepted that clinicians would frequently make different diagnostic and therapeutic decisions at an oxygenation of 84% versus 97%.

**TFa-1™ DISPOSABLE FOREHEAD SENSOR**

Expanding its versatility of sensors, Masimo now offers the TFa-1 transflectance forehead adhesive sensor as an alternative to traditional digit sensors. The forehead provides rapid detection of saturation changes compared to digit sites during low perfusion and offers easy access during surgery, resuscitation, and in patients with finger deformities or when the digit is not accessible.

**X-CAL™ TECHNOLOGY FOR ENHANCED PATIENT SAFETY**

Masimo has implemented a new technology called X-Cal in its sensors, cables, and monitors to increase patient safety and improve clinical 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. Illegible Masimo sensors and cables
2. Cables and sensors used for beyond their expected life
3. Third-party reverse-engineered pulse oximetry sensors

**HOW X-CAL WORKS**

X-Cal seamlessly integrates into Masimo sensors, cables, and circuit boards and is provided as no additional cost to end-users. X-Cal can detect in-use cables and sensors and measures the actual 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 is not asserted outside of active patient monitoring to avoid disruption to clinical practice. For example, if the end of a single-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. The next re-application of the same sensor, the monitor will display a message to advise the clinician to replace the sensor.

X-Cal™ Technology for Enhanced Patient Safety

1. SENSOR
2. CABLE
3. MONITOR

Masimo Set® Measure-through Motion and Low Perfusion™ pulse oximetry has three system components: 1) the sensor that connects to the patient; 2) the patient cable that connects the sensor to the Masimo circuit board in the monitor; 3) the circuit board (SET® SpO2 or rainbow® Pulse CO-oximetry) installed in a multi-parameter patient monitor or Masimo pulse oximeter.
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 TRANSFUSION

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. While blood loss during surgery is a known risk factor, RBC transfusion overuse can increase patient risk and the cost of care. A 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) compared to those who did not receive RBC transfusions. Multiple randomized controlled trials indicate that restrictive transfusion practices — those in which significantly lower hemoglobin triggers are used to determine need for transfusion — are safe. In addition, the cost of each RBC unit is estimated between $522 and $1,183 per unit, without including morbidity-associated costs. Beyond the cost of transfusion, each RBC unit transfused is associated with increased cost of care and transfusions that occur at higher hemoglobin levels increase the cost of care more than those given at lower hemoglobin levels. With the growing recognition of the need to reduce transfusions, noninvasive and continuous hemoglobin (SpHb) can be a key tool to help clinicians overcome the limitations of existing approaches, although SpHb monitoring is not intended to replace laboratory 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

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

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. 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. With SpHb monitoring, you can help drive the decision to transfuse, and in some cases avoid unnecessary transfusions.

Continuous hemoglobin trend monitoring 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

- Frequency of Intraoperative Blood Transfusions
  - Standard Care Group: 4.5%
  - SpHb Group: 0.6%
  - Reduction: 87%

SpHb Helped Clinicians Decrease the Time to Transfusion, When a Transfusion is Truly Indicated

- Average RBC Units Transfused Per Patient
  - Standard Care Group: 0.4%
  - SpHb Group: 0.1%
  - Reduction: 90%

Range of Potential Blood Cost Savings Per Patient with SpHb Monitoring

- Projected SpHb Savings
  - Low Blood Loss Surgery: $218
  - High Blood Loss Surgery: $1,085

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.

- In lower blood loss surgery, the 0.09 lower RBC units per patient with SpHb monitoring is projected to reduce RBC costs by $47 to $106 per patient monitored.
- In higher blood loss surgery, the 0.90 lower RBC units per patient with SpHb monitoring is projected to reduce RBC costs by $470 to $1,065 per patient monitored. 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.
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.** BLEEDING IS CONSIDERED A SIGNIFICANT RISK FACTOR FOR PATIENTS, AND LATE DETECTION FURTHER INCREASES RISK AND COST. 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.

**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 it is only assessed intermittently and requires a blood draw and laboratory analysis. 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.

