

Automating Care





## Automating Care



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# Reflecting on the Past and Defining the Future

## Looking Back

I founded Masimo in 1989, nine years later we launched Masimo SET® worldwide, and nine years after that, in August 2007, we took Masimo public. From the beginning, we took a long-term view, developing products and only launching them when we believed they would make a clinical difference. With a clear and consistent strategy, we remained relentlessly focused on execution, no matter what obstacles and hurdles were thrown in front of us. Today, Masimo's technologies help clinicians take better care of over 100 million patients a year, and the exceptional impact our revolutionary technologies have had on patient care throughout the world has created significant shareholder value.

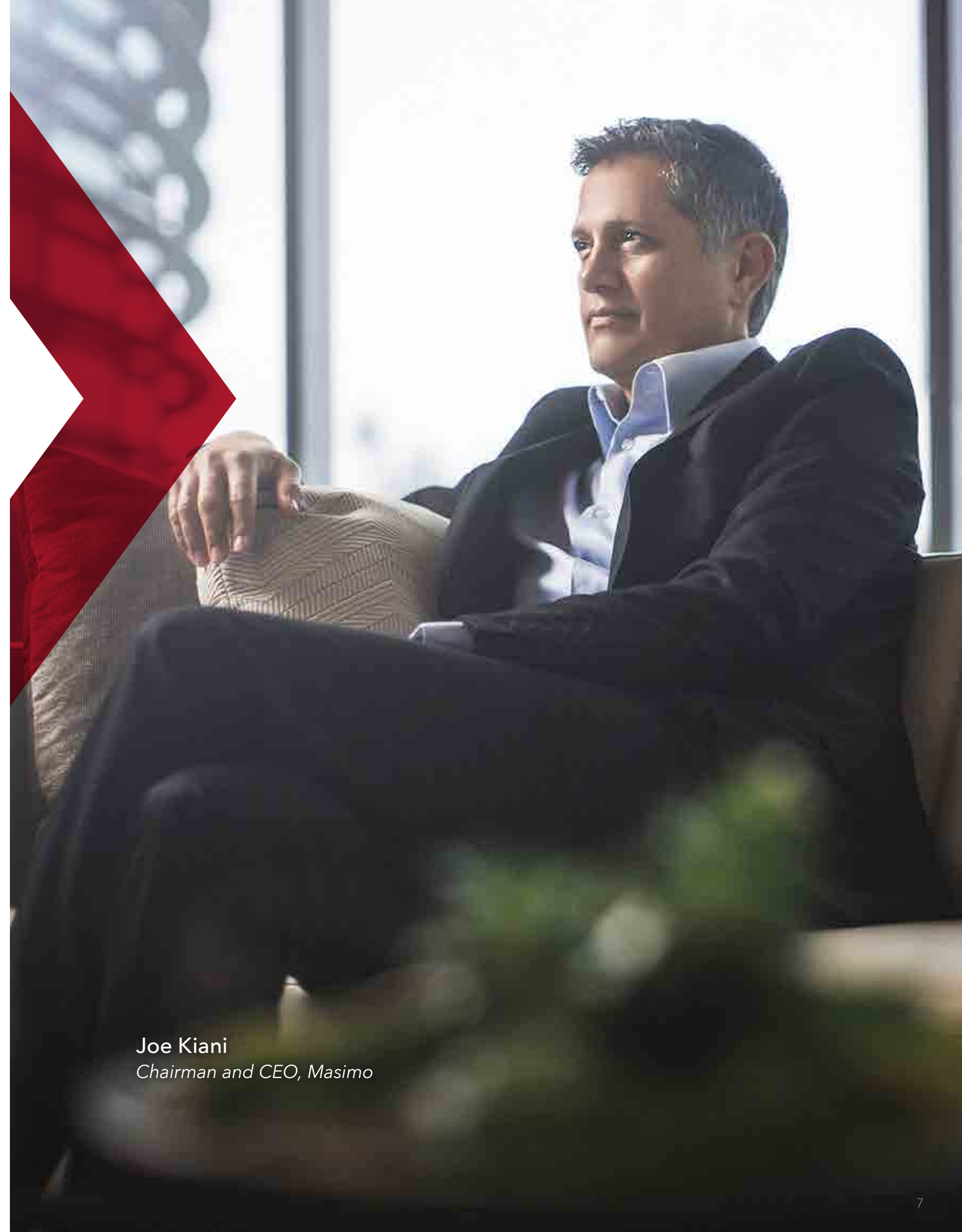
2017 marked the end of our ten-year, post-IPO plan. One of our many 2017 accomplishments was record hospital-wide pulse oximetry contract

bookings. While this alone is great news for you, our shareholders, you will be delighted to hear the feedback I received from one of our largest customers, who in 2017 renewed their system-wide pulse oximetry agreement with us. When I called to thank their chief medical stakeholder, she said "We are happy to renew our agreement with Masimo because Masimo is advancing medicine at an unprecedented rate, and we are just trying to keep up with it." She added, "Your service is also the best, bar none, and your prices are competitive." Perhaps I could end my letter with this because it truly says it all, but I want you to know this feedback did what our customer may have intended – drive us to double down on innovation that will advance medicine, double down on the level of service we provide, and double down on treating our customers fairly, helping them to improve patient outcomes and reduce cost of care.

Today, Masimo technologies save countless lives as they touch over 100 million patients every year, or about 3 patients every second<sup>1</sup>



Joe Kiani  
Chairman and CEO, Masimo



## Looking Forward

In the coming years, we will remain committed to the same guiding principles that have served us well for 29 years, while expanding our mission to focus on improving patient outcomes and reducing the cost of care through any possible means. We will continue to advance technology and products in our core business of noninvasive monitoring while also expanding our portfolio into new markets. Our growth will be driven by internal R&D, and we will look for unique opportunities to supplement those efforts with external licensing and acquisitions. In doing so, we will leverage our strengths in signal processing, systems theory, clinical research, and manufacturing. With steadfast adherence to our guiding principles, we will expand our opportunities, deepen our impact on global health, and increase long-term shareholder value.

We know that healthcare systems are intensely focused on improving quality and decreasing costs, but we also see that clinicians are faced with growing workloads as the number of patients and the severity of their illnesses increase. The available

healthcare budgets around the world cannot keep up with these additional demands, but in these challenges we see opportunities to help. We can reduce the cost of care by helping clinicians improve patient safety and dismantle many of the barriers – such as disconnection between devices and increased documentation requirements – that hinder patient-clinician interaction. We believe there is a tremendous opportunity for automating care by leveraging technology that lessens clinician cognitive overload, providing clinicians the extra time and decision-support tools required to improve patient outcomes and patient satisfaction.

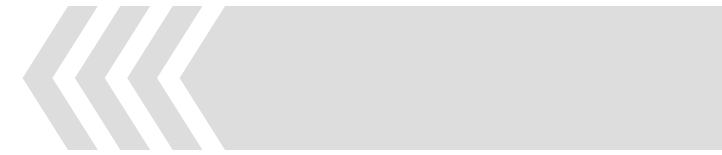
Our focus on how our products can help automate care has expanded over time. When we invented SET® Measure-through Motion and Low Perfusion™ pulse oximetry, we saw how more accurate and reliable monitoring helped facilitate care by reducing the time clinicians spent walking to the bedside to investigate false alarms, by reducing the number of invasive blood samples they took to confirm measurements, and by reducing the need to use multiple sensors per patient just to

### MISSION STATEMENT

*Improve patient outcomes and reduce the cost of care*

### 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



obtain a reliable measurement. Next, we saw how more accurate SET® pulse oximetry measurements helped clinicians make better clinical decisions for children, such as premature babies, helping to reduce the rate of retinopathy of prematurity and helping to identify newborns at risk of critical congenital heart disease. Then, we saw how our accurate SET® pulse oximetry measurements allowed, for the first time, reliable monitoring of patients on the general ward – resulting in decreased rapid response activations, ICU transfers, and mortality in post-surgical patients.

When we introduced noninvasive blood constituent monitoring with rainbow SET™ Pulse CO-Oximetry, we saw how new noninvasive measurements, previously only possible through invasive or complex procedures, helped automate care by quickly and easily identifying important aspects of patient status, such as monitoring for carbon monoxide in the blood not only of asymptomatic patients but also of fire services personnel at the scene of a fire. We also saw how adding continuous and noninvasive hemoglobin measurements to supplement intermittent and delayed lab results could change patient management, for example, by monitoring hemoglobin levels during surgery to help clinicians avoid unnecessary blood transfusions when hemoglobin is stable or speed up necessary transfusions when hemoglobin is dropping.

Over the next several years, we believe we can help automate care even more with the Root patient monitoring and connectivity platform by reducing complexity through the integration of data from multiple disparate monitors and therapeutic devices, by deploying decision support algorithms, by saving time through semi-automated and automated bedside vital signs measurement and documentation, and by improving data interpretation through adaptable and intuitive displays.

We envision a future where patients are more comfortable and connected to their families and caregivers, manual steps are streamlined, data from multiple sources are integrated and easier to interpret in less time, device control is centralized, and all patients can receive best-in-class care through real-time decision support systems – made possible through predictive algorithms and expert learning systems.

Healthcare technology that was once considered science fiction is becoming reality. We have already automated and improved care with both SET® and rainbow®. The third chapter of our automating care story is poised to sustain and enrich our heritage of advancing medicine. It is an exciting time for patients, clinicians, and for all of us at Masimo as we continue pursuing our long-term mission of improving patient outcomes and reducing cost of care.

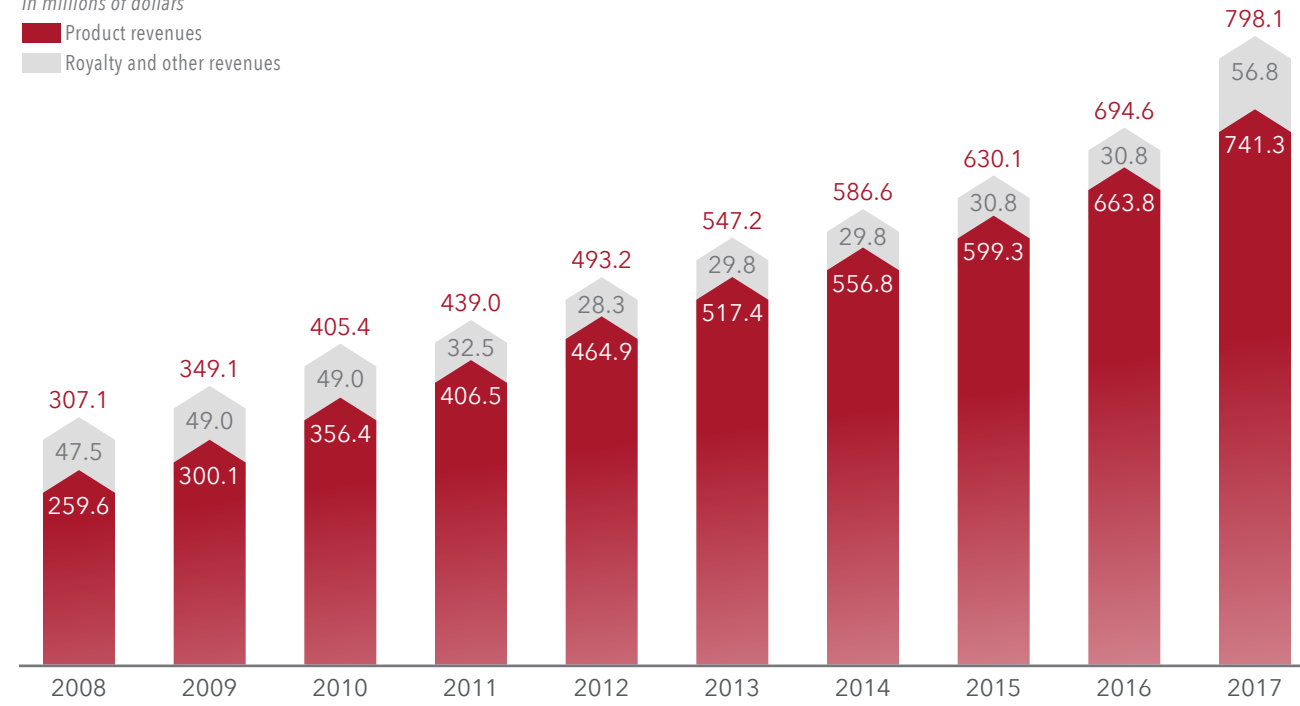
**Joe Kiani**  
Chairman and CEO

# 2017 Financial Highlights

## Revenues

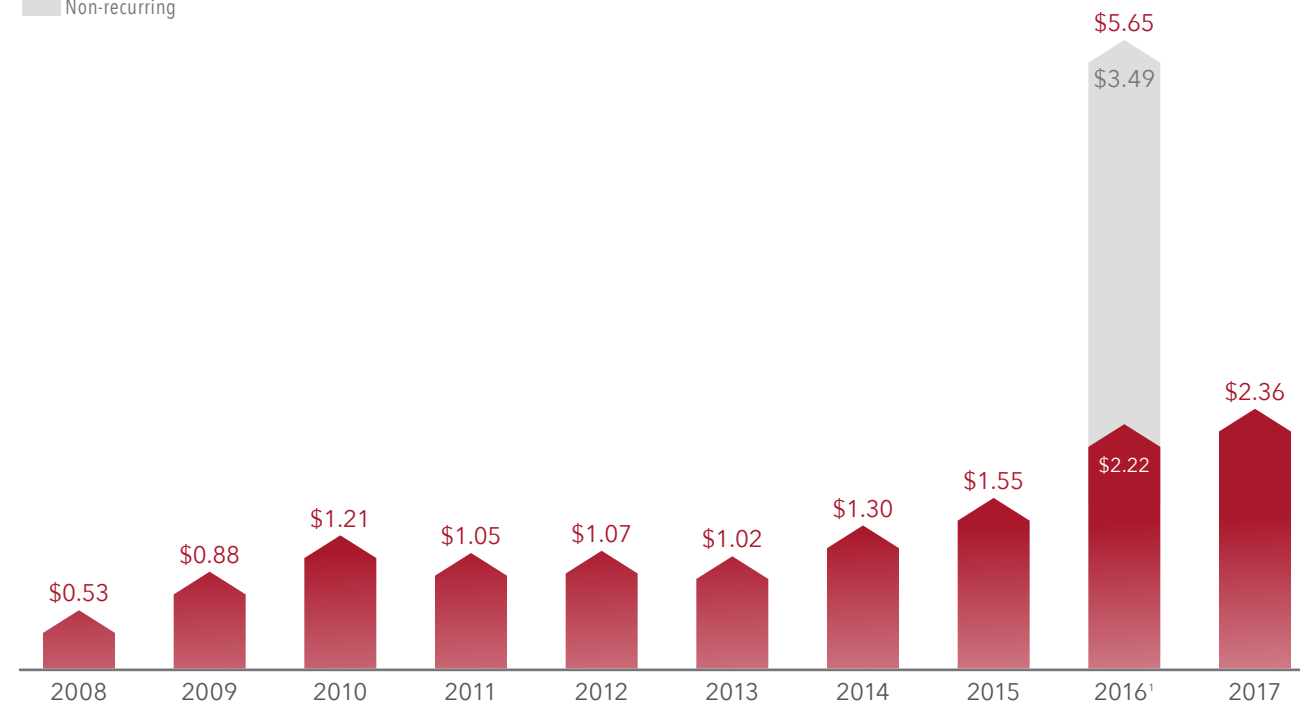
In millions of dollars

■ Product revenues  
■ Royalty and other revenues



## Earnings Per Share

■ Non-recurring



<sup>1</sup>Included in the FY2016 Historical GAAP Earning Per Share was \$3.49 per diluted share related to a \$300.0 million settlement agreement, of which \$270.0 million was recognized as a gain on the Statement of Operations at December 31, 2016.

## Financial Results Summary

2017 Total Revenues

\$798,108,000

2017 EPS

\$2.36

# 2017 New Product Highlights

Among the many new products you will see in this annual report, we announced the following in 2017:

## Measurements

RPVi

**rainbow PVi (RPVi)**, a multi-wavelength version of the currently available PVi. PVi, while being a noninvasive technology to help clinicians monitor fluid responsiveness in mechanically ventilated patients, in studies has been shown to be as good as invasive techniques. Created with our unwavering commitment to improve noninvasive measurements, RPVi was designed to provide enhanced specificity to changes in fluid volume compared to PVi<sup>1</sup>

SpHb 2.0

**Next Generation Spot-Check SpHb** (noninvasive hemoglobin) technology with the rainbow DCI<sup>®</sup>-mini sensor for improved motion tolerance, faster time to display SpHb results, and enhanced field performance

## Devices

- **Rad-G™** pulse oximeter, developed in partnership with the Bill & Melinda Gates Foundation, to enable guided screening in low-resource settings around the world
- **Rad-67** handheld Pulse CO-Oximeter<sup>®</sup>, providing Next Generation Spot-Check SpHb and rainbow SET technology and advanced communication capabilities in a portable spot-check device with touch screen user interface
- **Rad-97** portable and compact Pulse CO-Oximeter, for hospital and telehealth home monitoring hub, including configurations with integrated NomoLine capnography and noninvasive blood pressure (NIBP) measurement



## Sensors

- **rainbow<sup>®</sup> DCI Mini Super Sensor**, providing the ability to simultaneously measure total hemoglobin (SpHb), carboxyhemoglobin (SpCO), methemoglobin (SpMet), arterial oxygen saturation (SpO<sub>2</sub>), and other measurements for a total of nine parameters on the same noninvasive sensor
- **RD rainbow Lite SET** single-patient-use adhesive sensors, featuring Oxygen Reserve Index (ORi) along with rainbow<sup>®</sup> PVi (RPVi) and Masimo SET<sup>®</sup> Measure-through Motion and Low Perfusion technology (SpO<sub>2</sub>, PR, and Pi), for cost-effective access to these advanced parameters

## Hospital Automation Solutions

- **Root with Kite**, expanding visibility of patient data for clinicians by allowing data from Masimo devices to be simultaneously viewed on a TV or tablet in customized configurations depending on the area of care, including patient alarms for quick notification of changes in a patient's physiological status
- **UniView**, which gathers data from multiple sources such as patient monitors, ventilators, anesthesia gas machines, IV pumps, lab and radiology results, and surgical views, to project on large displays integrated patient information from all connected devices and systems in the hospital
- **Root with Early Warning Score (EWS)** with the ability to use either predefined EWS protocols or multiple customized EWS profiles and contributors for a specific care area or patient population
- **Trace**, a software solution offering clinicians the ability to review and focus on the patient's most important data patterns, in the format that provides the most insight



rainbow DCI-mini sensor



RD rainbow Lite SET single-patient-use sensor



Root with Kite



UniView



Root with EWS





# Automating Care



# Challenges to Improving Value in Healthcare

Changes in healthcare payment systems have contributed to the shift from a volume-based focus of increasing procedures and patients toward a value-based focus of improving quality and decreasing costs.<sup>1</sup>

While hospitals are clearly focused on improving value, clinicians are faced with a number of barriers including:

- Heavy cognitive and physical workload
- Increasing documentation demands with decreasing time for patients
- Variability in clinical knowledge and skill
- Emphasis on manual assessments and procedures
- Lack of effective communication and care coordination systems
- Complex and cluttered care environments
- Disparate and disconnected sources of data
- Lack of accurate, relevant, and timely data

As a result, care delivery can be inefficient and ineffective with a high amount of variability in quality and cost – both between hospitals and between different clinicians at the same hospital.

Care delivery can be inefficient and ineffective with a high amount of variability in quality and cost



Automating some aspects of healthcare can give skilled clinicians the time and tools to consistently deliver optimal care at a lower cost

## Automating Care

Automating some aspects of healthcare can give skilled clinicians the time and tools to consistently deliver optimal care at a lower cost. Masimo's approach to automating care is intended to help healthcare systems:

- Simplify care delivery
- Maximize resources on patient care
- Decrease variability
- Decrease errors of omission
- Improve patient outcomes
- Increase patient satisfaction
- Reduce costs

Masimo's approach will help healthcare systems by:

### Automating Assessment of the Patient Status Through Measurements

- Delivering accurate data with context to reduce the time spent responding to false alarms and verifying measurements
- Enabling simple, noninvasive ways to obtain data
- Filling in the gaps in awareness by continuously monitoring instead of relying only on intermittent and delayed measurements

### Automating Clinician and Patient Interactions Through Products

- Creating decision support tools by monitoring data over time
- Providing customized approaches to best fit various patients, care areas, and clinicians
- Displaying data in a way that makes it simple and convenient to identify relevant data
- Integrating and aggregating measurements from disparate sources
- Expanding data flow in both directions through dynamic and seamless data exchange
- Prioritizing events and enabling seamless documentation
- Improving the ease and quality of communication between caregivers and patients
- Increasing patient comfort and family engagement to improve patient satisfaction
- Facilitating patient flow and scheduling to ease handoffs, transfers, and discharges

### Automating Patient Management Across the Continuum of Care with Solutions

- Combining best-in-class approaches to each care area
- Reducing manual steps and procedures
- Providing a platform for potential future advancements such as centralized device control, decision support, and closed loop management
- Extending automation technologies into the home

# Measurements: Automating Assessment of Patient Status



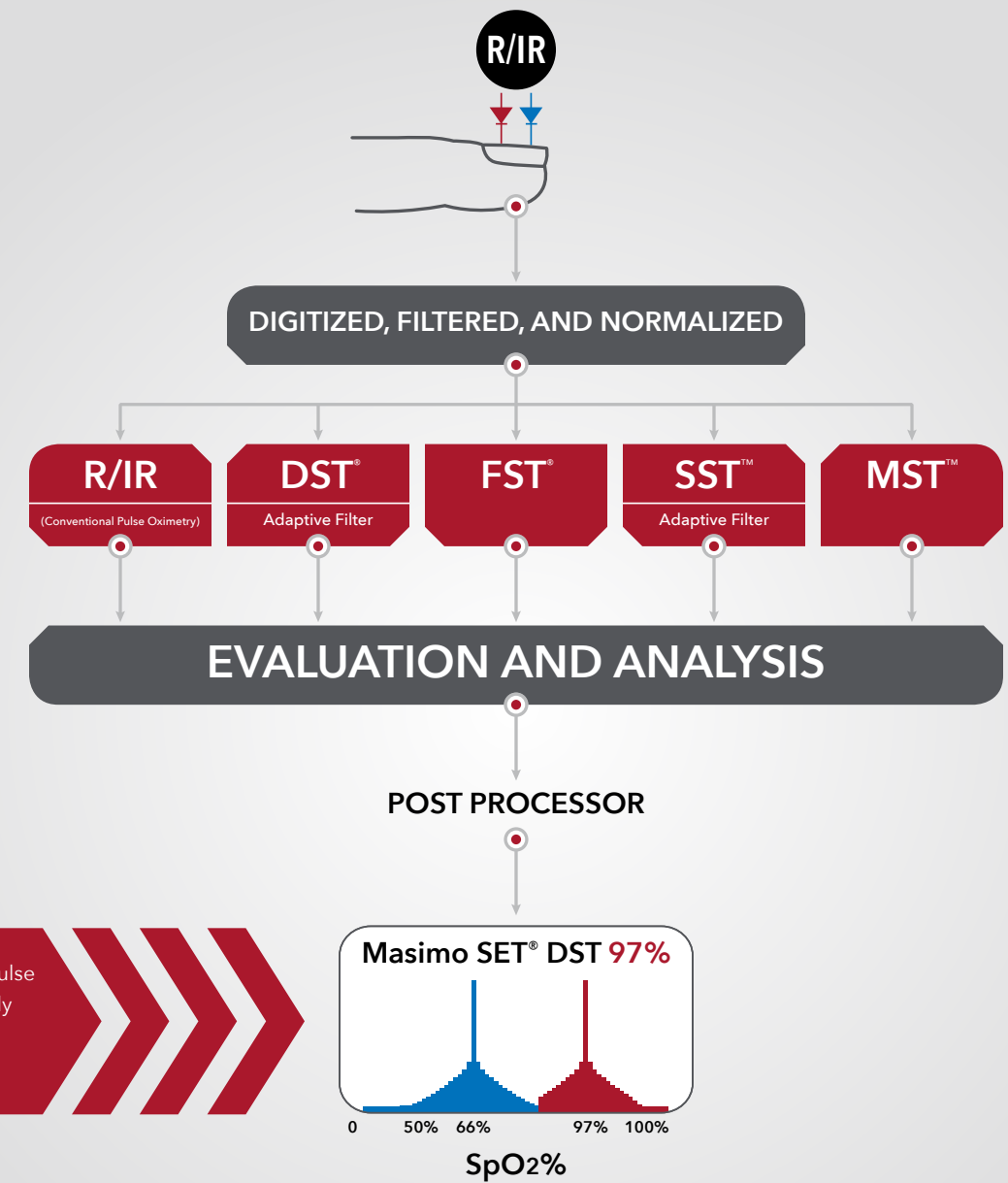
# Solving the Unsolvable with SET<sup>®</sup>

## Overcoming the Limitations of Conventional Pulse Oximetry

Prior to Masimo Signal Extraction Technology<sup>®</sup> (SET<sup>®</sup>), pulse oximetry was often unreliable when it was needed most – during patient motion and low perfusion. The industry considered the problem unsolvable and clinicians and patients were forced to live with false alarms that hampered productivity and missed true alarms that impacted patient care. Conventional pulse oximetry inaccuracy during motion and low perfusion is caused by its difficulty in determining the true arterial blood signal – because moving venous blood appears to pulsate like arterial blood.<sup>1</sup>

Twenty-nine years ago, two young engineers named Joe Kiani and Mohamed Diab asked how pulse oximetry could work during motion and low perfusion and in doing so, started a revolution in patient monitoring. Masimo SET<sup>®</sup> works by recognizing that both arterial and venous blood can pulsate. Using parallel signal processing engines – DST, FST, SST, and MST – Masimo SET<sup>®</sup> separates the true arterial signal from sources of noise, including the venous signal.<sup>2</sup> By measuring through patient motion and low perfusion, Masimo SET<sup>®</sup> has helped pulse oximetry become a clinically reliable tool.

Masimo SET<sup>®</sup> has helped pulse oximetry become a clinically reliable tool for accurately monitoring patient status



Conventional pulse oximetry uses the standard red over infrared algorithm to provide SpO<sub>2</sub>, while Masimo SET<sup>®</sup> includes four additional algorithms, running in parallel. These algorithms distinguish between the arterial signal and non-arterial and venous signal noise – during motion and low perfusion – by identifying and isolating the non-arterial and venous noise SpO<sub>2</sub> (left peak, shown in blue) from the true arterial SpO<sub>2</sub> components (right peak, shown in red) in the signal.



SpO<sub>2</sub>

Arterial Oxygen Saturation

PR

Pulse Rate

Pi

Perfusion Index

PVi

Pleth Variability Index

RRp

Respiration Rate from the Pleth

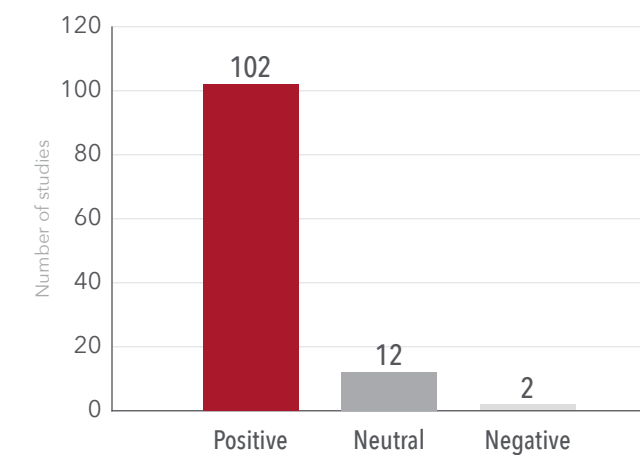
*“Conventional pulse oximeters are a fair-weather friend. Masimo SET® is a foul-weather friend.”*

**Jeremy Swan, MD**  
(1922-2005)

Former Chairman of the Masimo Scientific Advisory Board  
Former Chairman Emeritus, Cedars Sinai Medical Center's Division of Cardiology



## Masimo SET®: Comparative Studies



### Masimo SET®: Validated by Independent and Objective Research

Over 100 independent and objective studies have shown that Masimo SET® outperforms other pulse oximetry technologies during motion and low perfusion conditions, providing clinicians with increased sensitivity and specificity to help them make critical patient care decisions.<sup>1</sup>

# Unleashing Breakthrough Performance with SET®

Before Masimo SET® pulse oximetry, up to 90% of alarms that occurred outside the operating room were false alarms.<sup>1-3</sup> In a study of twenty-thousand surgical patients, not only did conventional pulse oximeters fail to monitor 7% of the time in the operating room with the highest risk patients (ASA class IV), but the use of conventional pulse oximetry did not appear to reduce the rate of post-operative complications.<sup>4,5</sup>

*“Masimo SET® is advantageous because even though it significantly reduces false alarms, it doesn’t do that by ignoring physiological changes.”*

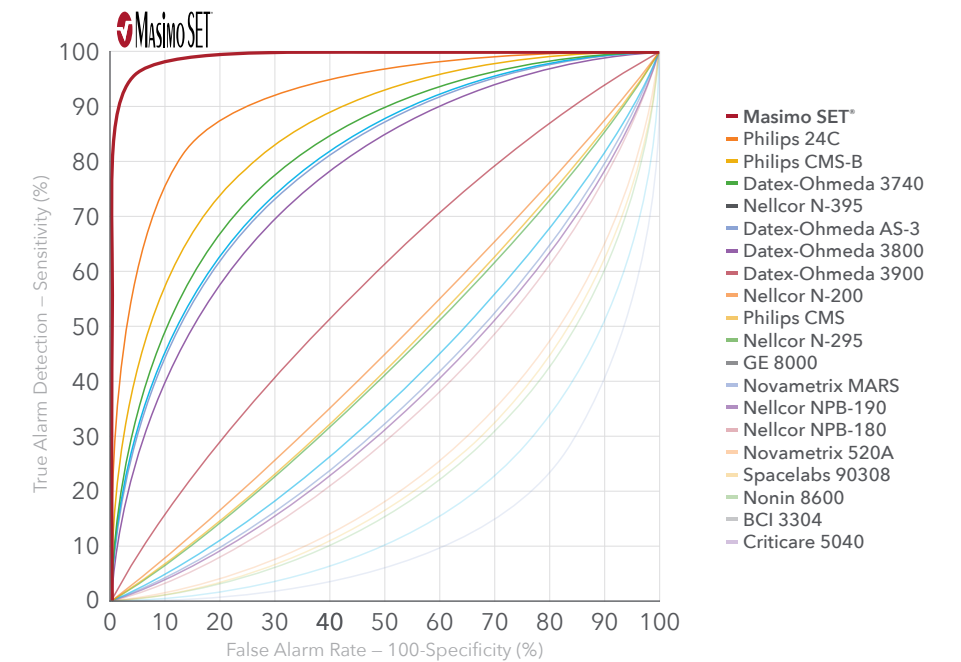
**Christian Poets, MD**

Department of Neonatology, University Children’s Hospital, Tübingen, Germany



Performance of 20 Pulse Oximeters During Motion and Low Perfusion<sup>6</sup>

Volunteer subjects (N=70) were tested in a cool environment using a motorized table that produced different hand motions. Each motion was studied during both room air breathing and hypoxemia. Pulse oximeters on the stationary hand were used to provide control measurements for comparison. Sensitivity was defined as the ability to detect a true SpO<sub>2</sub> value <90%. Specificity was defined as the ability to detect a true SpO<sub>2</sub> value ≥90%. Drop outs were included.<sup>6</sup>



<sup>1</sup>Lawless ST et al. *Crit Care Med* 1994;22:981-5. <sup>2</sup>Wiklund L et al. *J Clin Anesth* 1994;67:182-8. <sup>3</sup>Dumas C et al. *Anesth Analg* 1996;83:269-72. <sup>4</sup>Moller JT et al. *Anesthesiology*. 1993 Mar;78(3):436-44. <sup>5</sup>Moller JT et al. *Anesthesiology*. 1993 Mar;78(3):445-53. <sup>6</sup>Barker SJ. *Anesth Analg*. 2002;95(4):967-72.

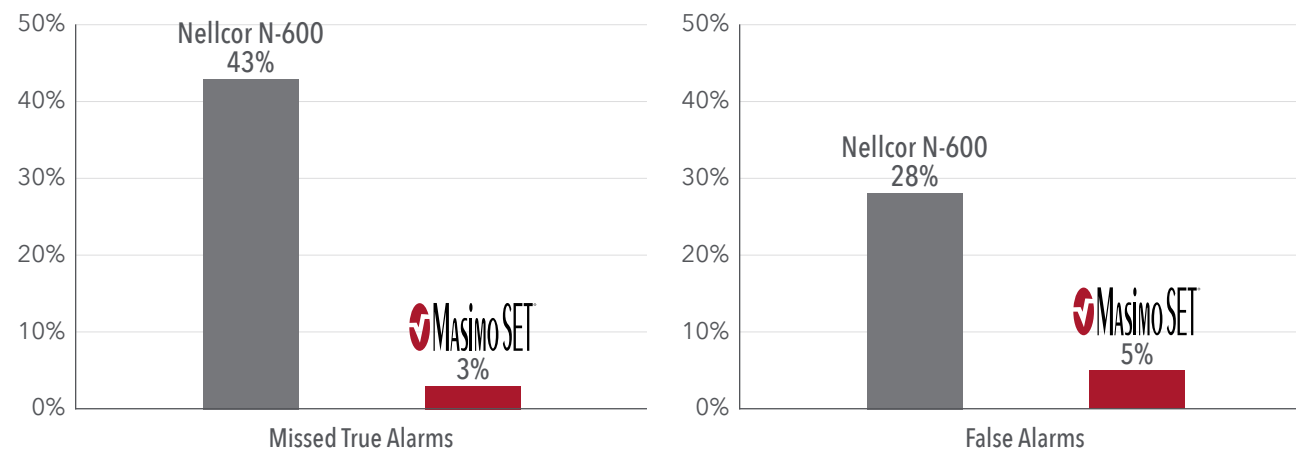


## Automating Pulse Oximetry Monitoring and Expanding Clinical Impact

By reducing false alarms and increasing true alarm detection,<sup>1</sup> Masimo SET<sup>®</sup> has helped automate pulse oximetry monitoring by significantly reducing the time required by clinicians to respond to false alarms and verify measurements while also increasing clinicians' ability to rely on the pulse oximeter to help make patient management decisions. Outcome studies with Masimo SET<sup>®</sup>, in conjunction with

clinician assessment, have been shown to help clinicians reduce retinopathy of prematurity in neonates,<sup>2</sup> improve critical congenital heart disease screening in newborns,<sup>3</sup> and reduce ICU transfers and rapid response team activations on the general ward.<sup>4</sup> Today, Masimo SET<sup>®</sup> is the primary pulse oximetry at 17 of the top 20 hospitals listed in the 2017-18 U.S. News and World Report Best Hospitals Honor Roll.<sup>5</sup>

Alarm Reliability During Motion and Low Perfusion<sup>1</sup>



Volunteer subjects (N=10) were tested in a cool environment during motion and low perfusion conditions and the false alarm rate was calculated during 120 full oxygenation events (specificity) and the true alarm rate was calculated during 40 deoxygenated events (sensitivity). Sensitivity was defined as the ability to detect a true SpO<sub>2</sub> value <90%. Specificity was defined as the ability to detect a true SpO<sub>2</sub> value ≥90%. Results shown are calculated by combining the sensitivity and specificity of both machine-generated and volunteer-generated motion.<sup>1</sup>

Compared to the Nellcor N-600 during motion and low perfusion, Masimo SET<sup>®</sup> reduced false alarms by 82% (28% vs. 5%) and reduced missed true alarms by 93% (43% vs. 3%)<sup>1</sup>





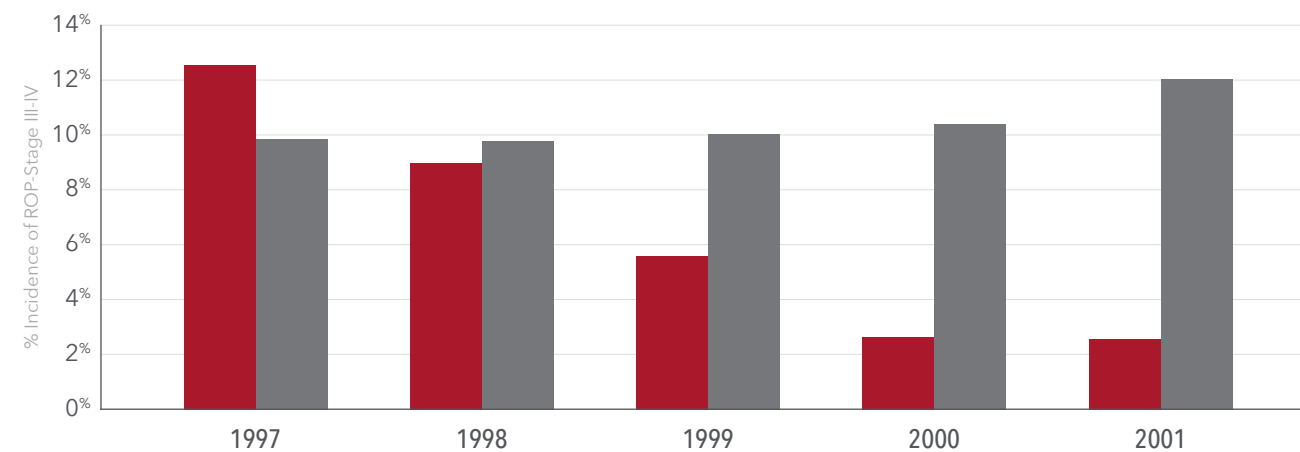
# Reducing Retinopathy of Prematurity with SET®

Premature infants in neonatal intensive care are routinely administered supplemental oxygen to help preserve vital organ function. However, too much oxygen administration can cause severe eye damage from retinopathy of prematurity (ROP). Clinicians use pulse oximetry to help guide when and how much oxygen to provide, but unreliable pulse oximetry measurements can result in over-administration of oxygen and subsequent ROP. Three studies have shown Masimo SET®, coupled with changes in practice, helps clinicians reduce the rate of severe ROP in premature infants.<sup>1-3</sup>

In the first study, following the implementation of Masimo SET® with a new oxygen protocol in the neonatal intensive care unit at Cedars-Sinai Medical Center, the incidence of severe ROP in very low birth weight infants decreased over a five-year period

from 12.5% to 2.5%. The ROP rates were compared over the same time period to the data reported by the Vermont Oxford Network (VON), a nonprofit voluntary collaboration of >400 NICUs that maintains a database including >25,000 infants.<sup>1</sup>

Retinopathy of Prematurity Rates in Very Low Birth Weight Infants



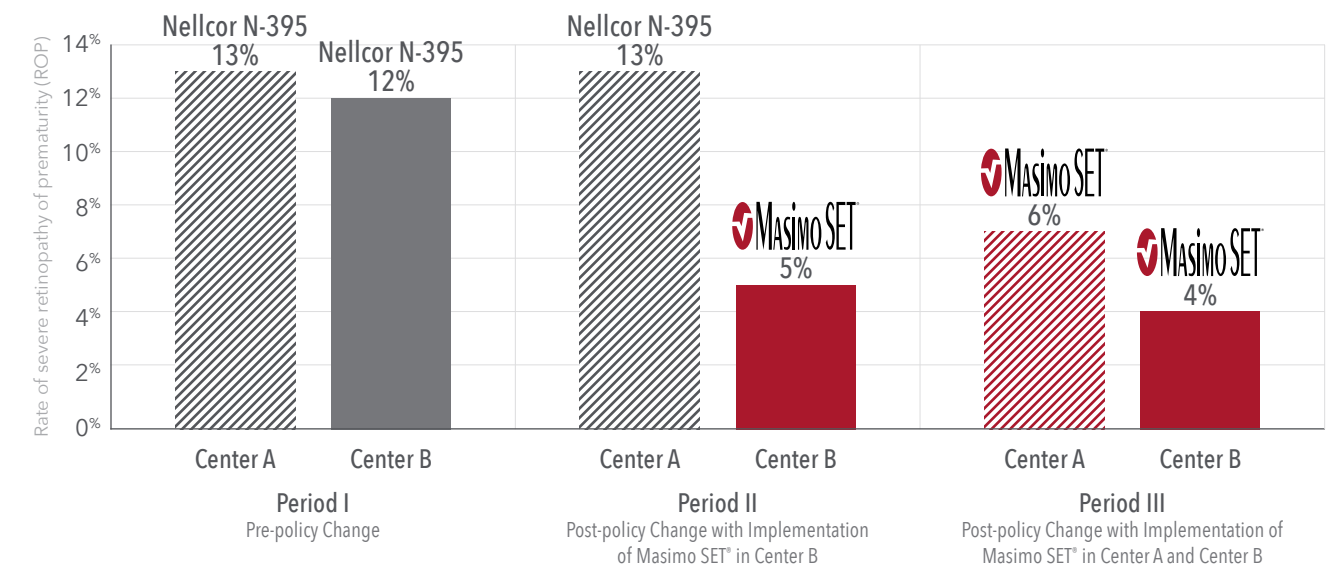
Incidence of ROP stages 3 to 4 for infants with birthweight of 500 to 1500 g at CSMC and in the VON for the years 1997 to 2001.<sup>1</sup>

■ Cedars-Sinai Medical Center (CSMC), after implementation of Masimo SET® with a new oxygen protocol  
 ■ Vermont Oxford Network (VON)

A follow-up study was performed at two separate centers within Emory University in which the same physician and nurse staff worked in both centers. Both centers simultaneously changed their neonatal oxygen targeting policy and one of the centers switched from Nellcor to Masimo SET® pulse oximetry. In the first phase of the study, there was

no decrease of severe ROP at the center using Nellcor but there was a 58% reduction (from 12% to 5%) of severe ROP at the center using Masimo SET®. In the second phase of the study, the center still using Nellcor switched to Masimo SET® and experienced a similar reduction (from 13% to 6%) of severe ROP.<sup>2</sup>

Severe Retinopathy of Prematurity Rate<sup>2</sup>



*“Masimo SET® has played a critical role in helping to virtually eliminate severe infant eye damage.”*

**Augusto Sola, MD**

American Academy of Pediatrics Christopherson Award winner for his contribution to international child health

In the most recent study at Yale New Haven Medical Center, the outcomes of 304 very low birth weight infants whose oxygen targeting was performed with non-Masimo SET® pulse oximetry were compared with 396 post-initiative infants whose oxygen targeting was performed with a new oxygen protocol after switching to Masimo SET® pulse oximetry. After the switch, there was a 37% reduction in incidence of severe ROP (from 24.6% to 15.4%) and a 53% reduction in ROP requiring surgery.<sup>3</sup>

# Challenges to Identifying a Life-Threatening Disorder

Critical congenital heart disease (CCHD) is a serious heart defect that is present at birth as a result of abnormal heart formation during early embryonic development. CCHD prevents the heart from pumping blood effectively so organs and tissues throughout the body do not receive enough oxygen, which can lead to organ damage and life-threatening complications.<sup>1</sup> CCHD occurs in approximately one to two babies per 1,000 live births and requires intervention soon after birth to prevent significant morbidity and mortality.<sup>2,3</sup> Some babies with CCHD can appear healthy at first, so in the past up to 30% of deaths due to CCHD were in babies discharged from the hospital before their heart defects were detected.<sup>4</sup>

In the past, up to 30% of deaths due to CCHD were in babies discharged from the hospital before their heart defects were detected.<sup>4</sup>

*"She died in my arms so I thought I had done something wrong, but it turned out I had done nothing wrong. The coroner called me two days later and for the first time in my life, I heard the phrase, 'congenital heart disease.' Now, I believe that that simple screening might have given my daughter a shot. She might have lived."<sup>5</sup>*

**Kristine Brite McCormick**

Mother of Cora, a baby girl who unexpectedly died from CCHD

## Limitations of Conventional Pulse Oximetry

In theory, pulse oximetry would identify lower oxygen saturation measurements in babies with CCHD. However, in one of the earliest CCHD studies evaluating pulse oximetry, researchers abandoned use of a conventional pulse oximeter due to its inability to obtain measurements in some babies and a high false positive rate.<sup>6</sup>

<sup>1</sup> NIH US National Library of Medicine, Genetics Home Reference (<https://ghr.nlm.nih.gov/condition/critical-congenital-heart-disease>) <sup>2</sup>Wren C et al. *Arch Dis Child Fetal Neonatal Ed* 2008;93:F33-5. <sup>3</sup>Chang RK et al. *Arch Pediatr Adolesc Med* 2008;162:969-74. <sup>4</sup>Motulsky H. *Intuitive biostatistics*. Oxford: Oxford University Press, 1995. <sup>5</sup>Cora's Story. 2013 Patient Safety Summit. Kristine Brite McCormick. <sup>6</sup>Granelli et al. *Acta Paediatrica* 2005;94:1590-1596.

