MASIMO CORP
Form 10-K
February 26, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)
þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 29, 2018
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number 001-33642

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

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

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

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

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

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

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer þ Accelerated filer ¨ Non accelerated filer ¨ Smaller reporting company ¨
Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2018, the last business day of the registrant’s most recently completed second fiscal quarter, as reported on the Nasdaq Global Select Market, was approximately $4.3 billion. Shares of stock held by officers, directors and 5 percent or more stockholders have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. At January 25, 2019, the registrant had 53,172,028 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K incorporate information by reference from the registrant’s proxy statement for the registrant’s 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

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

PART I

ITEM 1. BUSINESS

Overview

We are a global medical technology company that develops, manufactures and markets a variety of noninvasive monitoring technologies. We provide our products directly and through distributors and original equipment manufacturers (OEM) partners to hospitals, emergency medical service (EMS) providers, long-term care facilities, physician offices, veterinarians and consumers. Our mission is to improve patient outcomes and reduce the cost of care. We were incorporated in California in May 1989 and reincorporated in Delaware in May 1996.

Our core business is Measure-through Motion and Low Perfusion® pulse oximetry monitoring, known as Masimo Signal Extraction Technology® (SET®) pulse oximetry. Our product offerings have expanded significantly over the years to also include noninvasive monitoring of blood constituents with an optical signature, optical organ oximetry monitoring, electrical brain function monitoring, acoustic respiration monitoring and exhaled gas monitoring. In addition, we have developed the Root™ patient monitoring and connectivity platform, the Radical-7® and Rad-97™ bedside and portable patient monitors and the Radius-7® wearable wireless patient monitor. We have also developed the Masimo Patient SafetyNet[1] supplemental remote patient surveillance and monitoring system, which currently allows up to 200 patients to be monitored and viewed simultaneously and remotely through a PC-based monitor or by care providers through their pagers, voice-over-IP phones or smartphones. As part of our hospital automation product suite, we recently launched UniView,™ an integrated display of real-time data and alarms from multiple Masimo and third-party devices, designed to reduce clinician cognitive overload, improve patient safety and promote data sharing and team coordination among multiple clinicians.

Our solutions and related products are based upon our proprietary Masimo SET® and rainbow® algorithms. These technologies are incorporated into a variety of product platforms designed to meet our customers' needs. In addition, we provide our technologies to OEMs in a form factor that is easy to integrate into their patient monitors, defibrillators, infant incubators and other devices.

Our technology is supported by a substantial intellectual property portfolio that we have built through internal development and, to a lesser extent, acquisitions and license agreements. We have also exclusively licensed from Cercacor Laboratories, Inc. (Cercacor) the right to certain OEM rainbow® technologies and to incorporate certain rainbow® technology into our products intended to be used by professional caregivers, including, but not limited to, hospital caregivers and alternate care facility caregivers.

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[1] The use of the trademark Patient SafetyNet is under license from the University HealthSystem Consortium.

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Conventional Pulse Oximetry

Pulse oximetry enables the noninvasive measurement of the oxygen saturation level of arterial blood (SpO_2), which delivers oxygen to the body's tissues. Pulse oximetry also measures pulse rate (PR), which, when measured by electrocardiogram (ECG), is called heart rate. Pulse oximeters use sensors attached to an extremity, typically the fingertip or certain core body sites. These sensors contain two light-emitting diodes that transmit red and infrared light from one side of the extremity through the tissue to a photodetector on the other side of the extremity. The photodetector in the sensor measures the amount of red and infrared light absorbed by the tissue. A microprocessor then analyzes the changes in light absorption to provide a continuous, real-time measurement of the amount of oxygen in the patient's arterial blood. Pulse oximeters typically give audio and visual alerts, or alarms, when the patient's arterial blood oxygen saturation level or pulse rate falls outside of a user-designated range. As a result, clinicians have the opportunity to assess patients who may need immediate treatment to prevent the serious clinical consequences of hypoxemia, or low arterial blood oxygen saturation levels, and hyperoxemia, or high arterial blood oxygen levels.