**“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 signals undetected bleeding through a dramatic drop in hemoglobin over a 5-minute period.

**POTENTIAL FOR EARLIER IDENTIFICATION OF FALLING HEMOGLOBIN VALUES**

<table>
<thead>
<tr>
<th>Hb Value (g/dL)</th>
<th>Standing lab order</th>
<th>19</th>
<th>18</th>
<th>17</th>
<th>16</th>
<th>15</th>
<th>14</th>
<th>13</th>
<th>12</th>
<th>11</th>
<th>10</th>
<th>Blood transfusion initiated</th>
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The results of an independent study conducted in a surgical intensive care unit illustrate the variation that can be expected between hemoglobin device methods. A total of 471 hemoglobin measurements were evaluated from 62 patients. Noninvasive and continuous hemoglobin (SpHb), a satellite laboratory CO-oximeter (Siemens RapidPoint 405), and a point-of-care device (HemoCue 301) were all compared to reference hemoglobin from the central laboratory hematology analyzer (Sysmex Xt2000i).

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

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.
Fluid administration is one of the most common hospital interventions. Although it is critical to improve patient status and enabling end organ preservation, unnecessary fluid administration is associated with increased morbidity and mortality. 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.

**Helping Assess Fluid Responsiveness with PVi**

Masimo®’s pulse oximetry technology has the unique ability to also provide dynamic fluid responsiveness variables called path variability index (PVi) that is similar to SVV and PPV but PVi is noninvasive. PVi is displayed in the same monitor and obtained with the same sensors as are used for Masimo SET® pulse oximetry or Masimo SET® haemodynamic monitoring with respect to its experimental procedural cost. PVi has been shown to help clinicians assess fluid responsiveness in mechanically ventilated patients under general anaesthesia during surgery2-5 when in stable and critical care settings, PVi is a reliable estimator for fluid responsiveness in intensive care unit patients in early stages of shock in the emergency department.6

**Helping Improve Fluid Management with PVi**

PVi has also shown allows to improve fluid management compared to standard care in two randomized controlled trials, reducing intraoperative fluid infused and intraoperative lactate levels.7 Moreover, in addition, compared to goal-directed therapy with invasive dynamic monitoring technologies (PPV and SVV), goal-directed therapy with PVi showed similar fluid management decisions and patient outcomes in two randomized controlled trials.8-10 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 per patient and median length of stay was reduced by 2 days.19

**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 2013, the United Kingdom’s National Health Service (NHS) included PVi in the Inter-Operative Fluid Management Path, which serves as a guide for hospitals implementing fluid responsiveness monitoring to improve patient outcomes.10 In 2015, the World Congress for Anesthesiologists and the International Congress for Anaesthesia and Intensive Care (ESICM) added PVi to its guidelines for optimal hemodynamic management of surgical patients.11

**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) Protocol, fluid was shown to help reduce 30-day hospital costs by $2,867 per patient and reduce median length of stay by 2 days.19

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**AIDING CLINICIAN ASSESSMENT OF FLUID RESPONSIVENESS AND FLUID MANAGEMENT WITH PVi**

**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 (SVR) 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 12 days. Depending on the morbidity rate of the patient population, goal-directed fluid management with dynamic monitoring technologies is estimated to save between $880 to $17,000 per patient. While these technologies have been shown to improve clinical and cost outcomes, they are invasive and/or complicated and are therefore underutilized and still only justified for the highest risk patients.12 As a result, many patients who could benefit from goal-directed fluid management are not receiving it.
Pulse oximetry (SpO2) provides noninvasive and continuous visibility to arterial blood oxygenation in hypoxia (less than normal oxygenation) and normoxia (normal oxygenation). During supplemental oxygen administration, clinicians often use the partial pressure of oxygen (PaO2), which is invasive and intermittent, to monitor levels of hyperoxia (higher than normal oxygenation). Between invasive sampling, changes in PaO2 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 (PaO2 of approximately 100 to 200mmHg). Ori is intended to supplement, not replace, SpO2 monitoring and PaO2 measurements. As an “index” parameter with a unit-less scale between 0.00 and 1.00, Ori can be trended and has optional alarms to notify clinicians of changes in a patient’s oxygen reserve. 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.