# Improving Screening for Critical Congenital Heart Disease with SET®

In a study of 39,821 infants, researchers observed an increase in CCHD detection from 63% with physical exam alone to 83% with physical exam and use of Masimo SET® pulse oximetry.<sup>1</sup> A follow-up study of 20,055 infants showed Masimo SET® measurements alone identified 75% of CCHD cases.<sup>2</sup> In the largest CCHD screening study to date – including over 122,738 subjects – the combined use of Masimo SET® and clinical assessment increased screening sensitivity from 77% to 93% versus clinical assessment alone.<sup>3</sup>

CCHD screening with EVE™ p. 194

## CCHD Screening with Masimo SET®<sup>1</sup>

n = 39,821 babies

|                                | Physical Exam Alone | Physical Exam + Masimo SET® |
|--------------------------------|---------------------|-----------------------------|
| Sensitivity for CCHD Detection | 63%                 | 83%                         |
| Specificity for CCHD Detection | 98%                 | 99.8%                       |

CCHD Screening with Masimo SET® was conducted on 39,821 newborn babies, preductally (palm of right hand) and postductally (either foot) before routine physical examination. The baby was considered to be screening positive if: 1) Either a single preductal or postductal SpO<sub>2</sub> measurement was ≤90%; or 2) If in three repeat measurements, both preductal and postductal SpO<sub>2</sub> were <95%, or the difference between the two measurements was >3%.<sup>1</sup>

## Enabling a New Standard of Care

In 2011, CCHD screening with motion-tolerant pulse oximetry was added to the U.S. Department of Health and Human Services' Recommended Uniform Screening Panel. Masimo SET® pulse oximeters and sensors were exclusively used in the two studies<sup>1,2</sup> (59,876 subjects) that were the basis for the CCHD workgroup recommendation for universal CCHD screening.<sup>4</sup> As a result, the U.S. has gone from virtually no CCHD screening to near universal CCHD screening today.<sup>5</sup> In 2017, both European and Canadian workgroups also recommended universal CCHD screening with motion-tolerant pulse oximetry.<sup>6,7</sup> Outside the U.S.,

it has been estimated that millions of babies are now being screened.<sup>5</sup>

With Masimo SET® now proven as an effective CCHD screening tool, Masimo looks forward to helping more clinicians save newborn lives as CCHD screening spreads to other parts of the world. Masimo also believes it is possible that CCHD detection rates could increase even further, based on research performed with the perfusion index (Pi) measurement from Masimo SET®. Using Pi, investigators have observed that in some babies without oxygen saturation abnormalities, a Pi <0.70 can identify additional cases of CCHD.<sup>8</sup>

*"Screening all babies in maternity units with Masimo SET® pulse oximetry significantly improves CCHD detection."*

Anne de-Wahl Granelli, PhD

<sup>1</sup> de-Wahl Granelli A et al. *BMJ*. 2009;338. <sup>2</sup> Ewer AK et al. *Lancet*. 2011 Aug 27;378(9793):785-94. <sup>3</sup> Zhao QM et al. *Lancet*. 2014 Aug 30;384(9945):747-54. <sup>4</sup> Kemper et al. *Pediatrics*, 2011, Nov;128(5):e1259-67. <sup>5</sup> <http://www.newbornfoundation.org/impact> <sup>6</sup> Manzoni P et al. *The Lancet Child & Adolescent Health*. 2017; 1(2):88 - 90. <sup>7</sup> Wong KK et al. *Can J Cardiol*. 2017 Feb;33(2):199-208. <sup>8</sup> de-Wahl Granelli et al. *Acta Paediatr*. 2007;96(2):1455-1459. Eve is not available in the U.S.




# Limitations of Existing Methods to Support Fluid Therapy

Intravenous fluid administration is one of the most common hospital interventions. Clinicians use fluid therapy in the operating room and intensive care unit to improve blood flow, or cardiac output.<sup>1</sup> Although fluid administration can be critical to enable organ preservation and improve patient status, both the over- and under-administration of fluid are associated with increased post-operative complications.<sup>2,3</sup> In addition, there is a large degree of variability between clinicians in the use of fluid during surgery.<sup>4</sup>

Multiple studies have shown that traditional “static” parameters are not reliable predictors of fluid responsiveness<sup>5</sup> – defined as an increase in cardiac output with fluid administration. Therefore, experts recommend the use of more accurate “dynamic” parameters derived from the arterial pressure waveform, such as pulse pressure variation (PPV) and stroke volume variation (SVV). These parameters are considered “dynamic” because in mechanically ventilated patients, they measure dynamic physiologic variation over the respiratory cycle – which enable accurate monitoring of the likelihood of fluid responsiveness *before* fluid is administered to the patient.<sup>6</sup>

A meta-analysis of 31 randomized controlled trials showed that using dynamic parameters such as PPV or SVV in goal-directed fluid management reduced surgical complications by 32%.<sup>7</sup> While studies have shown dynamic parameters to be beneficial, most dynamic methods remain invasive, complex, and/or costly.



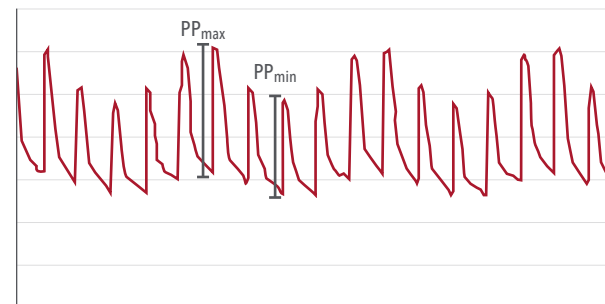
**A meta-analysis of 31 randomized controlled trials showed that using dynamic parameters such as PPV or SVV in goal-directed fluid management reduced surgical complications by 32%<sup>7</sup>**



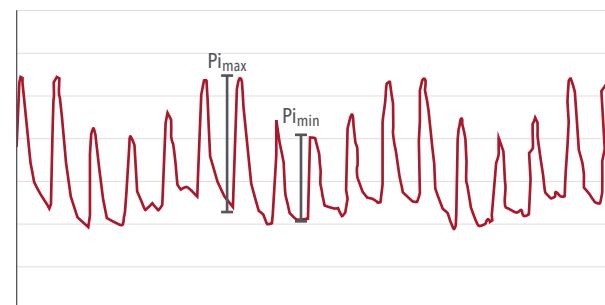
# Enabling Noninvasive Fluid Responsiveness Monitoring with PVi

Masimo SET® pulse oximetry can noninvasively provide a dynamic parameter from the plethysmographic waveform called Pleth Variability Index (PVi) which, like pulse pressure variation (PPV) and stroke volume variation (SVV), provides a measure of dynamic physiologic variation over the respiratory cycle. Because PVi is displayed on the same monitor and measured with the same sensors already being applied for Masimo SET® pulse oximetry or rainbow SET Pulse CO-Oximetry, PVi can help automate fluid responsiveness monitoring when other methods are not justified.

## Similarity of Arterial Pressure and Plethysmographic Waveforms



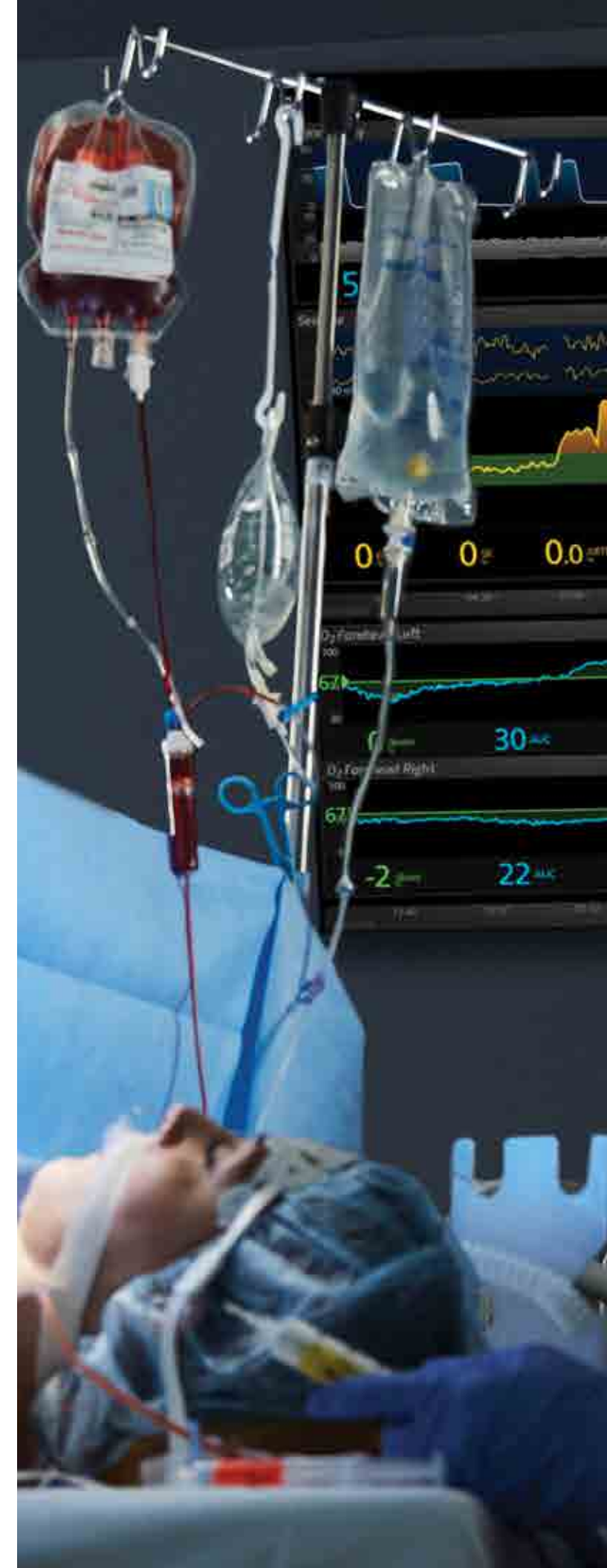
Arterial Pressure Waveform



Plethysmographic Waveform

Relation between respiratory variation in the arterial pressure and plethysmographic waveforms in mechanically ventilated patients. Adapted from Cannesson et al., 2005.<sup>1</sup>

**PVi can help automate fluid responsiveness monitoring when other methods are not justified**



## How PVi Works

Perfusion index (Pi) reflects the amplitude of the pulse oximeter waveform and is calculated as the pulsatile infrared signal, indexed against the non-pulsatile infrared signal. PVi is an automatic measure of the dynamic changes in Pi that occur over the respiratory cycle.

$$PVi = \frac{Pi_{max} - Pi_{min}}{Pi_{max}} \times 100$$

The greater the plethysmographic waveform variation in amplitude, the higher the PVi value. Studies show that higher PVi values indicate a mechanically ventilated patient is more likely to respond to fluid administration.<sup>1</sup> However, PVi may also show changes that reflect multiple physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions. Masimo also introduced rainbow® PVi (RPVi), a multi-wavelength version of PVi, designed to provide enhanced specificity to changes in fluid volume.

RPVi  
p. 66

# Comparing PVi to Other Methods for Fluid Responsiveness Monitoring

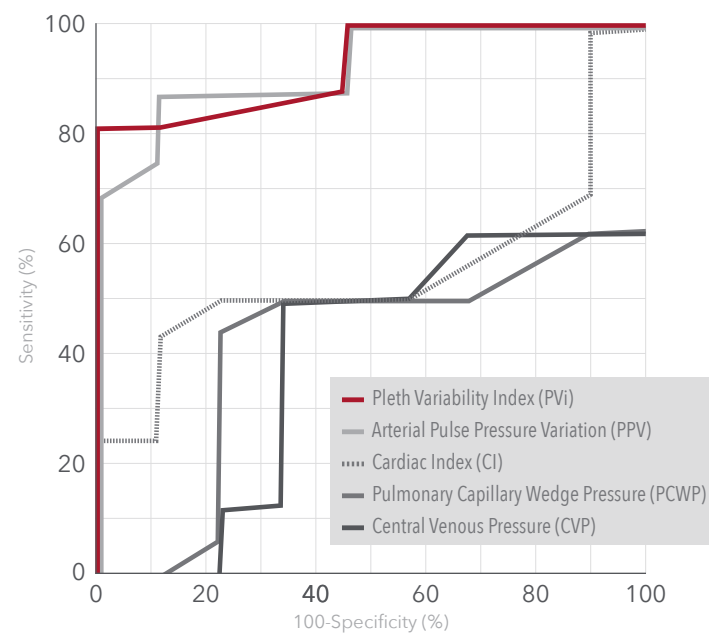
## Monitoring Fluid Responsiveness

In multiple studies in mechanically ventilated patients in the operating room and intensive care unit, Masimo's noninvasive Pleth Variability Index (PVi) has shown a similar ability to monitor fluid responsiveness as invasive dynamic parameters such as pulse pressure variation (PPV) and stroke volume variation (SVV).<sup>1-3</sup> Masimo rainbow® PVi (RPVi) is also available and is designed to provide enhanced specificity to changes in fluid volume.

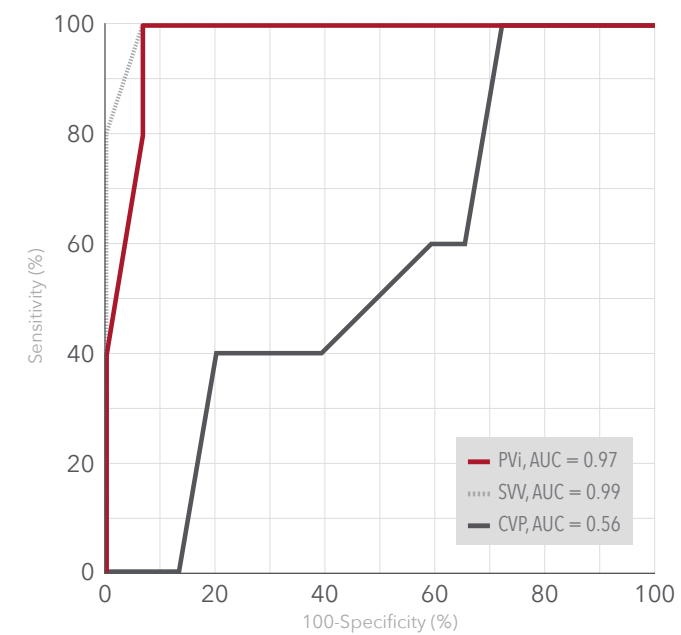
RPVi  
p. 66

This observational study evaluated 25 surgical patients before and after volume expansion, with fluid responders (sensitivity) defined as a cardiac index increase of  $\geq 15\%$  and fluid non-responders (specificity) defined as a cardiac index increase of  $< 15\%$ .<sup>2</sup>

PVi vs. Pulse Pressure Variation to Monitor Fluid Responsiveness<sup>2</sup>



PVi vs. Stroke Volume Variation to Monitor Fluid Responsiveness<sup>3</sup>



This observational study evaluated 20 surgical patients before and after volume expansion, with fluid responders (sensitivity) defined as a cardiac index increase of  $\geq 15\%$  and fluid non-responders (specificity) defined as a cardiac index increase of  $< 15\%$ .<sup>3</sup>

<sup>1</sup>Published studies on PVi can be found on our website at: <http://www.masimo.com>. <sup>2</sup>Cannesson M et al. *Br J Anaesth*. 2008;101(2):200-6. <sup>3</sup>Zimmermann M et al. *Eur J Anaesthesiol*. 2010 Jun;27(6):555-61.

PVi has shown a similar ability to monitor fluid responsiveness as invasive dynamic parameters such as PPV and SVV.<sup>1-3</sup>



# Advancing Goal-Directed Fluid Therapy with PVi

## Impact on Fluid Therapy and Outcomes

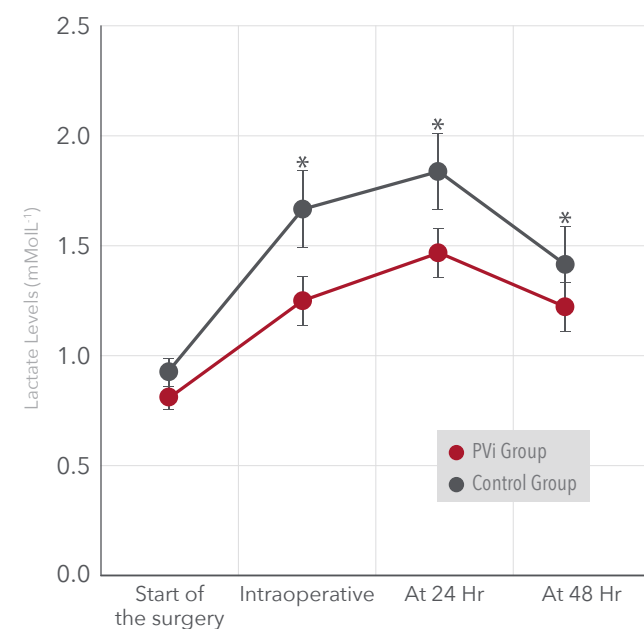
Pleth Variability Index (PVi) has been shown to help clinicians reduce intra-operative fluid administration<sup>1-3</sup> and lactate levels<sup>1,2</sup> – considered an important predictor of patient outcomes.<sup>4</sup> PVi has also been shown to help reduce length of stay and costs as part of multi-modal perioperative management.<sup>3</sup> Masimo rainbow® PVi (RPVi) is also available and is designed to provide enhanced specificity to changes in fluid volume.



RPVi  
p. 66

## Effect on Fluid Administration and Lactate Levels During Surgery

In a randomized controlled trial of 82 abdominal surgery patients, compared to management by the static parameter central venous pressure (CVP), PVi-based, goal-directed fluid management helped clinicians reduce the volume of intra-operative fluid infused and reduced intra-operative and post-operative lactate levels.<sup>1</sup>



## Clinical and Financial Benefits of Using Enhanced Recovery After Surgery Protocol Including PVi for Goal-Directed Therapy

In a study of colorectal surgery patients managed with an Enhanced Recovery After Surgery (ERAS) protocol, PVi was integrated into multi-modal perioperative management. Compared to the conventional approach, the ERAS approach including PVi resulted in a 69% decrease in intra-operative fluid administration, a 32% decrease in length of stay, a 47% decrease in complications, and a 35% decrease in 30-day hospital costs.<sup>3</sup>

| Outcome                           | Conventional Approach without PVi | ERAS Approach Including PVi | Relative Reduction with ERAS Approach Including PVi |
|-----------------------------------|-----------------------------------|-----------------------------|---|
| Intra-operative net fluid balance | 2,733 mL                          | 848 mL                      | 69%   |
| Length of Stay                    | 6.8 days                          | 4.6 days                    | 32%   |
| Any complication                  | 30%                               | 16%                         | 47%   |
| 30-day direct costs               | \$20,435                          | \$13,306                    | 35%   |

All p values <0.05

## Inclusion of PVi in Clinical Guidelines

The positive evidence for PVi has led to its inclusion in guidelines and best practices for fluid management. In 2012, the United Kingdom's National Health Service (NHS) included PVi in its Intra-Operative Fluid Management Pack, which serves as a guide for hospitals implementing fluid responsiveness monitoring to improve patient outcomes.<sup>5</sup> In 2013, the French Society for Anaesthesia and Intensive Care (SFAR) included PVi in its guidelines for optimal hemodynamic management of surgical patients.<sup>6</sup> In 2016, the American Society for Enhanced Recovery (ASER) and Perioperative Quality Initiative (POQI) indicated that dynamic variables from both arterial and plethysmographic waveforms were feasible to help monitor fluid responsiveness.<sup>7</sup>

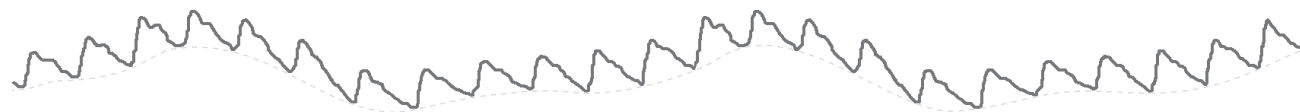
**Compared to the conventional approach, the ERAS approach including PVi resulted in savings of \$7,129 in 30-day direct costs.<sup>7</sup>**

# Monitoring Breath Rate with RRp

Traditional approaches to measuring respiration rate, or the number of breaths per minute, have limitations. Manually counting the number of breaths provides only intermittent data. Impedance monitoring with chest ECG leads is frequently used but has limited accuracy.<sup>1</sup> Capnography requires a mask or nasal cannula so it can result in low tolerance in conscious patients.<sup>2</sup> Masimo's rainbow Acoustic Monitoring requires only a small, adhesive sensor on the neck and offers an excellent alternative to traditional methods, with similar accuracy as capnography but with high patient tolerance.<sup>1-3</sup>

With respiration rate from the pleth (RRp), Masimo can provide another alternative for continuous respiration rate – using the same Masimo SET® or rainbow SET sensor that is already being applied to measure other optical-based measurements. While RRp cannot detect cessation of breathing, continuous RRp monitoring is appropriate for situations in which other continuous respiration rate methods are not considered feasible but intermittent, manual counting is not sufficient. RRp may also be appropriate for spot-check respiration rate measurements in the clinic, with emergency medical services, or at a patient's home.

## Changes in the Plethysmographic Waveform During Breathing



Advanced signal processing is utilized to analyze baseline, amplitude, and frequency changes to the plethysmographic waveform over the respiratory cycle to calculate respiration rate.



**Continuous RRp monitoring is appropriate for situations in which other continuous respiration rate methods are not considered feasible but intermittent, manual counting is not sufficient**

## RRp Accuracy

| Number of Subjects | Number of Estimates | Bias (rpm) | Precision (rpm) | ARMS* (rpm) |
|--------------------|---------------------|------------|-----------------|-------------|
| 194                | 1,090               | 0.2        | 1.9             | 1.9         |

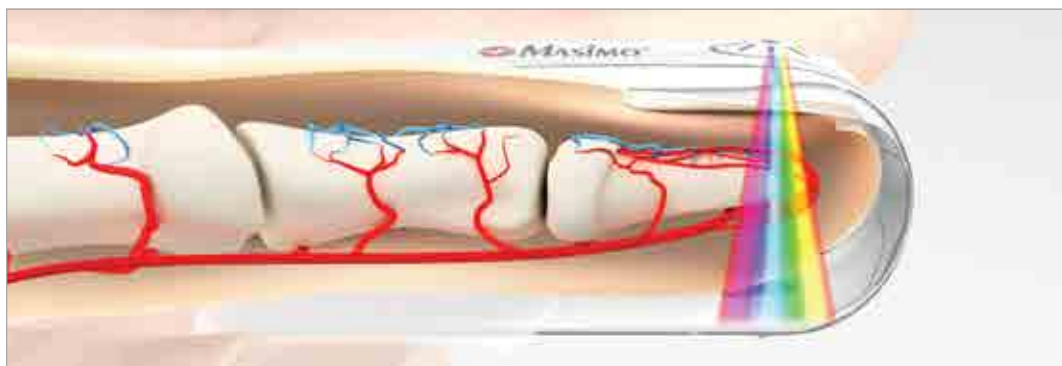
RRp accuracy was determined in healthy volunteers by comparing the RRp value to a reference respiration rate value in the range of 4 to 35 respirations per minute (rpm).<sup>4</sup>



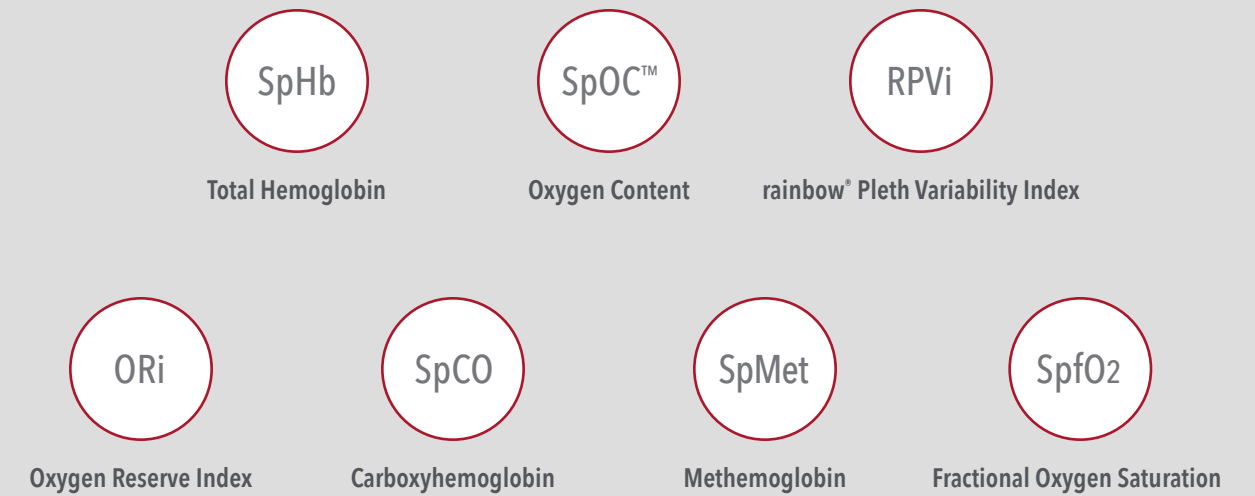
# Shining Light on Physiology with rainbow® Pulse CO-Oximetry

After solving the “unsolvable” problems of motion and low perfusion with Masimo SET® pulse oximetry, we set our sights higher with the invention of rainbow® Pulse CO-Oximetry. By leveraging multiple wavelengths of light and breakthrough signal processing, multiple noninvasive and continuous parameters that previously could only be measured by invasive techniques are now possible.

## How rainbow® Pulse CO-Oximetry Works



rainbow® Pulse CO-Oximetry uses more than seven wavelengths of light to measure blood characteristics based on light absorption. Advanced signal processing algorithms and unique adaptive filters work together to isolate, identify, and quantify hemoglobin, carboxyhemoglobin, methemoglobin, and four additional parameters. The results are then displayed numerically and graphically on select Masimo and OEM partner instruments.



rainbow SET measurements also include all Masimo SET® measurements: SpO2, PR, Pi, PVi, RRp



## Automating Assessment of the Patient Status in Multiple Ways

With 12 measurements now available from a single optical sensor, Masimo's rainbow® technologies provide noninvasive and continuous measurements that automate patient care by helping clinicians quickly and easily identify important aspects of patient status that were otherwise unknown – either because they were not assessed or were only assessed intermittently.

Masimo's rainbow® technologies may help clinicians:<sup>1</sup>

- Reduce unnecessary blood transfusions, facilitate more timely transfusions, and identify hemoglobin changes that may be associated with bleeding with SpHb monitoring<sup>2,3,4</sup>
- Reduce mortality with PVi and SpHb monitoring as part of a vascular filling protocol<sup>5</sup>
- Monitor for low hemoglobin with spot-check SpHb
- Indicate impending hypoxia earlier with ORi<sup>6</sup>
- Simplify fluid responsiveness monitoring with RPVi
- Monitor for carbon monoxide in the blood with SpCO
- Reveal elevated methemoglobin levels from drug reactions with SpMet
- Overcome the limitations of conventional pulse oximetry with SpfO2

*Masimo's rainbow® technologies provide noninvasive and continuous measurements that automate patient care by helping clinicians quickly and easily identify important aspects of patient status that were otherwise unknown – either because they were not assessed or were only assessed intermittently*

<sup>1</sup>Published studies can be found on our website at: <http://www.masimo.com>. <sup>2</sup>Awada WN et al. *J Clin Monit Comput*. 2015 Dec;29(6):733-40. <sup>3</sup>Ehrenfeld JM et al. *J Blood Disorders Transf*. 2014. 5:237. <sup>4</sup>McEvoy M et al. *Am J Crit Care*. 2013 Nov;22(6 Suppl):eS1-13. <sup>5</sup>Nathan N et al. *Anesthesiology*. 2016;A1103(abstract). <sup>6</sup>Szmuk P et al. *Anesthesiology*. 2016 Apr;124(4):779-84. Masimo's rainbow® measurements are not intended to replace lab testing but can provide immediate and additional information to aid patient assessment. Clinical decisions regarding therapeutic interventions should be based on the clinician's judgment considering among other factors: patient condition, continuous monitoring data, and laboratory diagnostic tests using blood samples. ORi, RPVi, and SpfO2 are not available in the U.S.

# Risks and Costs of Red Blood Cell Transfusions

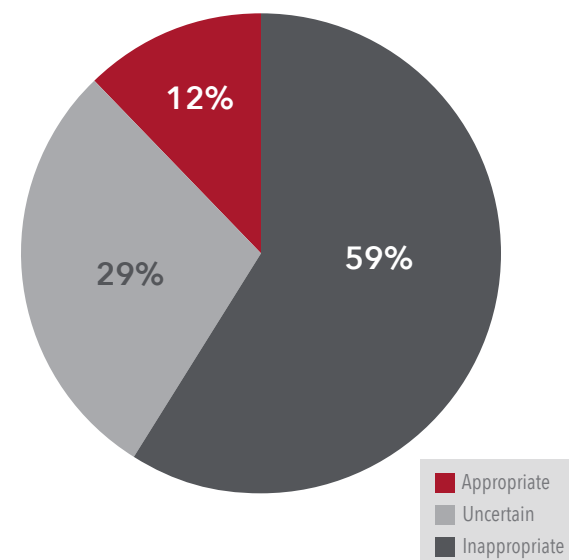
Red blood cell transfusions are the most common procedure performed in hospitals today, occurring in about one of every ten inpatient stays.<sup>1</sup> The decision to transfuse is subjective, as evidenced by the high variability in transfusion practices between physicians and different types of procedures.<sup>2</sup>

Multiple trials and meta-analyses have also reported risk associated with inappropriate transfusions and some suggest that restrictive blood transfusion practices may improve clinical outcomes.<sup>3-5</sup> Even without taking morbidity-associated costs into account, the cost to acquire, store, and administer blood in the U.S. is estimated between \$786 and \$1,183 per unit – so inappropriate transfusions can significantly increase cost of care.<sup>6</sup>

When an expert international consensus panel systematically reviewed data from 494 published studies, they concluded that 59% of transfusions were “inappropriate”.<sup>7</sup>

As a result, there is a growing global recognition of the need to reduce unnecessary transfusions.

Appropriate Use of Transfusion<sup>7</sup>



The Joint Commission and the American Medical Association have listed transfusions in their top five interventions targeted for “overuse” and noted that “while blood transfusions can be life-saving, they also carry risks that range from mild complications to death”.<sup>8</sup> To improve the quality and reduce the cost of care, many hospitals are implementing patient blood management programs and protocols.<sup>9</sup>



# Adding to Traditional Blood Sampling for Hemoglobin Measurement with SpHb

## Limitations of Traditional Blood Sampling Methods

Even when bleeding can be observed by clinicians, visual estimation of blood loss can be inaccurate.<sup>1,2</sup> Hemoglobin concentration often drops when bleeding occurs, so clinicians naturally rely on laboratory hemoglobin measurement to help assess bleeding. However, invasive blood samples can only provide intermittent and often delayed laboratory hemoglobin results. This means that clinicians can make treatment decisions without also knowing the patient's real-time hemoglobin status.



Draw blood

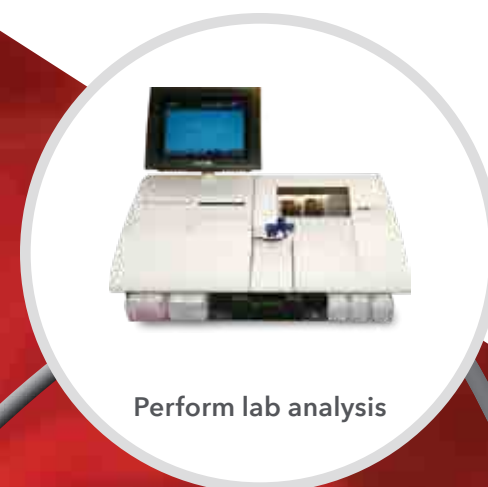


Label vial and send to lab

Multiple steps in laboratory hemoglobin determination



Wait...



Perform lab analysis



Wait...



Get results

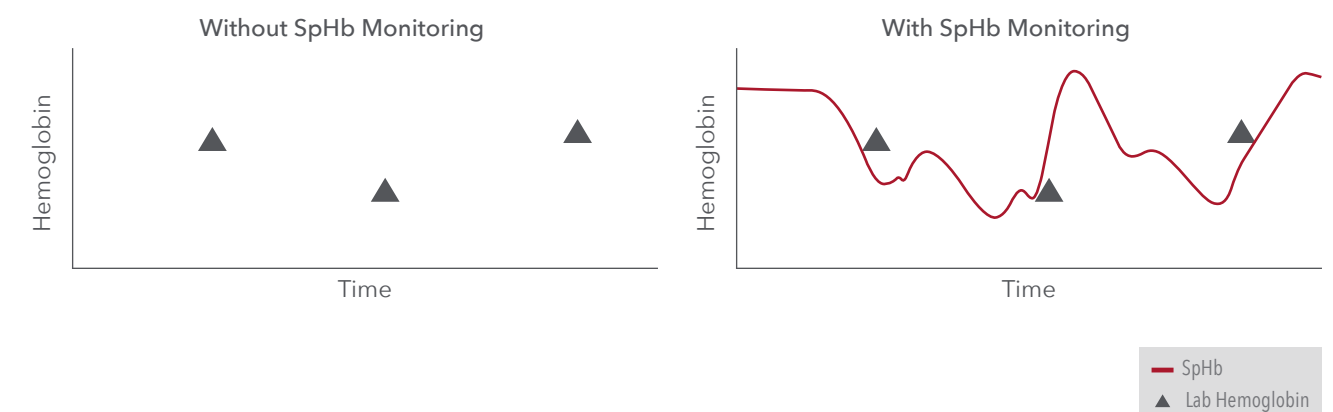
## SpHb: Helping Clinicians Make More Informed and Timely Assessments

Noninvasive and continuous hemoglobin (SpHb) monitoring helps automate the patient's hemoglobin status and provides real-time visibility to changes – or lack of changes – in hemoglobin between invasive blood samples.

SpHb monitoring may provide additional insight between invasive blood samples, such as when:<sup>3</sup>

- The SpHb trend is stable and the clinician may otherwise think hemoglobin is dropping
- The SpHb trend is rising and the clinician may otherwise think hemoglobin is not rising
- The SpHb trend is dropping and the clinician may otherwise think hemoglobin is stable

## Comparison Between Hemoglobin Without SpHb Monitoring vs. with SpHb Monitoring



<sup>1</sup> Rothermel RD et al. *Surgery*. 2016 Oct;160(4):946-953. <sup>2</sup> Guinn NR et al. *Transfusion*. 2013 Nov;53(11):2790-4. <sup>3</sup> Barker SJ et al. *Anesth Analg*. 2016 Feb;122(2):565-72. SpHb is not intended to replace lab testing. Clinical decisions regarding red blood cell transfusions should be based on the clinician's judgment considering among other factors: patient condition, continuous SpHb monitoring, and laboratory diagnostic tests using blood samples.

# Validating SpHb Compared to Common Invasive Methodologies

## Variability in Hemoglobin Measurements

While hemoglobin is one of the most common laboratory tests performed, most clinicians are unaware of the variation that should be expected from laboratory devices. The lack of awareness stems from the fact that clinicians do not typically obtain two or more laboratory hemoglobin measurements from the same patient at the same time.<sup>1</sup> Hemoglobin measurement variation can be caused by, among other things, patient physiology, phlebotomy, blood sample handling, and lab instrument variability.<sup>1</sup>

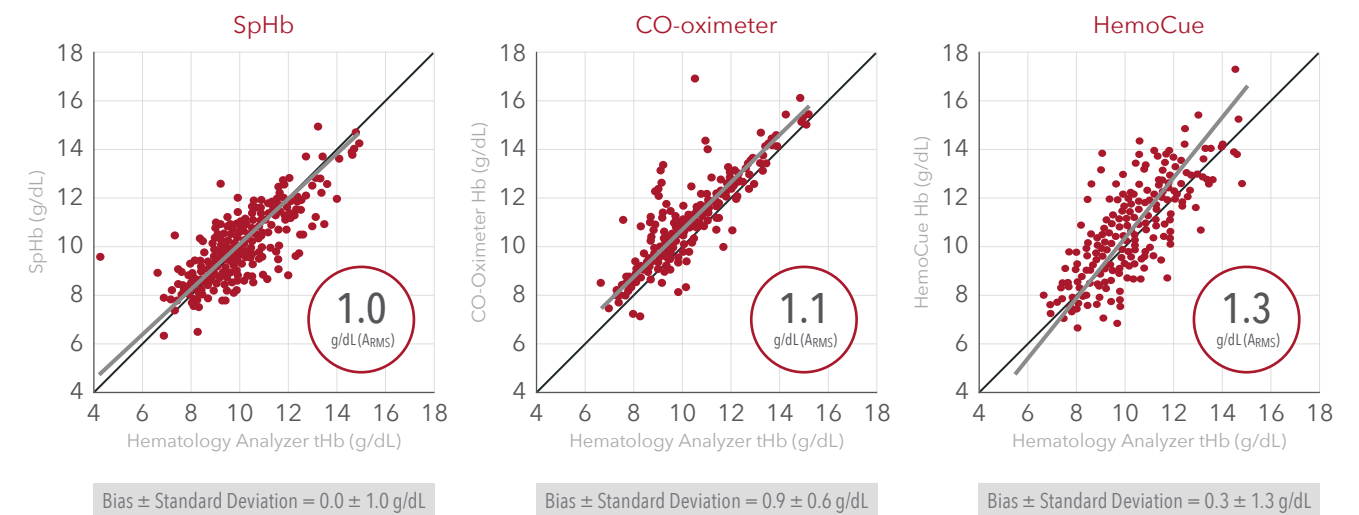
## Accuracy of SpHb and Other Methods Compared to Reference Hemoglobin

The results of a study conducted in a surgical intensive care unit illustrate the variation that can be expected between hemoglobin measurements from different devices. A total of 471 hemoglobin measurements were evaluated from 62 patients. Measurements from noninvasive and continuous hemoglobin (SpHb), a satellite laboratory CO-oximeter (Siemens RapidPoint 405), and a point-of-care device (HemoCue 301) were all compared to reference hemoglobin from the central laboratory hematology analyzer (Sysmex XT2000i). In this study, the absolute accuracy and trending accuracy of SpHb was similar to the two widely used invasive methods<sup>2</sup> as compared to the central laboratory hemoglobin analyzer. Some independent researchers have conducted their own testing and obtained similar results to the presented cases, while other researchers have reported larger, or in some cases smaller, differences when comparing SpHb measurements to laboratory measurements.<sup>2</sup>

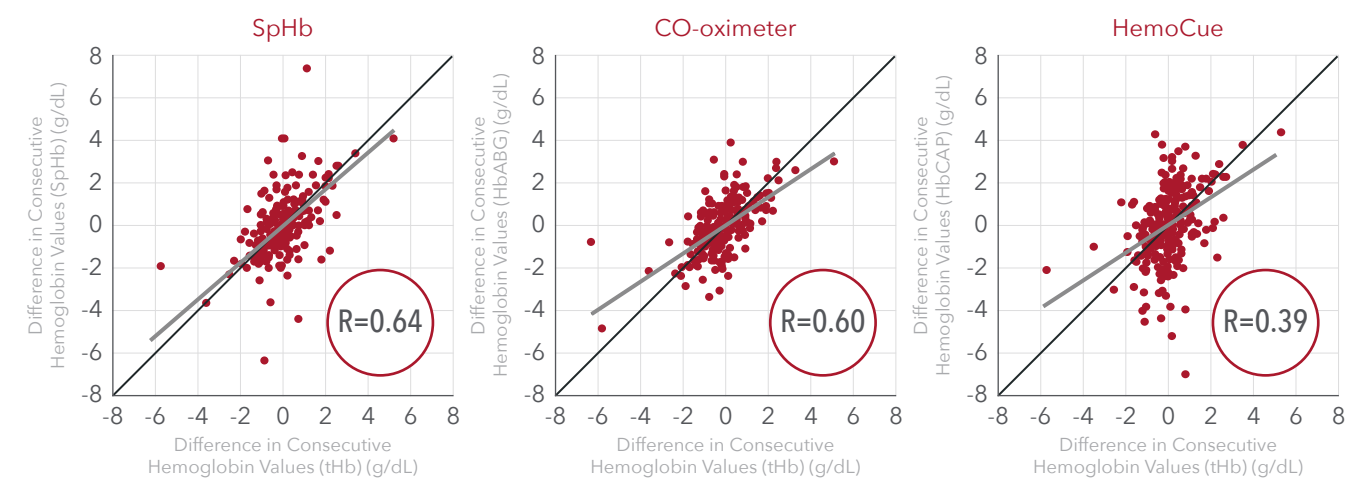
## Now Included in Guidelines

In 2017, both the European Society of Anaesthesiology's Guidelines for the Management of Severe Perioperative Bleeding and the Italian Ministry of Health's Blood Management Program Guidelines included noninvasive and continuous hemoglobin monitoring as a recommended tool.<sup>3,4</sup>

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



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



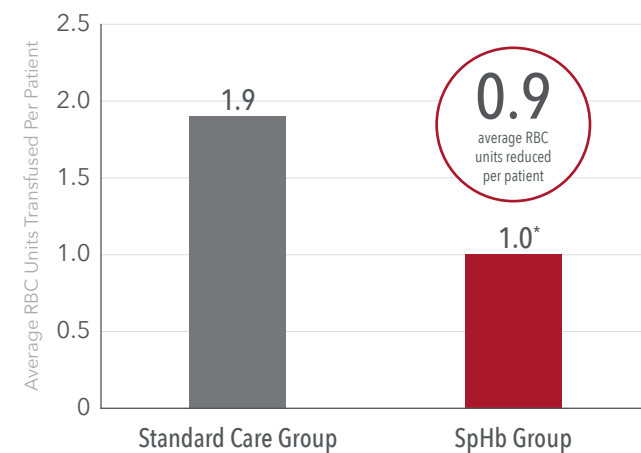
# Helping Manage Blood Transfusion Decisions with SpHb Monitoring

In two studies of high and low blood loss surgery, noninvasive and continuous hemoglobin (SpHb) monitoring helped clinicians reduce blood transfusions.