As one of the most common technologies used in and out of hospitals around the world, pulse oximetry has gained widespread clinical acceptance as a standard patient vital sign measurement because it can give clinicians a warning of possible hypoxemia or hyperoxemia. SpO_2 monitoring of oxygen saturation is critical because hypoxemia can lead to a lack of oxygen in the body's tissues, which can be toxic and result in organ damage or death. Pulse oximeters are used in a variety of critical care settings, including surgery, recovery rooms, intensive care units (ICUs), emergency departments and general care floors, as well as alternative care settings, such as long-term care facilities, physician offices and the home monitoring of patients with chronic conditions.

Clinicians also use pulse oximeters to monitor oxygen saturation in premature babies to ensure that appropriate oxygen saturation levels are maintained. In premature babies, oxygen saturation levels above clinically acceptable limits may lead to a condition known as retinopathy of prematurity (ROP), which, if left untreated, can lead to permanent eye damage or blindness. By ensuring that oxygen saturation levels in babies remain within clinically acceptable limits, clinicians believe they can lower the incidence of ROP.

Conventional pulse oximetry has limitations that can reduce its effectiveness and the quality of patient care. In particular, when using conventional pulse oximetry, oxygen saturation measurements can be distorted by motion artifact, or patient movement, and low perfusion, or low arterial blood flow at the measurement site. Motion artifact can cause conventional pulse oximeters to inaccurately measure the arterial blood oxygen saturation level, due mainly to the effect of movement-induced pulsations of venous blood, which is at a lower oxygen saturation than arterial blood. Low perfusion can also cause conventional pulse oximeters to report inaccurate measurements or, in some cases, no measurement at all. In addition, conventional pulse oximeters cannot distinguish oxygenated hemoglobin from dyshemoglobin, including the most prevalent forms of dyshemoglobins, carboxyhemoglobin and methemoglobin. As a result, conventional pulse oximeters may report falsely high oxygen levels when these dyshemoglobins are present in the blood. Furthermore, conventional pulse oximetry readings can also be impacted by bright light and electrical interference caused by the presence of electrical surgical equipment.

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

Lastly, because conventional pulse oximetry cannot consistently measure SpO_2 and pulse rate in the presence of motion artifact or low perfusion, its use is limited in lower acuity settings in the hospital, such as in general care areas, where a hospital's staff-to-patient ratio is significantly lower and the staff have less tolerance for false alarms. In addition, two-wavelength pulse oximeters cannot distinguish oxygenated hemoglobin from dyshemoglobin, including the most prevalent forms of carboxyhemoglobin and methemoglobin. As a result of these dyshemoglobins, pulse oximeters will report falsely high oxygen levels when they are present in the blood.

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Masimo SET® Pulse Oximetry

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

The performance of Masimo SET® pulse oximetry has been evaluated in more than 100 independent studies and thousands of clinical evaluations. We believe that Masimo SET® is trusted by clinicians to safely monitor in excess of approximately 100 million patients each year and has been chosen as the primary pulse oximeter technology used by nine of the top ten hospitals listed on the 2018-2019 U.S. News & World Report Best Hospitals Honor Roll.

Compared to conventional pulse oximeters, during patient motion and low perfusion, Masimo SET® provides measurements when other pulse oximeters cannot, significantly reduces false alarms (improved specificity), and accurately detects true alarms (improved sensitivity). Clinical studies have shown that the use of Masimo SET® pulse oximetry, in conjunction with modified clinical protocols, has helped clinicians reduce ROP in neonates and improve screening for newborns with critical congenital heart disease (CCHD). Clinical studies have also shown a reduction in rapid response activations and ICU transfers when Masimo SET® is used to continuously monitor patients on general wards. Additionally, researchers have found that the use of Masimo SET® is associated with reduced ventilator weaning time and arterial blood gas measurements in the ICU.