In utilizing Ori the researchers noted mean of 40 sec advance alarm before SpO2 reached 98% and about 52 seconds advance alarm before the patients reached 90% SpO2.

AT THE ROOT OF TRANSFORMING PATIENT CARE
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.

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

**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.

**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.
The Mobility of Patient Monitoring and Assessment
Studies have shown that patient mobility is a key factor in more rapid patient recovery. 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 (Spo2) 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 alarms2, 3
- Respiration rate monitoring through either rainbow Acoustic Monitoring™ for acoustic respiration rate (RRa®) or through the plethysmograph waveform (RRp™*) to identify respiratory depression or tachypnea3
- Noninvasive and continuous hemoglobin (SpHb) monitoring with rainbow® Pulse co-oximetry to help clinicians detect bleeding earlier, avoid unnecessary blood draws, and optimize transfusion decisions.

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 Power of Masimo Breakthrough Measurements in a Patient-Worn Monitor

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

**FLEXIBLE MEASUREMENT EXPANSION IN ROOT WITH MASIMO OPEN CONNECT**

**EXPANDING MASIMO MEASUREMENTS**

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

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 is not currently available in the U.S.
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. 1

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

David Drover, MD
Stanford University Hospital, Stanford, CA

O3™ regional oximetry uses near-infrared spectroscopy (NIRS) and reflectance pulse oximetry to enable simultaneous monitoring of tissue oxygen saturation (rSo2) in the brain and arterial blood oxygenation (Spo2).

O3™ MONITeRING

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

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. 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 rSo2 and Spo2, taken from either the O3 sensor or from the Radical-7 docked in Root.

“Masimo O3 Regional Oximetry will have the unique ability to measure both rSO2 and Masimo SET® SpO2 pulse oximetry simultaneously from the same forehead sensor. This may provide the anesthesiologist or perfusionist for the first time with a differential analysis of cerebral 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
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.

**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.
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 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 of integrating and validating custom HL7 implementations, and demonstrates Masimo’s commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture.

Despite huge advances in medical technology, the lack of device communication and integration creates risks to patient safety in hospitals around the world. Existing approaches for device interoperability require separate hardware, software, and/or network infrastructure, which can clutter the patient room, burden IT management, and increase the complexity and cost of care. Root with Iris offers a built-in connectivity gateway that can integrate multiple standalone devices such as IV pumps, ventilators, beds, and other patient monitors. Iris allows device information to be remotely viewed with Patient SafetyNet, transmitted through notification systems or to electronic health record (EHR) systems to the clinical better patient care and meaningful use, and eventually displayed on Root at the point of care to facilitate decision support.

IRIS® INTEGRATION PLATFORM®

IRIS® INTEGRATION PLATFORM®

Through Iris, Root is designed to provide built-in integration to multiple standalone devices, including IV pumps, ventilators, beds, and other patient monitors.

Device connectivity with Iris is designed to leverage existing network infrastructures and reduce costs while enhancing workflows and decision support to improve patient safety, whether the clinician is at the bedside, down the hall, or across the globe.
ENHANCING PATIENT SAFETY THROUGHOUT THE HOSPITAL
Helping Protect Patients From Hidden Dangers With SpMet®

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 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.

Medications Known to Cause Methemoglobinemia

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

Prevalence of Methemoglobinemia

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

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.

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.

"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

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

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.1 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.

**RAINBOW ACOUSTIC MONITORING™** Continuously monitors respiration rate on the rainbow® platform’s pulse oximetry platform, providing additional information to existing pulse oximetry data.

RAINBOW ACOUSTIC MONITORING™, the audio sensor, is water-resistant and reusable, and provides clinical measurements from sound.