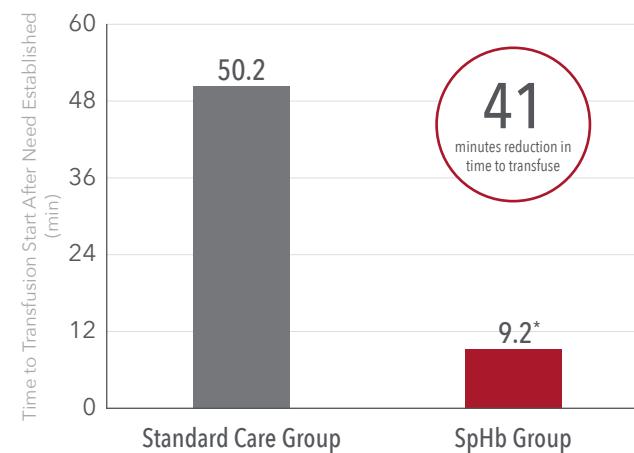
## High Blood Loss Surgery

A prospective cohort study of 106 neurosurgical patients evaluated adding SpHb monitoring to standard of care blood management and reported that it resulted in decreased blood utilization in high blood loss neurosurgery, while also facilitating earlier transfusions. The investigators concluded, "Adding SpHb monitoring to standard of care blood management resulted in decreased blood utilization in high blood loss neurosurgery, while facilitating earlier transfusions."<sup>1</sup>

SpHb Helped Clinicians Reduce Blood Transfusions in High Blood Loss Surgery<sup>1</sup>



SpHb Helped Clinicians Decrease the Time to Transfusion<sup>1</sup>

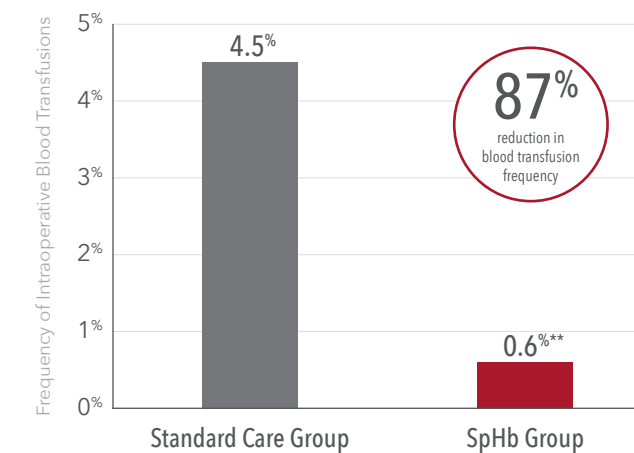


Prospective cohort study in 106 neurosurgery patients \* p<0.001  
 Patients were enrolled into either a cohort group (Standard Care Group) that received intraoperative hemoglobin measurement by intermittent blood sampling, or an intervention group (SpHb Group) in which SpHb was continuously monitored. In each group, if researchers noted hemoglobin trended downward below 10g/dL, a red blood cell transfusion was started and continued until hemoglobin trended upward, above 10g/dL. The blood sampling technique was the same for patients in both the Standard Care Group and the SpHb Group. Arterial blood was drawn from a 20 gauge radial artery cannula into 2mL ethylenediaminetetraacetic acid collection tubes, thoroughly mixed then sent immediately to the central lab for analysis by a hematology analyzer (Coulter GEN-S Hematology Analyzer). The transfusion threshold of 10g/dL was predetermined by the study protocol and may not be appropriate for all patients.<sup>1</sup>

## Low Blood Loss Surgery

The researchers in a randomized controlled trial of 327 patients undergoing elective orthopedic surgery conducted at Massachusetts General Hospital concluded, "We believe that the availability of SpHb decreases inappropriate transfusion."<sup>2</sup>

SpHb Helped Clinicians Reduce Blood Transfusions in Low Blood Loss Surgery<sup>2</sup>



\*\* p=0.03

*"We believe that the availability of SpHb decreases inappropriate transfusion"<sup>2</sup>*



## Identifying Changes in Hemoglobin Associated with Bleeding with SpHb Monitoring

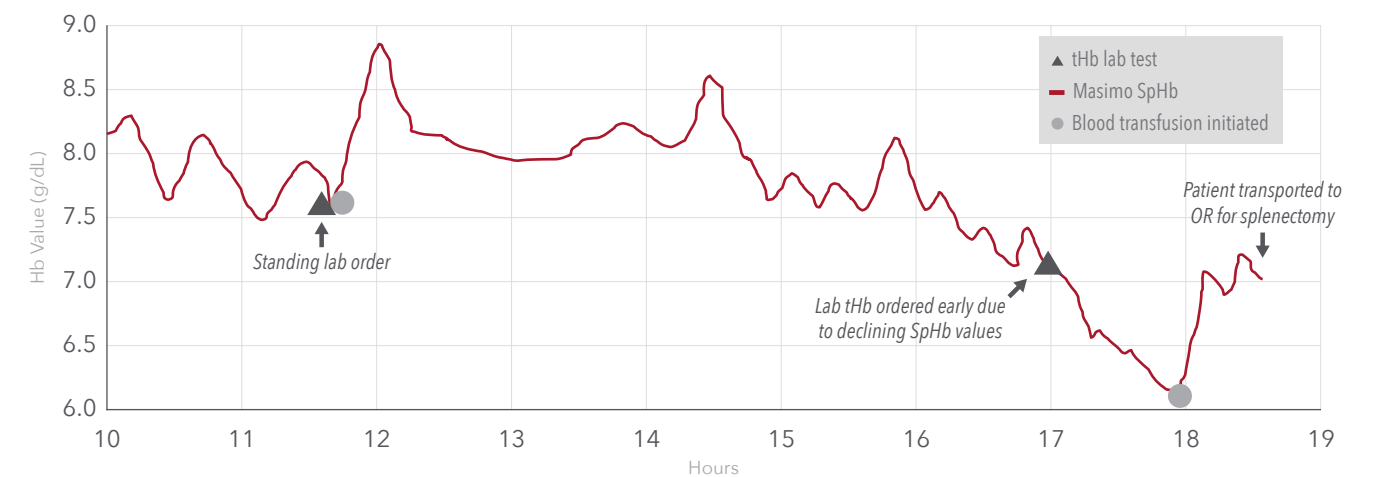
In addition to assisting with transfusion management, noninvasive and continuous hemoglobin (SpHb) monitoring may help clinicians inside and outside the operating room identify changes in hemoglobin that may be associated with bleeding.<sup>1,2</sup>

### Risk and Cost of Internal Bleeding

Internal bleeding is considered a significant risk factor for patients, and late detection further increases risk and cost.<sup>3</sup> Vital signs are not a reliable indicator of bleeding, but a drop in hemoglobin over a period of time is considered a reliable indicator of bleeding.<sup>4</sup> However, traditional hemoglobin measurement requires blood sampling and laboratory analysis, which means results are often intermittent and delayed. This means that detection of changes in hemoglobin due to internal bleeding can be significantly delayed.<sup>5</sup>

### Example of How SpHb Monitoring Can Help Identify Hemoglobin Changes Associated with Bleeding<sup>2</sup>

A declining SpHb trend may allow clinicians to investigate dropping hemoglobin levels sooner.<sup>2</sup>

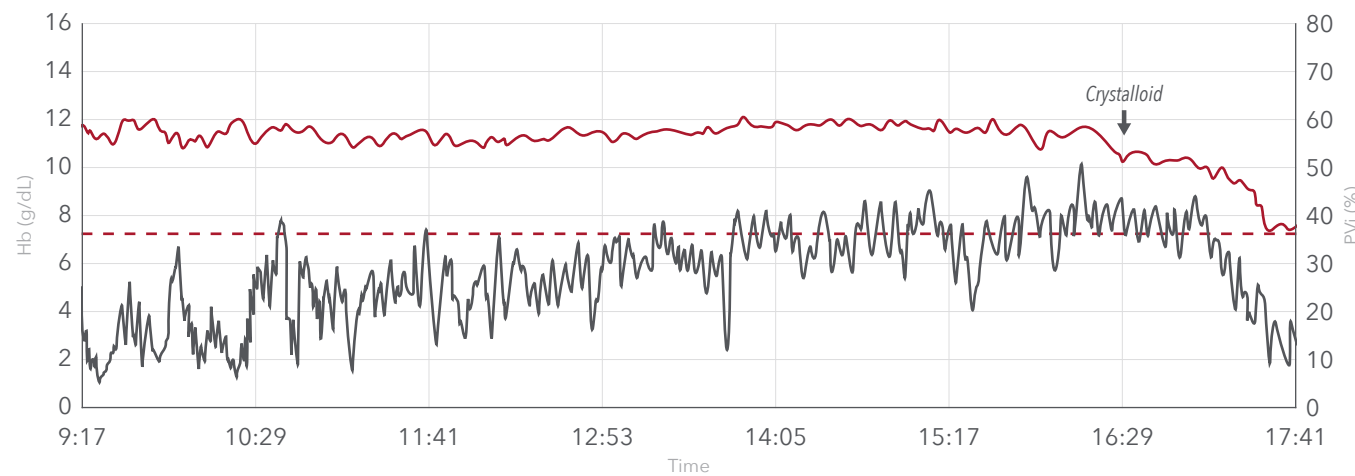


# Differentiating Causes of Hemoglobin Drops Using SpHb and PVi Together

While hemoglobin decreases are often due to blood loss, they can also occur due to blood dilution that occurs as a result of excess fluid administration – decreasing delivery of oxygen to the tissues.<sup>1</sup> Excess fluid administration can cause tissue edema and subsequent morbidity and increased length of stay.<sup>2</sup> This unintended or “iatrogenic anemia” can also cause clinicians to order blood transfusions in the absence of significant bleeding.<sup>3,4</sup>

By using SpHb and PVi together, it is possible to noninvasively monitor both hemoglobin and fluid responsiveness on a single device. This visibility may help automate the assessment of the cause of hemoglobin drops – and potentially help clinicians avoid the over-administration of fluid or blood.<sup>1</sup>

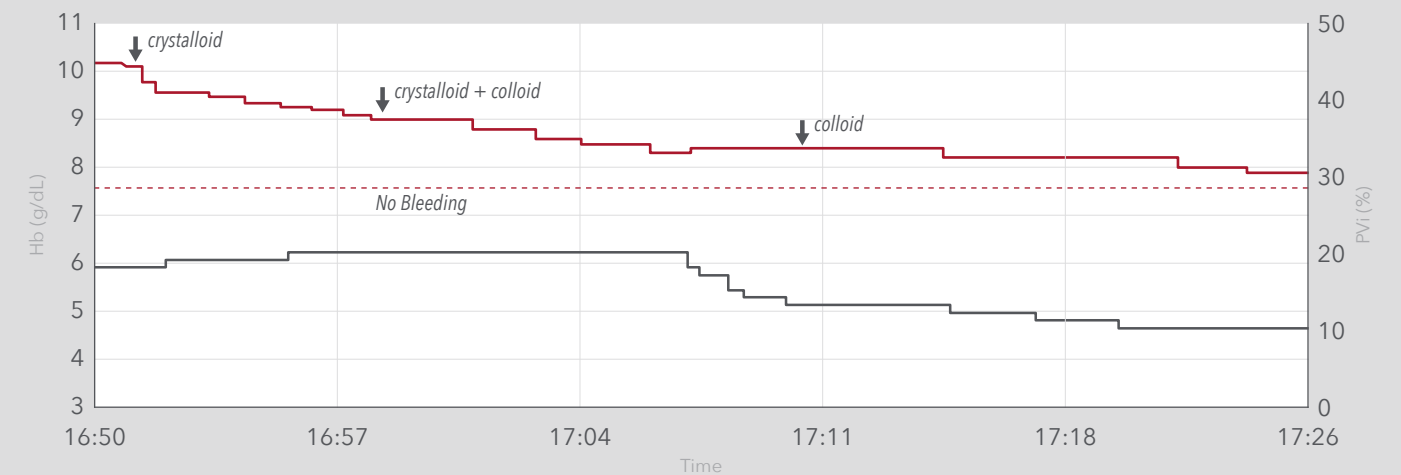
Hepatic Surgery: Example of Hemoglobin Drop Caused by Blood Loss and Fluid Administration<sup>1</sup>



SpHb and PVi were continuously monitored during hepatic surgery. The gradual PVi increase to very high levels along with SpHb decrease from about 12 to 10 g/dL may indicate hypovolemia due to blood loss. Subsequent fluid administration with crystalloid resulted in a PVi decrease along with another SpHb decrease from about 10 to 8 g/dL that may indicate hemodilution and iatrogenic anemia.<sup>1</sup>



Spinal Surgery: Example of Hemoglobin Drop Caused by Fluid Administration<sup>1</sup>



SpHb and PVi were continuously monitored during spine surgery. The PVi decrease along with SpHb decrease from about 10 to 8 g/dL may indicate hemodilution and iatrogenic anemia.<sup>1</sup>



By using SpHb and PVi together, it is possible to noninvasively monitor both hemoglobin and fluid responsiveness on a single device



# Improving Outcomes in Surgical Patients with SpHb and PVi

A recent study evaluated the impact of using both noninvasive and continuous hemoglobin (SpHb) and Pleth Variability Index (PVi) on anesthesia-related surgical mortality.<sup>1</sup>

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

**“We know that anemia and inadequate volume filling are two important factors in morbidity and mortality after anesthesia.”<sup>2</sup>**

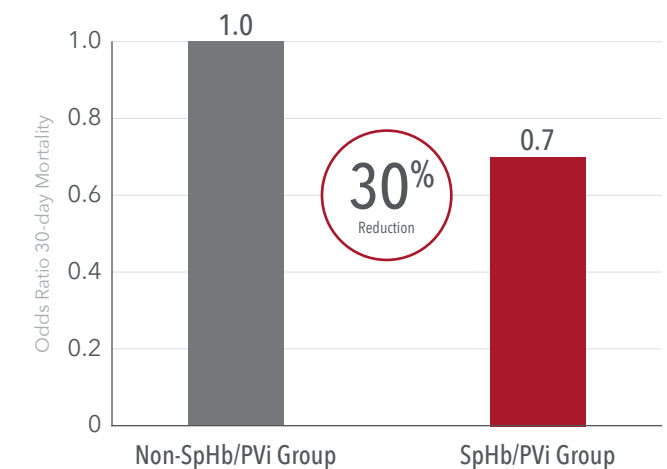
**Nathalie Nathan, MD**

Head of the Department of Anesthesiology  
Centre Hospitalier Universitaire de Limoges, in Limoges, France



**“(SpHb and PVi) allowed earlier transfusion and reduces mortality at a scale of a whole hospital with different clinical practices (and practitioners) and unselected patients”<sup>1</sup>**

Reduction in Mortality Between Non-Monitored Group and SpHb/PVi Group<sup>1</sup>



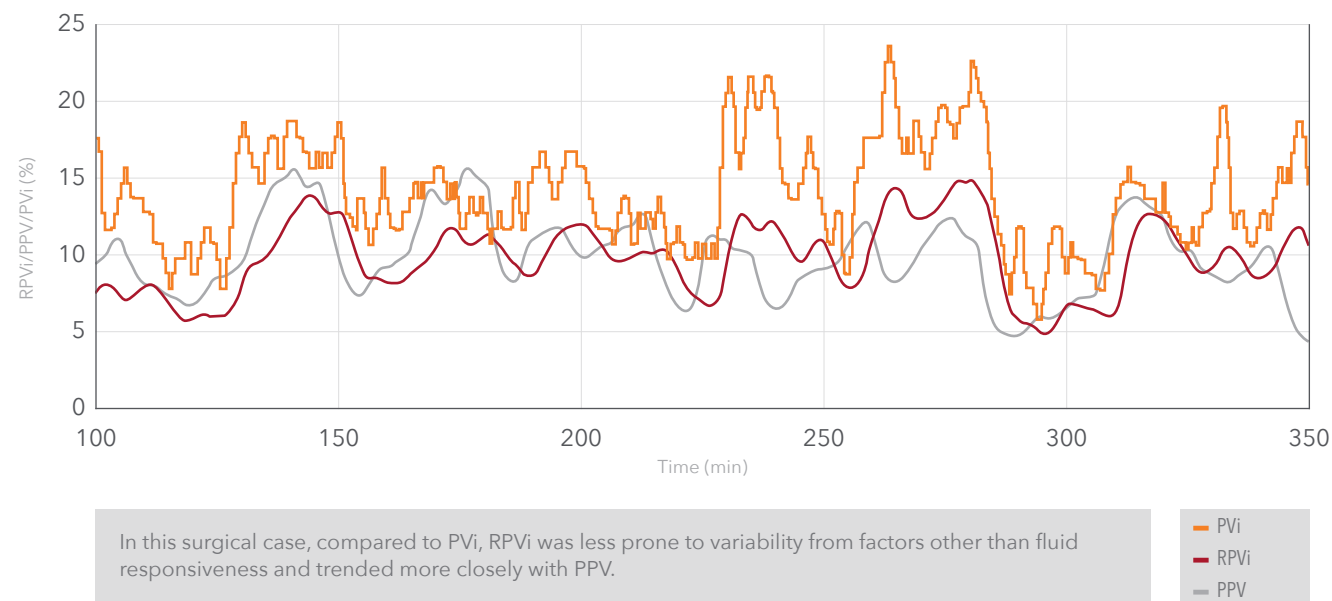
The study included 18,867 patients, of whom 3,540 underwent SpHb and PVi monitoring installed in all operating rooms, recovery rooms, and intensive care units, along with Masimo Patient SafetyNet\*. Patients in the SpHb/PVi group received vascular filling with crystalloids or blood, according to the clinical algorithm. Demographic, anesthesia, surgical, and transfusion data were collected in electronic files and Patient SafetyNet. The researchers compared the transfusion rate within the first postoperative 48 hours and the mortality rates for each group at 30 and 90 days following surgery. The researchers found that SpHb/PVi group had a 30% reduction in mortality at 30 days (odds ratio 0.7) and a 25% reduction in mortality at 90 days (odds ratio 0.75) compared to the non-monitored group. The overall transfusion rate and number of units transfused within 48 hours were not significantly different between groups, but non-cardiac surgical patients in the SpHb/PVi group were transfused more often while they were still in the operating room (72.9% vs. 56.1%) instead of later in their hospital stay.<sup>1</sup>

<sup>1</sup>Nathan N et al. *Anesthesiology*. 2016;A1103(abstract). <sup>2</sup>Vlessides M. *Anesthesiology News* Feb 15, 2017. Retrieved from <http://www.anesthesiologynews.com>. \*The use of the trademark SafetyNet is under license from University HealthSystem Consortium.

# Simplifying Fluid Responsiveness Monitoring with RPi

Pleth Variability Index (PVi), available with Masimo SET® pulse oximetry,<sup>1</sup> is now available in a multi-wavelength version called rainbow PVi (RPVi). While PVi has been shown to help clinicians monitor fluid responsiveness,<sup>1</sup> PVi is also reflective of changes in vasomotor tone, intra-thoracic pressure excursions, and other physiologic factors. RPi may further simplify fluid responsiveness monitoring for clinicians because it is designed to provide enhanced specificity to changes in fluid volume.<sup>2</sup>

Case Example of PVi vs. RPi vs. PPV<sup>2</sup>



RPVi is specifically designed to provide enhanced specificity to changes in fluid volume<sup>2</sup>

# Going Beyond Pulse Oximetry in Monitoring Oxygenation

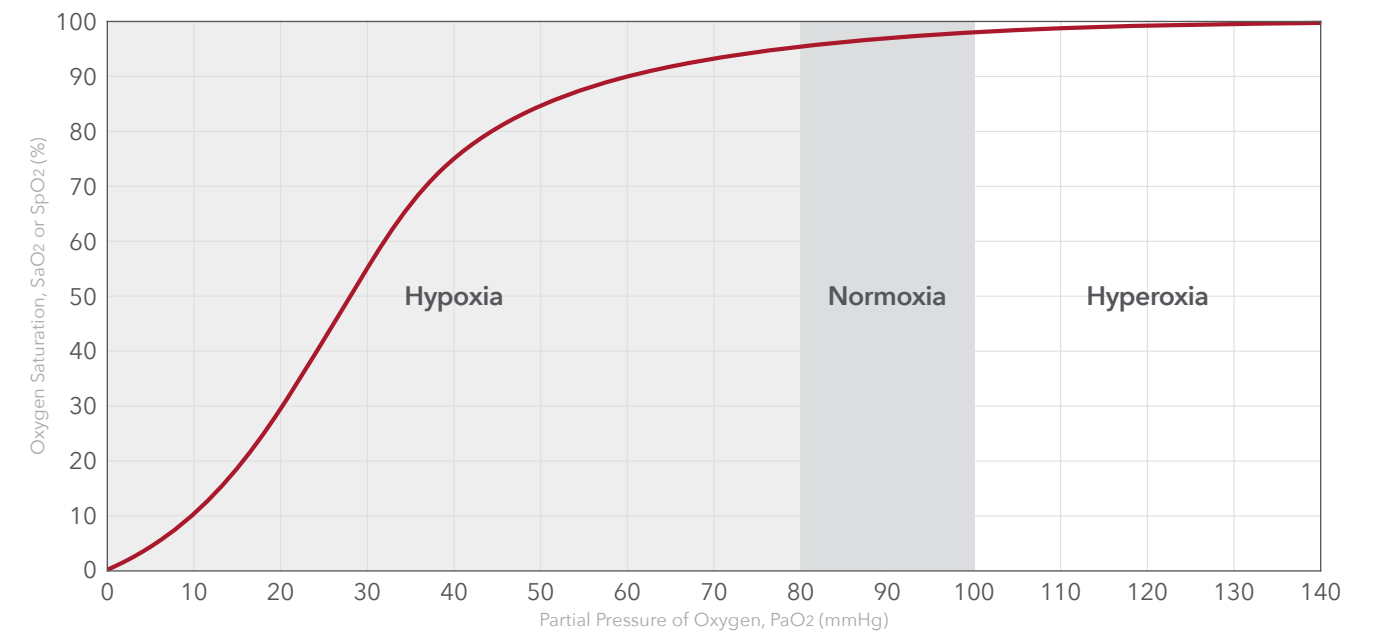
## Limitations of Pulse Oximetry During Supplemental Oxygen Administration in Identifying Impending Hypoxia

Oxygen is transported in the arterial blood by hemoglobin and pulse oximetry enables continuous oxygen saturation monitoring in the hypoxic (low oxygenation) or normoxic (normal oxygenation) ranges. Clinicians often administer supplemental oxygen to surgical or critically ill patients, which is transported in the blood by plasma to achieve a moderate hyperoxic (higher than normal oxygenation) state and provide a supply of reserve oxygen – should it be needed.



However, pulse oximetry cannot monitor hyperoxia. During supplemental oxygen administration, clinicians can use the partial pressure of oxygen (PaO<sub>2</sub>) to assess hyperoxia, but this requires invasive blood sampling and laboratory analysis which is intermittent and delayed. Between invasive samples, significant changes in PaO<sub>2</sub> cannot be assessed and therefore unexpected hypoxia or unintended hyperoxia can occur.

Inability of Pulse Oximetry to Monitor Hyperoxia



The oxyhemoglobin dissociation curve can be used to visually represent the oxygenation ranges and shows the inability of SpO<sub>2</sub> to monitor hyperoxic states, requiring direct PaO<sub>2</sub> measurement.



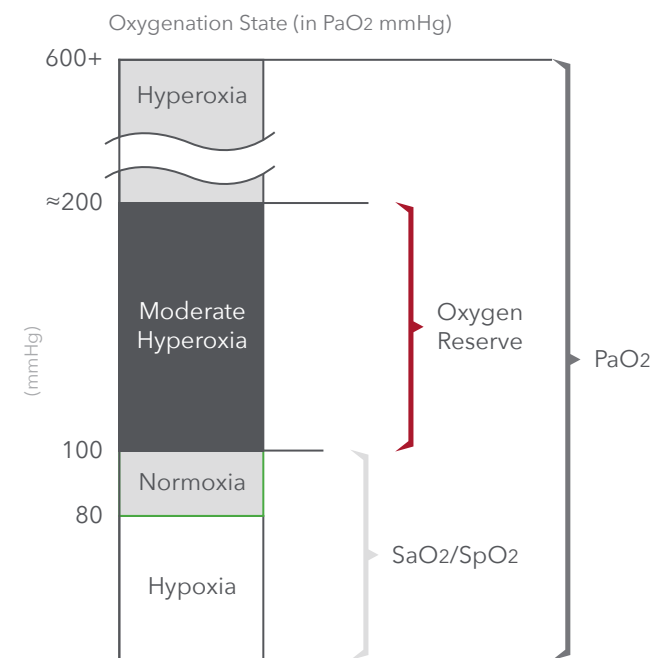
Between invasive samples, significant changes in PaO<sub>2</sub> cannot be assessed and therefore unexpected hypoxia or unintended hyperoxia can occur.

## ORi: Noninvasive Monitoring of the Hyperoxic Status

Oxygen Reserve Index (ORi) represents a fundamental step forward in oxygenation visibility. ORi is made possible through multi-wavelength light absorption in the rainbow SET Pulse CO-Oximetry platform that enables the monitoring of blood characteristics related to the moderate hyperoxic state.

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

### PaO<sub>2</sub> Range and Available Monitoring Methods



ORi provides additional insight in the moderate hyperoxia range, above hypoxic and normoxic levels indicated by SpO<sub>2</sub>/SaO<sub>2</sub>.

ORi represents a fundamental step forward in oxygenation visibility

### ORi Clinical Application

In patients receiving supplemental oxygen, such as those in surgery, under conscious sedation, or in the intensive care unit, ORi may:<sup>1</sup>

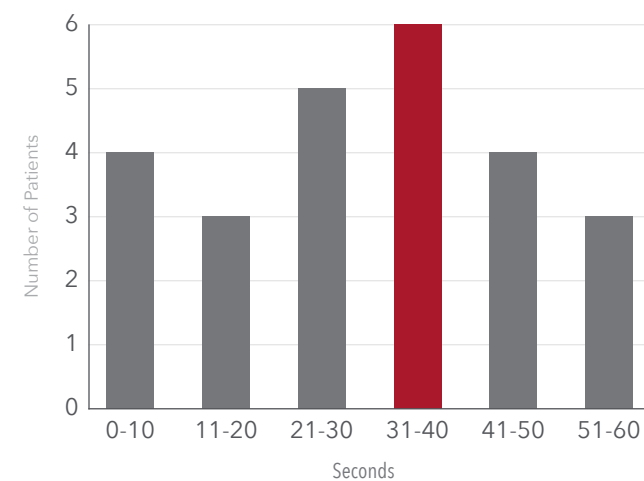
- Provide an early alarm when oxygen reserve drops before any changes in SpO<sub>2</sub> occur
- Reflect response to oxygen administration, such as in a preoxygenation period before intubating and extubating
- Facilitate oxygen titration and prevent unintended hyperoxia

# Indicating Impending Hypoxia Earlier with ORi

## Clinical Evidence for the Utility of ORi

In a study published in *Anesthesiology*, researchers found that during prolonged apnea in healthy anesthetized children, Oxygen Reserve Index (ORi) detected impending desaturation a median of 31.5 seconds before noticeable changes in SpO<sub>2</sub> occurred.<sup>1</sup>

Early Warning Time with ORi<sup>1</sup>



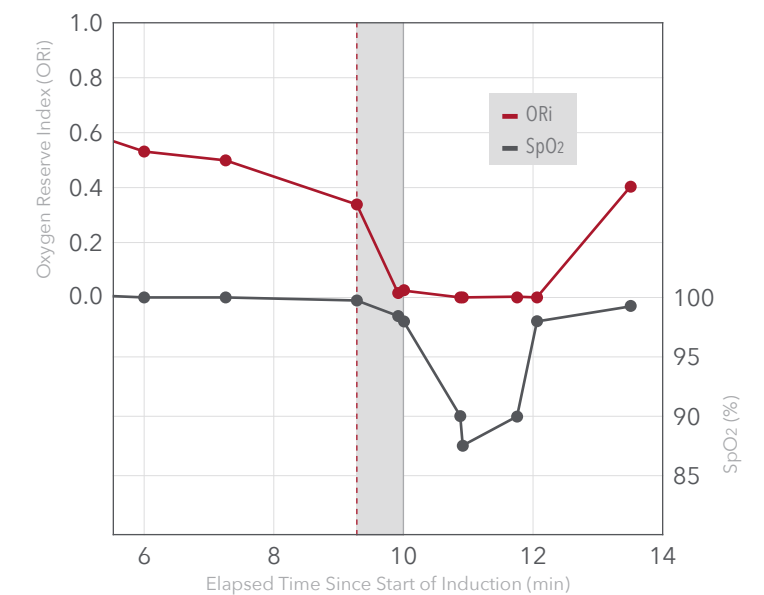
33 pediatric surgical patients were enrolled in the study. Eight of these resumed spontaneous ventilation during the study period, leaving 25 apneic patients to evaluate, with an average age of 7.6 years. Data were recorded continuously with a Masimo Radical-7 Pulse CO-Oximeter. ORi was retrospectively calculated and was not visible to investigators. The amount of early warning time with ORi by the number of patients observed is summarized in the histogram.<sup>1</sup>

*“Our major finding is that monitoring the ORi before and during intubation detected impending desaturation in median of 31.5 seconds before noticeable changes in SpO<sub>2</sub> occurred”<sup>1</sup>*

*“All anesthesiologists should appreciate advanced warning of impending oxygen desaturation. Every second counts during those crucial moments, and novel technology that has the potential to warn clinicians sooner than the current technology is worth a much closer look”<sup>3</sup>*

In a study published in *Anesthesia & Analgesia*, researchers found a significant relationship between change in PaO<sub>2</sub> and change in ORi. The researchers concluded: “Decreases in ORi to near 0.24 may provide advance indication of falling PaO<sub>2</sub> approaching 100 mmHg when SpO<sub>2</sub> is >98%.”<sup>2</sup>

Case Example of Early Warning with ORi<sup>1</sup>



ORi levels rise after 100% FiO<sub>2</sub> period. ORi levels drop prior to 30% FiO<sub>2</sub> and intubation periods, and minutes before the SpO<sub>2</sub> drop. ORi then rises during re-oxygenation. ORi was retrospectively determined using offline data analysis.

# Helping Emergency Personnel Monitor Carbon Monoxide in the Blood with SpCO

## Carbon Monoxide: A Silent Killer

Carbon monoxide (CO) is a toxic, colorless, odorless gas that is a product of combustion. Unintentional, non-fire related CO poisoning is the leading cause of poisoning deaths in the U.S. and results in over 21,000 emergency department visits per year.<sup>1</sup> Symptoms of CO exposure are non-specific so they are often overlooked, and some victims have no symptoms at all.<sup>2</sup>

First responders are at the greatest risk because just one severe CO exposure event nearly doubles the risk of premature death, and consistent CO exposure may cause long-term heart and brain damage.<sup>3,4</sup> When even mild levels of CO are circulating in the blood, the heart and brain are robbed of critical oxygen. This can cause mental confusion, leading to poor decision making in dangerous situations and increasing the risk of heart disease or stroke – two conditions that account for nearly 50% of on-duty firefighter deaths.<sup>5,6</sup>

Researchers using SpCO to monitor emergency department patients concluded that 69% of patients with CO poisoning would not have been identified without SpCO monitoring.<sup>12</sup>

## Deadly Exposure Revealed with SpCO

Noninvasive carboxyhemoglobin (SpCO) enables quick and noninvasive monitoring of CO levels in the blood, and may lead to the identification of elevated CO levels that might otherwise go unnoticed in front-line settings such as fire rehabilitation and mass casualty scenarios.<sup>7,8</sup> Results from clinical studies conducted on emergency room patients demonstrate that SpCO technology may be a valuable tool for monitoring a large number of patients for possible CO exposure,<sup>9,10</sup> supporting the possible use of SpCO in emergency patients.<sup>11</sup> A recent study at the Medical University of Vienna assessed SpCO in 32,396 emergency room patients. The researchers concluded that of the 32 patients with a diagnosis of CO poisoning, 22 (69%) would not have been identified without SpCO monitoring.<sup>12</sup>

## Saving Lives Every Day

Industry-leading organizations have lined up to support CO education and the National Fire Protection Association (NFPA) released an updated Fire Rehabilitation Standard (NFPA 1584) which requires fire fighters exposed to smoke at incident scenes and during training be assessed on the scene for elevated CO levels.<sup>13</sup>

*"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, Illinois, USA

<sup>1</sup> Sircar K et al. *Am J Emerg Med.* 2015 Sep; 33(9): 1140-1145. <sup>2</sup> Centers for Disease Control and Prevention (CDC). *MMWR Morb Mortal Wkly Rep* 2005;54:36-9. <sup>3</sup> Hampson NB et al. *Crit Care Med.* 2009 Jun;37(6):1941-7. <sup>4</sup> Bledsoe BE. *J Emerg Med Svcs.* 2007;132:54-59. <sup>5</sup> Jakubowski G. *FireRescue Magazine.* 22(11):52-55, 2004. <sup>6</sup> Bledsoe BE. *FireRescue Magazine.* September 2005. <sup>7</sup> Augustine JJ. *JEMS.* 2007. May;64:71. <sup>8</sup> Bledsoe BE et al. *Prehosp Emerg Care.* 2010 Jan-Mar;14(1):131-3. <sup>9</sup> Suner S. et al. *J Emerg Med.* 2008 May;34(4):441-50. <sup>10</sup> Roth D et al. *Ann Emerg Med.* 2011 Jul;58(1): 74-9. <sup>11</sup> Sebbane M et al. *Respir Care.* 2013 Oct;58(10):1614-20. <sup>12</sup> Roth Det al. *Int J Clin Pract.* 2014 Oct;68(10):1239-45. <sup>13</sup> National Fire Protection Association 1584. 2015. Accessed at: <http://www.nfpa.org>.

SpCO is intended to be used to monitor CO levels in the blood. SpCO monitoring is not intended to replace laboratory blood testing and not to be used as the sole basis for making diagnosis or treatment decisions related to CO poisoning. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

# Revealing Elevated Methemoglobin in the Blood with SpMet

## The Dangers of Methemoglobinemia

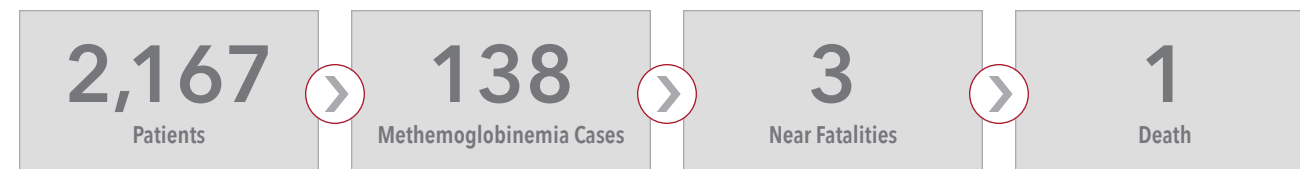
Methemoglobinemia is a blood disorder in which there is an abnormal amount of methemoglobin, a form of hemoglobin that is unable to effectively bind to oxygen. Many drugs commonly used in hospitals – such as lidocaine, benzocaine, dapsone, and nitrates – may cause a dangerous reaction known as acquired methemoglobinemia.<sup>1</sup> Inhaled nitric oxide (iNO) therapy, and even topical anesthetics containing benzocaine or prilocaine, can cause elevated levels of methemoglobin in neonates and infants.<sup>2,3</sup> Occupational exposure on the skin to aniline, a chemical used in furniture making, or with inhalation of nitrobenzene, a chemical used to make aniline, can also cause severe methemoglobinemia.<sup>4</sup>

While methemoglobinemia can occur in all care areas and patients, it is often unrecognized and undiagnosed<sup>1</sup>

## Prevalence of Methemoglobinemia

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, indicate that while methemoglobinemia can occur in all care areas and patients, it is often unrecognized and undiagnosed.<sup>1</sup>

### Results from a Retrospective Study at Two Johns Hopkins Hospitals Over a 28-month Period<sup>1</sup>

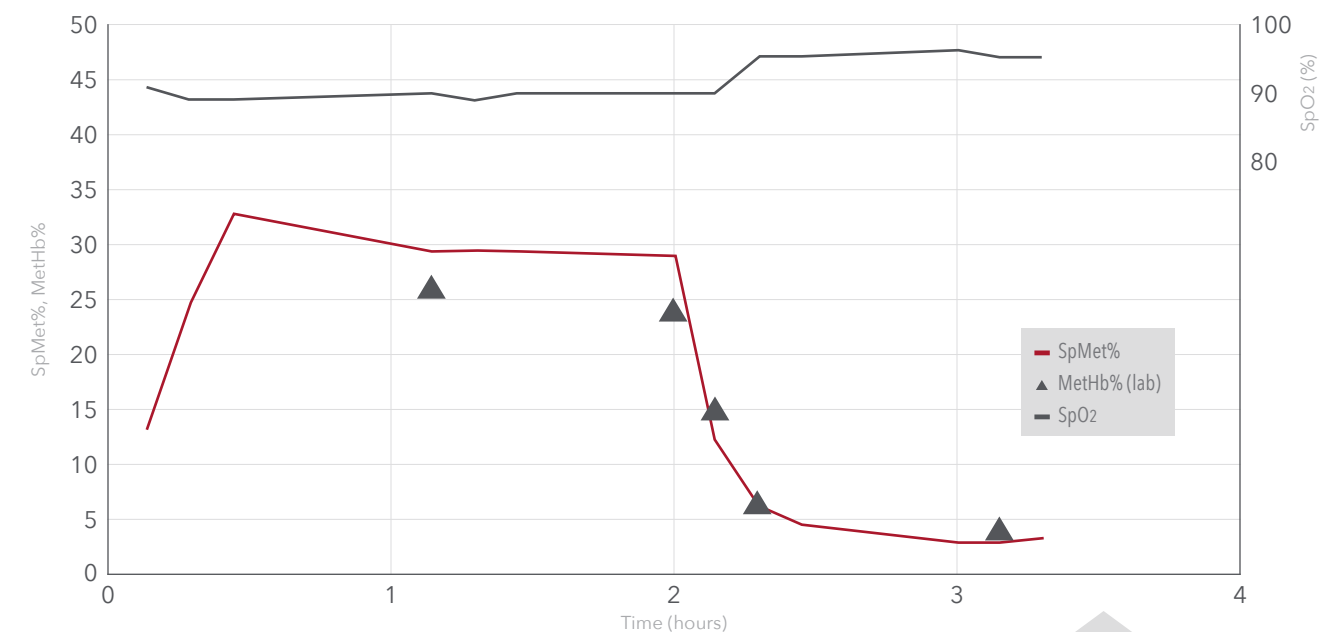


## Monitoring Methemoglobin with SpMet

Masimo rainbow® Pulse CO-Oximetry enables noninvasive and continuous monitoring of methemoglobin in the blood. SpMet helps clinicians monitor for elevated methemoglobin in care areas where the drugs that cause methemoglobinemia are most common, such as in procedure labs and the operating room. With real-time information at the patient bedside, SpMet may help clinicians respond quickly to elevated methemoglobin levels and thereby address potentially life-threatening situations.

### SpMet Clinical Case

In the following case, SpMet correlates with the methemoglobin values from a laboratory CO-oximeter (MetHb) and also responds to an injection of methylene blue at approximately two hours.<sup>5</sup>



SpMet may help clinicians respond quickly to elevated methemoglobin levels and thereby address potentially life-threatening situations

<sup>1</sup>Ash-Bernal R et al. *Medicine (Baltimore)*. 2004 Sep. 83(5):265-73. <sup>2</sup>Riou Y et al. *Pediatric Research* (1998) 43, 295-295. <sup>3</sup>U.S. Food & Drug, Consumer Updates, Benzocaine and Babies: Not a Good Mix. <sup>4</sup>Lee CH et al. *Ann Occup Environ Med*. 2013 Nov 1;25(1):31. <sup>5</sup>Annabi EH et al. *Anesth Analg*. 2009 Mar;108(3):898-9. SpMet is intended to be used to monitor methemoglobin levels in the blood. SpMet monitoring is not intended to replace laboratory blood testing and not to be used as the sole basis for making diagnosis or

treatment decisions related to methemoglobinemia. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

# Overcoming a Limitation of Conventional Pulse Oximetry with SpfO<sub>2</sub>

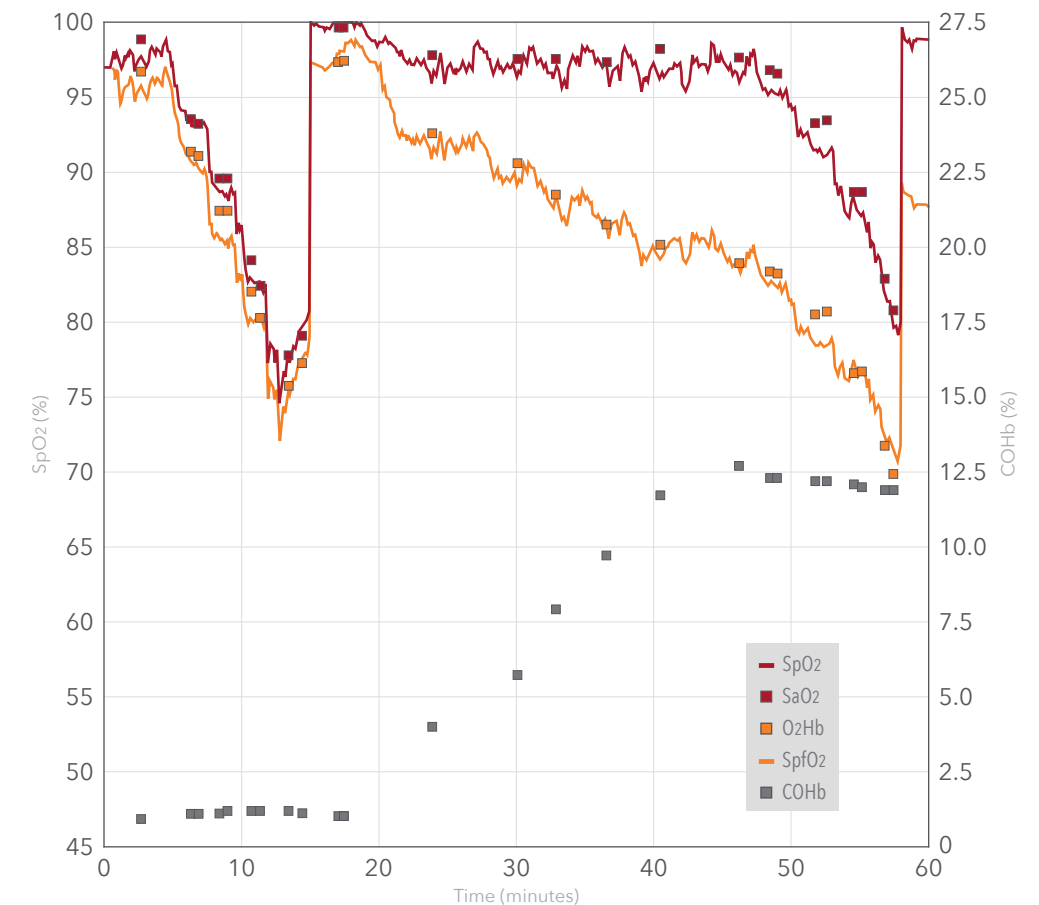
## Potential Inaccuracy in the Presence of Dyshemoglobins

All two-wavelength pulse oximeters (including Masimo's) can only measure "functional" oxygen saturation with SpO<sub>2</sub>, which means they cannot distinguish oxygenated hemoglobin from dyshemoglobins, including the most prevalent forms of carboxyhemoglobin and methemoglobin.<sup>1</sup>

In the presence of dyshemoglobins, this means pulse oximeters will report falsely high oxygen saturation levels. Laboratory CO-oximeters can measure "fractional" oxygen saturation, which takes into account the presence of dyshemoglobins in oxygen saturation measurement, but measurements are only possible with invasive blood sampling and laboratory analysis.