RAINBOW ACOUSTIC MONITORING™ provides noninvasive and continuous respiration rate that has been shown to be accurate, easy-to-use, and enhances patient compliance.2 Acoustic Respiration Rate (RRa) may help clinicians reliably and continuously assess breathing—facilitating earlier detection of respiratory compromise and patient distress—allowing more patients to be monitored, more safely than ever before.

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

RAINBOW ACOUSTIC MONITORING™ and acoustic Respiration Rate (RRa) provide the ability to detect respiratory pauses and is well-tolerated.

**Sensitivity**

| Sensitivity (respiratory pause detected when actual respiratory pause occurs) | 62% | 81% |

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

**Capnography** (Orion Capnostream 20)

**rainbow Acoustic Monitoring**

**Masimo rainbow Acoustic Monitoring™ v7R04**
Halo index™ enables assessment of patient status
Halo Index is a new indicator for cumulative trending assessment of the global patient status. Physiologic deterioration often occurs long before a patient crisis and manifests through subtle and often undetected changes in multiple physiologic parameters. Masimo designed Halo Index to mimic the systematic approach that expert clinicians use in assessing patient physiologic deterioration – analyzing the patient history and extracting key vital sign parameter characteristics to assess global patient status. Halo Index currently uses available Masimo parameters but is scalable to include additional information from the patient data repository. Each parameter's significance is weighted and combined into the Halo Index, a single displayed number with a range from 0 to 100 that provides a cumulative trending assessment of global patient status. Increases in Halo Index suggest physiologic deterioration and may indicate a need for clinicians to more closely assess the patient.

In 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.1 Patient SafetyNet – combined with Masimo SET® pulse oximetry and rainbow Acoustic Monitoring™ or standard capnography – offers a clinically proven, cost-effective approach to continuous postoperative monitoring with high nursing satisfaction and patient compliance.

HELPING IMPROVE OUTCOMES ON MEDICAL-SURGICAL FLOORS WITH MASIMO PATIENT SAFETynet

In this example, Halo Index can display actual parameter values (above) or color-coded alarm states (left), which allows more patients to be viewed simultaneously on screen.

0 Patients Suffered Brain Damage or Died Over a 5-year Period†
65
Reduction in Rapid Response Team Activations
56
48
Reduction in ICU Transfers
76
1.48
Annual Cost Savings

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 quality of these patients' care an elusive goal. In the last decade, Masimo SET® has shown its robustness in improving the process of care in intensive and pediatrics patients due to its Measure-through Motion and Low Perfusion™ performance. However, a landmark study in 2010 showed that Masimo SET® also improves clinical outcomes in adults. After implementing Masimo SET® 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 parameter-based by 66% and ICU transfers by 46%, and saved $144 million annually. In addition, there were zero brain-damaged patients over a 5-year period, as just a pulse oximeter has become a standard of care in the OR, PACU, and ICU, we now believe that Measure-through Motion and Low Perfusion™ pulse oximetry will become a standard of care on the general floor. With Masimo technologies on the general floor, clinicians can be confident their patients are being watched even when they aren't at the bedside, while families can be assured their loved ones are receiving maximum protection.

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. Mean monthly reductions in rapid response activations, from 9.4 ± 4.5 to 3.2 ± 2.7 per 1,000 patient discharges, and in ICU transfers, from 4.6 ± 2.7 to 2.6 ± 2.2 per 1,000 patient days after implementation, resulted in annual opportunity cost savings of $1.48 million and 25% fewer activations of the rapid response team, respectively, during the study period and future years (right).

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

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*. If no clinician is in the room, the patient and family may be best served with a device alarm status with a green, yellow, or red color indicating device alarm status.

MyView empowers clinicians to see things their way.

* Halo index is CE Marked. Currently not available in the U.S.
EXPANDING OUR IMPACT BEYOND THE HOSPITAL
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.”

"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

"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
Montréal Children’s Hospital, Montréal, Canada

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

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.
**Quick and Noninvasive SpHb and Spo2 Assessment**

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-checks into any clinician’s hands in almost any environment, including hospitals, clinics, blood donation centers,* and emergency medical services.

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

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* 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.
“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.”

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

EMMA™ — EMERGENCY MAINSTREAM ANALYZER

Capnography measures carbon dioxide (CO2) concentrations in expired gases. They are used during anesthesia, emergency care, and intensive care—where capnography is often used as a substitute for blood gas measurement or to monitor the performance of assisted ventilation. EMMA™ is a compact, portable, lightweight mainstream capnograph that requires virtually no warm-up time with full accuracy in 15 seconds. The continuous 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). Its primary use is short-term monitoring of end-tidal CO2 and respiration rate in adults, pediatric, and infant patients.

EMMA fits onto a breathing circuit, facilitating CPR.
HELPING CLINICIANS IDENTIFY CARBON MONOXIDE POISONING WITH SpCO

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

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 30,396 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.2

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.3

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Helping clinicians identify carbon monoxide poisoning with SpCO

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"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

SAYING 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 also helps 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.4,5

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.6 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.

"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, Champaign (Ill.) Fire Department

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

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.

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.

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“iSpo2® is the world’s first pulse oximeter for iOS and Android mobile platforms. Combining Masimo’s “board-in-cable”, reusable on disposable sensors, and an application running on a smartphone or tablet device, iSpo2™ feature Masimo’s proven Measure-through Motion and Low Perfusion™ pulse oximetry – SpO2, pulse rate, and perfusion index.

“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

“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.

Leading the mHealth Revolution
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 (SpO₂) and pulse rate (PR) monitoring, particularly in the most challenging conditions of motion and low perfusion. 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% of these deaths are related to cardiovascular or respiratory problems.1 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.2

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**Masimo SET® 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-1 Tip-Cap Ear Sensor is suited for animals over 30 kg.

LOOKING FORWARD TO THE NEXT 25 YEARS
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.

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 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.

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

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 U.S. 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.
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.

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.

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

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 debate: empathy and love.

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 love but not least, 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
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 McClanahan, 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
RAINBOW® pulse CO-oximetry and acoustic monitoring
- carboxyhemoglobin (SpCO®)
- Methemoglobin (SpMet®)
- total Hemoglobin (SpHb®)
- oxygen content (SpO2®)
- Fractional oxygen Saturation (SpfO2™)
- oxygen Reserve index (oRI™)

Plus all Masimo SET® measurements

rainbow® acoustic monitoring™
- acoustic Respiration Rate (RRa®)

Brain Function monitoring
- Patient State index (PSi)

Measure-through Motion and low Perfusion™ pulse oximetry
- Functional oxygen Saturation (SpO2)
- Pulse Rate (PR)
- Perfusion Index (Pi)
- Pleth Variability index (PVi®)

Capnography and Gas Monitoring
- End-tidal Carbon Dioxide (etCO2)
- Fractional concentration of inspired Carbon Dioxide (FiCO2)
- Respiration Rate (RR)
- Minimum Value (Min)
- Drug (Drug)
- Inhalation Anesthetic Agent Identification (Agent ID)

TECHNOLOGIES AND PRODUCTS

MONITORS
- Pronto®
- Rad-8V
- Rainbow®
- Rainbow® iM
- Rainbow®
- Rainbow® iD
- Radical-7
- Masimo SET®
- Root®

RAINBOW®
- Functional oxygen Saturation (SpO2)
- Pulse Rate (PR)
- Perfusion Index (Pi)
- Pleth Variability index (PVi®)
- Respiratory Rate (RR)
- Minimum Value (Min)
- Drug (Drug)
- Inhalation Anesthetic Agent Identification (Agent ID)

TECHNOLOGIES AND PARAMETERS

rainbow® acoustic monitoring™
- Acoustic Respiration Rate (RRa®)

Brain Function Monitoring
- Patient State Index (PSi)

Capnography and Gas Monitoring
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EXTERNAL MEASUREMENT TECHNOLOGIES