Case Illustrating Increased Accuracy of SpfO<sub>2</sub> with Elevated Carboxyhemoglobin<sup>2</sup>



In the presence of elevated carboxyhemoglobin levels and a hypoxic state, SpO<sub>2</sub> can overestimate oxygen saturation levels while SpfO<sub>2</sub> can provide truer estimates of oxygen saturation.

## Masimo SpfO<sub>2</sub> Fractional Measurement

By utilizing multiple wavelengths of light, Masimo rainbow SET Pulse CO-Oximeters can measure SpfO<sub>2</sub>, the first noninvasive fractional oxygen saturation measurement. SpfO<sub>2</sub> allows truer arterial oxygenation monitoring in patients with elevated dyshemoglobins – common throughout hospital and pre-hospital settings – as compared to functional oxygen saturation.

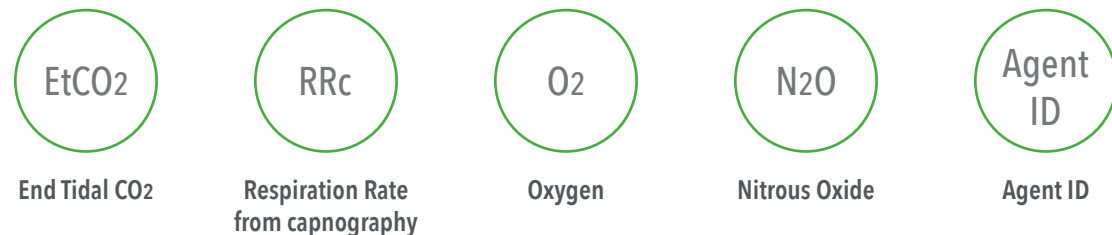
<sup>1</sup>Barker SJ et al. *Anesthesiology*. 1989 Jan;70(1):112-7. <sup>2</sup>Masimo data on file. SpfO<sub>2</sub> is not available in the U.S.



# Monitoring Capnography and Gas with NomoLine

Changes in expired respiratory gas can be an early indicator of an adverse respiratory event. Capnography can help clinicians quickly spot hypoventilation, hyperventilation, airway obstruction, and other potentially life-threatening conditions.<sup>1</sup> During surgery, capnography and gas monitoring also provide insight into the effectiveness of the anesthesia breathing circuit, helping maintain proper gas concentrations and ventilation levels. Masimo's NomoLine capnography and gas monitoring technologies complement our breakthrough noninvasive portfolio with innovative, multi-spectral technologies for measuring respiratory gases and inhaled anesthetic agents. The solutions range from integrated OEM solutions, to external "plug in and measure" gas analyzers, to handheld devices.

## NomoLine Capnography and Gas Parameters



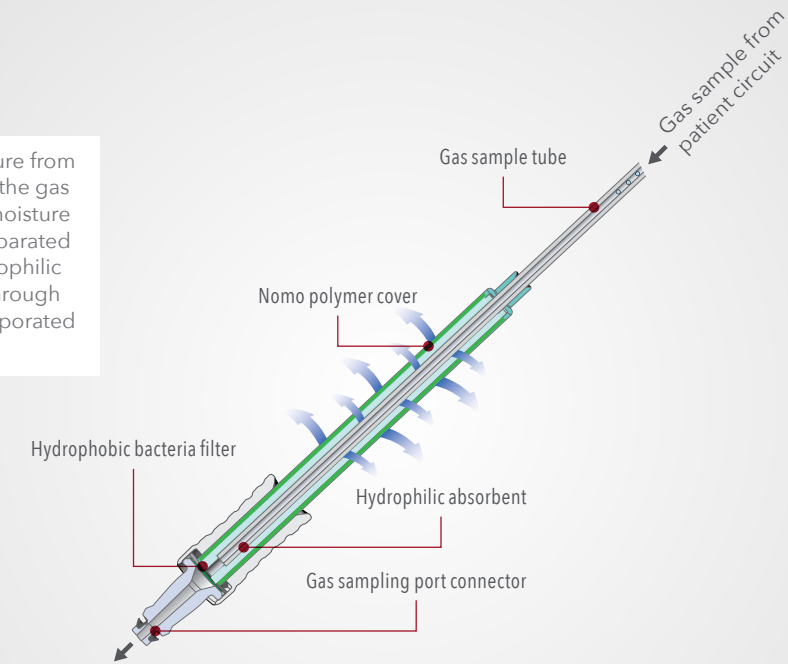
## Overcoming Common Sampling Problems with NomoLine Technology

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

NomoLine technology reduces common problems associated with conventional sidestream gas analysis. Incorporating a unique, patented polymer, NomoLine allows water in the sampling line to evaporate into the surrounding air while leaving oxygen, carbon dioxide, and anesthetic gases unaffected. This eliminates the need for a water trap and issues related to their handling, and enables a NomoLine to last much longer than conventional capnography sampling line solutions.

## How NomoLine Works

Gas and condensed moisture from the patient enters through the gas sample tube, condensed moisture and aspirated water are separated and collected using a hydrophilic absorbent, then diffused through the polymer cover and evaporated into surrounding air.



## Mainstream and Sidestream Options

Some capnography and gas monitoring technologies offer only a sidestream approach. With NomoLine, Masimo offers multiple capnography and gas measurements delivered through either mainstream or sidestream options. Clinicians can now benefit from capnography and gas monitoring in a range of hospital environments – from the operating room, to intensive care, to the general ward.

## Fast Start Up and No Calibration Delays During Monitoring

NomoLine capnography and gas monitoring technologies do not require a warm-up period, enabling fast start ups with no delay. In addition, NomoLine capnography and gas monitoring technologies do not auto calibrate during monitoring, eliminating delays present with other technologies.



# Protecting More Patients by Monitoring Every Breath with rainbow Acoustic Monitoring

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

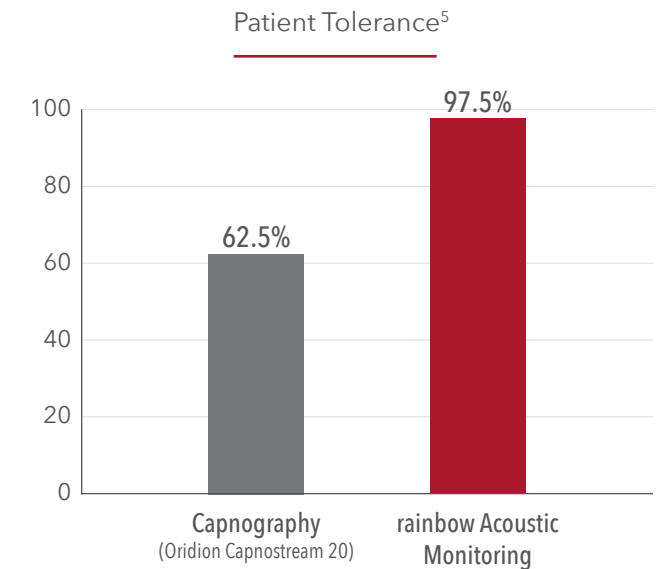
## The Need for Respiration Rate Monitoring

Opioid-based pain medications can slow and eventually stop breathing in some patients, which makes continuous monitoring of respiration rate especially important for post-surgical patients receiving patient-controlled analgesia for pain management. The Anesthesia Patient Safety Foundation and The Joint Commission recommend continuous

oxygenation and ventilation monitoring for all patients receiving opioid-based pain medications.<sup>1,2</sup> Conscious sedation can also induce respiratory depression and place patients at considerable risk of serious injury or death.<sup>3</sup> However, the use of traditional capnography for respiration rate monitoring may be limited by patient tolerance.<sup>4</sup>

## Introducing rainbow Acoustic Monitoring

rainbow Acoustic Monitoring uses breathing sounds from an acoustic sensor on the neck to provide Acoustic Respiration Rate (RRa®), an accurate, easy-to-use, and reliable monitoring solution that also results in higher patient tolerance.<sup>5</sup> RRa may facilitate monitoring of respiratory compromise and patient distress, offering a breakthrough in patient safety for post-surgical patients and for conscious sedation procedures.<sup>6-8</sup> While Masimo offers capnography solutions, rainbow Acoustic Monitoring may be better suited for post-surgical monitoring, conscious sedation, and anyone who cannot tolerate a nasal cannula – such as pediatric and neonatal patients.



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

## Ability to Detect Respiratory Pause<sup>6</sup>

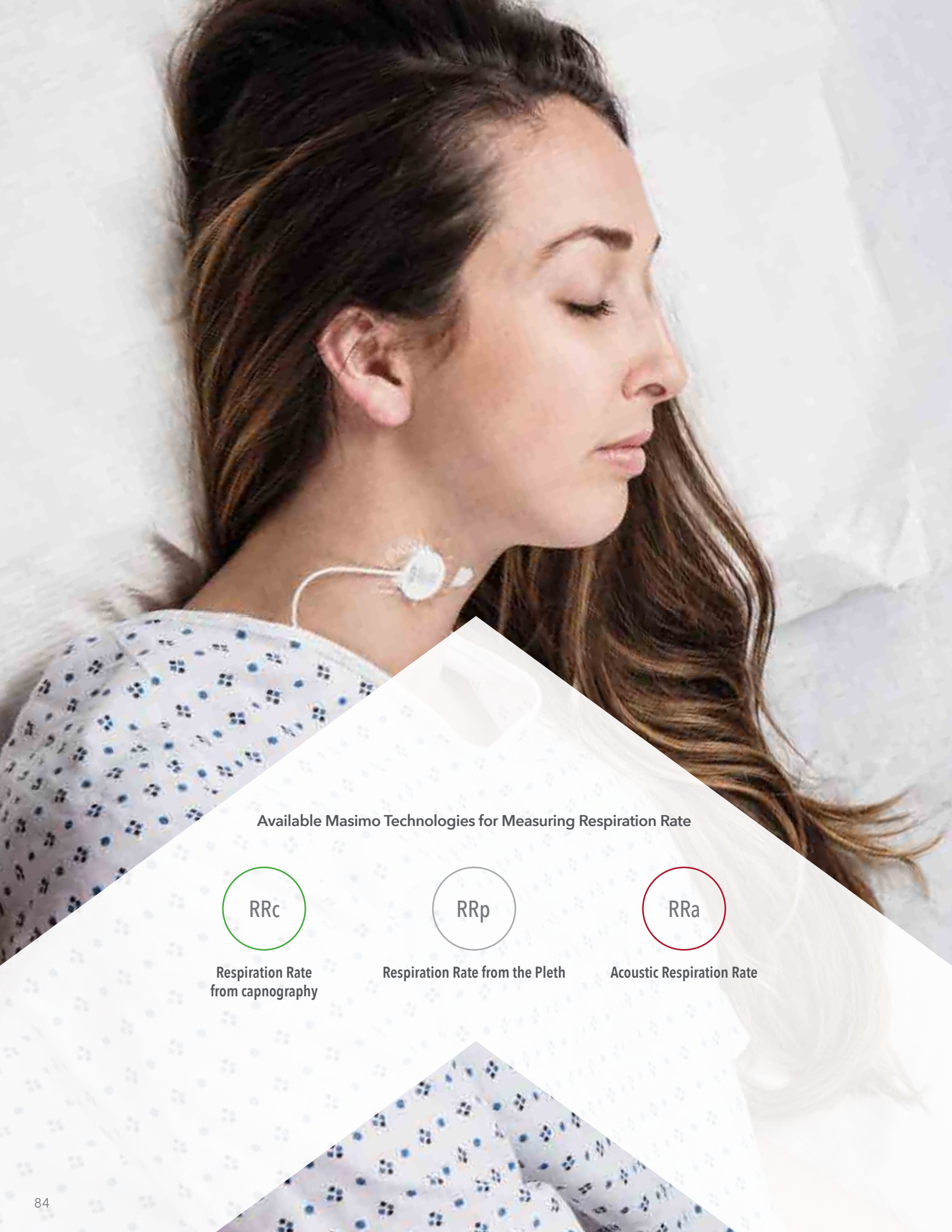
| Respiration Rate Method  | Oridion Capnostream SARA v4.5 | Masimo rainbow Acoustic Monitoring v7804 |
|--|-------------------------------|--|
| <b>Sensitivity</b><br><i>(respiratory pause detected when actual respiratory pause occurs)</i> | 62%                           | 81%                                      |

Retrospective analysis of 33 PACU subjects. Reference respiration rate determined by expert observer. A total of 21 episodes of respiratory pause were identified, defined as 30 seconds with no breathing activity.

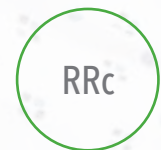
<sup>1</sup>Stoelting RK et al. *APSF Newsletter*. 2011. (www.apsf.org). <sup>2</sup>The Joint Commission Sentinel Event Alert. Issue 49, August 8, 2012. [https://www.jointcommission.org/assets/1/18/SEA\\_49\\_opioids\\_8\\_2\\_12\\_final.pdf](https://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf) <sup>3</sup>American Society of Anesthesiologists, "Standard for Basic Anesthetic Monitoring," American Society of Anesthesiologists, Inc., Park Ridge, 2011.

<sup>4</sup>Friesen RH et al. *J Clin Monit*. 1996 Mar;12(2):155-9. <sup>5</sup>Patino M et al. *Anesth Analg*. 2017 Jun;124(6):1937-1942. <sup>6</sup>Ramsay M et al. *Anesth Analg*. 2013 Jul;117(1):69-75. <sup>7</sup>Applegate RL et al. *Anesth Analg*. 2016 Apr;122(4):1070-8. <sup>8</sup>Goudra BG et al. *Open J Anesthesiol*. 2013; 3:74-79. RRa for neonatal application is not available in the U.S.





Available Masimo Technologies for Measuring Respiration Rate



Respiration Rate from capnography



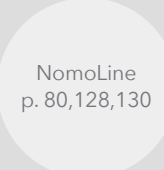
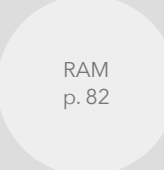

Respiration Rate from the Pleth

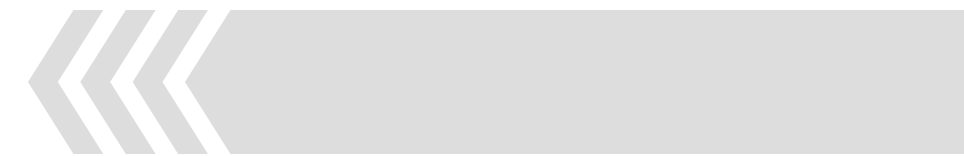


Acoustic Respiration Rate

## Evaluating Respiration Rate Technologies

Each technology for respiration rate measurement has advantages and disadvantages.

| Monitoring Technology  | Parameters  | Advantages  | Disadvantages  | Ideal Applications  |
|--|---|---|--|---|
| <b>Capnography</b><br><br>NomoLine<br>p. 80,128,130 | <ul style="list-style-type: none"> <li>Respiration rate (RRc)</li> <li>End tidal CO<sub>2</sub> concentration (EtCO<sub>2</sub>)</li> </ul> | <ul style="list-style-type: none"> <li>Also provides indication of cellular metabolism with EtCO<sub>2</sub></li> <li>Waveform considered useful by some clinicians for monitoring breathing</li> </ul> | <ul style="list-style-type: none"> <li>Patient tolerance in conscious patients</li> <li>Cannula placement</li> <li>Mouth breathing with cannulas</li> </ul>      | <ul style="list-style-type: none"> <li>Surgery, procedural sedation</li> </ul>  |
| <b>Acoustic monitoring</b><br><br>RAM<br>p. 82    | <ul style="list-style-type: none"> <li>Acoustic respiration rate (RRa)</li> </ul>   | <ul style="list-style-type: none"> <li>Similar or better accuracy than capnography</li> <li>Patient tolerance</li> <li>Waveform can visually indicate low RR or respiratory pause</li> </ul>            | <ul style="list-style-type: none"> <li>No EtCO<sub>2</sub> values</li> <li>Difficulty monitoring in high ambient noise or high vibration environments</li> </ul> | <ul style="list-style-type: none"> <li>General ward, procedural sedation, non-intubated surgery</li> </ul>            |
| <b>Pulse oximetry</b><br><br>RRp<br>p. 46         | <ul style="list-style-type: none"> <li>Respiration rate from the pleth waveform of SET<sup>®</sup> pulse oximetry (RRp)</li> </ul>          | <ul style="list-style-type: none"> <li>No added sensor</li> <li>Patient tolerance</li> </ul>  | <ul style="list-style-type: none"> <li>Inability to detect respiratory pause</li> </ul>  | <ul style="list-style-type: none"> <li>General ward and spot-check environments such as the home or clinic</li> </ul> |



# Estimating Depth of Sedation with SedLine® Brain Function Monitoring

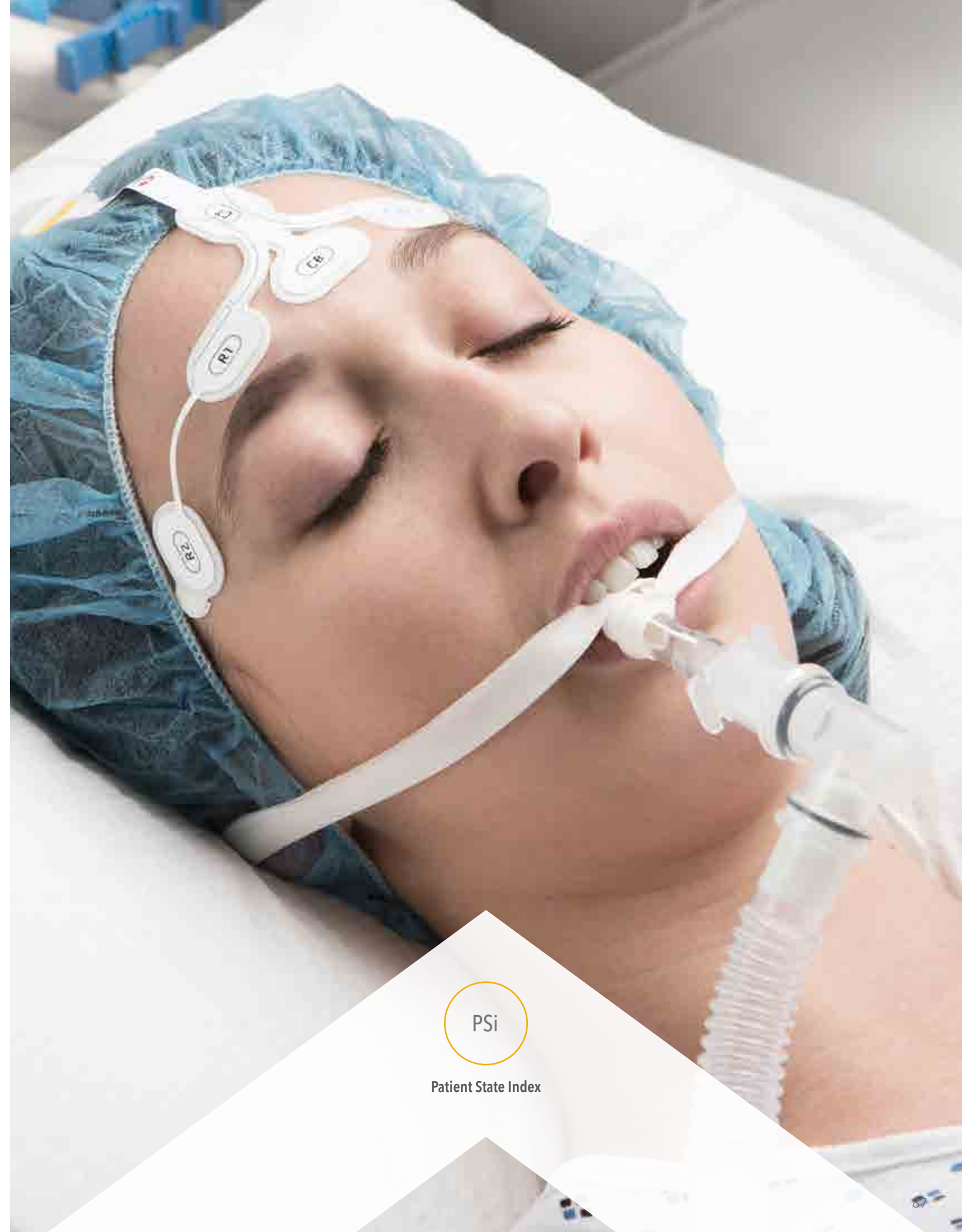
Patients respond differently to anesthetics and sedatives, which can lead to over- or under-administration in surgery, during conscious sedation, and in the intensive care unit. Some studies have suggested that greater sedation depth is associated with higher rates of post-operative delirium and mortality.<sup>1,2</sup>

SedLine brain function monitoring provides continuous information and can help automate the monitoring of a patient's response to anesthesia. With four simultaneous channels of frontal electroencephalogram (EEG) waveforms, SedLine enables bilateral data acquisition and processing of EEG signals. SedLine also offers the Patient State Index (PSi), a processed EEG parameter that is related to the effect of anesthetic agents, and a Density Spectral Array (DSA) display, which contains left and right spectrograms representing the power of the EEG on both sides of the brain.

**PSi has been shown to help clinicians administer lower doses of both inhaled and intravenous anesthetics without an increase in unwanted events.<sup>3,4</sup>**

## SedLine's Impact on Emergence

PSi has been shown to help clinicians administer lower doses of inhaled anesthetics without an increase in unwanted events.<sup>3</sup> In a randomized controlled trial of 306 surgical patients at Stanford Medical Center, PSi was shown to help clinicians administer lower doses of intravenous anesthetics and achieve shorter emergence time, extubation time, and time to discharge from the operating room.<sup>4</sup>



# Improving Anesthetic Drug Response with Next Generation SedLine

Patient State Index (PSi) with Next Generation SedLine offers improved anesthetic drug response<sup>1</sup> and utilizes Masimo's Parallel Signal Processing Engines to extract a clearer EEG signal, making PSi less susceptible to EMG interference and with improved performance in low power EEG cases.

## Rigorous Scientific Study Helps Develop and Validate Next Generation PSi Performance<sup>1</sup>

With the goal of significantly advancing the science of brain function monitoring, a rigorous clinical study was recently completed in adult volunteer subjects at University Medical Center Groningen in The Netherlands.

A total of 41 subjects completed the study with data included from 145 cases. During each case, each subject was given a combination of inhalant and intravenous anesthetic agents with stepwise increasing doses until burst suppression and decreasing doses thereafter. By design, each subject was scheduled for four data collection sessions on different days; one time each for Propofol-only, Propofol with Remifentanyl, Sevoflurane-only, and Sevoflurane with Remifentanyl. The set of 145 cases was then partitioned into 80 training cases that were used to help develop the algorithm for the Next

Generation SedLine PSi, and 65 validation cases. Modified Observer's Assessment of Alertness/Sedation (MOAAS) scores, a subjective score of responsiveness, were recorded after step change. SedLine brain function monitoring data and vital signs were collected in all subjects.

To evaluate the performance of Original PSi and Next Generation PSi, independent EEG experts reviewed the 65 validation cases with both Original PSi and Next Generation PSi (blinded to the version), along with additional clinical information (MOAAS scores, EEG waveforms, drug doses, vital signs). Compared to the expert-assessed anesthetic depth, an error was defined as a case when expert assessment of PSi was 'Low' or 'High' and success was defined as a case when the expert assessment of PSi was 'Good'.

*"Next Generation PSi has enhanced signal stability and a better description of the dose/response relationship. Next Generation PSi has therefore improved capacity as a pharmacodynamic monitor of anesthesia compared to the original PSi"*<sup>1</sup>

**Drs. Kuizenga, Colin, Vereecke, and Struys**

University Medical Center Groningen, Dept of Anaesthesiology, Groningen, Netherlands

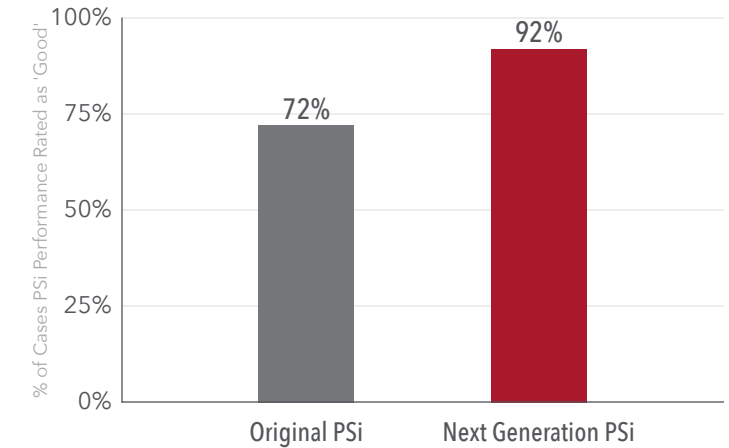
## Expert Scoring of Next Generation SedLine

EEG experts scored the improvement in PSi performance in response to anesthetic drugs between the original SedLine PSi and Next Generation SedLine PSi.<sup>1</sup>

Specific anesthetic drug scoring found:

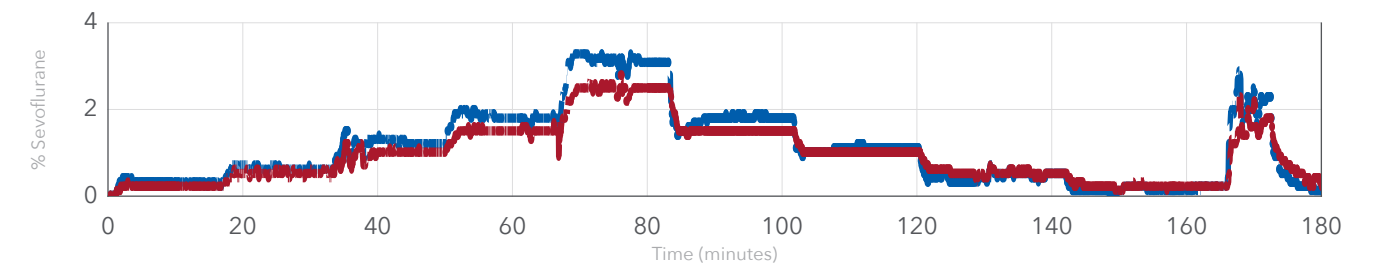
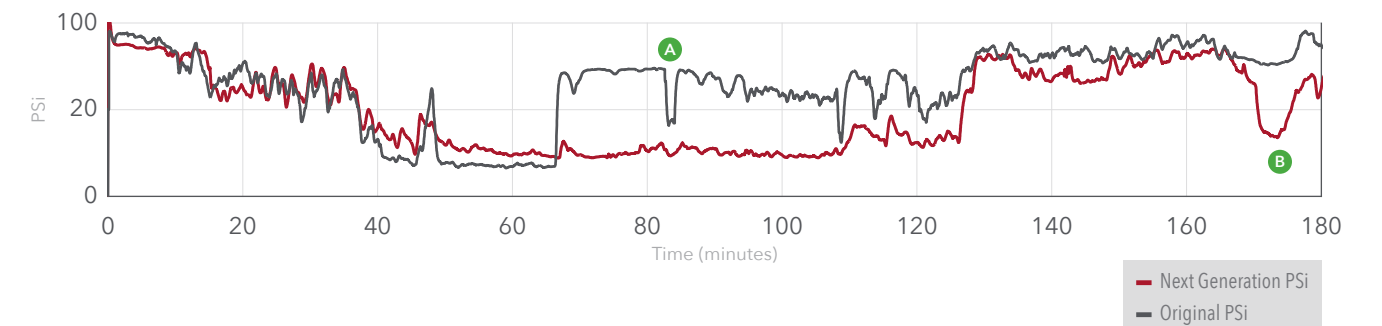
- 31% improvement with Sevoflurane
- 20% improvement with Propofol

Overall PSi Performance in Response to All Anesthetic Drugs Tested



Experts found an overall 20% improvement in Next Generation PSi performance in response to all anesthetic drugs tested.

Case During Step-wise Dosing of Sevoflurane

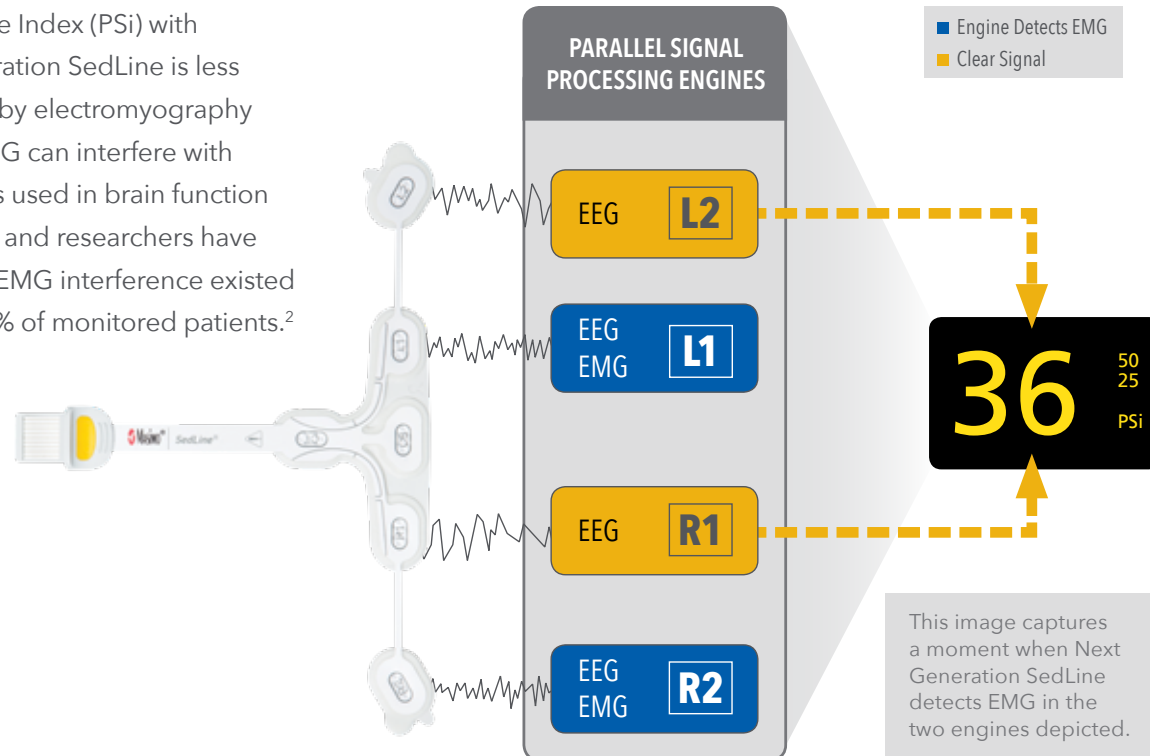


In this case with Sevoflurane only, EEG experts rates Next Generation PSi as 'good' and Original PSi as 'high'. During high doses of Sevoflurane at points A and B, Original PSi is higher than Next Generation PSi.

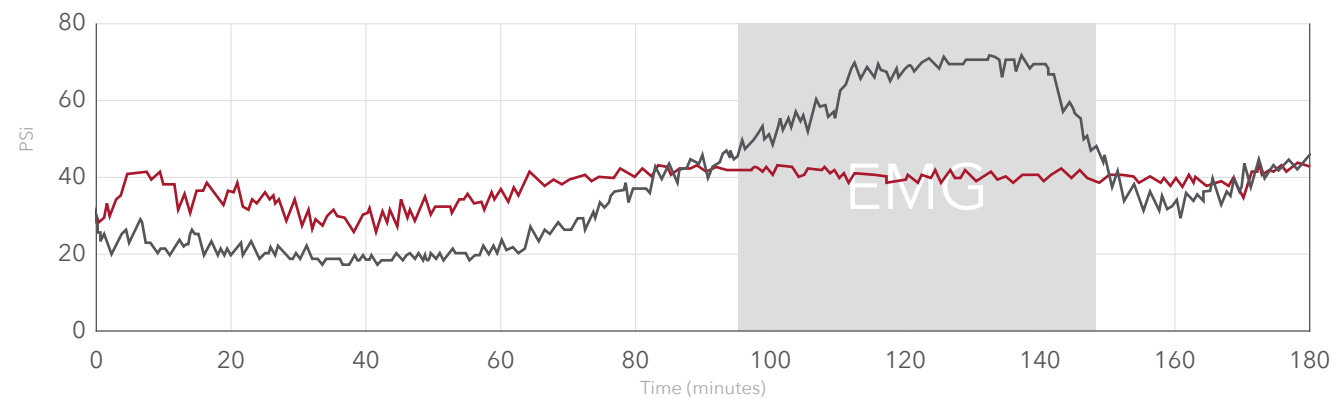
— Inspiration  
— Expiration

# Reducing Electromyography (EMG) Susceptibility with Next Generation SedLine

Patient State Index (PSi) with Next Generation SedLine is less influenced by electromyography (EMG).<sup>1</sup> EMG can interfere with EEG signals used in brain function monitoring and researchers have found that EMG interference existed in up to 38% of monitored patients.<sup>2</sup>

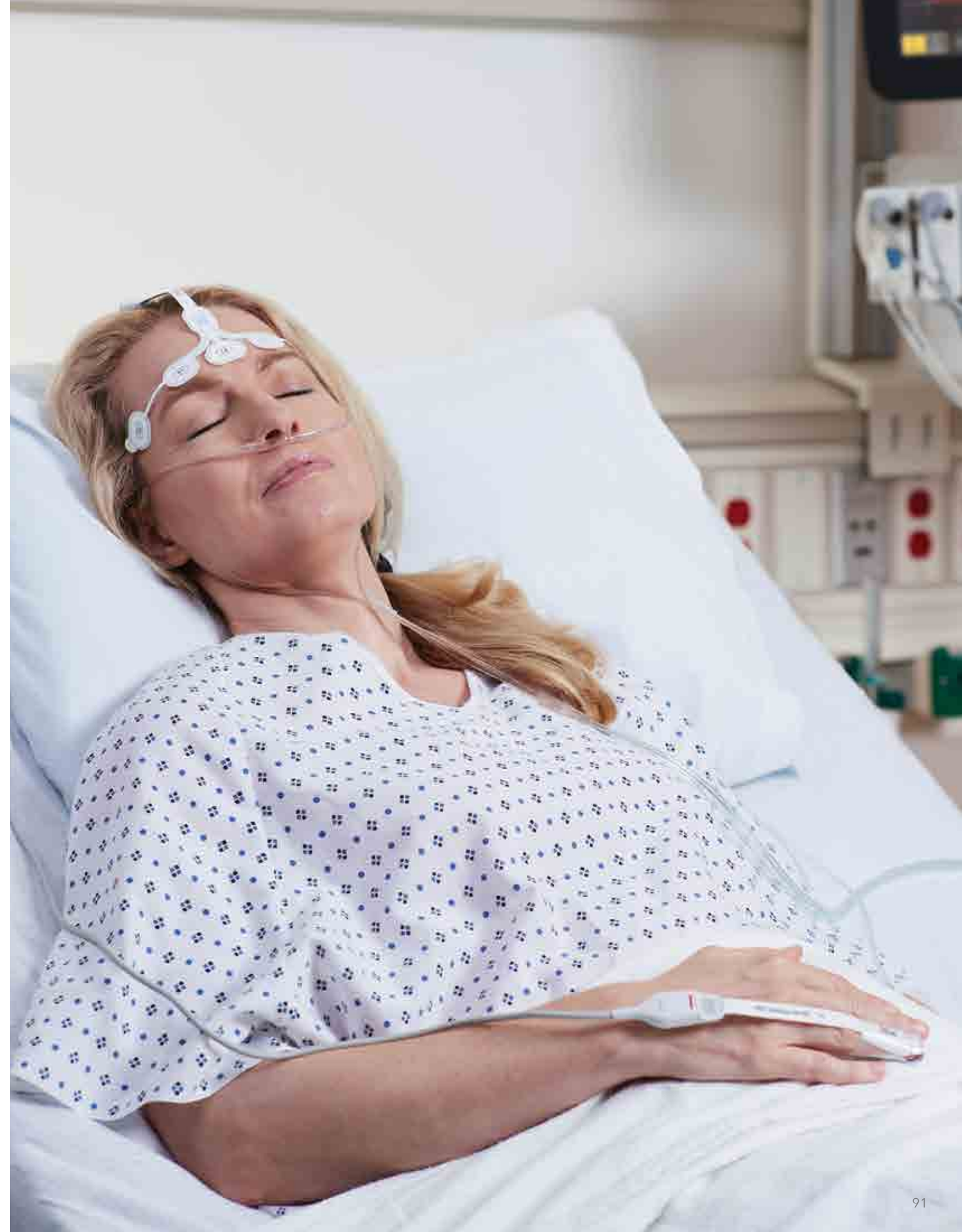


Case with Period of EMG Interference<sup>3</sup>



The case demonstrates Next Generation SedLine's improvement to PSi in the presence of EMG interference.

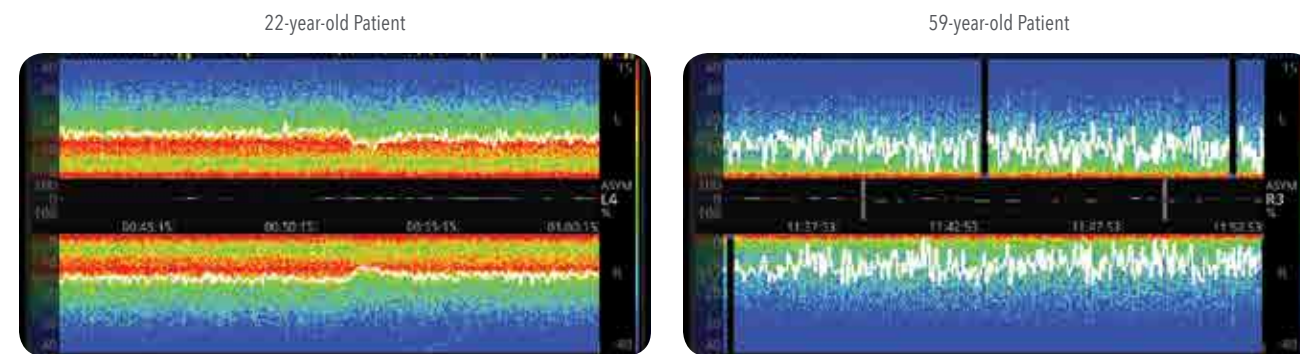
— Next Generation PSi  
— Original PSi



# Enhancing Low Power EEG Performance with Next Generation SedLine

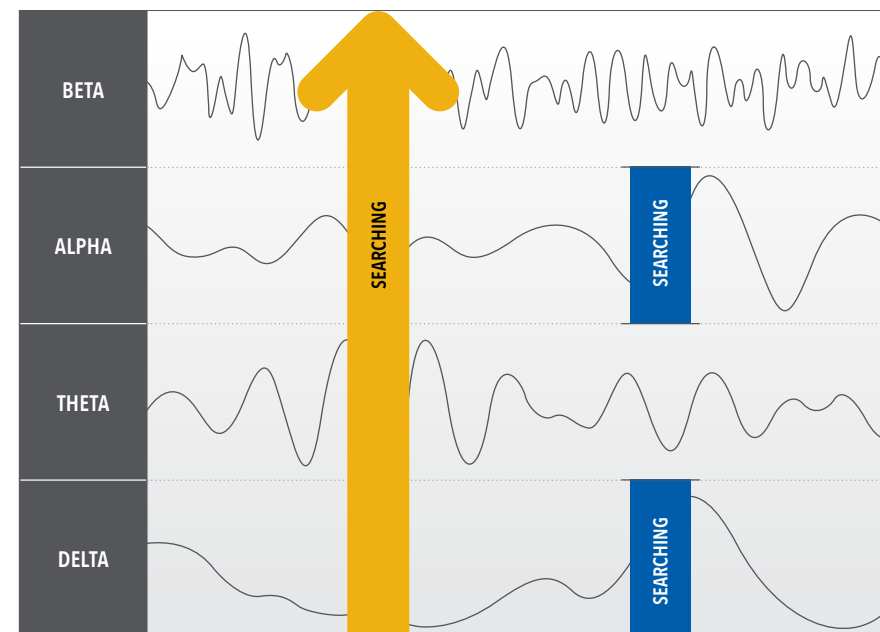
## Next Generation PSi Searches for EEG Features Across Many Frequency Bands

Power across all frequency bands decreases with age.<sup>1</sup> Low power can provide a challenge for conventional brain function monitors when noise is present in the signal.