CIRCUIT BOARDS
- MS-2013
- MS-2040
- M4-S

SENSORS
- Masimo SET® Sensors
- MightySat® Sensors
- iS™ Sensors
- o3™ Sensors

CANNULAS AND ADAPTERS
- Nomoline™
- Nasal Cannula
- Mainstream Adapter

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

NEW TECHNOLOGY INTRODUCED
- See Regulatory Notice

RAINBOW®
- Functional oxygen Saturation (SpO2)
- Pulse Rate (PR)
- Perfusion Index (Pi)
- Pleth Variability index (PVi®)

Masimo SET® Sensors
- Spo2, PR, Pi, PVi
- SpHb®, SpO2, PR, Pi, PVi

rAINBOW®
- Functional oxygen Saturation (SpO2)
- Pulse Rate (PR)
- Perfusion Index (Pi)
- Pleth Variability index (PVi®)
- Respiratory Rate (RR)
- Minimum Value (Min)
- Drug (Drug)
- Inhalation Anesthetic Agent Identification (Agent ID)

TECHNOLOGIES AND PARAMETERS

rainbow® acoustic monitoring™
- Acoustic Respiration Rate (RRa®)

Brain Function Monitoring
- Patient State Index (PSi)

Capnography and Gas Monitoring
- End-tidal Carbon Dioxide (etCO2)
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- Drug (Drug)
- Inhalation Anesthetic Agent Identification (Agent ID)
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.
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.

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      - Korakuen Bldg.
      - 17F
      - 1-4-1, Koishikawa, Bunkyo-ku
      - Tokyo 112-0002
      - Japan
      - Tel: +81-3-3868-5201
  - Australia
    - Suite 3, Building 7
      - 49 Frenchs Forest Rd.
      - Frenchs Forest, NSW 2086
      - Australia
      - Tel: +61-2-9452-3763

**International Operations**
- **CORPORATE HEADQUARTERS**
  - 50 Discovery Irvine, CA 92618 USA
  - Tel: 949-297-7000

- **INTERNATIONAL HEADQUARTERS**
  - 200 North 5650 West
  - Salt Lake City, UT 84120 USA
  - Tel: 435-251-1150

**Manufacturing Centers**
- **U.S. MANUFACTURING**
  - Irvine, CA 92618 USA
- **MEXICO MANUFACTURING**
  - Manzana 9, Masismo 21395 Mexico

**OEM Partners Worldwide**
- **6 Continents Have Masimo Technologies**

**Subsidiaries**
- **Masimo Distributors**
- **Masimo OEMs**
## FINANCIALS

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
<td>$556,764</td>
<td>$517,429</td>
</tr>
<tr>
<td><strong>Royalty</strong></td>
<td>29,879</td>
<td>29,816</td>
</tr>
<tr>
<td><strong>Total revenue</strong></td>
<td>586,643</td>
<td>547,245</td>
</tr>
<tr>
<td><strong>Cost of goods sold</strong></td>
<td>195,864</td>
<td>188,418</td>
</tr>
<tr>
<td><strong>Gross profit</strong></td>
<td>$390,779</td>
<td>$358,827</td>
</tr>
<tr>
<td><strong>Operating expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selling, general and administrative</td>
<td>241,016</td>
<td>215,469</td>
</tr>
<tr>
<td>Research and development</td>
<td>56,581</td>
<td>55,631</td>
</tr>
<tr>
<td>Litigation award and defense costs</td>
<td>(10,331)</td>
<td>8,010</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>287,266</td>
<td>279,110</td>
</tr>
<tr>
<td><strong>Operating income</strong></td>
<td>$103,513</td>
<td>$79,717</td>
</tr>
<tr>
<td><strong>Non-operating expense</strong></td>
<td>1,472</td>
<td>3,981</td>
</tr>
<tr>
<td>Income before provision for income taxes</td>
<td>$102,041</td>
<td>75,726</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>27,678</td>
<td>20,005</td>
</tr>
<tr>
<td><strong>Net income including noncontrolling interest</strong></td>
<td>$74,363</td>
<td>$55,721</td>
</tr>
<tr>
<td><strong>Net income (loss) attributable to noncontrolling interest</strong></td>
<td>(1,845)</td>
<td>(2,660)</td>
</tr>
<tr>
<td><strong>Net income attributable to Masimo Corporation stockholders</strong></td>
<td>$72,518</td>
<td>$58,381</td>
</tr>
<tr>
<td><strong>Net income per share attributable to Masimo Corporation stockholders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>$1.33</td>
<td>$1.03</td>
</tr>
<tr>
<td>Diluted</td>
<td>$1.30</td>
<td>$1.02</td>
</tr>
<tr>
<td>Weighted-average shares used in per share calculations:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>54,708</td>
<td>56,690</td>
</tr>
<tr>
<td>Diluted</td>
<td>55,571</td>
<td>57,480</td>
</tr>
</tbody>
</table>
## Balance Sheet