These two subjects were administered Propofol and were in a comparable anesthetic state, but their EEG waveforms and DSA screen varied.<sup>2</sup>

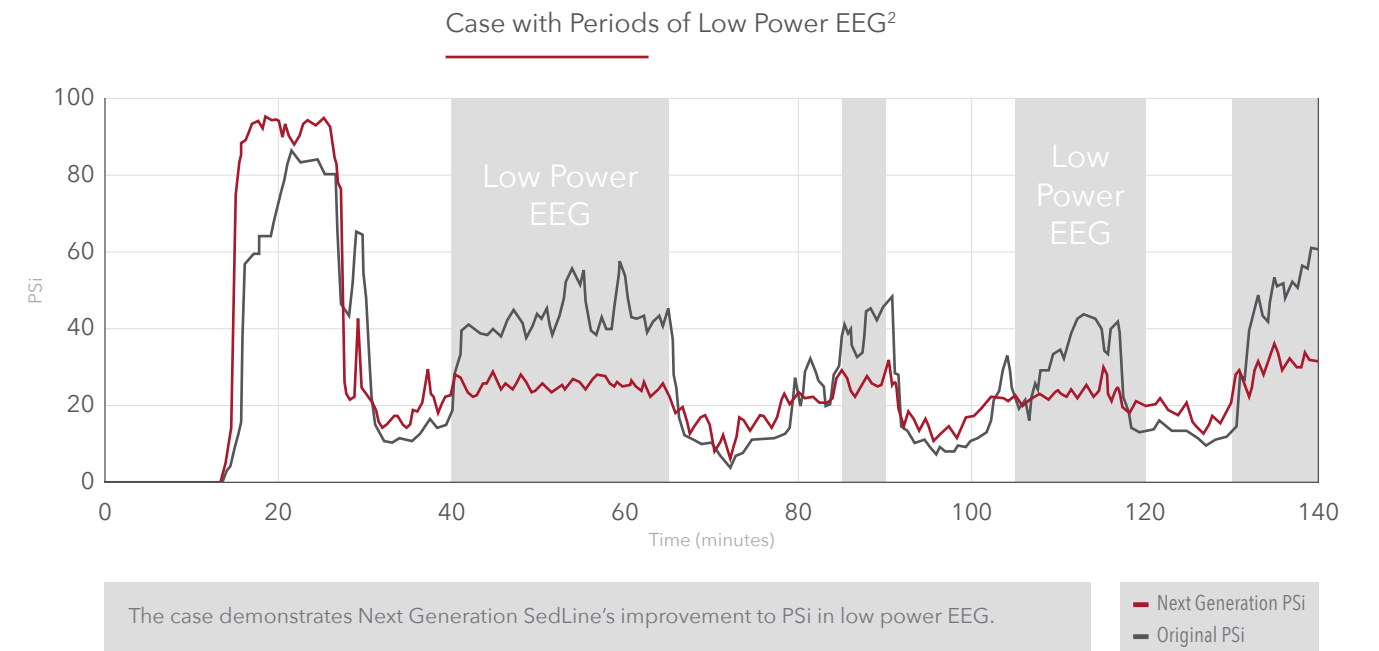
## Next Generation PSi Uses Adaptive Signal Processing with Band-Independent Features



Next Generation PSi uses adaptive signal processing with band-independent features to offer improved PSi performance in cases of low power EEG.

Next Generation SedLine processes across all EEG bands.

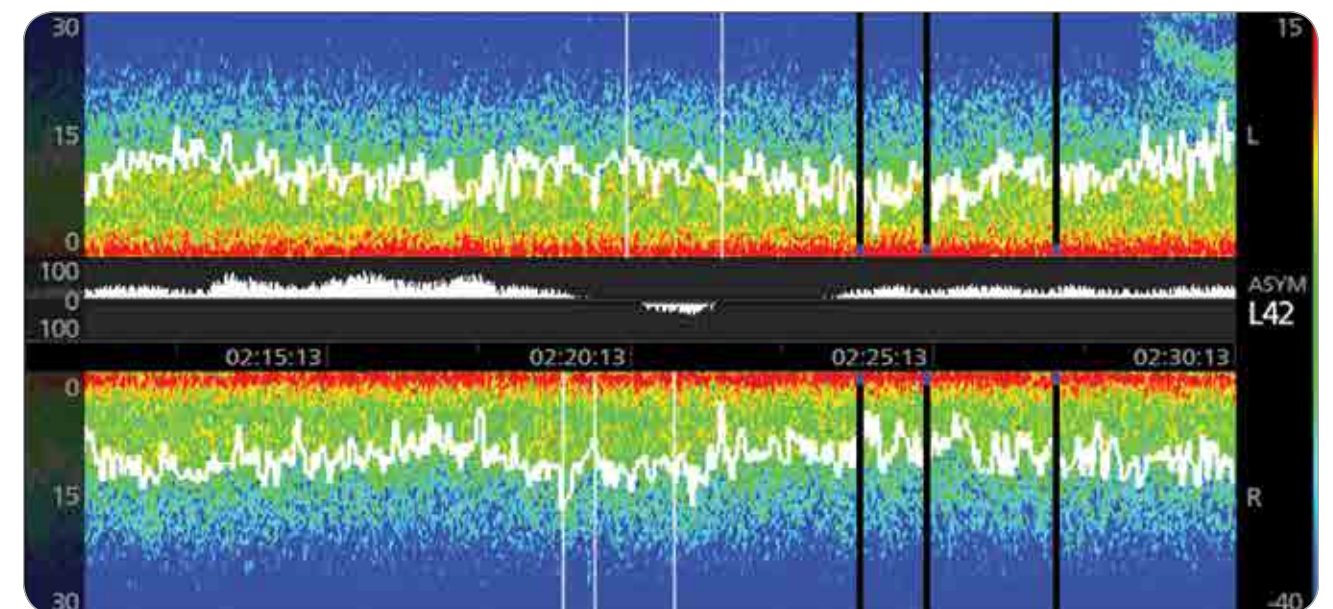
■ Next Generation SedLine Adaptive Signal Processing  
■ Conventional Monitor



The case demonstrates Next Generation SedLine's improvement to PSi in low power EEG.

## Multitaper Density Spectral Array (DSA)

Next Generation SedLine also offers clinicians the flexibility of choosing to display either an enhanced Multitaper Density Spectral Array (DSA), or a standard Hanning DSA. The DSA contains left and right spectrograms representing the power of the EEG on both sides of the brain.



When using a Multitaper DSA, EEG data are transformed into the frequency domain, which may provide a better display of EEG features.

# Indicating Brain Oxygenation with O3 Regional Oximetry



Regional Oxygen Saturation

## Importance of Monitoring Brain Oxygenation

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

Decreases in cerebral oxygen saturation are associated with post-operative cardiac dysfunction,<sup>1</sup> neurological injury,<sup>2,3</sup> increased length of hospital stays,<sup>3</sup> and increased time on mechanical ventilation.<sup>4</sup> Early detection and correction of imbalances in oxygen delivery to the brain are important tools in helping patients avoid post-operative morbidity and adverse outcomes.<sup>5</sup>

## Automating Brain Oxygenation Monitoring with O3 Regional Oximetry

Masimo's O3 regional oximetry uses four wavelengths of light to monitor oxygen saturation (rSO<sub>2</sub>) in both sides the brain in adult and pediatric patients. O3 regional oximetry can help clinicians automate assessment of the brain oxygenation status and identify low oxygenation or significant changes in oxygenation.

**O3 regional oximetry can help clinicians automate monitoring of the brain oxygenation status and identify low oxygenation or significant changes in oxygenation**

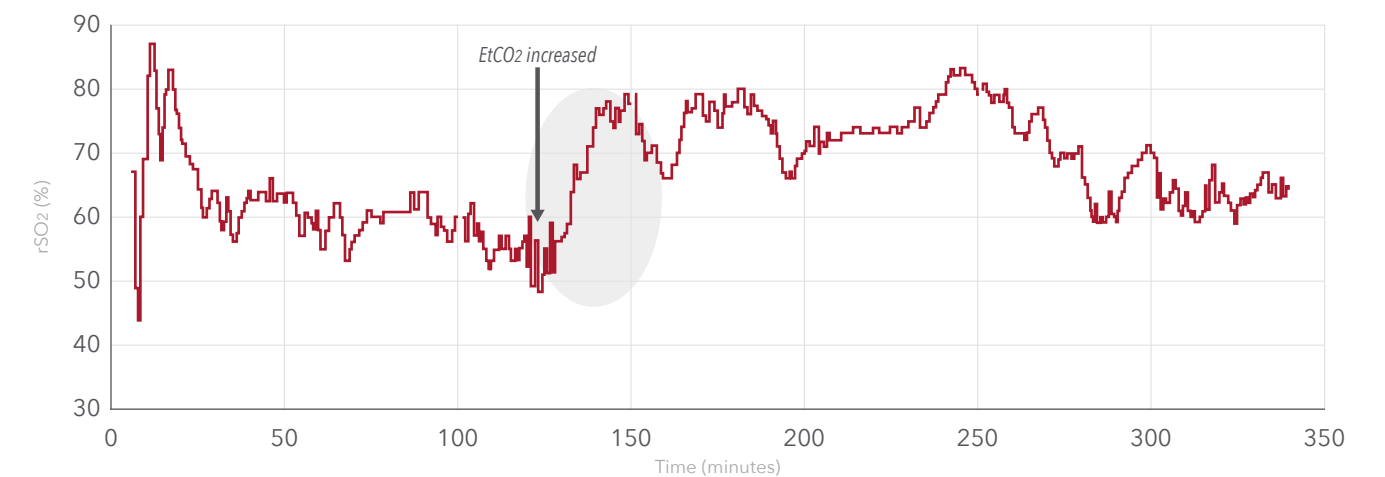
## Accuracy of O3 Regional Oximetry

In a study on 27 subjects published in *Anesthesia and Analgesia*, researchers compared cerebral oxygen saturation measurements obtained from O3 with saturations obtained from blood samples (SavO<sub>2</sub>) through induced hypoxia. O3 regional oximetry provided absolute root-mean-squared error of 4% and relative root-mean-squared error of 2.1%.<sup>6</sup> This study did not require that end tidal carbon dioxide (EtCO<sub>2</sub>) levels be fixed in the study protocol, allowing the O3 measurement to be responsive to changes in tissue oxygen saturation due to changes in CO<sub>2</sub> in the blood. Follow-up studies with O3 extended the subject pool to 74 subjects and demonstrated that O3 maintained its absolute and relative accuracy.<sup>7</sup>

O3 Regional Oximetry Accuracy Specifications

|  | Adult   | Pediatric |
|--|---------|-----------|
| Body Weight  | ≥ 40 kg | < 40 kg   |
| Trending Regional Oxygen Saturation (rSO <sub>2</sub> ) Accuracy (RMS)*  | 3%      | 3%        |
| Absolute Regional Oxygen Saturation (rSO <sub>2</sub> ) Accuracy (RMS)** | 4%      | 5%        |

Masimo rSO<sub>2</sub> Responsiveness During Surgery



At 120 minutes, EtCO<sub>2</sub> increased. The rSO<sub>2</sub> from O3 regional oximetry is sensitive to changes in blood flow that occur due to vasodilation after the increase in EtCO<sub>2</sub>, moving from approximately 50% to almost 80%.<sup>7</sup>

<sup>1</sup>Schoen J et al. *Crit Care*. 2011;15(5):R218. <sup>2</sup>Colak Z et al. *Eur J Cardiothorac Surg*. 2015 Mar;47(3):447-54. <sup>3</sup>Slater JP et al. *Ann Thorac Surg*. 2009;87:36-45. <sup>4</sup>Goldman S et al. *Heart Surg Forum*. 2004;7(5):E376-81. <sup>5</sup>Booth EA et al. *Surg. Neurol Int*. 2010; 1: 75. <sup>6</sup>Redford D et al. *Anesth Analg*. 2014 Dec;119(6):1315-9. <sup>7</sup>Masimo data on file. \* ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS

of the reference measurements in a controlled study. \*\* Absolute rSO<sub>2</sub> accuracy (RMS) was determined by testing on healthy adult volunteers with light to dark pigmentation in the range of 45% to 85% SavO<sub>2</sub> against 30% arterial and 70% jugular venous blood oxygen saturations, measured with a laboratory CO-Oximometer.





## Combining O3 and SedLine for Simultaneous Brain Monitoring



Most brain function monitoring and regional oximetry technologies have sensors that compete for the same space on the patient's forehead, preventing simultaneous monitoring of both monitoring modalities and forcing clinicians to choose one.

Masimo has specifically designed the O3 and SedLine sensors to not interfere with each other, enabling simultaneous monitoring with both modalities. The combination of O3's accurate regional oximetry measurements and Next Generation SedLine brain function monitoring provides clinicians with even more information about the brain's response to anesthesia and surgery on the same monitoring platform.

Patients can be monitored with SedLine or O3 only, or SedLine and O3 together for a more complete brain monitoring picture.



# Products: Automating Clinician and Patient Interactions in the Care Environment



# Delivering Multiple Advancements with the RD Sensor System

Sensor technology is at the core of our noninvasive measurement technologies. The RD Sensor System is intended to replace our existing optical sensor lines and was designed with the following in mind:

## Enhancing Patient Comfort

- Small and thin optical components
- Low profile internal components allow the sensor to better conform to finger shape with less pressure on the measurement site



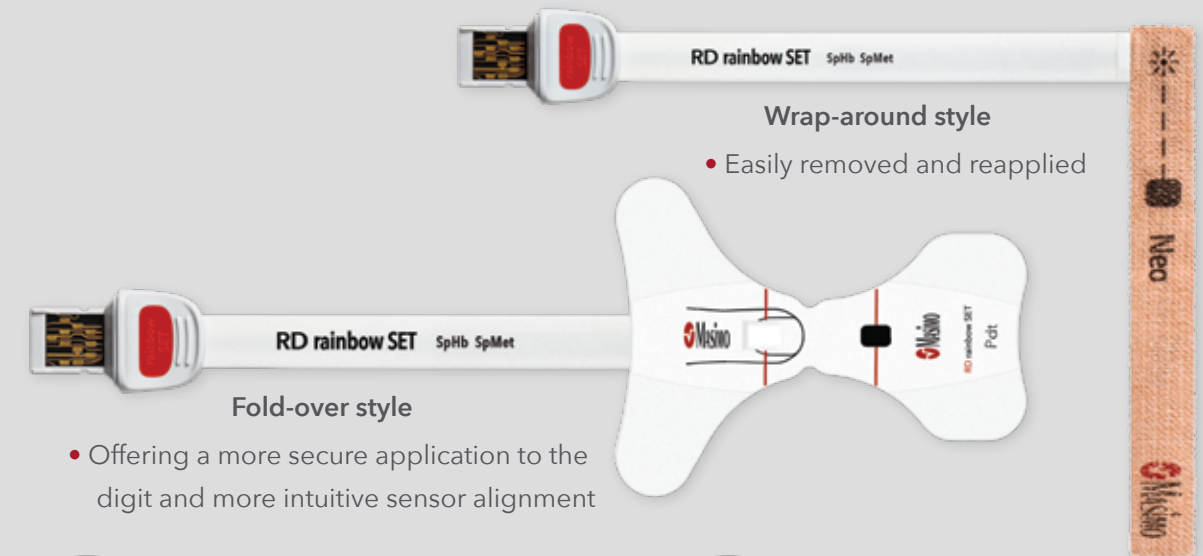
- **Flat sensor cable** – flat, lightweight sensor cable with smooth edges lies comfortably on the patient’s hand or foot



- **Lightweight connector** – made from materials that result in a lightweight connector with no moving parts

## Optimizing Clinician Workflow

- Two styles of sensors for use on different patient types



### Wrap-around style

- Easily removed and reapplied

### Fold-over style

- Offering a more secure application to the digit and more intuitive sensor alignment



### Quick connection

- Intuitive sensor to cable connection
- Tactile and audible feedback ensuring proper connection



### Sensor graphics to guide proper sensor application

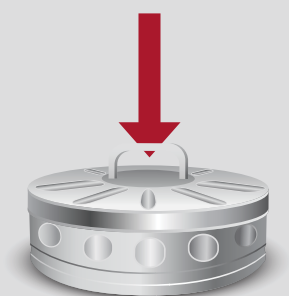
- Assists with sensor application for optimal performance

## Helping Hospitals Meet Their Green Initiatives

- Lightweight sensor results in less material waste
- Sleek, recyclable packaging reduces storage space



Up to 84% less waste



## Three Sensor Lines Based on Your Measurement Needs



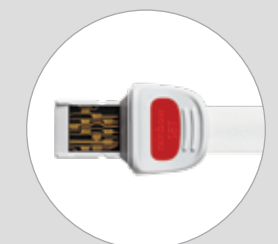
### RD SET

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



### RD rainbow Lite SET

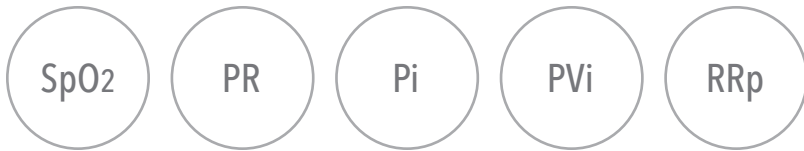
- SpO<sub>2</sub>, PR, Pi, PVi, RRp, RPVi, ORI



### RD rainbow SET

- SpO<sub>2</sub>, PR, Pi, PVi, RRp, SpHb, SpOC, RPVi, ORI, SpCO, SpMet, SpfO<sub>2</sub>

# Advancing Two-LED Monitoring with RD SET™ Sensors



RD SET Sensors use two wavelengths of light and are designed for use with Masimo SET® pulse oximetry. As part of the RD Sensor System, RD SET Sensors were designed to enhance patient comfort, optimize clinician workflows, and help hospitals meet their green initiatives.

~~RD SET Sensors use two wavelengths of light to provide Masimo SET® parameters~~

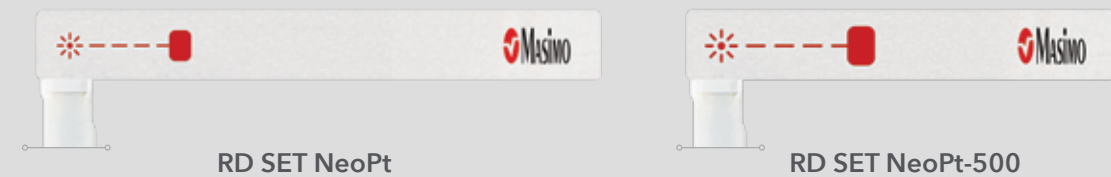
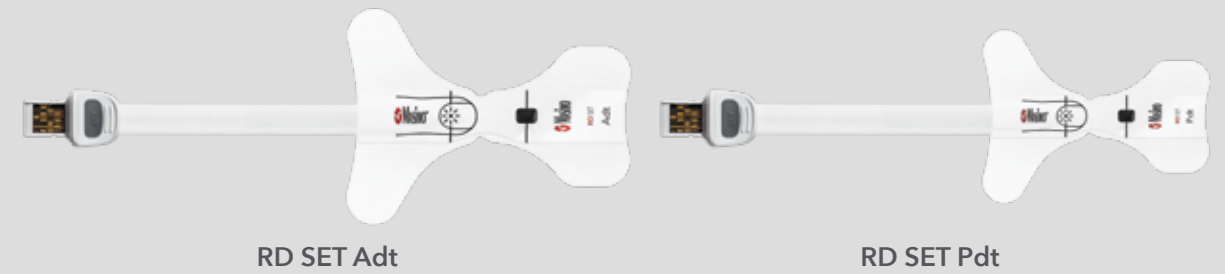
## Helping Hospitals Meet Their Green Initiatives

- Lighter than traditional cable-based sensors
- Up to 84% less waste with Adult RD SET sensors versus traditional cable-based sensors<sup>1</sup>

**Sleek recyclable packaging reduces storage space by 44%<sup>1</sup>**



## RD SET Sensor Options and Application



**RD SET Adt**  
• Finger application



**RD SET Pdt**  
• Finger application



**RD SET Neo**  
• Adult finger application



**RD SET Neo**  
• Neonatal foot application



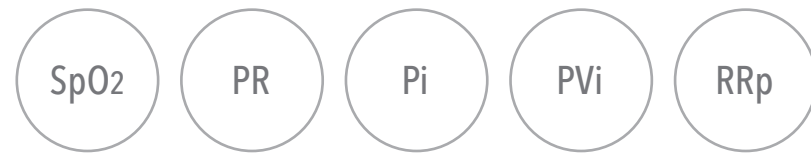
**RD SET Inf**  
• Thumb application



**RD SET NeoPt-500**  
• Foot application

<sup>1</sup>Masimo data on file. Waste calculated by comparing the sensor and packaging weight of traditional cable based sensors versus Adult RD adhesive sensors. RRp is not available in the U.S.

# Customizing Applications with Masimo SET® Specialty Sensors



Masimo SET® Sensors are also available in a variety of specialty sensors for specific clinical applications.

## E-1® Sensor

The E-1 single-patient-use ear sensor is placed in the cavum conchae (the deep hollow near the ear canal opening) and provides an alternative to digit sensors. The ear site enables faster detection of saturation changes compared to digit sites during low perfusion, and provides easy access in scenarios where the digit and forehead may not be accessible, such as emergency transport.



## Newborn Sensor

Every second matters during newborn resuscitation when oxygen saturation is rapidly changing. The Newborn Sensor together with Masimo SET® technology automatically configures the fastest response time with maximum sensitivity –allowing clinicians to focus on the patient, not device settings.



## Trauma Sensor

In trauma situations, SpO2 can change rapidly and peripheral perfusion can be very low. The Trauma Sensor together with Masimo SET® technology automatically configures the fastest response time with maximum sensitivity in adult trauma patients.



## Blue® Sensor

Cyanotic heart disease refers to congenital heart defects that result in a low blood oxygen level that can cause the skin to turn a bluish color.<sup>1</sup> The Blue Sensor with Masimo SET® pulse oximetry is specifically designed for use with cyanotic infant, neonatal, and pediatric patients with congenital heart disease, and is accurate on cyanotic patients with oxygen saturation as low as 60%.<sup>2</sup> Studies have demonstrated that the Blue Sensor offers improved accuracy in cyanotic infants and children compared to Nellcor sensors<sup>3,4</sup> and standard Masimo sensors.<sup>3</sup> In a study on cyanotic infants, the Blue Sensor was shown to help clinicians accurately maintain targeted oxygen saturation levels.<sup>5</sup>

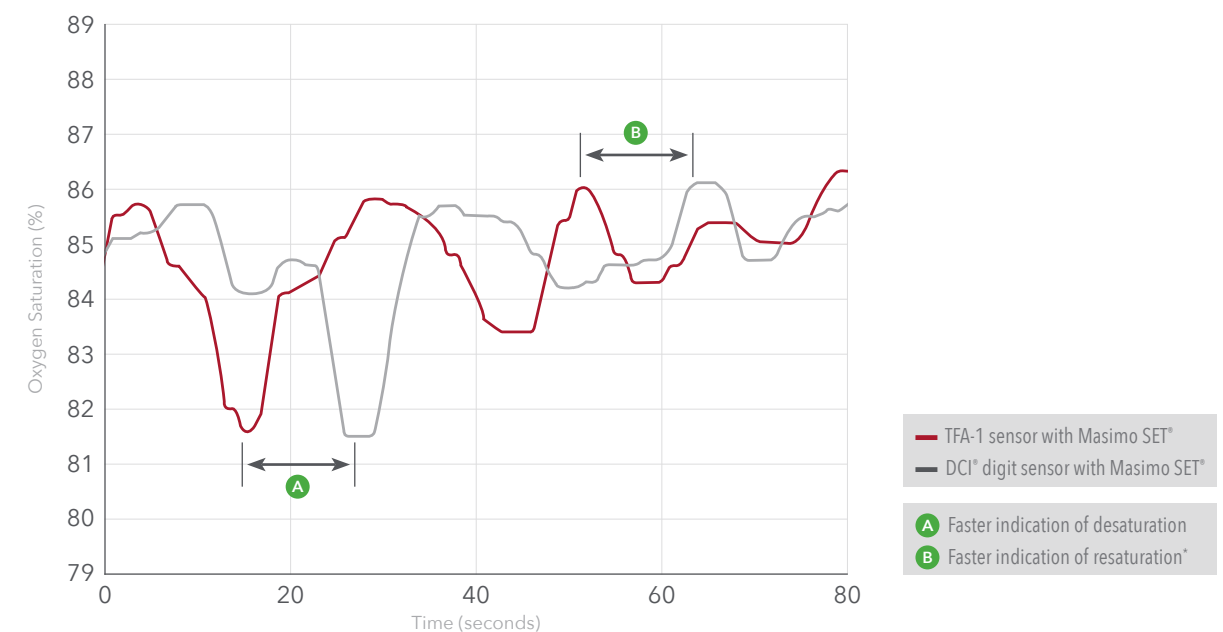


## TFA-1® Sensor

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



### TFA-1 Faster Response to Oxygenation Changes



<sup>1</sup>Waldman JD et al. *Pediatr Clin North Am.* 1999 Apr;46(2):385-404. <sup>2</sup>Masimo data on file and FDA 510(k) K051439. 2005. <sup>3</sup>Harris BU et al. *Pediatr Care Med.* 2016 Apr;17(4):315-20. <sup>4</sup>Cannesson M et al. *Ann Fr Anesth Reanim.* 2008 Oct;27(10):808-12. <sup>5</sup>Cox PN et al. *Anesthesiology.* 2007;107:A1540. (abstract). \* Data on file. RRp is not available in the U.S.

# Accessing Advanced Parameters with RD rainbow Lite SET™ Sensors



RD rainbow Lite SET Sensors are designed for use with Masimo rainbow SET Pulse CO-Oximetry and provide two additional rainbow® parameters, ORi and RPVi, in addition to all SET® parameters. RD rainbow Lite Sensors include the same patient comfort, accuracy, workflow, and green initiative benefits as RD SET Sensors, but use four wavelengths of light instead of the two wavelengths of light used in RD SET Sensors. RD rainbow Lite Sensors can provide large clinical value but are offered at only a small incremental price above RD SET Sensors.

**RD rainbow Lite SET Sensors use four wavelengths of light to provide ORi and RPVi in addition to all SET® parameters**



## RD rainbow Lite SET Sensor Options and Application



RD rainbow Lite SET Adt



RD rainbow Lite SET Pdt



RD rainbow Lite SET Neo



RD rainbow Lite SET Inf



RD rainbow Lite SET Adt

- Finger application



RD rainbow Lite SET Pdt

- Finger application



RD rainbow Lite SET Neo

- Adult finger application



RD rainbow Lite SET Neo

- Neonatal foot application



RD rainbow Lite SET Inf

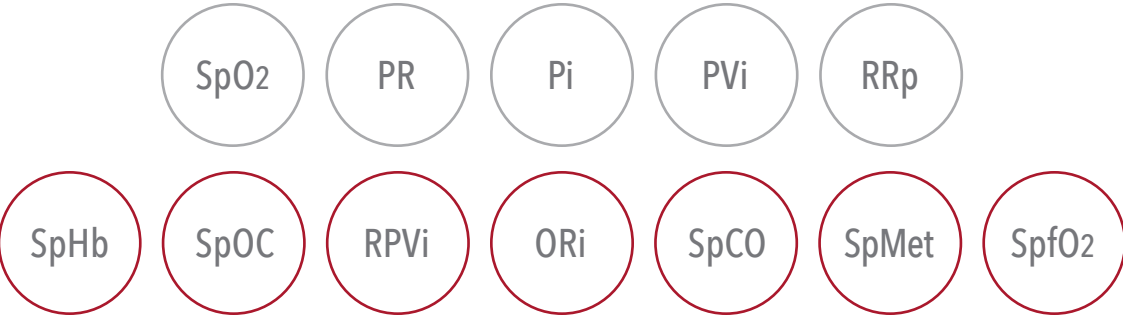
- Finger application



RD rainbow Lite SET Inf

- Thumb application

# Advancing Multi-wavelength Monitoring with RD rainbow SET™ Sensors



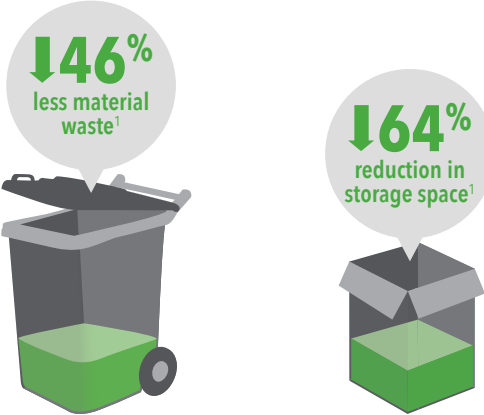
RD rainbow SET Sensors are designed for use with Masimo rainbow SET Pulse CO-Oximetry, using more than seven wavelengths of light to provide rainbow® parameters in addition to all SET® parameters. As part of the RD Sensor System, RD rainbow SET Sensors were designed to enhance patient comfort, optimize clinician workflows, and help hospitals meet their green initiatives.

RD rainbow SET Sensors use more than seven wavelengths of light to provide rainbow SET parameters



### Helping Hospitals Meet Their Green Initiatives ♻️

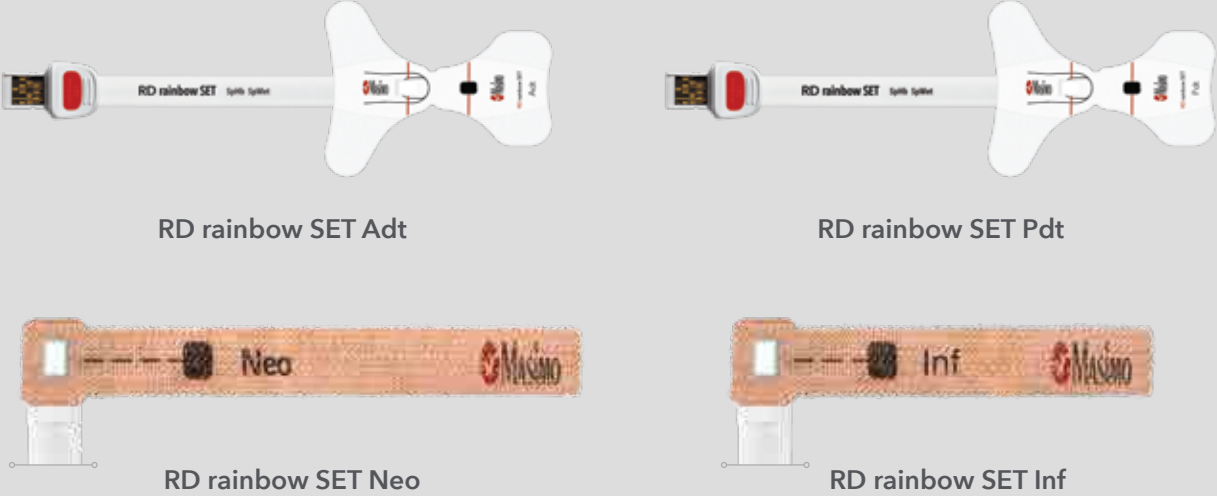
Lightweight design and sleek, recyclable packaging with RD rainbow SET



Compared to previous generation rainbow® Disposable R1 25.

¹Masimo data on file. RRp, RPVi, ORi, and SpfO2 are not available in the U.S.

### RD rainbow SET Sensor Options and Application



|  |   |   |
|--|---|---|
| <p><b>RD rainbow SET Adt</b></p> <ul style="list-style-type: none"> <li>• Finger application</li> </ul>        | <p><b>RD rainbow SET Pdt</b></p> <ul style="list-style-type: none"> <li>• Finger application</li> </ul> | <p><b>RD rainbow SET Neo</b></p> <ul style="list-style-type: none"> <li>• Adult finger application</li> </ul> |
| <p><b>RD rainbow SET Neo</b></p> <ul style="list-style-type: none"> <li>• Neonatal foot application</li> </ul> | <p><b>RD rainbow SET Inf</b></p> <ul style="list-style-type: none"> <li>• Finger application</li> </ul> | <p><b>RD rainbow SET Inf</b></p> <ul style="list-style-type: none"> <li>• Thumb application</li> </ul>        |

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

## A Systems Approach to Safety

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

The origin of the "X-Cal" name comes from "calibration", since X-Cal sensors store unique characteristics of individual sensors that permit X-Cal-enabled Masimo technology boards to adapt to the specific sensor in use. In addition to facilitating improved performance, the X-Cal design permits sensors designed in the future to be compatible with an X-Cal enabled board installed in a host monitor.



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

## How X-Cal Works

X-Cal helps reduce measurement inaccuracy and patient safety risks that may be caused by violations of the aforementioned principles, such as with imitation cables and sensors that use components and manufacturing processes that do not meet Masimo quality and performance specifications. These specifications are required to provide consistent high performance. When an unreliable or imitation sensor or cable is connected to an X-Cal-enabled monitor, a message alerts the user that the cable or sensor should be replaced.

To address the reliability risks associated with failures that can occur in cables and sensors used beyond their expected lives, such as inaccurate measurements that may lead to false alarms or even mask true events such as hypoxemia, X-Cal technology is designed to automatically track the aggregate time that individual cables and sensors are used for active patient monitoring. When a specific sensor or cable has been used well beyond its expected life, the system notifies the user, reducing the likelihood of a sensor or cable failure that could affect patient safety or create work-flow inefficiencies for clinical and biomedical staff.

X-Cal also includes Site ID, which encodes the sensor with a unique identifier upon use.



X-Cal technology can alert you when an unreliable or imitation sensor or cable is connected, and also when a sensor or cable has been used beyond its expected life.



# Adapting to Changing Monitoring Needs with Radical-7<sup>®</sup>

Radical-7 incorporates rainbow SET technology to enable measurements of 13 parameters in a bedside monitor.



Radical-7 is highly adaptable as a 5-in-1 monitor

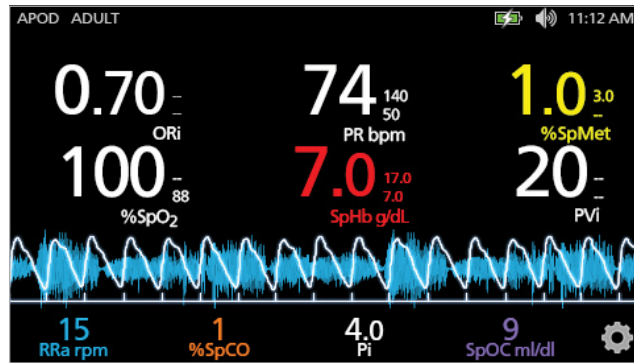


- Integration with the Root patient monitoring and connectivity platform
- Use with SatShare<sup>®</sup> to upgrade the performance of conventional pulse oximetry in legacy multi-parameter monitors to Masimo SET<sup>®</sup> performance



- Standalone Monitor
- Handheld
- Transport

# Radical-7



- **Customize the display** to view the highest priority parameters for your clinical setting



- Use simple gestures to move, expand, or collapse **parameter trends** for deeper analysis



- Configure parameter and alarm settings by patient population, with the option to select from pre-configured **Patient Profiles**



- Audible and visual **alarms** allow quick identification of alarming parameters with two speakers for added safety in case one speaker ever fails

## Rechargeable Battery

- 4-hour battery life for extended monitoring as handheld device

## Connectivity Options

- Integrated wireless connectivity with 802.11 radio and Bluetooth

## Intuitive User Interface

- Easily navigate and configure settings using the high-definition, multi-touch display

## Electronic Charting

- Automated documentation of patient data using Masimo Patient SafetyNet or Iris Gateway™ to interface with hospital EMR system

## Waveform View

- High resolution plethysmographic waveform and optional acoustic waveform from RRA to provide real-time physiologic visibility

## Automatic Display Rotation

- Versatile screen automatically adjusts to device orientation



## Seamless Upgrade to Root

- Docking capability on Root patient monitoring and connectivity system for expanded view, measurement, and documentation capabilities



# Getting to the Root of Better Care

Root is a powerful patient monitoring and connectivity platform that can automate clinician interactions with data, display, documentation, and patients. Root can be configured in numerous ways to meet various clinical needs.

## Multiple Measurement Options

- **Radical-7 or Radius-7**

Root includes a dock for the Radical-7 handheld monitor or Radius-7 patient-worn monitor, enabling a large screen display of Masimo SET® pulse oximetry or rainbow SET Pulse CO-Oximetry measurements.



- **Integrated Blood Pressure and Temperature**

In addition to Masimo technologies, clinicians can also use Root to measure noninvasive blood pressure (NIBP) and temperature with optional internal modules. In addition, customers have an external temperature option with Masimo's Caregiver handheld, touch-free thermometer that requires no disposables.



- **Masimo Open Connect**

Through Masimo Open Connect (MOC), Root augments breakthrough rainbow SET measurements with multiple additional technologies – including SedLine brain function monitoring, O3 regional oximetry, and NomoLine capnography and gas monitoring. Through MOC partner development, multiple additional technologies will be available on Root in the future.



MOC-9 ports enable expansion measurements from Masimo or MOC partners.

## Available Connectivity with Iris

Root's Iris ports enable connectivity with third-party devices such as infusion pumps, ventilators, and anesthesia machines. Root integrates multiple streams of data for electronic medical record (EMR) documentation and remote reviewing, simplifying workflows and helping caregivers make quicker assessments, which may enable earlier intervention and better clinical decisions.



Iris ports act as a connectivity hub for third-party standalone devices, such as IV pumps and ventilators.

Versatile, High-visibility Display

The adaptive display on Root is designed to aid clinicians' rapid assessment of patient status.



In Analog view, virtual gauges show measurement values in relation to alarm ranges.



In Trend view, each measurement value is displayed alongside its graphical trend.



With alarm status visualizer, a three-dimensional, anatomical image associates alarm status with green, yellow, or red colors.

Intuitive Multi-touch Navigation

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



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

# Mobilizing Measurements with Radius-7<sup>®</sup>

## The Power of Masimo's Breakthrough Measurements in a Patient-worn Monitor

Studies have shown that patient ambulation is a key factor in faster patient recovery,<sup>1</sup> but movement can cause frequent drop outs and false alarms with conventional pulse oximetry. Radius-7 with rainbow SET Pulse CO-Oximetry leverages SET<sup>®</sup> Measure-through Motion and Low Perfusion performance to enable accurate monitoring while the patient is moving, along with continuous monitoring for earlier identification of clinical deterioration.





Radius-7 is the first and only wearable and wireless device to enable noninvasive and continuous monitoring of rainbow SET measurements while patients are mobile, including indices of:

- Oxygenation and Circulation**  
 Oxygen saturation (SpO<sub>2</sub>) and pulse rate monitoring with Masimo SET® Measure-through Motion and Low Perfusion pulse oximetry for reliable detection of desaturation and accurate pulse rate while dramatically reducing false alarms<sup>1,2</sup>
- Respiration**  
 Respiration rate monitoring through either rainbow Acoustic Monitoring for acoustic respiration rate (RRa) or through the plethysmographic waveform (RRp) to identify respiratory depression or tachypnea<sup>3</sup>
- Hemoglobin**  
 Noninvasive and continuous hemoglobin (SpHb) monitoring with rainbow SET Pulse CO-Oximetry may help clinicians identify changes in hemoglobin that may be associated with bleeding and stable hemoglobin to help reduce inappropriate transfusions

## Radius-7

### Untethered Monitoring and Ambulation

Placed on the patient arm or wrist with a comfortable disposable strap, Radius-7 is designed to promote greater patient comfort and independence and reduce the need for nurses to disconnect the monitor each time the patient gets out of bed.

### Keeping Patients Connected to Clinicians

Root with Radius-7 can alert clinicians to critical changes in a patient's physiologic status at the bedside or with supplemental remote monitoring and notification remotely through Masimo Patient SafetyNet, ensuring patients can be continuously monitored and connected to caregivers while they are moving – in or outside their rooms. Bluetooth wireless technology allows short-range communication with Root and optional WiFi enables longer-range communication throughout the hospital.

### Flexible Functionality

Radius-7 has two “hot-swappable” rechargeable modules with a 12-hour battery (one on Radius-7, one charging in Root), providing seamless replacement at shift change and automatic pairing with Root to minimize disruptions to nursing workflow. Radius-7 also has a display shut-off feature to minimize patient distraction and support privacy while ambulating.



Each Radius-7 comes with two rechargeable, “hot-swappable” modules, enabling uninterrupted monitoring and a quick exchange at the bedside.

<sup>1</sup>Taenzer AH et al. *Anesthesiology*. 2010 Feb;112(2):282-7. <sup>2</sup>Pyke J et al. *Patient Safety & Quality Healthcare*. May/June 2009. <sup>3</sup>Ramsay MA et al. *Anesth Analg*. 2013 Jul;117(1):69-75. Radius-7 with RRp, RPVI, and SpfO<sub>2</sub> are not available in the U.S

# Personalizing Monitoring with MyView™

MyView empowers clinicians to see things their way. While the type of displayed information can change dramatically by clinician and care area, patient monitors historically function in a static manner with the same parameters, waveforms, and trends displayed in the same location at all times.

MyView technology – a feature enabled by Masimo Patient SafetyNet – allows wireless sensing of the device, clinician, and patient to provide the parameters, waveforms, and trends that clinicians, patients, and their families each want to see. While a physician may want to see all parameters and waveforms, a medical assistant may only want to see a few parameters and no waveforms. If no clinician is in the room, the patient and family members may be best served with no specific information but rather a color-coded device alarm status.



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



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

When no clinician is present, select a device display that is primarily green, yellow, or red, depending on the alarm status, with parameters displayed in smaller font within the parameter well. This eliminates a common distraction for the patient and family members while limiting unnecessary concerns and questions. When clinicians enter the room, MyView recognizes them and displays their preferred view.



# Expanding Measurements with Masimo Open Connect<sup>®</sup>

Root enables flexible measurement expansion through Masimo Open Connect (MOC) with either wired external modules (MOC-9) or wireless communication (MOC-C).

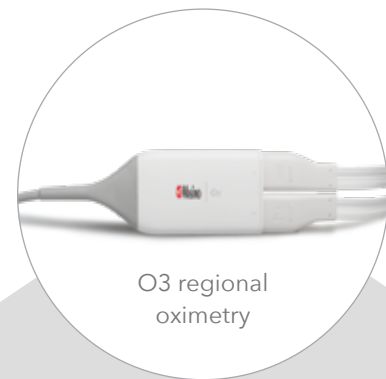
## Masimo MOC Measurements

Three Masimo measurement technologies are currently available for Root through MOC-9 modules:

- SedLine brain function monitoring
- O3 regional oximetry
- NomoLine capnography and gas monitoring



SedLine brain function monitoring



O3 regional oximetry



NomoLine capnography and gas monitoring

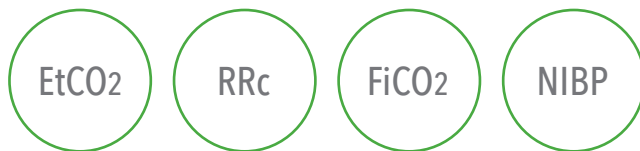
MOC-9 ports allow up to three modules to be connected at one time.