### Current Assets
- Cash and cash equivalents: $134,453
- Accounts receivable, net: $71,017
- Inventories: $69,718
- Prepaid income taxes: $417
- Other current assets: $21,471

### Non-Current Assets
- Long-term debt: $125,145
- Other assets: $7,485

### Total Assets
$565,006

### Current Liabilities
- Accounts payable: $38,045
- Accrued compensation: $33,600
- Accrued liabilities: $24,541
- Income taxes payable: $6,562
- Deferred revenue: $21,067

### Non-Current Liabilities
- Long-term debt: $125,145
- Other liabilities: $7,737

### Total Liabilities
$257,265

### Equity
- Masimo Corporation stockholders' equity:
  - Common stock: $52
  - Treasury stock: $(185,906)
  - Additional paid-in capital: $288,686
  - Accumulated other comprehensive (loss) income: $(2,093)
  - Retained earnings: $205,260

- Noncontrolling interest: $1,742

### Total Equity
$305,999

### Total Liabilities and Equity
$565,006

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## Financial Statements

### Net Income Including Noncontrolling Interest
- January 3, 2015: $74,363
- December 28, 2013: $55,721

### Operating Activities
- Depreciation and amortization: $12,818
- Share-based compensation: $11,005
- Loss on disposal of property and equipment: $3,353
- Provision for doubtful accounts: $583
- Benefit from deferred income taxes: $320
- Income tax benefit from exercise of stock options granted prior to January 1, 2006: $264
- Excess tax deficit from share-based compensation arrangements: $396
- Changes in operating assets and liabilities:
  - Decrease (increase) in accounts receivable: $4,862
  - Increase in inventories: $(13,434)
  - Increase in deferred cost of goods sold: $(5,888)
  - Decrease (increase) in prepaid income taxes: $3,316
  - Increase in other assets: $(2,619)
  - Decrease (increase) in accounts payable: $(1,375)
  - Increase in accrued compensation: $4,948
  - Increase in accrued liabilities: $1,837
  - Increase in income taxes payable: $(3,003)
  - Increase in deferred revenue: $199
  - Increase (decrease) in other liabilities: $227

### Net Cash Provided by Operating Activities
$95,459

### Investing Activities
- Purchases of property and equipment: $(78,414)
- Proceeds from issuance of common stock: $4,680
- Excess tax deficit benefits from share-based compensation arrangements: $(396)
- Increase (decrease) in cash and cash equivalents: $38,987

### Financing Activities
- Borrowings under revolving line of credit: $125,000
- Repurchases of common stock: $(102,453)
- Net Cash Provided by (used in) Financing Activities: $26,246

### Net Increase (Decrease) in Cash and Cash Equivalents
$38,987

### Cash and Cash Equivalents at Beginning of Period
$95,466

### Cash and Cash Equivalents at End of Period
$134,453

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## Footnotes

- **Notes to the Financial Statements**
- **Supplementary Data**
- **Capitalization**
- **Other Information**
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 our “Risk Factors” section of our most recent periodic reports filed with the Securities and Exchange Commission (“SEC”) including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, all of which you may obtain for free on the SEC website at www.sec.gov. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. 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.