SedLine brain function monitoring and O3 regional oximetry are plug-and-play MOC-9 modules for Root.



# Offering Solutions for a Variety of NomoLine® Capnography and Gas Applications



NomoLine capnography and gas monitoring is available in multiple configurations to meet various clinical needs.

## ISA – A High Performance Sidestream Analyzer

Using state-of-the-art spectrometer technology that utilizes nine different wavelengths of light and powerful signal processing algorithms, the ISA sidestream analyzer provides clinicians with capnography and gas measurements. With minimal warm-up time, ISA supports quick assessment in critical situations. ISA is factory-calibrated and does not require field calibration, minimizing hospital-level maintenance. ISA sidestream analyzers are available as standalone or easy-to-integrate OEM modules.

## IRMA – A Complete Monitor in a Probe

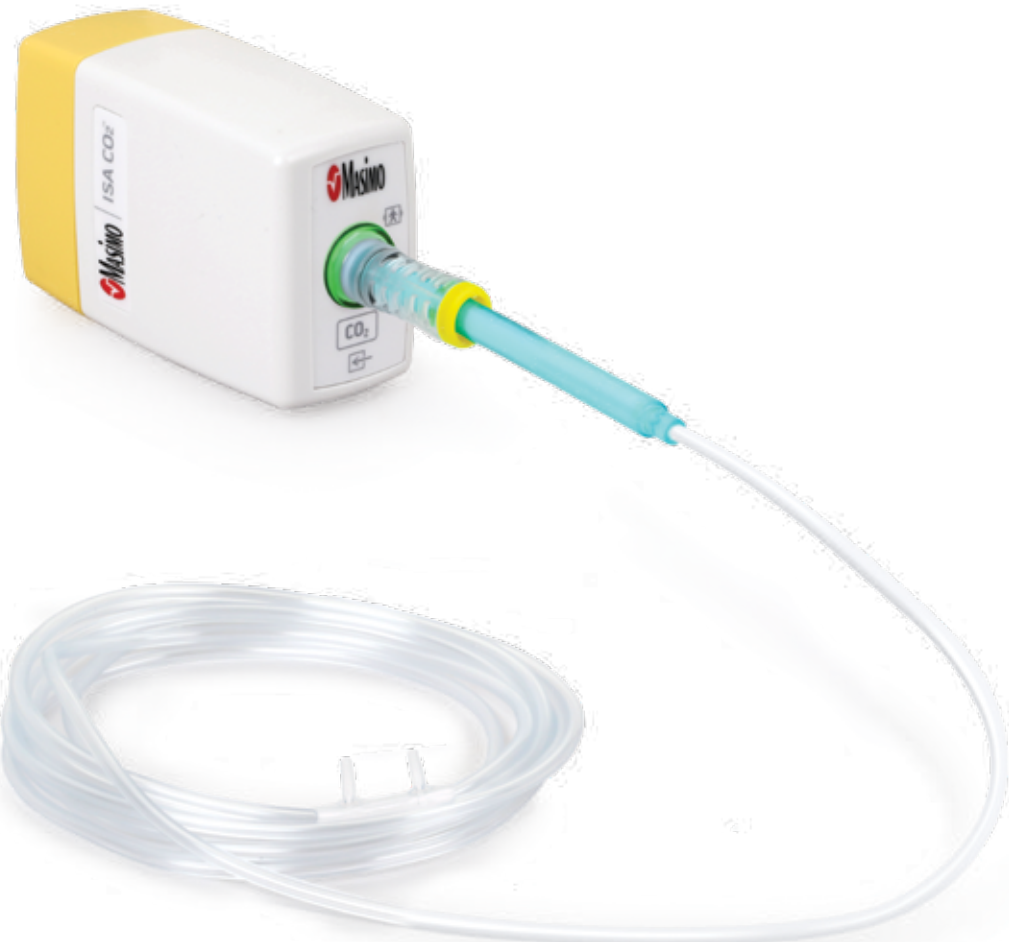
With its compact size and microprocessor technology, the versatile IRMA mainstream analyzer weighs less than one ounce and fits in the palm of your hand. IRMA's mainstream capability allows clinicians to monitor directly from the breathing circuit and avoid sampling lines.



ISA CO2 is a plug-and-play module for Root that can be quickly disconnected from and re-deployed to any available Root.

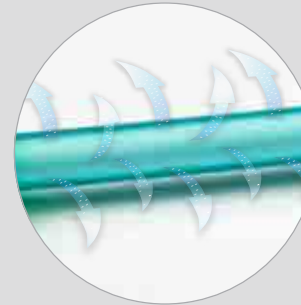
# Overcoming the Challenges of Traditional Gas Sampling with NomoLine Cannulas

Designed for low-flow applications, with functionality in any orientation, NomoLine sampling lines can be used in a variety of clinical scenarios on both intubated and non-intubated adult, pediatric, infant, and neonatal patients, in both low- and high-humidity configurations.

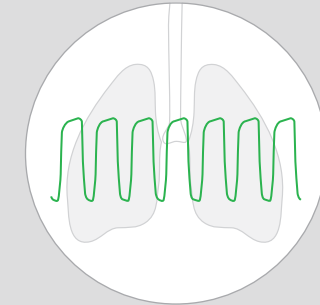


A selection of convenient single-patient-use cannulas.

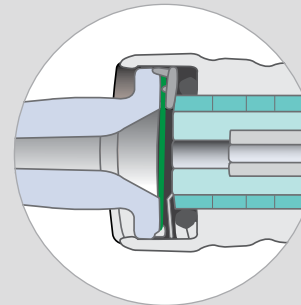
## NomoLine Technology Benefits



- Revolutionary polymer collects and removes water in the sampling line to extend product life and eliminate the need for a water trap



- Designed for low tidal volumes and high breath rates to provide suitability for a wide range of clinical applications



- Hydrophobic bacteria filter protects the ISA module from bacteria and water intrusion



- Cannulas with soft, ergonomically curved design provide greater patient comfort



- Leak-free, click-in gas sampling port connector enables easy-to-use sampling lines

# Fueling Innovation with Masimo Open Connect

When new monitoring technologies are introduced, traditional multi-parameter monitoring companies often wait for significant market adoption to occur before integrating these new technologies in their products. This means that new technologies are often only available in standalone versions. Hospitals often have a strong desire to add new technologies to existing multi-parameter monitors, so the lack of an integrated solution can limit hospital adoption and patient benefit.

## Designed to Stimulate Third-Party Innovation

Masimo's unique approach to medical technology integration through Masimo Open Connect (MOC) partnerships addresses these barriers to new technology adoption in patient monitoring. Root's open architecture and built-in connectivity enable third-party companies to bypass barriers and time it takes for traditional multi-parameter monitor integration by controlling their own Root integration project.

Third parties can then independently develop, obtain regulatory approvals, and commercialize their own external MOC-9 module or Masimo Open Connect Control (MOC-C) app for Root using Masimo's MOC software development kit (SDK). Masimo's engineering team will support MOC partner development as needed and Masimo's commercial team will help increase awareness of the availability of MOC-9 modules and MOC-C apps from MOC partners. In turn, MOC partners will use their existing distribution channels to sell their MOC-9 module or MOC-C app to Masimo customers already using Root, as well as offering the product to their potential customers as an additional way to deploy their technology.



*"We believe that Root with Masimo Open Connect can do for patient monitoring what the PC did for computing: speed up the patient innovation cycle, reduce the cost of equipment, and prolong the useful life of the equipment."*

**Joe Kiani**  
Chairman and CEO, Masimo

In 2017, Masimo and Mdloris announced the first MOC-9 module, with Analgesia Nociception Index (ANI) technology.<sup>1</sup> The ANI MOC-9 module for Root will provide an objective, noninvasive, and continuous way to monitor the pain level of patients. Multiple additional MOC-9 modules and MOC-C apps are in development by MOC partners.



Up to three MOC-9 modules can be used at the same time on Root.

# Addressing Safety Challenges on the General Ward with Patient SafetyNet™

A sentinel event is defined as an unanticipated death or serious injury to a patient that is not related to the natural course of the patient's illness. The last thing anyone expects when otherwise healthy patients are admitted for routine procedures is that they won't go home due to a sentinel event. The combination of pain management medications and lower staff-to-patient ratios on general care floors make it less likely that a clinician can be there to observe an alarm that could precede an avoidable adverse event.

In August 2012, The Joint Commission Sentinel Event Alert on the safe use of opioids in hospitals

recommended implementation of better dosing along with continuous oxygenation and ventilation monitoring (instead of spot checks) in post-surgical patients.<sup>1</sup> This alert reported the incidence of respiratory depression at 0.5%, which means a hospital with 10,000 surgeries per year would experience one patient per week with respiratory depression. Failure to recognize respiratory depression and institute timely intervention can lead to cardiopulmonary arrest, resulting in brain injury or death. A retrospective multi-center study of 14,720 cardiopulmonary arrest cases showed that 44% were respiratory related and more than 35% occurred on the general care floor.<sup>2</sup>

## Connecting Patients and Caregivers Quickly, Easily, and Accurately

Masimo Patient SafetyNet remote monitoring and clinician notification system combines bedside monitoring with Masimo's monitoring technologies with clinician notification via pager, IP phone, or smart phone. Patient SafetyNet provides patient safety on the general floor in a system that can be integrated into your existing wired or wireless network. Patient SafetyNet may facilitate appropriate early clinical response, preemptions of sentinel events, and avoidance of unnecessary transfers, while helping you meet The Joint Commission,<sup>1</sup> Institute for Safe Medication Practices (ISMP),<sup>3</sup> Anesthesia Patient Safety Foundation (APSF),<sup>4</sup> and American Society of Anesthesiologists (ASA) guidelines.<sup>5</sup>



The last thing anyone expects when otherwise healthy patients are admitted for routine procedures is that they won't go home due to a sentinel event



## Impact of Patient SafetyNet at One Hospital



*"In my opinion as Quality and Safety Officer, our results strongly demonstrate that continued patient surveillance with Masimo SET<sup>®</sup> and Patient SafetyNet increase healthcare value by significantly improving clinical outcomes while reducing costs."*

**George Blike, MD**  
Dartmouth-Hitchcock Medical Center

## Improving Outcomes on the General Ward with Patient SafetyNet

### Reducing Rescues and ICU Transfers

Clinicians understand the risks of not continuously monitoring patients on the general floor. In the past, excessive false alarms due to patient motion often precluded continuous monitoring in these care areas. In the last decade, Masimo SET<sup>®</sup> has been shown to improve the process of care in neonates and pediatric patients due to its Measure-through Motion and Low Perfusion performance.<sup>1,2</sup> However, in a landmark study published in *Anesthesiology* in 2010, researchers found that continuously monitoring adult patients on a post-surgical floor at Dartmouth-Hitchcock Medical Center using Masimo Patient SafetyNet with Masimo bedside devices resulted in a 65% reduction of rapid response team activations and a 48% reduction in transfers back to the ICU.<sup>3</sup>

Following the initial implementation and positive results in one post-surgical ward, Patient SafetyNet with Masimo bedside devices was expanded to cover more than 200 inpatient beds in all medical and surgical units. In subsequent articles published in the *Anesthesia Patient Safety Foundation Newsletter* in 2012 and *The Joint Commission Journal on Quality and Patient Safety* in 2016, researchers reported that Patient SafetyNet enabled the facility, over a five-year period, to achieve their goal of zero preventable deaths or brain damage due to opioids,<sup>4</sup> and over a ten-year period, maintain a 50% reduction in unplanned transfers and 60% reduction in rescue events, despite increases in patient acuity and occupancy.<sup>5</sup>

### Proven Cost-effectiveness

As a result of the Patient SafetyNet implementation, Dartmouth-Hitchcock Medical Center saved \$1.48 million annually,<sup>4</sup> showing that implementing Masimo SET<sup>®</sup> and Patient SafetyNet to more safely monitor post-surgical patients can also have a significant impact on a hospital's bottom line by increasing ICU bed availability and reducing the costs associated with emergency rescue events. With both clinical and financial justifications now in place, hospitals are increasingly implementing general floor monitoring with Masimo technologies.

<sup>1</sup>Hay WW et al. *J Perinatol*. 2002 Jul-Aug;22(5):360-6. <sup>2</sup>Brouillette LL et al. *Anesth Analg*. 2002 Jan;94(1 Suppl):S47-53. <sup>3</sup>Taenzer AH et al. *Anesthesiology*. 2010;112(2):282-287. <sup>4</sup>Taenzer AH et al. *Anesthesia Patient Safety Foundation Newsletter*. Spring-Summer 2012. <sup>5</sup>McGrath SP et al. *The Joint Commission Journal on Quality and Patient Safety*. 2016 Jul;42(7):293-302.

# Simplifying and Integrating Multiple Measurements with Halo Index™

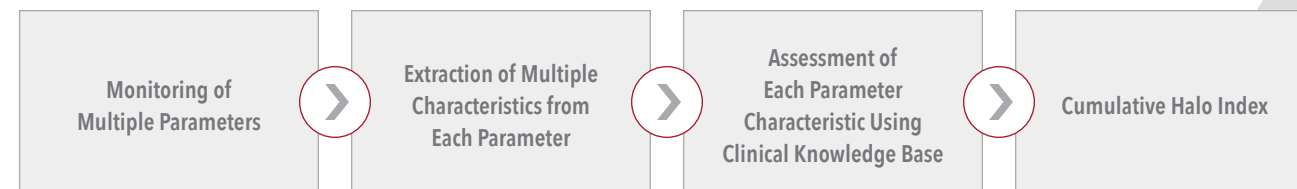
## Halo Index Mimics an Expert Clinician

Physiologic deterioration often occurs long before a crisis event and manifests through subtle and often undetected changes across multiple physiologic parameters. Masimo designed Halo Index to mimic the systematic approach that expert clinicians use in assessing physiologic deterioration – analyzing patient history and extracting key continuous vital sign parameter characteristics to monitor global patient status over time.

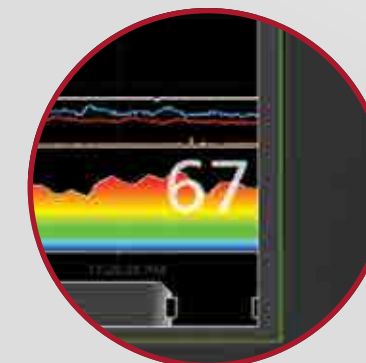
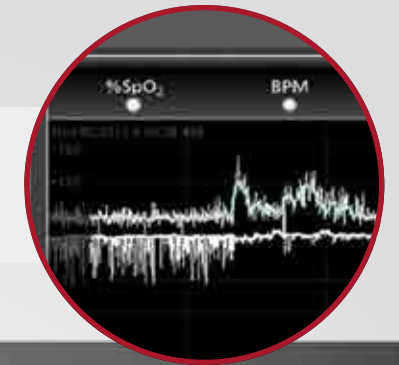
Halo Index uses available Masimo parameters and is scalable to include additional information from the patient record. Each parameter's significance is weighted and combined into the Halo Index – a single displayed number with a range from 0 to 100 that provides a cumulative trending of global patient status. An increase in a patient's Halo Index may indicate the need for clinicians to more closely assess the patient.

## Halo Index: How it Works

To calculate Halo Index, parameters are continuously analyzed over relevant time intervals in order to extract parameter characteristics. It is important to note that the parameter characteristics are not merely instantaneous values, but include historical parameter data and parameter relationships to support an integrated assessment of a patient's underlying physiology.



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



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

# Deploying Root with Noninvasive Blood Pressure and Temperature

With the addition of noninvasive blood pressure and temperature monitoring capabilities, Root can also function as a powerful and versatile vital signs monitor, suitable for use at the bedside or as a rolling spot-check device.



## Integrated Temperature

Oral temperature probe enables quick spot-check temperature measurements.



## Integrated Noninvasive Blood Pressure

Spot-check and customizable interval measurement options.

- Spot-check blood pressure measurements can be taken at any time
- Automatic interval mode routinely takes blood pressure measurements once every desired time interval, eliminating the need to do so manually
- Stat interval mode continuously measures blood pressure for a desired duration of 5 or 10 minutes



## Non-contact Temperature Option with Caregiver\*

Root is also available with an easy-to-use, clinical-grade infrared thermometer with Bluetooth connectivity.

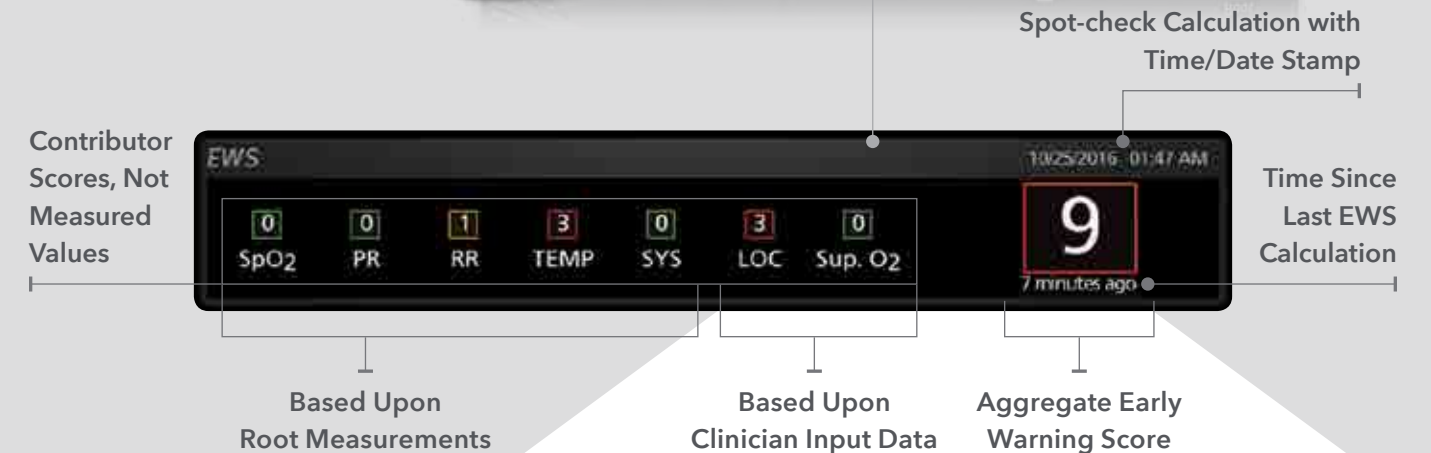
- Comparable accuracy to oral measurements
- Simple, one-button operation delivers instant results, reducing time to take temperature measurements
- Bluetooth automates data transfer to a connected Masimo device enabling streamlined integration into the bedside device and EMR
- Non-contact module reduces costs and waste by eliminating the need to purchase additional disposables such as probe covers



# Computing an Early Warning Score with Root

Integrating multiple spot-check measurements into an Early Warning Score (EWS) can aid in the automatic monitoring of potential patient deterioration.<sup>1</sup> Root can automatically calculate an EWS from existing device measurements and additional clinician inputs which represents the potential degree of patient deterioration. EWS contributor scores are calculated using measured values and clinician input, then combined into an aggregate EWS. As with other patient data, the EWS, which must be clinician-initiated, can be pushed to the Electronic Medical Record (EMR) directly when Root is connected to Masimo Patient SafetyNet or Iris Gateway.

Early warning scores are based on multiple contributors, including vital signs such as oxygen saturation, pulse rate, respiration rate, body temperature, and systolic blood pressure – and contributors entered by clinicians, which can include customized inputs which clinicians are prompted to enter, such as level of consciousness, use of supplemental oxygen, and urine output. The weighting and number of contributors differ depending upon which EWS protocol is used. Root can be customized with up to eight EWS profiles using one of multiple predefined EWS protocols or a custom-configured EWS in which hospitals determine their own set of required contributors and their relative weights to create an EWS unique to their care environment.





# Keeping Patients and Clinicians Connected to the EMR through Adaptive Connectivity Engine

Hospitals are increasingly using electronic medical records (EMRs) to chart changes in vital signs and document clinical interventions. Compared to manual documentation, automatic transfer between medical devices and EMRs can improve productivity and reduce the likelihood of transcription errors.<sup>1</sup>

Masimo Patient SafetyNet and Iris Gateway provide clinicians with a solution to automate the transmission and subsequent recording of key data to and from Root devices and the EMR, helping clinicians spend less time recording information

and more time caring for patients. Patient SafetyNet and Iris Gateway incorporate Adaptive Connectivity Engine (ACE), which enables two-way, HL7-based connectivity to other hospital systems, including EMR systems. ACE significantly reduces the complexity of integrating and validating custom HL7 implementations, which means the EMR validation can be completed quickly, cost-effectively, and often without the aid of EMR vendors. Masimo's entire approach to connectivity is based on this fundamental principle: automating patient care with open, scalable, and standards-based architecture.

## Patient Admit / Association

Patient SafetyNet and Root interface with hospital Admit Discharge Transfer (ADT) systems allowing clinicians to associate patients to their data through a drop-down list or barcode scanning.



- Patient data, including EWS, is captured by Root
- Patient SafetyNet or Iris Gateway converts data into HL7
- Patient SafetyNet or Iris Gateway automates data transfer to the hospital EMR

## Documentation / Results Out / Electronic Charting

Patient SafetyNet provides automated documentation of patient data to the EMR at hospital-specified intervals, and also enables clinician bedside verification to reduce time required for documentation at the EMR workstation.



Bedside documentation of vital signs from Root along with common fields such as urine output, level of consciousness, and pain scale.

# Automating Workflows for Data Collection

## Guided Workflows

Variability in clinician workflows can reduce the consistency of care and reduce productivity. Root or Rad-97 with Iris or Masimo Patient SafetyNet allow hospitals to customize and automate workflows for spot-check or continuous monitoring scenarios. Hospitals can create their own rules engine in Iris or Patient SafetyNet to enable onscreen direction in all connected devices to guide which measurements to capture and which additional data to input on Root. Based on measurement or score values, clinicians can also be prompted to enter more information or take specific actions.

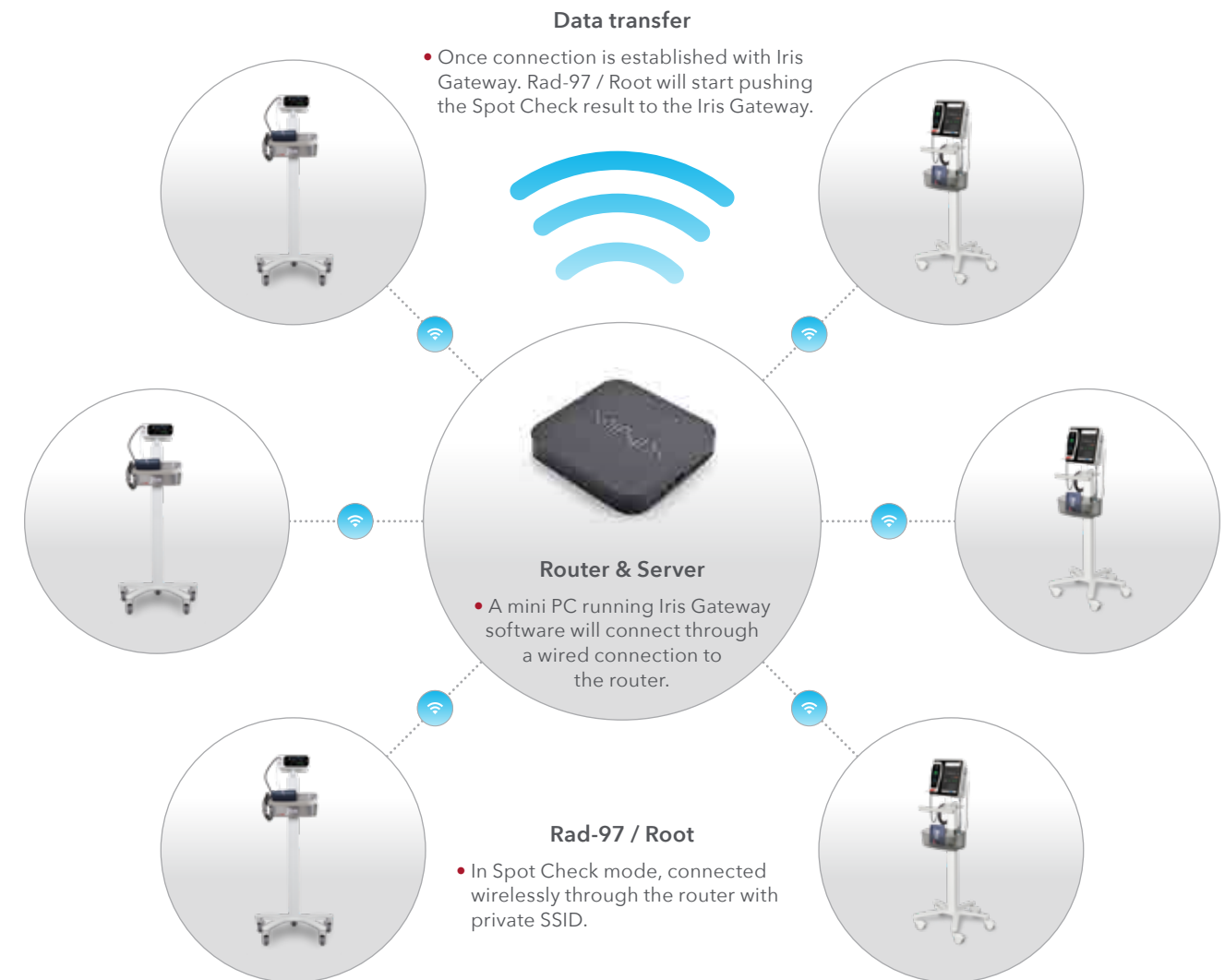


Hospitals can configure Root to prompt clinicians to take specific actions based on specific measurements or early warning score thresholds

Root enables vital sign documentation at the bedside for both measurements and hospital-configured manual inputs

## Capturing Data Even When Devices Are Not Connected

Most spot-check vital signs monitors require a continuous wireless network connection to enable vital signs documentation to the electronic medical record (EMR). Root and Rad-97 bypass this limitation with the ability to locally store the data collected from multiple patients, and then automatically transfer the collected data via Bluetooth to a network relay station that enables documentation to the EMR. This feature is expected to minimize manual documentation from disconnected devices and lessen the need for additional wireless infrastructure.



Root and Rad-97 can locally store the spot-check data collected from multiple patients, and then automatically transfer the collected data via Bluetooth to a network relay station that enables documentation to the EMR

# Connecting and Controlling Third-Party Devices with Iris™

## Device Interoperability Challenges

Despite advances in medical technology, the lack of device interoperability is a serious patient safety risk.<sup>1</sup> Data generated from medical devices often remain captive within each device and may not be captured in patient records. Existing approaches for device interoperability may 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 Gateway

Root's Iris ports, along with Iris Gateway, integrate monitoring and connectivity to bridge medical device data silos. Device connectivity with Iris is vendor agnostic and is designed to leverage existing network infrastructure and reduce costs while enhancing workflows and decision support. With Iris, Root can be used to associate patients with multiple third-party devices and systems and connect them to the electronic medical record (EMR). Root with Iris is appropriate both in high-acuity settings like the operating room or intensive care unit and in low-acuity settings like the general floor. Whenever medical device data are readily available in the EMR, clinicians have a more complete, timelier picture of the patient.



Automatic transfer between medical devices and EMRs could improve productivity and reduce the likelihood of transcription errors<sup>2</sup>

# Iris



- Third-party standalone devices and systems can silo valuable patient data

- Iris Gateway converts all Masimo and third-party standalone device data into HL7



- Root's built-in Iris ports act as a connectivity hub for third-party standalone devices

- Iris Gateway interfaces with EMRs for documentation and device data

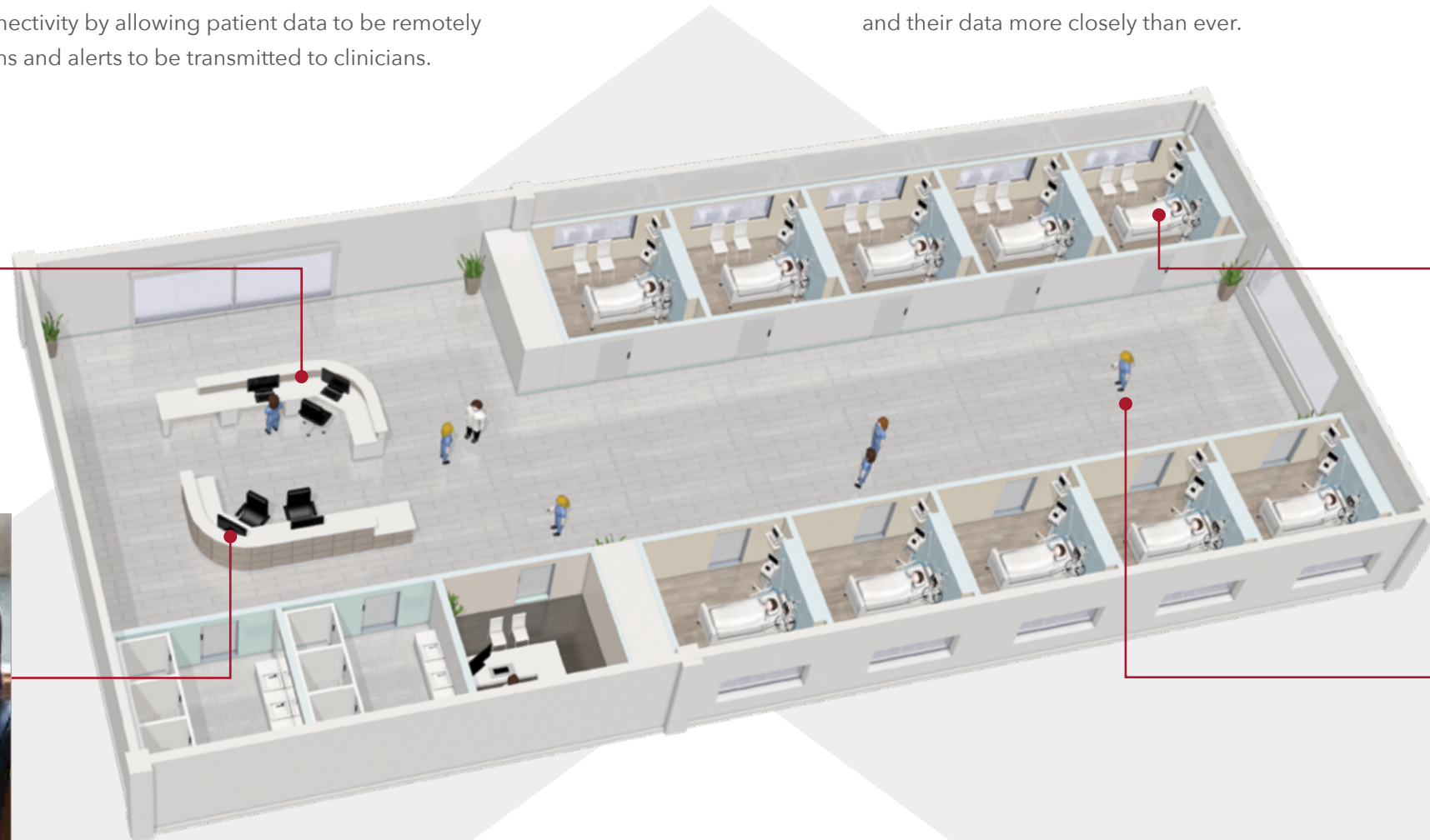
## Iris Gateway and Patient SafetyNet

In addition to automated documentation of patient data from multiple devices in the EMR, Patient SafetyNet with Iris Gateway further enhances connectivity by allowing patient data to be remotely viewed at central stations and supplemental alarms and alerts to be transmitted to clinicians.

Together, Root with Iris, Iris Gateway, and Patient SafetyNet are helping to connect clinicians, patients, and their data more closely than ever.



- Simplified Workflow with Barcode ADT Integration



- Bedside Device Connectivity



- Customizable View Station



- Mobile Clinician Notification

# Seeing Your Patient No Matter Where You Are with Replica™ and Built-in Camera

With Patient SafetyNet, when clinicians are out of the patient room, patients are continuously monitored and clinicians are notified when an alarm occurs. Replica takes connecting with patients through Patient SafetyNet to a new level, delivering patient data – including urgent notification of alerts and alarms – to the hand of any clinician. Replica also allows clinicians to monitor patient data in real time, modify device settings, and receive and

make video calls – all from a single app. Notification verification can be limited with standard paging and VoIP phones, only escalating notifications once fixed time periods have elapsed. Replica enables timely notification escalation because it has the ability to verify that a clinician's smart phone is powered on and has displayed the notification, as well as whether they have acknowledged or declined the notification.



Rad-97 and Root with camera allow clinicians to see and hear patients from a Masimo Patient SafetyNet View Station or from Replica.

## Replica Views



- Receive and accept or decline alerts
- View all patients in dashboard view
- View real-time data
- View all alerts



# Extending Visibility with Kite™

Masimo bedside monitoring devices provide clinicians with many types of data. During complex care, monitoring can involve so many forms of real-time output – all of value to clinicians – that displaying them simultaneously on the primary device's smaller display may be inconvenient or impractical.

## Maximizing Focus with Kite

Kite expands visibility of patient data for clinicians by allowing data from Masimo devices to be simultaneously viewed on different displays in customized configurations. Kite connects to Masimo devices via a wired or wireless connection on the same IP network and displays monitoring data from the connected device on a TV or tablet.

Kite's supplementary display can be customized to enable clinicians to view monitoring parameters, waveforms, and other data they require for that patient and type of care or operation. Kite also projects patient alarms from the monitoring device, providing quick notification of changes in a patient's physiological status.

*"Kite greatly enhanced the visibility of the Masimo monitor. During bypass I could easily view cerebral blood flow, allowing time to validate adequate perfusion to my patient and maintain my attention on my bypass circuit."*

**Dr. Don Marketto, D.O., Anesthesiologist**  
Mountain View Regional Hospital, Las Cruces, New Mexico

Ideal for Operating Rooms, Emergency Rooms, and Individual Patient Rooms

All the clinicians in the room can easily view multiple monitoring modalities on a large, centrally-located screen, in the clinicians' preferred configuration.



Kite During Surgery



Kite in the ICU

# Bringing Next Generation Data Aggregation and Display with UniView™

Building on the projection and customization capabilities of Kite, UniView\* will take the aggregation and customizable display of patient data to a new level. Through a wired or wireless connection to Iris Gateway, which gathers data from multiple sources, UniView will be able to project, on large displays, integrated patient information from all connected systems in the hospital. UniView will provide a central, convenient, and customizable display of data from patient monitors, ventilators, anesthesia gas machines, IV pumps, lab and radiology results, surgical views, and a myriad of other sources. In high acuity departments where comprehensive, clearly organized, and timely data are key to making the best clinical decisions and providing the best patient care, UniView may make all the difference.

**UniView will take the aggregation and customizable display of patient data to a new level**

UniView capabilities are designed to expand in the future to include therapeutic device control with automated decision support and eventual closed loop therapies, increasing care consistency and decreasing lag time between decision and execution.

UniView's automated data integration and display are designed to help clinicians identify changes in patient status and coordinate complex decisions, resulting in optimized treatment.



## Augmented Display

# Virtualizing Monitoring with AirGlass

Masimo AirGlass brings the adaptable and customizable display concept of UniView to a personal level through augmented reality. Using AirGlass, clinicians such as anesthesiologists and surgeons no longer need to physically adjust monitors or take their eyes off the patient to receive monitoring and therapeutic device data. Clinicians can also use AirGlass while they are out of the room to continue monitoring the patient. Seeing what's in front of them while always keeping patient data in sight allows clinicians to remain focused on the patient while coordinating patient management decisions.

By using motion gestures in the air with their hands, Masimo AirGlass allows clinicians to interact with data, such as enlarging key information and responding to alerts and alarms.

*"Healthcare technology that was once considered science fiction is becoming reality."*

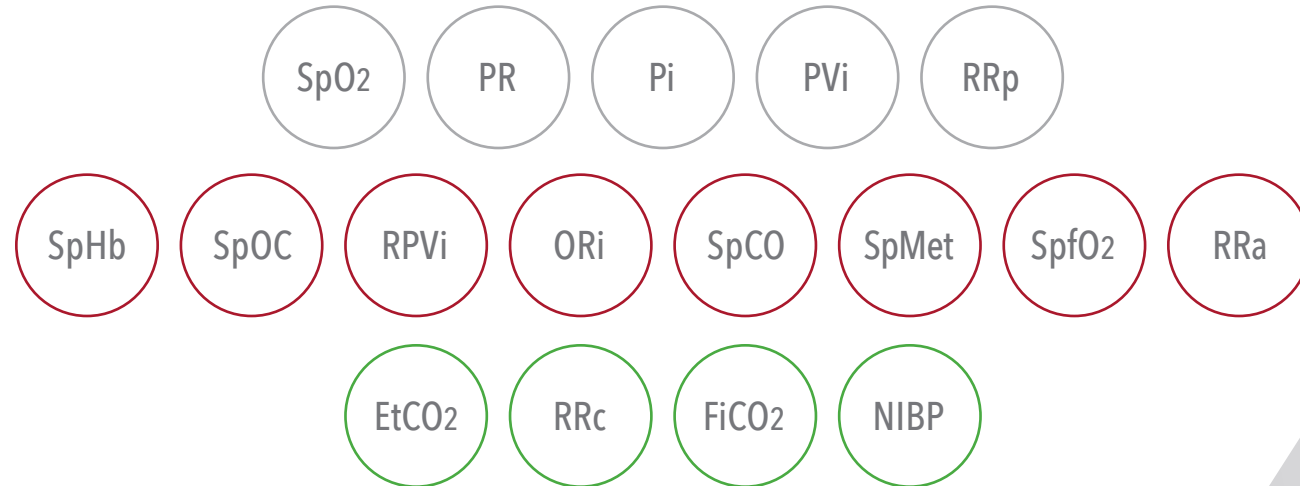
**Joe Kiani, Chairman and CEO**  
Masimo





# Taking Flexibility to the Next Level with Rad-97™

Rad-97 incorporates Masimo rainbow SET Pulse CO-Oximetry – and optional NomoLine capnography or noninvasive blood pressure – to enable measurements of 17 parameters in a portable and upgradeable bedside monitor. Rad-97 will also allow future expandability through Bluetooth communication with Masimo Caregiver for non-contact thermometry and third-party measurement devices such as weight scales and glucometers.



## Flexible Uses with Powerful Expandability



• Bedside monitor



• Connection to Masimo Patient SafetyNet for remote monitoring of multiple patients as well as clinician notification



• Spot-check vital signs monitoring with optional cart



• Optional Masimo Caregiver for non-contact thermometry with Bluetooth communication

Optional camera enables remote viewing and communication with the patient

Real-time EtCO2 waveform provides an easily interpretable display of capnography measurements

Connectivity solutions facilitate electronic charting of patient data in the EMR, automated by Patient SafetyNet or Iris Gateway

Integrated port for direct connection of either NomoLine sampling lines for capnography or NIBP



Use simple gestures on the multi-touch screen to move, expand, or collapse parameter trends for real-time analysis

Data can be displayed in numeric view or trend view

Customizable display allows for quick monitoring of patient status and provides pertinent data at a glance

Ethernet, Nurse Call Interface, and USB ports enable seamless integration into wired infrastructures

Light Emitting Gas Inlet indicator illuminates in different colors to provide visual indicators of capnography module status

# Redefining Handheld Monitoring with the Revolutionary Rad-67™



## Next Generation SpHb

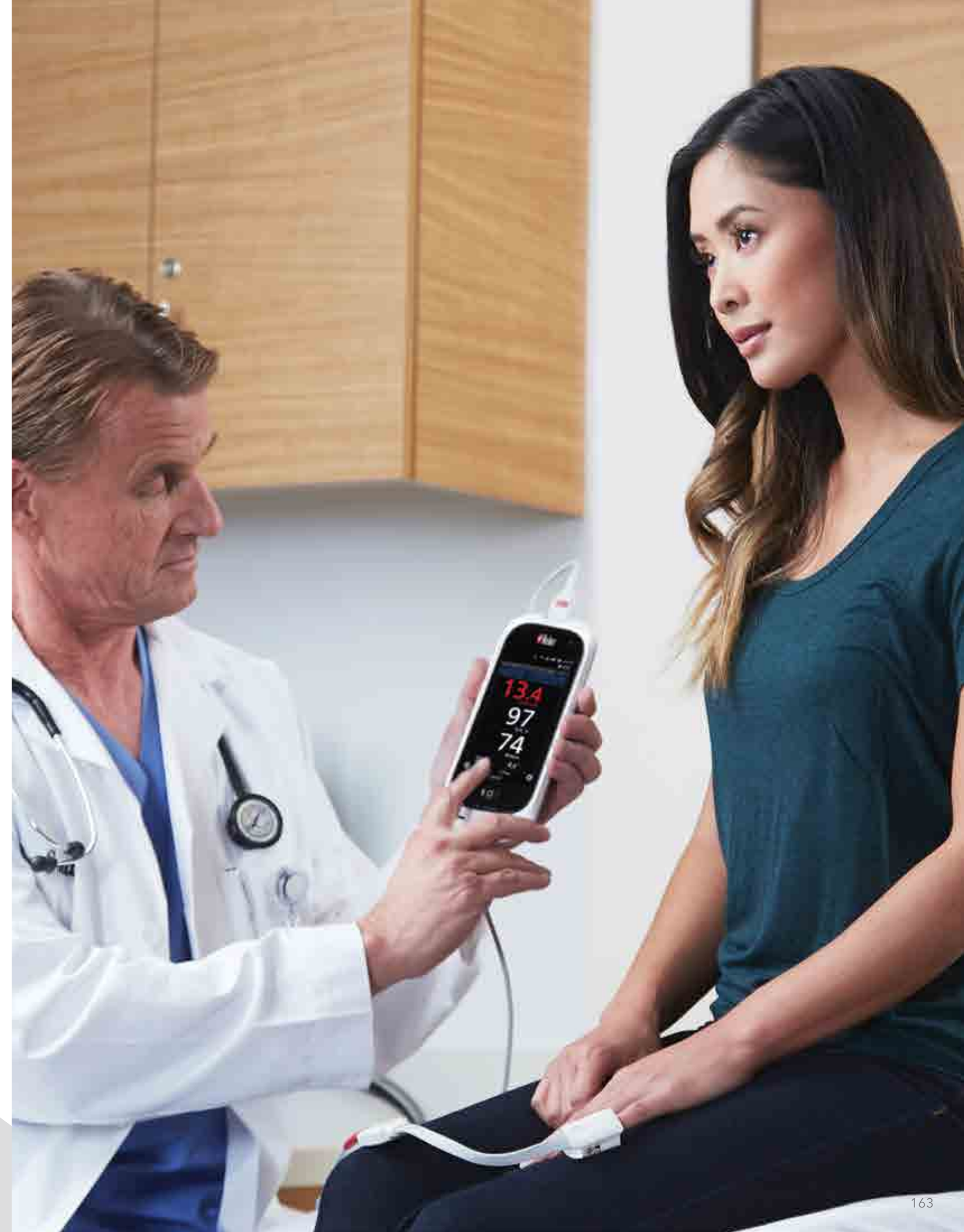
Next Generation SpHb significantly advances noninvasive hemoglobin spot-checking with improved motion tolerance, faster time to display SpHb results, and enhanced field performance in low hemoglobin ranges.

- Improved motion tolerance
- Enhanced SpHb field performance
- Results displayed in as few as 30 seconds

*"The ability to monitor noninvasive hemoglobin (SpHb) is a great advancement. Once low SpHb is reported, confirmation with a conventional laboratory test will further explore the possible causes."*

**Dr. Aryeh Shander**

Chief of Anesthesiology & Critical Care Medicine, Englewood Hospital and Medical Center



## Next Generation SpHb

Next Generation SpHb significantly advances noninvasive hemoglobin spot-checking with improved motion tolerance, faster time to display SpHb results, and enhanced field performance in low hemoglobin ranges.

The following table represents the accuracy of SpHb measurements obtained using Rad-67 with Next Generation Spot-check SpHb Technology and measurements using an invasive point-of-care device, each compared to a laboratory reference device.<sup>1</sup>

Accuracy of Next Generation SpHb and Invasive Point-of-care Device vs. Laboratory Hematology Analyzer

| Dataset   | Number of Subjects | Number of Samples | Precision (g/dL) | Bias (g/dL) | Root-Mean Square (ARMS) Accuracy <sup>2</sup> (g/dL) |
|---|--------------------|-------------------|------------------|-------------|--|
| SpHb vs. Laboratory Hematology Analyzer   | 289                | 542               | 1.0              | 0.4         | 1.1  |
| Invasive Point-of-care Device vs. Laboratory Hematology Analyzer (Capillary Blood Draw) | 289                | 289               | 1.1              | -0.1        | 1.1  |



- Improved motion tolerance



- Enhanced SpHb field performance in the lower hemoglobin ranges



- Results displayed in as few as 30 seconds



Wired and wireless connectivity enables transfer of patient data

Rechargeable battery with up to 6-hour battery life

Intuitive touchscreen and finger gestures facilitate quick navigation

High definition, color LCD display with ambient light sensor automatically adjusts screen brightness to optimize visibility



- Feedback screens provide alerts regarding signal quality and possible solutions



- Label spot-check measurements with unique patient identifiers for convenient historical data review



- Download patient data directly from the device using a wired or wireless connection



- Bluetooth enables printing of results at the point of care

<sup>1</sup>Masimo study. Data collected at six different centers on healthy and sick subjects. <sup>2</sup>Rounded ARMS accuracy obtained meets the 1 g/dL accuracy requirement. ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within  $\pm$  ARMS of the reference measurements in a controlled study. SpHb monitoring with Rad-67 is not intended to replace laboratory blood testing. Blood samples should be analyzed by laboratory instruments prior to clinical decision making. Rad-67 is not available in the U.S.

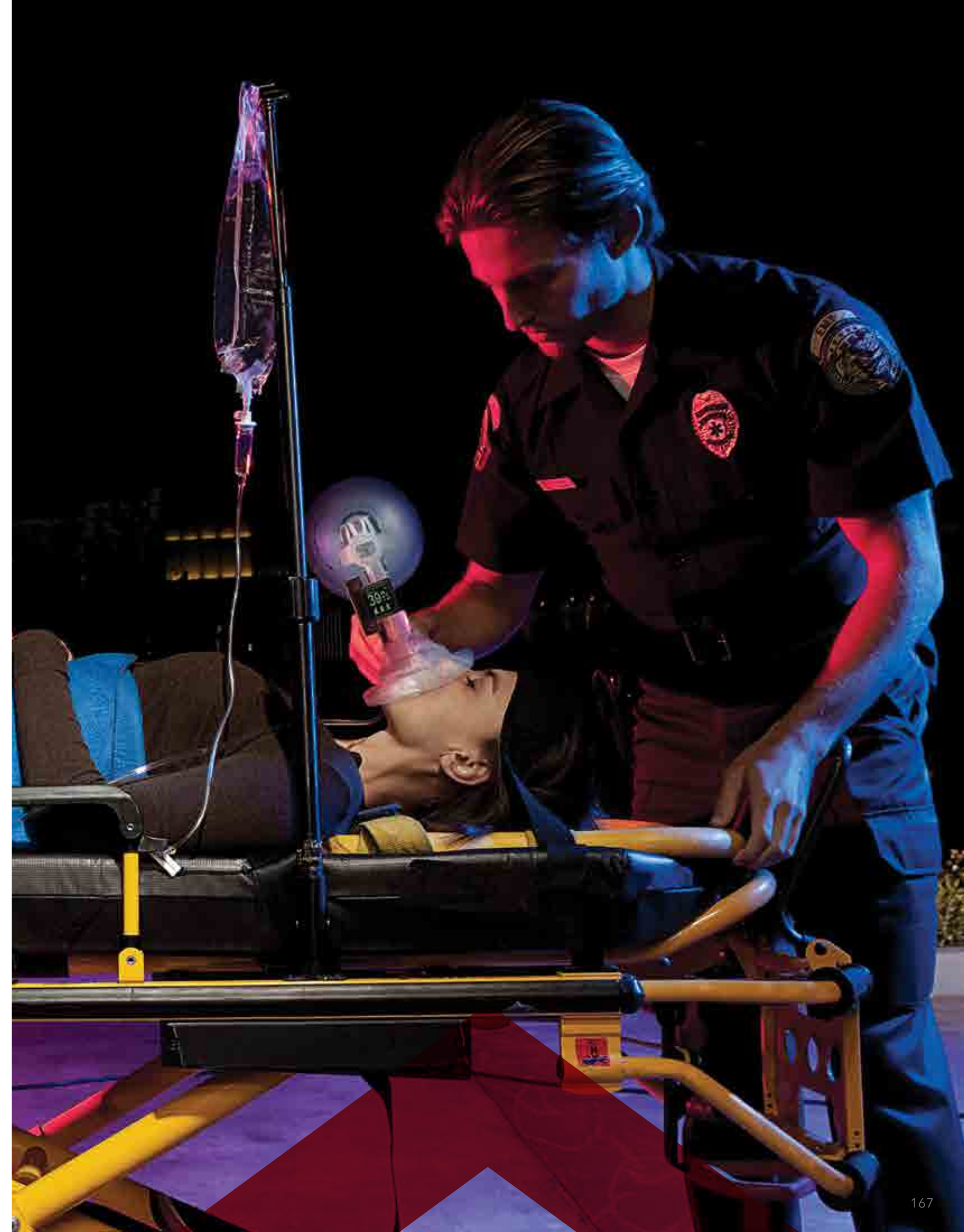
# Accessing Immediate Capnography at the Point of Patient Contact with EMMA™

The Masimo Emergency Mainstream Analyzer (EMMA) is a compact, portable, and lightweight mainstream capnograph that requires minimal warm-up time, with full accuracy in 15 seconds.

EtCO<sub>2</sub>

RRc

EMMA is ideal for short-term monitoring of end-tidal CO<sub>2</sub> levels and respiration rate in adult, pediatric, and infant patients. EMMA is often used during anesthesia, emergency care, and intensive care, where capnography is also used to confirm endotracheal intubation and to monitor assisted ventilation performance. The continuous capnograph allows clinicians to confirm effective resuscitation, to assess the depth and effectiveness of compressions, and to recognize the return of spontaneous circulation.<sup>1,2</sup>



# Carrying the Most Powerful Pulse Oximeter in Your Pocket with MightySat™ Rx

MightySat Rx is the first fingertip pulse oximeter with Masimo SET® parameters, and is the only fingertip oximeter with Pleth Variability Index (PVi) and respiration rate from the pleth (RRp).\*



MightySat Rx is intended for professional use or by patients as required, with prescription. The compact, battery-powered unit with color screen can be rotated for real-time display of the pleth waveform and other measurements. Optional Bluetooth wireless functionality enables measurement display via a free, downloadable app on iOS and Android mobile devices, or transmission to a third-party app through a wireless protocol.<sup>1</sup>

The Masimo Professional Health App includes a high resolution plethysmographic waveform, audible pulse tone feature, and trending

functionality. The app enables users to view their measurements in real time or over a trended graphical display on a compatible smart device. The app also interfaces with the Apple Health Kit for iOS users, further expanding its utility. The app empowers clinicians and patients by allowing the captured data to be shared via email.

Through Bluetooth communication, MightySat Rx data can also be integrated into multiple third-party telehome monitoring solutions for complex care management, chronic disease management, and readmission management.



iSpO2 Rx enables spot-check of continuous monitoring with Masimo single-patient-use or reusable sensors and is powered by a smart phone or tablet with data display on the Masimo Professional Health app



View measurements on a compatible smart device.



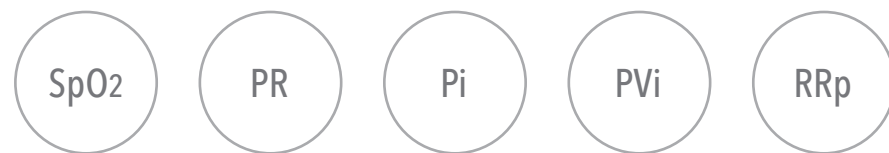
Trend measurements over time and view graphically.



Share data via email or through Bluetooth wireless protocol.<sup>1</sup>

# Providing Better Data for Better Performance with MightySat

The same revolutionary Masimo SET® technology available for professional use in the MightySat Rx is also available as MightySat for personal use by consumers for health and wellness applications.



## What Better Data Means to You

MightySat is ideal for people who know they want a fingertip pulse oximeter and want the best available technology. MightySat is also for people who want to improve their health, wellness, or fitness by providing more accurate SpO2 and pulse rate as well as key measurements that are not available on other health and wellness devices.

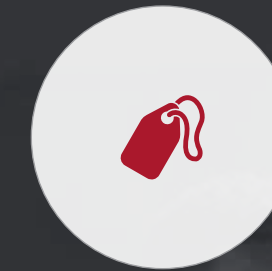
*"MightySat is very easy to use and a great tool for all levels of athletes. The accurate data from MightySat helps me get the most from my workouts."*

**Garry Harris**  
Professional Basketball Player, Denver Nuggets

## App Features



- Ability to create multiple user profiles



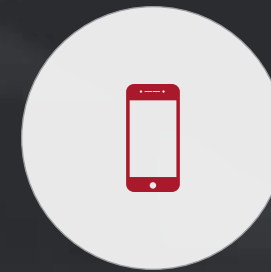
- Tag your sessions



- Share multiple sessions



- Share your data through email and social media



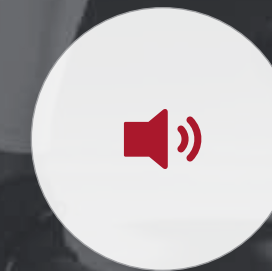
- View live measurements throughout the app



- Automatically store your data in Apple Health and TrainingPeaks



- Set your low and high thresholds for each measurement



- Audible notifications depending on your preferences and settings

## Do More with Your Data

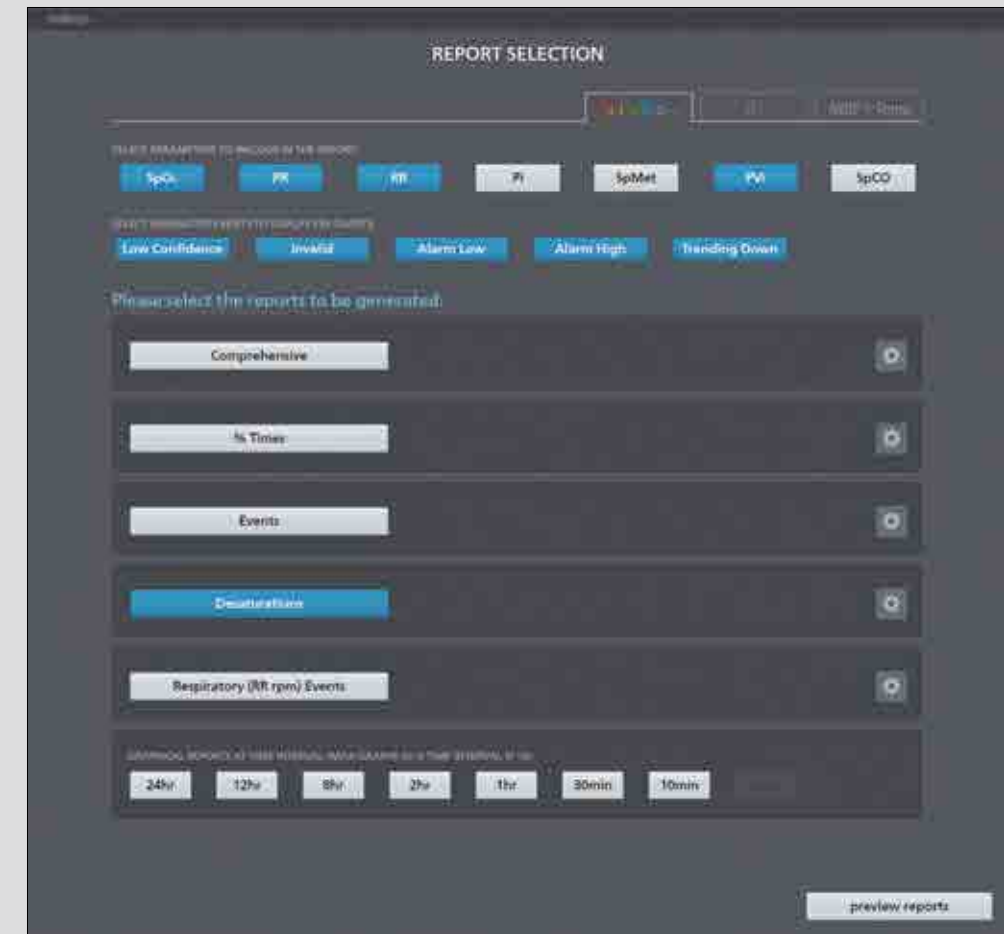
Leverage the free Masimo Personal Health App for expanded capabilities.



# Analyzing Patient Data with Trace™

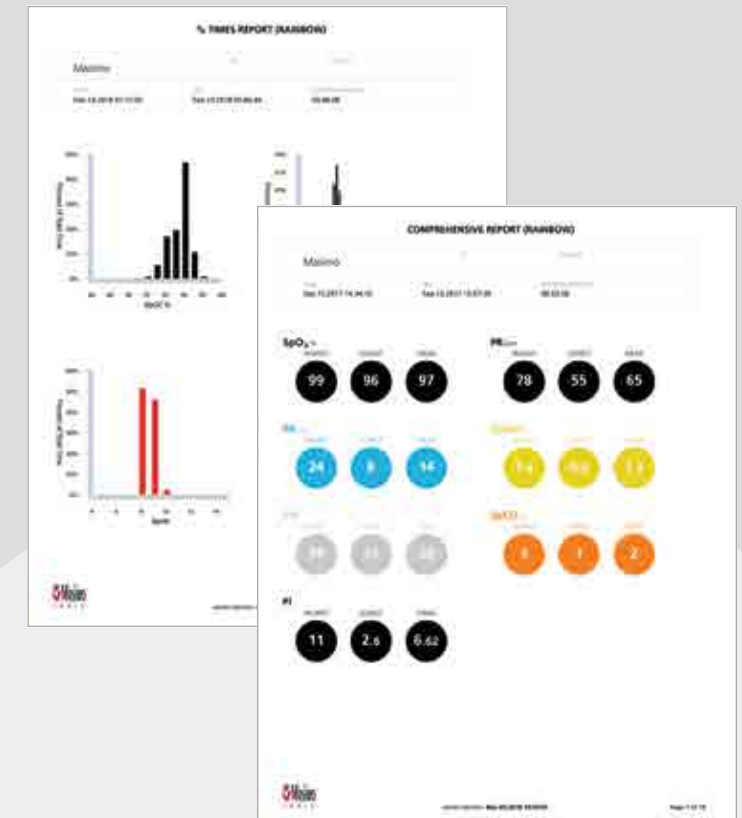
Trace is the first reporting software compatible with the full capabilities of the Masimo Root patient monitoring and connectivity platform, including Radical-7 and Radius-7 Pulse CO-Oximeters, Root with integrated noninvasive blood pressure and temperature, and connected MOC-9 modules such as SedLine brain function monitoring, NomoLine capnography and gas monitoring, and O3 regional oximetry.

With its unique versatility and customizability and with access to all of Masimo's advanced measurement technologies, Trace offers clinicians the ability to retrospectively review and focus on the patient data patterns that matter most for each case, in a user-friendly format.



## Powerful Retrospective Analysis

- Create easy-to-read patient reports that include parameter trends, histograms, event annotations, and key statistics
- Conveniently review reports for advanced Masimo measurements
- Connect remotely to networked Masimo devices
- Rapidly transfer up to 96 hours of device parameter data
- Review and generate additional reports for past patient data



# Integrating Technology into Leading Multi-parameter Monitors

## Industry-leading Pulse Oximetry

Clinicians all around the world count on Masimo SET® pulse oximetry to help them care for patients.



**MX-7™**  
Low power rainbow®  
OEM board



**MSX™**  
Very low power SET®  
OEM board

## The Pulse Oximetry Technology of Choice

Over 100 multi-parameter monitors from 50 leading brands have integrated Masimo SET® pulse oximetry. In addition, more and more of our partners are enhancing their monitoring solutions by integrating rainbow SET Pulse CO-Oximetry.



**Dräger®**  
**Infinity M540**  
with rainbow SET technology



**GE®**  
**CARESCAPE VC150**  
with rainbow SET technology



**Philips®**  
**MX800**  
with rainbow SET technology



**Physio-Control®**  
**LIFEPAK 15**  
with rainbow SET technology



**Welch Allyn®**  
**Connex 6300 Series**  
with rainbow SET technology

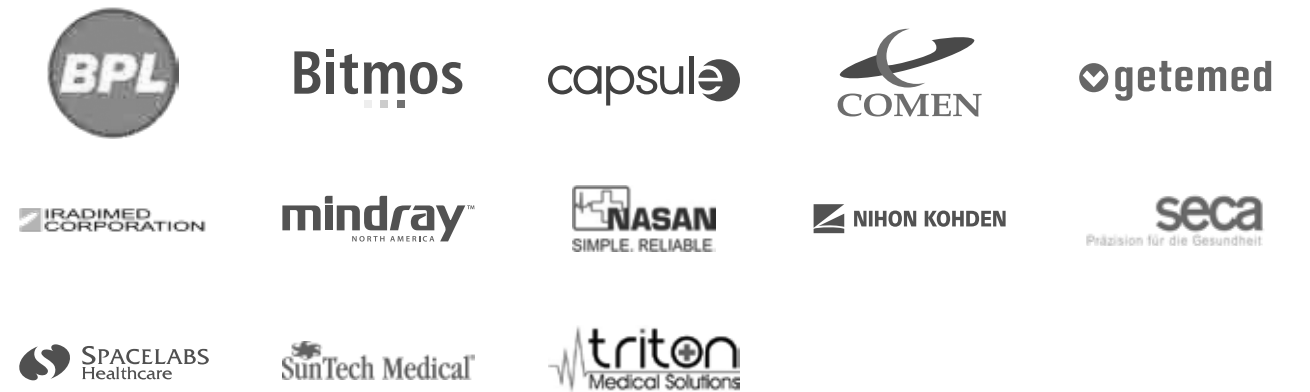


**ZOLL®**  
**X Series**  
with rainbow SET technology

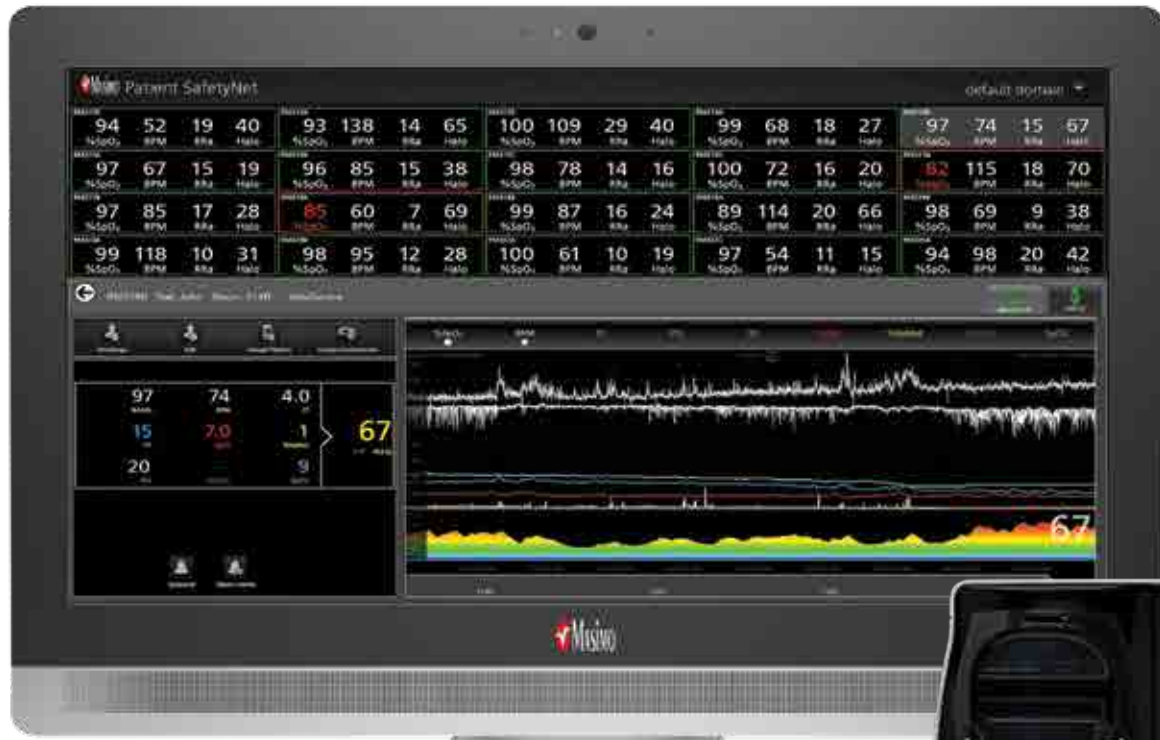


# Select OEM Partners

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



SURVEILLANCE MONITORING



**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

**Replica™**  
Supplemental remote monitoring clinician notification



**Root® with Radius-7®**  
rainbow SET™ with rainbow Acoustic Monitoring\*, MOC-9, Iris

TECHNOLOGIES AND PARAMETERS



**Masimo SET® Pulse Oximetry**

Measure-through Motion and Low Perfusion™ pulse oximetry

- Functional Oxygen Saturation (SpO2)
- Pulse Rate (PR)
- Perfusion Index (Pi)
- Pleth Variability Index (PVI\*)
- Respiration Rate from the Pleth (RRp\*)

**rainbow®**

**rainbow® Pulse CO-Oximetry and Acoustic Monitoring**

Noninvasive blood constituent and fluid responsiveness monitoring

- Total Hemoglobin (SpHb\*)
- Oxygen Content (SpOC™)
- rainbow Pleth Variability Index (RPVi™)
- Oxygen Reserve Index (ORI™)
- Carboxyhemoglobin (SpCO\*)
- Methemoglobin (SpMet\*)
- Fractional Arterial Oxygen Saturation (SpFO2™)
- Acoustic Respiration Rate (RRa\*)

- Plus all Masimo SET® measurements

**O3® Regional Oximetry**

- Tissue Oxygen Saturation (rSO2)

**Brain Function Monitoring**

- Noninvasive depth of sedation monitoring
- Patient State Index (PSi)

**Capnography and Gas Monitoring**

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

CONTINUOUS MONITORS



**Root®**  
rainbow SET with rainbow Acoustic Monitoring, MOC-9, Iris



**Root® with NIBPT**  
rainbow SET with rainbow Acoustic and blood pressure monitoring, temperature, MOC-9™, Iris™



**Radical-7®**  
rainbow SET Pulse CO-Oximeter\* with rainbow Acoustic Monitoring



**Rad-97™**  
rainbow SET Pulse CO-Oximeter with rainbow Acoustic and blood pressure monitoring



**Rad-67™**  
rainbow SET Pulse CO-Oximeter with SpHb spot-check



**Rad-57®**  
rainbow SET Pulse CO-Oximeter



**Rad-5®**  
Masimo SET® Pulse Oximeter



**Pronto®**  
rainbow SET Pulse CO-Oximeter with SpHb spot-check

SPOT-CHECK MONITORS

CIRCUIT BOARDS

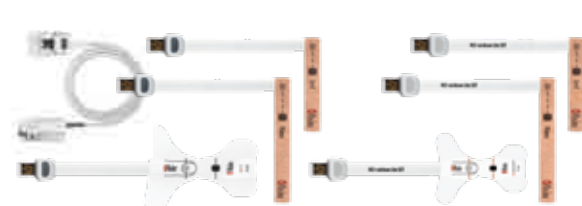


**MX-7™**  
Low power rainbow® OEM board



**MSX™**  
Very low power SET® OEM board

SENSORS



**RD SET™**  
SpO2, PR, Pi, PVi, RRp

**RD rainbow Lite SET™**  
SpO2, PR, Pi, PVi, RRp, RPVi, ORI



**Specialty Sensors**  
(Ear, Forehead, Blue®, Newborn)  
SpO2, PR, Pi, PVi, RRp

**RD rainbow SET™**  
SpO2, PR, Pi, PVi, RRp, SpHb, SpOC, RPVi, ORI, SpCO, SpMet, SpFO2



**rainbow® Sensors**  
SpO2, PR, Pi, PVi, SpHb, SpOC, RPVi, ORI, SpCO, SpMet



**rainbow® Acoustic Sensor**  
RRa



**RD SedLine® Sensor**  
PSi



**O3® Sensor**  
rSO2, SpO2\*



**NomoLine™**  
Sampling line

SAMPLING LINE

EXTERNAL MEASUREMENT TECHNOLOGIES



**EMMA™**  
Portable mainstream capnograph



**EMMA™**  
Portable mainstream capnometer



**ISA™**  
Sidestream Capnography and Gas Monitoring



**IRMA™**  
Mainstream Capnography and Gas Monitoring



**SedLine®**  
Brain Function Monitoring



**O3®**  
Regional Oximetry



**iSpO2™ & iSpO2™ Rx**  
SpO2, PR, Pi

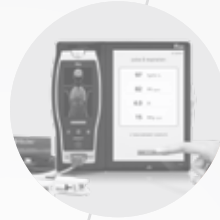


**MightySat™ & MightySat™ Rx**  
SpO2, PR, Pi, PVi, RRp



**MightySat™ & MightySat™ Rx**  
SpO2, PR, Pi, PVi, RRp

Improving Patient  
Outcomes and Reducing  
Cost of Care®



Solutions:  
Automating Patient  
Management Across  
the Continuum of Care



# Physician Office

## Improving Office Visits through Accurate and Advanced Measurements with Connectivity



In busy physician office environments, inaccurate data and inefficient monitors can make it difficult to deliver quality, efficient care. Masimo's physician office solutions help automate patient management by providing quick and accurate data with seamless documentation.

## Simplifying Workflows with Automatic Charting

Iris Gateway facilitates the seamless documentation of patient data from Masimo devices to the electronic medical record system.



Iris Connectivity  
p.148



Rad-97  
p.160

## Compact and Mobile Vital Signs with Rad-97

Rad-97 features Masimo rainbow SET Pulse CO-Oximetry with optional noninvasive hemoglobin (SpHb), integrated capnography or noninvasive blood pressure (NIBP), and wireless, non-contact temperature with Masimo Caregiver.



Rad-67  
p.162

## Quick Assessment with Rad-67

Rad-67 features rainbow SET Pulse CO-Oximetry and facilitates handheld spot-checking along with optional noninvasive hemoglobin (SpHb).



MightySat Rx  
p.168

## Spot-check on the Go with MightySat Rx

MightySat Rx fingertip pulse oximeter puts the power of Masimo SET® pulse oximetry in any clinician's pocket.

# Pharmacy Clinics

## Empowering Patients with an Alternative to Traditional Office Visits



Patients are increasingly seeking care in non-traditional settings such as in-pharmacy clinics. However, current approaches typically require that a clinician be on-site to take measurements, do not offer physician consultation, and do not enable real-time prescription transmission and pick up.

### Root with DIAB

Root with Radical-7 enables rainbow SET Pulse CO-Oximetry measurements, along with integrated noninvasive blood pressure (NIBP) and temperature measurements. Combined with these built-in measurements, Doc in a Box (DIAB), a Masimo software solution for Root, can enable automated in-pharmacy assessment, interaction, and prescription dispensing. When Root with DIAB is deployed in a pharmacy, patients use Root to take their own vital signs measurements and use DIAB to communicate

directly by video with a remote physician or nurse. The pharmacy receives immediate prescription orders from the remote clinician, allowing patients to receive their medications on the spot.

Root with DIAB is designed to reduce the need for an on-site clinician or medical assistant to take measurements, shorten the time for the patient to receive medical advice, and enable more efficient consultation and prescription fulfillment.



• Guided data collection



- Initial welcome and patient account set up or log in
- Vital signs results displayed
- Communication with remote clinician in real time
- Physician sends prescription order in real time for immediate patient pickup on-site

# Emergency Medical Services



## Rapid Monitoring Devices for First Responders



For first responders, assessments and interventions are often made in challenging conditions. Masimo's versatile, portable, and rugged devices enable quick spot-checking on the scene and during transport to aid assessment and help hospitals prepare for appropriate and timely care transitions.

## Rapid On-Scene Spot-checking with Advanced Handheld Devices



Rad-67  
p.162



EMMA  
p.166

### Rad-67 Pulse CO-Oximeter

Featuring color touchscreen operation and rainbow SET Pulse CO-Oximetry measurements, Rad-67 optional noninvasive measurements include carboxyhemoglobin (SpCO), hemoglobin (SpHb), methemoglobin (SpMet), and respiration rate from the pleth (RRp).

### EMMA Capnograph

Clear, real-time end-tidal CO<sub>2</sub> waveforms help give clinicians the ability to confirm effective resuscitation, assess the depth and effectiveness of compressions, and recognize the return of spontaneous circulation (ROSC).<sup>1,2</sup>

## Integrated Solutions

Masimo rainbow SET Pulse CO-Oximetry is integrated in defibrillator monitors from multiple companies, enabling advanced measurements inside life-saving devices.



Physio-Control®  
LIFEPAK 15



ZOLL® X Series

Integrated solutions  
p.174

## Versatile Sensor Solutions

Access a variety of sensor solutions designed to facilitate rapid monitoring, to stay securely in place during challenging conditions, and for monitoring sites less susceptible to changes in peripheral perfusion.

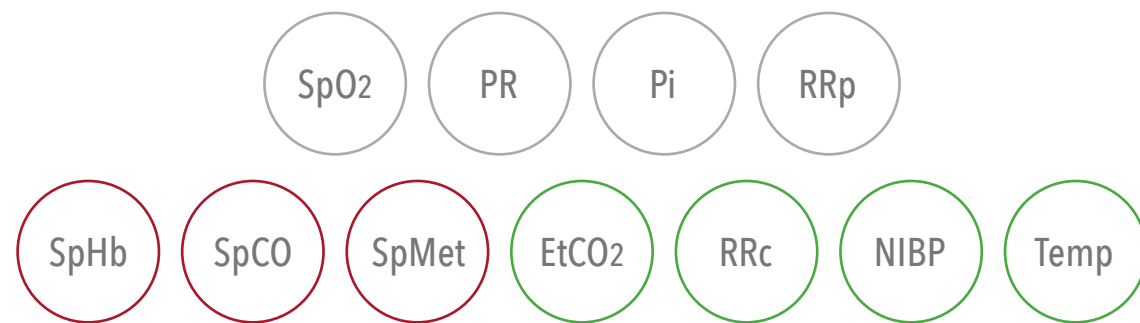


E1 sensor  
p.104

The E1 ear sensor provides an alternative monitoring site during emergency situations and can identify desaturation and resaturation faster than digit sensors.

# Emergency Department

## Responding Rapidly in a Constrained Environment



The emergency department (ED) is burdened by high patient volume, varying patient acuity, and a large number of standalone monitoring devices that often lack connectivity. Scarcity of time and space necessitate rapid patient assessment and triage to limit unanticipated patient deterioration and patient dissatisfaction.

From handheld monitors and vital signs monitors with automated data transfer to the electronic medical record (EMR), to wearable, tetherless, and portable devices designed for short-term monitoring, Masimo offers a number of solutions to enhance assessment and streamline clinician workflow in the ED.

## Efficient Vital Signs Monitoring with Root

Root offers quick and efficient spot-checking of SpO<sub>2</sub>, pulse rate, respiration rate, blood pressure, and temperature with a single, portable monitor. Root also enables optional, advanced spot-checking of noninvasive hemoglobin (SpHb) and carbon monoxide in the blood (SpCO). Root allows all measurements and customized clinical assessments, including pain and responsiveness scores such as "alert, voice, pain, unresponsive," or APVU, scores to be automatically transferred to the EMR.



Root with Noninvasive Blood Pressure and Temperature p. 140



Radius-7 p.120

## Continuous, Tetherless Monitoring with Radius-7

Radius-7 enables continuous, tetherless monitoring of patients in the waiting room with supplemental remote monitoring on Root, which may help clinicians adjust care prioritization based on changes in patient status.



Patient SafetyNet p.134

## Surveillance Monitoring with Masimo Patient SafetyNet

Patient SafetyNet is a remote monitoring and clinician notification system which displays information from any connected Masimo device at a central station and allows alarms and alerts to be sent directly to clinicians.



Iris Connectivity p.148

## Device Connectivity with Iris

When connected to Iris Gateway or Patient SafetyNet, Root automates the flow of patient data to the EMR, which may help streamline workflows (including the triage process), improve productivity, and reduce the likelihood of transcription errors.<sup>1</sup>



Rad-67 p.162

## Powerful, Handheld Monitoring with Rad-67

Rad-67 features color touchscreen operation and rainbow SET Pulse CO-Oximetry measurements to enable quick spot-checking of SpO<sub>2</sub> and pulse rate, as well as optional noninvasive hemoglobin (SpHb) and carboxyhemoglobin (SpCO).



Trauma Sensor p.104

## Fast Response Time with the Trauma Sensor

In trauma situations, SpO<sub>2</sub> can change rapidly and peripheral perfusion can be very low. The Trauma Sensor together with Masimo SET<sup>®</sup> technology automatically configures the fastest response time with maximum sensitivity in adult trauma patients.



EMMA p.166

## Flexible Capnography with EMMA

EMMA is a compact, lightweight, mainstream capnograph that requires minimal warm-up time and accuracy in 15 seconds. EMMA provides real-time EtCO<sub>2</sub> waveforms help clinicians to confirm effective resuscitation, assess the depth and effectiveness of compressions, and recognize the return of spontaneous circulation (ROSC).<sup>2,3</sup>



# Newborn Care

## Advanced Technology for When Every Second Counts

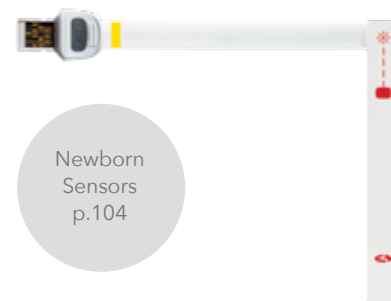


Accurate and timely monitoring is vital to assessing newborns. Masimo is committed to helping clinicians care for this at-risk patient population and has designed solutions specifically for newborns and their unique needs.

## Aiding Newborn Resuscitation

### Newborn Sensor

- The Newborn Sensor automatically configures Masimo SET® pulse oximeters for the fastest response time and maximum sensitivity settings, allowing clinicians to focus on patient care during newborn resuscitation. The Velaaid SofTouch design allows for quick application and repositioning on newborn skin and the hook and loop attachment strip helps keep the sensor secure, even when the site is wet.



### EMMA Capnograph

- Primary methods of confirming endotracheal tube placement include the detection of exhaled CO<sub>2</sub>. Neonatal Resuscitation Program (NRP) guidelines recommend that a CO<sub>2</sub> detector be connected to the endotracheal tube immediately after insertion to confirm the presence of CO<sub>2</sub> during exhalation.<sup>1</sup>

The portable EMMA mainstream capnograph is designed to fit easily onto a breathing circuit and provides a real-time end-tidal carbon dioxide (EtCO<sub>2</sub>) waveform displayed in as few as 15 seconds, in addition to displaying EtCO<sub>2</sub> and respiration rate (RR) measurements.



## Newborn Care

CCHD and Masimo SET®  
p. 34

### Simplifying CCHD Screening with Eve

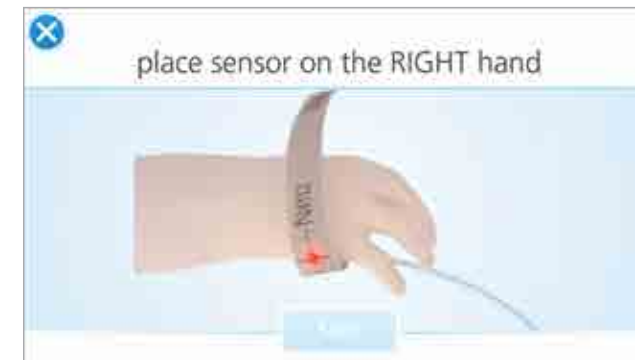
Masimo SET® Measure-through Motion and Low Perfusion pulse oximetry has helped clinicians increase CCHD detection through effective screening, saving the lives of babies throughout the world.

Eve is an intuitive critical congenital heart disease (CCHD) newborn screening application that transforms Radical-7 or Rad-97 into a simple yet powerful tool designed to help clinicians to quickly, reliably, and consistently screen newborn babies for CCHD. Eve combines the accuracy of Masimo SET® with a pre-ductal to post-ductal synchronization algorithm intended to help clinicians reduce calculation errors.

Eve simplifies the CCHD screening process by providing visual instructions, animations, an automatic synchronization algorithm, and a detailed, easy-to-interpret display of results. The ability to label results with unique patient identifiers for both mother and newborn facilitates intuitive session management and seamless electronic charting. Eve also allows clinicians to incorporate perfusion index into screening, which has been shown to increase sensitivity to the detection of CCHD in infants with pathologically low perfusion.<sup>1</sup>



Rad-97 and Radical-7 with Eve.\*



- Animations provide visual guidance to assist clinicians through the screening process



- Automated calculation, with an easy-to-interpret results screen, may reduce calculation errors



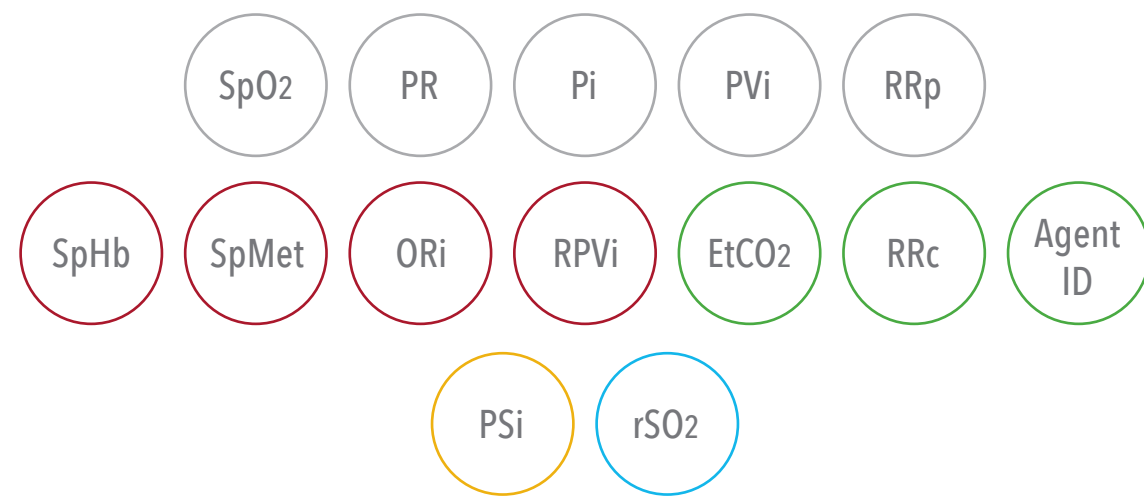
- Settings allow clinicians to incorporate perfusion index (Pi) measurement, which may increase sensitivity to detection of CCHD<sup>1</sup>



- EMR integration via Masimo Patient SafetyNet or Iris Gateway facilitates workflow and may help reduce reporting errors

# Operating Room and Post-Anesthesia Care Unit

## Optimizing Surgical Care with Advanced Measurements and Integrated Monitoring



In today's operating room (OR), clinicians are faced with increasingly complex patient conditions and the need to monitor changing patient status accurately and completely. Some continuous monitoring modalities have limited accuracy and some physiologic variables are only measured intermittently, if at all. With multiple standalone monitoring and therapeutic devices, clinicians must manually view each device separately to assimilate all of the data.

Masimo's solutions in the OR help automate care of the surgical patient by providing accurate measurements with standard-of-care monitoring modalities during challenging conditions; advanced noninvasive and continuous measurements that could previously only be measured intermittently and invasively; and connectivity, documentation, and display products that simplify workflows and data interpretation.

## Accurate Pulse Oximetry that Enables Noninvasive Fluid Responsiveness Monitoring

Masimo SET<sup>®</sup> pulse oximetry provides accurate measurements during challenging conditions along with pleth variability index (PVi) for noninvasive fluid responsiveness monitoring in mechanically ventilated patients.

PVi  
p. 40

## Advanced Hemoglobin and Oxygenation Monitoring with rainbow SET Pulse CO-Oximetry

Masimo rainbow SET Pulse CO-Oximetry includes all Masimo SET<sup>®</sup> measurements and also provides advanced noninvasive and continuous measurements such as hemoglobin (SpHb), which may help with patient blood management, oxygen reserve index (ORi), which can provide visibility to the patient's oxygen status in the moderate hyperoxic range and provide an advanced warning of impending desaturations, and rainbow PVi (RPVi), which can simplify noninvasive fluid responsiveness monitoring.

rainbow SET  
p. 48

## Measurement Integration in Multi-parameter Monitoring Systems or Root

Both Masimo SET<sup>®</sup> and rainbow SET are available in multiple leading multi-parameter monitors, as well as via Radical-7 and Radical-7 in Root.

Partnerships  
p. 176

Root  
p. 116



Masimo's OR technologies are available through Root or through OEM partners such as Philips IntelliVue MX800.

## Operating Room and Post-Anesthesia Care Unit

### 1 Accurate Brain Monitoring with SedLine and O3

SedLine and O3  
p. 86 and 94

Next Generation SedLine brain function monitoring uses advanced signal processing to overcome limitations of previous generation brain function monitoring and provide a more accurate and responsive indication of the brain's response to anesthesia and sedation. O3 regional oximetry provides accurate cerebral oxygenation, even when CO<sub>2</sub> levels are changing. Both SedLine and O3 sensors can be placed on the forehead at the same time, overcoming previous inability to monitor both modalities simultaneously. SedLine and O3 are available on Root and select multi-parameter monitoring systems.

### 2 Overcoming Previous Limitations with NomoLine Capnography and Gas Monitoring

NomoLine  
p. 80, 128, 130

NomoLine technology provides accurate capnography and gas with an innovative sampling line that eliminates the need for a water trap and enables cost-effective, hassle-free consumables. NomoLine technology is available on Root and select multi-parameter monitoring systems.

### 3 Expandable Root Monitoring and Connectivity Platform

Root  
p. 116

Masimo's standard-of-care and advanced measurements are all available on the Root patient monitoring and connectivity platform, offering a highly customizable and expandable solution that occupies a minimal footprint in the OR. Iris in combination with Root facilitates automated data transfer from Root and multiple third-party standalone monitors – such as IV pumps, ventilators, and anesthesia machines – to hospital electronic medical record (EMR) systems.



### 4 Integrate Data to Simplify Interpretation

UniView and AirGlass  
p. 156 and 158

UniView provides large displays with integrated patient data from all connected systems in the hospital, and AirGlass provides a wearable display solution leveraging augmented reality technology.

### 5 Advanced Surveillance in the Post-Anesthesia Care Unit

NomoLine  
p. 80, 128, 130

After surgery in the post-anesthesia care unit (PACU), it is important to recognize any signs of patient deterioration as soon as possible so clinicians can quickly intervene. Varying patient flow can create low clinician-to-patient ratios and make it more difficult to manually observe patient deterioration. Masimo's monitoring solutions help clinicians care for post-operative patients at risk of respiratory depression and other unforeseen complications.

NomoLine capnography provides a continuation of OR monitoring in the PACU. For patients who are not tolerant to a cannula or mask, rainbow Acoustic Monitoring offers noninvasive and continuous respiration rate (RRa) with similar accuracy to capnography but with the benefit of higher patient tolerance.

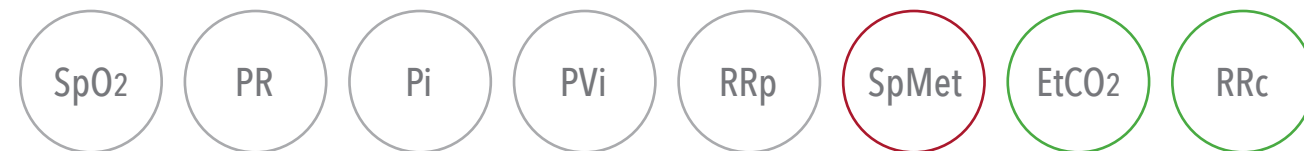
The Measure-through Motion and Low-Perfusion capabilities of Masimo SET<sup>®</sup> pulse oximetry can significantly reduce false alarms in the PACU and reduce the burden for clinicians otherwise responding to false alarms.



Masimo SET<sup>®</sup>  
p. 24

# Neonatal Intensive Care

## Focusing on the Most Vulnerable Patients



From the beginning, Masimo has remained dedicated to improving care in the neonatal intensive care unit (NICU) so even the most fragile patients have bright futures. While some companies may choose not to develop products specifically for neonates because the market is small compared to the adult market, Masimo takes the opposite approach. Masimo endeavors to develop new products for neonates first because their clinical need is greatest and because if a product can be made to work reliably on neonates, it is very likely to work well on pediatric and adult patients.

## Reducing False Alarms and Retinopathy of Prematurity with Masimo SET®

The Measure-through Motion and Low Perfusion performance of Masimo SET® pulse oximetry significantly reduces false alarms and the time spent by NICU clinicians responding to and investigating alarms. As a result, clinicians can spend more time on patient care. Perhaps more importantly, studies have shown that the accuracy of Masimo SET®, coupled with changes in practice, helps clinicians reduce the rate of severe retinopathy of prematurity (ROP) in premature infants by helping avoid too much oxygen administration.

ROP  
p. 32

## Sensors Designed for Neonatal Patients



Specialty sensors  
p. 104

Compared to Nellcor sensors in the NICU, Masimo SET® sensors can last up to 2.3 times longer (9.1 vs. 3.9 days).<sup>1</sup> In addition, Masimo's SofTouch line of sensors are designed to be used whenever skin sensitivity issues are a concern, such as with extremely low birth weight infants. Masimo SofTouch sensors incorporate soft foam and VelAid hook and loop attachment wraps that come in a variety of configurations to address a wide range of clinical situations.

The Blue Sensor with Masimo SET® pulse oximetry is specifically designed for use with cyanotic infant, neonatal, and pediatric patients with congenital heart disease, and is accurate on cyanotic patients with oxygen saturation as low as 60%.<sup>2</sup>

## Monitoring for Methemoglobinemia with SpMet

Many drugs commonly used in hospitals – such as lidocaine, benzocaine, dapsone, and nitrates – may cause a dangerous reaction known as acquired methemoglobinemia. Inhaled nitric oxide (iNO) therapy, and even topical anesthetics containing benzocaine or prilocaine, can cause elevated levels of methemoglobin in neonates and infants. Masimo rainbow SET Pulse CO-Oximetry offers a way to monitor noninvasive and continuous methemoglobin (SpMet). Real-time SpMet monitoring may help clinicians intervene quickly and appropriately in cases involving elevated methemoglobin levels.

SpMet  
p. 76

## Capnography Solutions with NomoLine

Masimo NomoLine capnography offers multiple sidestream capnography solutions to meet the challenges of ventilation monitoring in the NICU. NomoLine technology is designed for low-flow applications, with a very low sampling rate of 50 ml/min, supporting use on patients with low tidal volumes and high breath rates, common characteristics of neonatal patients.

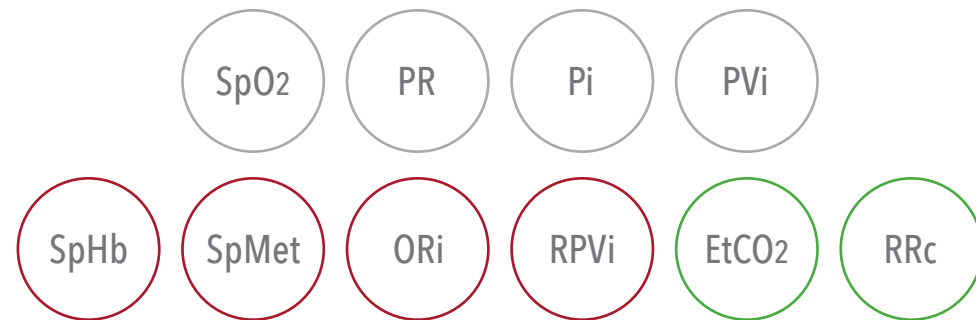


NomoLine  
p. 80, 128, 130



<sup>1</sup> Erler T et al. *J Perinatol*. 2003 Mar;23(2):133-5. <sup>2</sup> Masimo data on file and FDA 510(k) K051439. 2005. NomoLine has not obtained CE mark for neonates. RRp is not available in the U.S.

# Intensive Care



Patients in the intensive care unit (ICU) are at high risk of deterioration and with so many modalities to apply, so much data to manage, and so many alarms requiring a response, monitoring can be challenging. Adding to the challenge, rooms are often cluttered with disparate monitoring and therapeutic devices. Masimo's ICU solutions provide accurate standard-of-care measurements during challenging conditions, advanced noninvasive and continuous measurements that were previously only intermittent and/or invasive, and connectivity, documentation, and display products that simplify workflows and data interpretation.

## Accurate Pulse Oximetry that Translates to Better Clinical Care with Masimo SET®

The Measure-through Motion and Low Perfusion performance of Masimo SET® pulse oximetry significantly reduces false alarms and the time spent by ICU clinicians responding to and investigating alarms. As a result, clinicians can spend more time on patient care. Compared to non-Masimo SET® technology in the ICU, use of Masimo SET® in the ICU resulted in 34% fewer arterial blood gas tests performed (4.1 vs. 2.7 tests per patient).<sup>1</sup>

Masimo SET®  
p. 24

Accurate measurements may also help optimize therapeutic management in the ICU. Compared to non-Masimo SET® technology in the ICU, use of Masimo SET® resulted in 49% faster ventilator weaning time (348 vs. 176 minutes) with the same number of ventilator changes.<sup>1</sup> Use of Masimo SET® along with a ventilator weaning protocol has also been reported to result in reduced oxygen requirements, decreased ventilator time, and reduced ICU length of stay.<sup>2</sup>

## Noninvasive Fluid Responsiveness Monitoring with PVi

From the same sensor and monitor used for pulse oximetry monitoring, Masimo SET® also offers the unique ability of pleth variability index (PVi) to noninvasively monitor fluid responsiveness in mechanically ventilated patients.

PVi  
p. 40



## Intensive Care

### Advanced Hemoglobin and Oxygenation Monitoring with rainbow SET Pulse CO-Oximetry

Masimo rainbow SET Pulse CO-Oximetry includes all Masimo SET® measurements and also provides advanced noninvasive and continuous measurements such as:

- Noninvasive and Continuous hemoglobin (SpHb), which may help with patient blood management
- Oxygen Reserve index (ORi), which can provide an advanced warning of desaturations and may help provide insight into a patient's oxygen status in the moderate hyperoxic range
- rainbow PVi (RPVi), which provides noninvasive fluid responsiveness monitoring

SpHb,  
RPVi and ORi  
p. 54, 66  
and 72

### Monitoring Depth of Sedation with SedLine Brain Function Monitoring



SedLine  
p. 86

Next Generation SedLine brain function monitoring uses advanced signal processing to provide a more accurate and responsive indication of the brain's response to sedation. SedLine technology is available on the Root monitor.

### Overcoming Previous Limitations with NomoLine Capnography and Gas Monitoring



NomoLine  
p. 80, 128, 130

NomoLine technology provides accurate capnography and gas measurements while reducing common problems associated with conventional sidestream gas analysis. The innovative sampling line uses a patented polymer which collects and removes water in the sampling line, eliminating the need for a water trap and enabling cost-effective, hassle-free consumables. NomoLine technology is available on Root and select multi-parameter monitoring systems.

### Measurement Integration in Multi-parameter Monitoring Systems or Root

Both Masimo SET® and rainbow SET are available in many leading multi-parameter monitors, as well as via Radical-7 and Radical-7 in Root.

Masimo's ICU technologies are available through Root or through OEM partner products such as Philips IntelliVue MX800.



Root and  
Partnerships  
p. 116 and 176



### Expandable Root Monitoring and Connectivity Platform

Iris  
Connectivity  
p.148

Masimo's standard-of-care and advanced measurements are all available on the Root patient monitoring and connectivity platform, offering a highly customizable and expandable solution that occupies a minimal footprint in the OR. Iris in combination with Root facilitates automated data transfer from Root and multiple third-party standalone monitors – such as IV pumps, ventilators, and anesthesia machines – to hospital electronic medical record (EMR) systems.

### Integrate Data to Simplify Interpretation

UniView  
p.156

UniView provides large displays with integrated patient data from all connected systems in the hospital.

# General Ward

## Helping Improve Safety and Efficiency While Reducing Costs



Clinicians on the general ward are challenged by low nurse-to-patient ratios and increasing case complexity and variability between patients. Continuous monitoring provides constant surveillance for the greatest ability to identify early patient deterioration, but traditional approaches can result in numerous false alarms and can also tether patients to their beds. Intermittent spot-check monitoring is typically the minimum level of monitoring required, but can require manual documentation and clinical assessment to recognize changes in patient status. Masimo offers an integrated portfolio of solutions designed to keep patients on the general ward safe and mobile while helping clinicians improve workflows.

### Overcoming Alarm Fatigue with Masimo SET®

Continuous monitoring with conventional pulse oximetry can result in false alarms that burden clinicians and make continuous monitoring difficult. The Measure-through Motion and Low Perfusion performance of Masimo SET® pulse oximetry significantly reduces false alarms and the time spent by general ward clinicians responding to and investigating alarms. As a result, continuous monitoring on the general ward is feasible.

Over a ten-year period in the general wards at Dartmouth-Hitchcock Medical Center, the use of Masimo SET® pulse oximetry and Masimo Patient SafetyNet has resulted in a sustained alarm frequency of approximately two alarms per patient per 12-hour nursing shift – in spite of increasing patient acuity and unit occupancy.<sup>1</sup>

Masimo SET®  
p. 24

Patient  
SafetyNet  
p. 134

### Three Options for Ventilation Monitoring

The Root patient monitoring and connectivity platform offers three options for continuous respiration rate monitoring, each with advantages and disadvantages.

Respiration  
Rate Options  
p. 84



For patients on supplemental oxygen, Oxygen Reserve Index (ORi) using rainbow SET Pulse CO-Oximetry is designed to provide an early indication of impending desaturation for patients in the moderately hyperoxic range.





## General Ward

### Powerful and Flexible Monitoring and Connectivity with Root and Radius-7

Root is a powerful and flexible multi-modal monitoring and connectivity hub that brings together advanced rainbow SET Pulse CO-Oximetry, vital signs measurements, and capnography measurements on an easy-to-interpret and customizable display. Root includes a dock for the Radical-7 handheld monitor or Radius-7 tetherless monitor that enables accurate monitoring while the patient is mobile, along with continuous monitoring for identification of clinical deterioration. Root also serves as a central connectivity hub, with automated electronic charting of Masimo and third-party device data and alarms to electronic medical record (EMR) systems, which may improve clinician workflows through the reduction of manual data documentation.

Radius-7  
p. 120

EMR  
p. 144

### Remote Monitoring and Notification with Patient SafetyNet and Replica

Masimo Patient SafetyNet optimizes patient safety and clinician workflows through centralized, supplemental remote monitoring and automated charting. Near real-time information from any connected Masimo device, as well as supported third-party devices such as ventilators, is displayed at a central station, allowing clinicians in the ward or at an enterprise level to quickly monitor the status of up to 200 devices per server, review trend data, and investigate alarms. Patient SafetyNet with Replica also allows clinicians to monitor patient measurements and high fidelity waveforms remotely and in real time, modify device settings, and receive and make video calls – all from a single app.

Replica  
p. 152

Patient  
SafetyNet  
p. 134



### Improving Clinical and Cost Outcomes with Patient SafetyNet

Researchers at Dartmouth-Hitchcock Medical Center reported that Masimo SET® pulse oximetry and Patient SafetyNet enabled the facility, over a five-year period, to achieve their goal of zero preventable deaths or brain damage due to opioids, and over a ten-year period, maintain a 50% reduction in unplanned transfers and 60% reduction in rescue events, despite increases in patient acuity and occupancy.<sup>1,2</sup>



Patient  
SafetyNet  
p. 134

### Efficient Vital-Signs Monitoring with Root and Rad-97

Used in conjunction with Patient SafetyNet or Iris Gateway, Root can be placed on a roll stand as a portable spot-check vital signs monitor. Powerful Early Warning Score (EWS) calculations aggregate information from multiple vital signs and clinical observations to generate a score that represents the potential degree of patient deterioration, arming clinicians with more information to help make appropriate care decisions.

Root VS  
and Rad-97  
p. 140 and  
160

EWS  
p. 142

Automating  
Workflows  
p. 146

Patient SafetyNet provides automated documentation to the EMR of patient data at hospital-specified intervals, and also enables clinician bedside verification to reduce the time required for documentation at the EMR workstation.

If Root and Rad-97 are not connected to the network, they can also store data collected from multiple patients and then automatically transfer the collected data via Bluetooth to a network relay station that enables documentation to the EMR, minimizing manual documentation and lessening wireless infrastructure demand in care areas where wireless networks may not be feasible.

<sup>1</sup>Taenzer AH et al. *Anesthesiology*. 2010 Feb;112(2):282-287. <sup>2</sup>Taenzer AH et al. *Anesthesia Patient Safety Foundation Newsletter*. Spring-Summer 2012.

# Post-Acute Care

## Improving Patient Safety for Ventilator-Dependent Patients



When caring for ventilator-dependent patients outside the hospital environment in long-term care or sub-acute care settings, accurate oxygenation and ventilation monitoring are vital to providing high-quality care and improving patient safety. Many long-term acute care facilities are faced with low clinician-to-patient ratios and alarm fatigue, while needing to administer many different active therapies, wean patients off ventilation, and chart patient data. In sub-acute care facilities, ventilator-dependent patients still require continuous monitoring to recognize changes in status.

Masimo's noninvasive monitoring solutions can help clinicians in post-acute care environments improve patient safety and enhance workflows.

### Overcoming Alarm Fatigue with Masimo SET®

Continuous monitoring with conventional pulse oximetry can result in false alarms that burden clinicians and make continuous monitoring difficult in the post-acute care environment. The Measure-through Motion and Low Perfusion performance of Masimo SET® pulse oximetry significantly reduces false alarms and the time spent by clinicians responding to and investigating alarms.

Masimo SET®  
p. 24

### Continuous Oxygenation and Ventilation Monitoring

Root or Rad-97 with NomoLine Capnography features Masimo SET® pulse oximetry and an integrated sidestream gas analyzer for capnography – meeting continuous oxygenation and ventilation monitoring needs in a single device.

NomoLine  
p. 80, 128, 130



Root and  
Rad-97  
p. 116 and  
160



### Efficient Spot-Check Monitoring with Root or Rad-97

Root or Rad-97 can be placed on a roll stand to enable use as a portable spot-check vital signs monitor. Powerful Early Warning Score (EWS) calculations on Root aggregate information from multiple vital signs and clinical observations to generate a score that represents the potential degree of patient deterioration and can provide greater insight into patient status, arming clinicians with more information to help make appropriate care decisions.

### Pocket Spot-checks with MightySat Rx and EMMA

For spot-check measurements on the go, the MightySat Rx fingertip pulse oximeter helps physicians quickly and efficiently measure oxygen saturation, pulse rate, perfusion index, and respiration rate. In addition, the small, portable EMMA capnograph is designed to fit easily onto a breathing circuit and provides a real-time end-tidal carbon dioxide (EtCO<sub>2</sub>) waveform displayed in as few as 15 seconds, in addition to EtCO<sub>2</sub> and respiration rate (RRc) measurements. These pocket-sized solutions can be easily kept with the clinician during rounds or integrated into crash carts.

EMMA and  
MightySat Rx  
p. 166 and 168



### Supplemental Remote Monitoring

Masimo Patient SafetyNet optimizes patient safety and clinician workflows through centralized, supplemental remote monitoring and automated charting of up to 200 devices on a single server, along with Iris for integrated documentation of data from ventilator and IV pumps.

Patient  
SafetyNet  
p. 134



# Home Care

## Hospital-Grade and Easy-to-Use Monitoring at Home



Monitoring in the home environment can be even more challenging than the hospital. Technologies that provide accurate measurements while being easy to apply and operate are critical to home monitoring success. Masimo offers multiple solutions for home monitoring, customizable for each clinician's and patient's needs.

### Transition to Home for Medically-Fragile Patients

The American Thoracic Society recommends continuous monitoring using pulse oximetry for children requiring mechanical ventilation, especially when the child is asleep or unobserved.<sup>1</sup> Compared to other alternative technologies during challenging conditions, Masimo SET<sup>®</sup> pulse oximetry significantly reduces false alarms and increases true alarm detection, easing the burden on caregivers.

Rad-97 is a compact pulse oximeter with intuitive multi-touch display that is easy to use for clinicians and non-clinicians alike. *Home* mode on Rad-97 provides home users access only to relevant settings and messages, while hiding others and locking alarm settings, reducing the chances of inadvertent interference.

### Telehome Care with Rad-97



For monitoring in patients with chronic diseases such as chronic obstructive pulmonary disease or heart failure, or to monitor a newly discharged medical or surgical patient in the home, the Rad-97 Pulse CO-Oximeter offers a unique combination of powerful measurements, an easy-to-use interface, and advanced remote monitoring and communication capabilities. Rad-97, in addition to SET<sup>®</sup> pulse oximetry and advanced parameter monitoring technology through rainbow<sup>®</sup> noninvasive monitoring, is available with optional integrated blood pressure or capnography measurements. With its intuitive touchscreen interface, Rad-97 is easy to use for clinicians and non-clinicians alike, and can be easily customized to meet the needs of home users. The device can also be configured in *Home* mode to streamline use and minimize complexity, and its innovative communication capabilities allow monitoring data from a variety of third-party Bluetooth-enabled devices used at home, including thermometers, weight scales, and glucometers, to seamlessly transfer to Rad-97 – and from there to anywhere in the world, in real time. The optional integrated camera allows remote clinicians to interact with patients over live audio and video. Rad-97 brings hospital-grade technology to the home in a single, compact, integrated device that is a monitoring, connectivity, and telecommunications hub.

### Patient Surveillance using Patient SafetyNet



With its built-in enterprise WiFi capability, Rad-97 has the ability to connect wirelessly from the home to supplemental patient monitoring systems in the hospital, including Masimo Patient SafetyNet, allowing clinicians to remotely observe patient status while facilitating automatic data transfer to hospital electronic medical record (EMR) systems.

### MightySat Rx for Hospital-grade Spot-checks in the Home



For patients that do not require advanced measurements or continuous monitoring, the pocket-sized MightySat Rx can be used for quick spot-check measurements of oxygen saturation (SpO<sub>2</sub>) and pulse rate (PR), and its built-in Bluetooth capability enables communication with a variety of third-party home monitoring solutions.



<sup>1</sup>An Official American Thoracic Society Clinical Practice Guideline: Pediatric Chronic Home Invasive Ventilation. *Am J Respir Crit Care Med.* Vol 193, Iss 8, pp e16-e35, Apr 15, 2016. RRp is not available in the U.S.

# Global Health

## Advancing Assessment in Low-Resource Settings



Masimo is committed to deploying its lifesaving technologies in low resource settings in developing countries.

### Pneumonia Deaths are Preventable

Pneumonia remains the single largest treatable infectious cause of death in children worldwide, causing over 900,000 deaths each year among children under 5 years of age.<sup>1</sup> In settings where supplemental oxygen is available, the addition of pulse oximetry to standard integrated management of child illness protocols could reduce pneumonia mortality rates.<sup>2</sup> Recently, the World Health Organization (WHO) has been conducting a multi-country evaluation of enhanced community case management of pneumonia with the use of Masimo SET® pulse oximetry by community health workers.<sup>3</sup>

### Enhanced Monitoring is Promising

Enhancing spot-check monitoring in challenging conditions and environments is critically important to reducing the global burden of pneumonia. Moreover, enhanced monitoring may empower healthcare providers by supporting informed decisions related to pneumonia assessment.

### Rad-G for Monitoring in Low-Resource Settings

Rad-G is a combined pulse oximeter designed primarily for spot-checking in low-resource settings. The validation of the device is supported in part by a grant from the Bill and Melinda Gates Foundation (BMGF), announced in November 2016, as part of a partnership with Masimo to facilitate spot-checking by health workers in low-resource areas.

Low-cost yet rugged, with a rechargeable battery and LCD display, Rad-G uses Masimo Measure-through Motion and Low Perfusion SET® pulse oximetry technology to measure SpO<sub>2</sub>, along with respiration rate from the pleth (RRp), pulse rate (PR), and perfusion index (Pi).



*"The introduction of the Rad-G is a critical milestone in our partnership with the Bill and Melinda Gates Foundation to help improve pneumonia screening. We are grateful to have the opportunity to bring our proven SET® pulse oximetry technology to areas of the world that are in desperate need of better healthcare, and look forward to making a positive difference in the lives of many children."*

Joe Kiani  
Chairman and CEO, Masimo

# Company Info and Philanthropy



# Senior Management Team

**From left to right:** Matthew Anacone, Senior Vice President, North America Sales; Yongsam Lee, Executive Vice President, Chief Information Officer; Tao Levy, Executive Vice President, Business Development; Tom McClenahan, Executive Vice President, General Counsel; Jon Coleman, President, Worldwide Sales, Professional Services & Medical Affairs; Joe Kiani, Chief Executive Officer; Anand Sampath, Chief Operating Officer; Bilal Muhsin, Executive Vice President, Engineering, Marketing, and Regulatory Affairs; Micah Young, Executive Vice President, Chief Financial Officer; Stacey Orsat, President EMEA; Tetsuro Maniwa, President Japan

**Board of Directors (not pictured):** Joe Kiani, Chairman of the Board of Directors; Steven J. Barker, MD, PhD; Sanford Fitch; Senator Tom Harkin; Adam Mikkelson; Craig Reynolds



# Awards

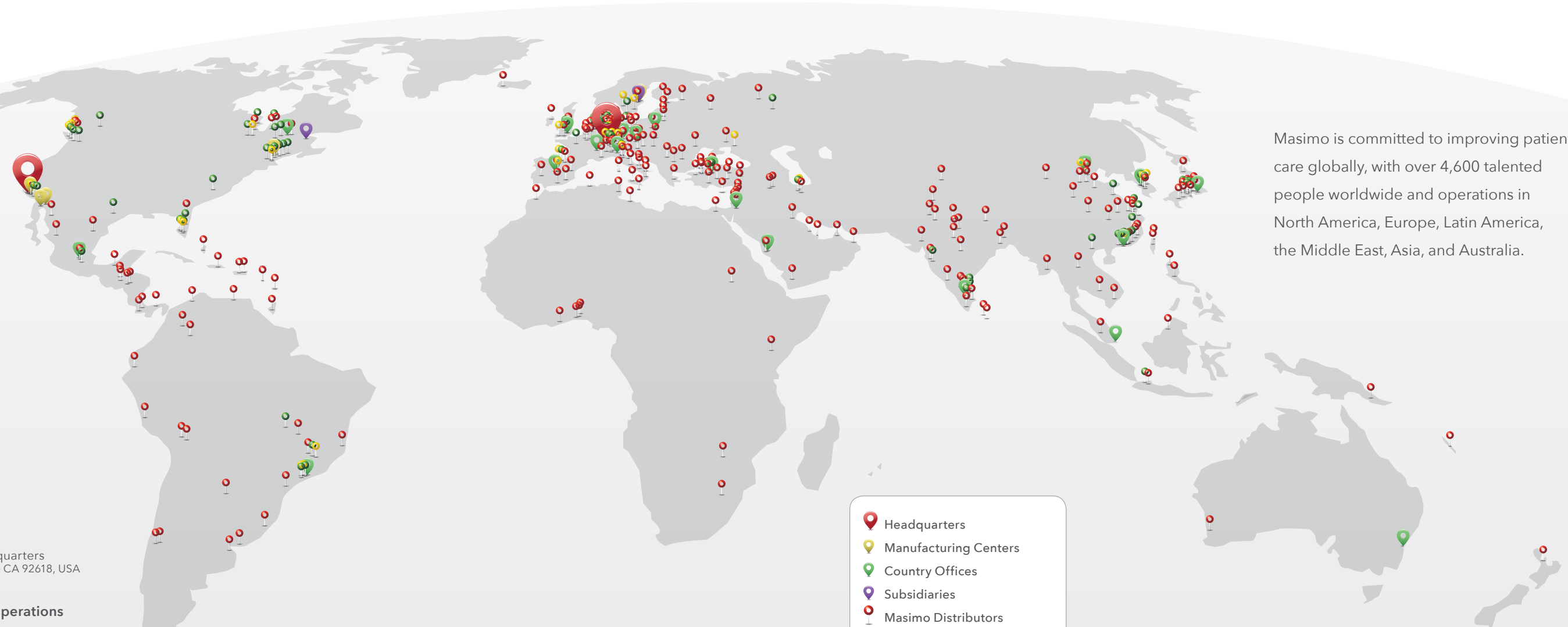
-  2017 Anti-Defamation League Humanitarian Award
-  2017 European Patient Blood Management Network Platinum Award
-  2017 Becker's Hospital Review Top 50 Leaders in Patient Safety
-  2016 Becker's Hospital Review Top 50 Leaders in Patient Safety
-  2015 Life Sciences IP Champion Award
-  2015 SafeCare Person of the Year
-  2015 Becker's Hospital Review Top 50 Leaders in Patient Safety
-  2015 GOLD Medical Design Excellence Award for Root
-  2014 Zenith Award
-  2014 Hubert H. Humphrey "Dawn of Life" Award
-  2014 Becker's Hospital Review Top 50 Leaders in Patient Safety

-  2013 Zenith Award at the American Association of Respiratory Care Congress
-  2013 Best Clinical Application of Technology Award for SpHb
-  2013 EMS World Top Innovation Award for EMMA
-  2013 Hot Product Award for EMMA and iSpO2
-  2012 Gold "Stevie" Award for Best New Health Product for the Pronto-7®
-  2012 National Entrepreneur of the Year Life Sciences Award Winner
-  2011 Zenith Award at the American Association of Respiratory Care Congress
-  2011 High-Tech Innovation for the Pronto-7
-  2011 Medical Design Excellence Gold for the Pronto-7
-  2011 Product Design Award for the Pronto-7
-  2010 Respiratory Product Best-in-Class Award

-  2009 Masimo SET® and Patient SafetyNet help Dartmouth-Hitchcock Medical Center win the 4th Annual Health Devices Achievement Award
-  2009 Patient Monitoring CEO of the Year
-  2009 Zenith Award
-  2009 Best in Class
-  2008 Zenith Award
-  2008 Best in Class
-  2008 Outstanding Medical Device Company
-  2008 Outstanding Growth
-  2008 Excellence in Medical Technology
-  2007 Patient Monitoring Technology Leadership of the Year
-  2007 Groundbreaking Innovation of rainbow® SET
-  2007 Excellence in Technology Innovation for Noninvasive Total Hemoglobin Monitoring
-  2006 Medical Design Excellence

-  2006 Application of Technology for Noninvasive Methemoglobin and Carboxyhemoglobin Monitoring
-  2005 Innovative Product and Technology
-  2003 Platform ABBY for Innovations in Healthcare
-  2003 Technology of the Year in Patient Monitoring
-  2003 New Standard of Care
-  2001 Medical Design Excellence
-  2001 Distinguished Leadership
-  2001 Innovative Product and Technology
-  2000 Technology Excellence
-  2000 Outstanding Medical Device Company
-  1995 Excellence in Technology Innovation for Measure-through Motion and Low Perfusion™ Pulse Oximetry

# Global Reach



Masimo is committed to improving patient care globally, with over 4,600 talented people worldwide and operations in North America, Europe, Latin America, the Middle East, Asia, and Australia.

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## Third Parties

Masimo Distributors  
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# Patient Safety Movement Foundation

## A Revolutionary Approach to Global Patient Safety

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

## ZERO Preventable Deaths by 2020

In February 2018, the Patient Safety Movement Foundation (which the The Masimo Foundation for Ethics, Innovation, and Competition in Healthcare founded in 2012 and continues to sponsor) hosted the 6<sup>th</sup> annual World Patient Safety, Science & Technology Summit in London. President Bill Clinton, Secretary of State for Health and Social Care Rt Hon Jeremy Hunt, MP and the World Health Organization's Director-General Dr. Tedros Adhanom Ghebreyesus keynoted the event. Diverse stakeholders from all parts of the global healthcare ecosystem came together to advance a vital mission: eliminating preventable patient deaths.

The Patient Safety Movement believes that “ZERO preventable deaths by 2020” is not only a worthy goal, but an attainable goal. By fostering and facilitating mass collaboration; by breaking down information silos that exist between hospitals, medical technology companies, the government, and other stakeholders; by promoting the data sharing that can identify at-risk patients before they're in danger; and by providing specific, Actionable Patient Safety Solutions (APSS) that healthcare professionals can implement today, we believe can eliminate preventable patient deaths. It is simply a matter of connecting all the dots.

For more information, visit:  
[www.PatientSafetyMovement.org](http://www.PatientSafetyMovement.org)



Keynote speakers at the 2018 World Patient Safety, Science, & Technology Summit in London.

## Helping Our Neighbors All Over the World

In addition to continuing support for the Patient Safety Movement Foundation, some additional efforts to help improve lives around the world include:

- Co-founding the *United for Oxygen Alliance*, a public-private partnership that seeks to expand access to medical oxygen and pulse oximetry for women and children in Ethiopia and beyond.
- In partnership with the Newborn Foundation, developing the BORN (Born Oximetry Routine for Newborns) Project, with the goal of reducing newborn mortality from CCHD, pneumonia, and sepsis.
- Co-founding the “Every Breath Counts” Coalition, dedicated to eliminating all pneumonia-related deaths. Masimo recently co-produced a documentary, *United for Oxygen*, examining the problem in more detail.
- Donating medical equipment to hospitals in Jordan to help improve patient care for the more than one million refugees from Syria and Iraq now living in Jordan, as well as supporting the work of Doctors Without Borders in the area.
- Partnering with Smile Train to help ensure the safety of patients undergoing cleft lip and/or palate surgery in low-resource settings around the world.
- Equipping hospitals in Macedonia with much-needed medical equipment.
- Funding school construction in Uganda.
- Funding UNICEF to provide assistance to refugees.
- Developing a program to increase hiring of refugees, the disabled, and veterans.
- Joining the *Tent Partnership for Refugees* Coalition, committed to supporting refugees around the world, and making a commitment to implement child and family health screening initiatives for and with refugees in countries that have accepted large refugee populations.
- Entering into a 4-year global impact partnership with the WFSA (World Federation of Societies of Anesthesiologists), “Safe Anesthesia - ASAP,” to improve anesthesia care in low-resource countries.

# Financial Performance

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

| ASSETS  | December 30, 2017 | December 31, 2016 |
|---|-------------------|-------------------|
| Current assets  |                   |                   |
| Cash and cash equivalents   | \$315,302         | \$305,970         |
| Trade accounts receivable, net of allowance for doubtful accounts | 121,309           | 101,667           |
| Inventories   | 95,944            | 72,542            |
| Prepaid income taxes  | 3,494             | 981               |
| Other current assets  | 28,070            | 26,067            |
| Total current assets  | 564,119           | 507,227           |
| Deferred cost of goods sold                                       | 99,600            | 79,948            |
| Property and equipment, net                                       | 164,096           | 135,996           |
| Intangible assets, net  | 27,123            | 29,376            |
| Goodwill  | 20,617            | 19,780            |
| Deferred income taxes   | 23,898            | 38,975            |
| Other assets  | 10,782            | 9,223             |
| Total assets  | \$910,235         | \$820,525         |

| LIABILITIES AND STOCKHOLDERS' EQUITY         | December 30, 2017 | December 31, 2016 |
|--|-------------------|-------------------|
| Current liabilities                          |                   |                   |
| Accounts payable                             | \$33,779          | \$34,335          |
| Accrued compensation                         | 39,515            | 43,180            |
| Accrued and other liabilities                | 38,052            | 28,266            |
| Income taxes payable                         | 4,292             | 76,316            |
| Deferred revenue                             | 35,929            | 38,198            |
| Current portion of capital lease obligations | –                 | 71                |
| Total current liabilities                    | 151,567           | 220,366           |
| Deferred revenue                             | 237               | 25,336            |
| Other liabilities                            | 51,520            | 14,587            |
| Total liabilities                            | 203,324           | 260,289           |
| Commitments and contingencies                |                   |                   |
| Stockholders' Equity                         |                   |                   |
| Preferred stock                              | –                 | –                 |
| Common stock                                 | 52                | 50                |
| Treasury stock                               | (472,536)         | (404,276)         |
| Additional paid-in capital                   | 461,494           | 382,263           |
| Accumulated other comprehensive loss         | (2,941)           | (7,027)           |
| Retained earnings                            | 720,842           | 589,226           |
| Total stockholders' equity                   | 706,911           | 560,236           |
| Total liabilities and stockholders' equity   | \$910,235         | \$820,525         |

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

| Revenue:  | Year Ended<br>December 30, 2017 | Year Ended<br>December 31, 2016 |
|---|---------------------------------|---------------------------------|
| Product   | \$741,324                       | \$663,846                       |
| Royalty and other revenue                                   | 56,784                          | 30,779                          |
| Total revenue   | 798,108                         | 694,625                         |
| Cost of goods sold  | 263,008                         | 230,826                         |
| Gross profit  | 535,100                         | 463,799                         |
| Operating expenses:   |                                 |                                 |
| Selling, general, and administrative                        | 275,786                         | 253,667                         |
| Research and development                                    | 61,953                          | 59,362                          |
| Litigation settlement, award and/or defense costs           | –                               | (270,000)                       |
| Total operating expenses                                    | 337,739                         | 43,029                          |
| Operating income  | 197,361                         | 420,770                         |
| Non-operating (income) expense                              | (2,013)                         | 2,429                           |
| Income before provision for income taxes                    | 199,374                         | 418,341                         |
| Provision for income taxes                                  | 67,758                          | 117,675                         |
| Net income including noncontrolling interests               | 131,616                         | 300,666                         |
| Net income (loss) attributable to noncontrolling interests  | –                               | –                               |
| Net income attributable to Masimo Corporation stockholders: | \$131,616                       | \$300,666                       |
| Basic   | \$2.55                          | \$6.07                          |
| Diluted   | \$2.36                          | \$5.65                          |
| Weighted-average shares used in per share calculations:     |                                 |                                 |
| Basic   | 51,516                          | 49,530                          |
| Diluted   | 55,874                          | 53,195                          |

# Financial Performance

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

|   | Year ended<br>December 30, 2017 | Year ended<br>December 31, 2016 |
|---|---------------------------------|---------------------------------|
| <b>Cash flows from operating activities:</b>  |                                 |                                 |
| Net income including noncontrolling interests   | \$131,616                       | \$300,666                       |
| Adjustments to reconcile net income including noncontrolling interest to net cash provided by operating activities: |                                 |                                 |
| Depreciation and amortization   | 20,061                          | 16,817                          |
| Stock-based compensation  | 17,187                          | 12,503                          |
| Loss on disposal of property, equipment and intangibles   | 522                             | 658                             |
| Provision for doubtful accounts   | 251                             | 259                             |
| Provision for amount due from former foreign agent  | 10,477                          | –                               |
| Gain on deconsolidation of variable interest entity   | –                               | (273)                           |
| Benefit from deferred income taxes  | 24,023                          | 5,405                           |
| Changes in operating assets and liabilities:  |                                 |                                 |
| Increase in trade accounts receivable   | (19,772)                        | (21,243)                        |
| Increase in inventories   | (22,923)                        | (10,831)                        |
| Increase in deferred cost of goods sold   | (19,438)                        | (8,251)                         |
| Increase in prepaid expenses  | (3,855)                         | (3,422)                         |
| (Increase) decrease in prepaid income taxes   | (2,498)                         | 1,355                           |
| Increase in other assets  | (10,952)                        | (1,609)                         |
| (Decrease) increase in accounts payable   | (4,057)                         | 11,048                          |
| (Decrease) increase in accrued compensation   | (4,292)                         | 5,675                           |
| Increase (decrease) in accrued and other current liabilities  | 11,156                          | (11,929)                        |
| (Decrease) increase in income taxes payable   | (72,087)                        | 73,755                          |
| (Decrease) increase in deferred revenue   | (27,370)                        | 41,977                          |
| Increase in other liabilities   | 28,013                          | 6,565                           |
| <b>Net cash provided by operating activities</b>  | <b>56,062</b>                   | <b>419,125</b>                  |

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

|  | Year ended<br>December 30, 2017 | Year ended<br>December 31, 2016 |
|--|---------------------------------|---------------------------------|
| <b>Cash flows from investing activities:</b>                                 |                                 |                                 |
| Purchases of property and equipment  | (43,684)                        | (19,707)                        |
| Increase in intangible assets  | (3,079)                         | (4,644)                         |
| Acquisition of long-term equity investments                                  | (1,145)                         | (200)                           |
| Reduction in cash resulting from deconsolidation of variable interest entity | –                               | (763)                           |
| <b>Net cash used in investing activities</b>                                 | <b>(47,908)</b>                 | <b>(25,314)</b>                 |
| <b>Cash flows from financing activities:</b>                                 |                                 |                                 |
| Borrowings under revolving line of credit                                    | –                               | 45,000                          |
| Repayments under revolving line of credit                                    | –                               | (230,000)                       |
| Debt issuance costs  | –                               | (621)                           |
| Repayments on capital lease obligations                                      | (71)                            | (75)                            |
| Proceeds from issuance of common stock                                       | 62,205                          | 37,290                          |
| Repurchases of common stock  | (66,272)                        | (68,218)                        |
| <b>Net cash used in financing activities</b>                                 | <b>(4,138)</b>                  | <b>(216,624)</b>                |
| Effect of foreign currency exchange rates on cash                            | 3,269                           | (1,451)                         |
| <b>Net increase in cash, cash equivalents and restricted cash</b>            | <b>7,285</b>                    | <b>175,736</b>                  |
| Cash, cash equivalents and restricted cash at beginning of period            | 308,198                         | 132,462                         |
| <b>Cash, cash equivalents and restricted cash at end of period</b>           | <b>\$315,483</b>                | <b>\$308,198</b>                |

# Forward Looking Statements

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All statements other than statements of historical facts included in this annual report that address activities, events or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Forward-looking statements include statements which are predictive in nature, which depend upon or refer to future events or conditions, or which include words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. These forward-looking statements are based on management’s current expectations and beliefs and are subject to uncertainties and factors, all of which are difficult to predict and many of which are beyond our control and could cause actual results to differ materially and adversely from those described in the forward-

looking statements. These risks include, but are not limited to, those related to: actual foreign currency exchange rates; our dependence on Masimo SET® and Masimo rainbowSET™ products and technologies for substantially all of our revenue; our ability to protect and enforce our intellectual property rights; potential exposure to competitors’ assertions of intellectual property claims; the highly competitive nature of the markets in which we sell our products and technologies; our ability to continue developing innovative products and technologies; the lack of acceptance of any of our current or future products and technologies; obtaining regulatory approval of our current and future products and technologies; the risk that the implementation of our international realignment will not continue to produce anticipated operational and financial benefits, including a continued lower effective tax rate; the loss of our

customers; our ability to retain and recruit senior management; product liability claims exposure; our ability to obtain expected returns from the amount of intangible assets we have recorded; the maintenance of our brand; the amount and type of equity awards that we may grant to employees and service providers in the future; our ongoing litigation and related matters; and other factors discussed in the “Risk Factors” section of our most recent periodic reports filed with the Securities and Exchange Commission (“SEC”), including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, all of which you may obtain for free on the SEC’s website at [www.sec.gov](http://www.sec.gov). Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. You are cautioned not to place undue

reliance on these forward-looking statements, which speak only as of the date hereof, even if subsequently made available by us on our website or otherwise. We do not undertake any obligation to update, amend or clarify these forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

**NOTE REGARDING THIS ANNUAL REPORT**  
Please note that this annual report does not constitute our “annual report to security holders” for purposes of the requirements of the SEC. For a copy of our annual report to security holders required under Rule 14a-3 of Regulation 14A of the Securities Exchange Act of 1934, as amended, please refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which you may obtain for free on the SEC’s website at [www.sec.gov](http://www.sec.gov).

# Automating Care



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