Our pulse oximetry technology is contained on a circuit board which can be placed inside a standalone pulse oximetry monitor, placed inside OEM multiparameter monitors, or included as part of an external "Board-in-Cable" solution that is plugged into a port on an OEM or other device. All of these solutions use our proprietary single-patient-use or reusable sensors and cables. We sell our products to end users through our direct sales force and through certain distributors, as well as to our OEM partners, for incorporation into their products. In 2013, we also began selling our pulse oximetry products in the consumer market.

To complement our Masimo SET® platform, we have developed a wide range of proprietary single-patient-use (disposable) and multi-patient-use (reusable) sensors, cables and other accessories designed specifically to work with Masimo SET® software and hardware. Our single-patient-use sensors offer several advantages over reusable sensors, including improved performance, cleanliness, increased comfort and greater reliability. In addition, our neonatal adhesive sensors have been designed to exhibit greater durability compared to competitive sensors. Although our technology platforms operate solely with our proprietary sensor lines, our sensors have the capability to work with certain competitive pulse oximetry monitors through the use of adapter cables.

Adhesive sensors are single-patient-use items, but the U.S. Food and Drug Administration (FDA) allows third parties to reprocess pulse oximetry sensors. In response to some hospitals' requests to implement environmentally friendly or "green" products, we offer sensor reprocessing as well as sensor recycling programs.

Masimo rainbow SET™ Platform

Since introducing Masimo SET®, we have continued to innovate by introducing noninvasive measurements that go beyond arterial blood oxygen saturation and pulse rate. In 2005, we introduced the Masimo rainbow SET™ platform, leveraging our Masimo SET® technology and incorporating licensed rainbow® technology to enable real-time monitoring of additional noninvasive measurements. Our rainbow SET™ platform includes our rainbow SET™ Pulse CO-Oximetry products, which we believe are the first devices cleared by the FDA to noninvasively and continuously monitor additional hemoglobin species that were previously only measurable using intermittent invasive procedures using multiple wavelengths of light. In addition to SpO_2, PR, perfusion index (Pi), Pleth Variability Index (PVi®) and respiration rate from the pleth (RRp®), rainbow® Pulse CO-Oximetry has the unique ability to measure and

distinguish oxygenated hemoglobins from the dyshemoglobins that are incapable of transporting oxygen, carboxyhemoglobin (SpCO®) and methemoglobin (SpMet®). Besides the ability to measure SpCO® and SpMet®, the Masimo rainbow SET™ platform also allows for the noninvasive and continuous monitoring of total hemoglobin concentration (SpHb®) as well as the monitoring of arterial oxygen saturation, in the presence of carboxyhemoglobin and methemoglobin, known as fractional arterial oxygen saturation ($SpfO_2$)™. Additionally, the rainbow SET™ platform also allows for the calculation of Oxygen Content (SpOC)™ and Oxygen Reserve Index™ (ORi)™. RRp®, $SpfO_2$™ and ORi™ have received CE Marking, but are not currently available for sale in the U.S.

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We believe that Masimo rainbow® Pulse CO-Oximetry products will become widely adopted for the noninvasive monitoring of these measurements. We also believe that the addition of acoustic respiration rate (RRa®), using our rainbow Acoustic Monitoring® technology, will strengthen the clinical demand for noninvasive and continuous monitoring using our rainbow® platform, especially in the growing general floor market.

Products with our MX circuit board contain our Masimo SET® pulse oximetry technology as well as circuitry to support rainbow® measurements. At the time of purchase, or at any time in the future, our customers and our OEMs' customers have the option of purchasing additional rainbow® software measurements, which allow the customer to incrementally expand their patient monitoring systems with a cost-effective solution. To date, over thirty-four companies have released rainbow SET™ equipped products or announced rainbow® integration plans.

Measurements

SpHb®

Hemoglobin is the oxygen-carrying component of red blood cells (RBCs). Hemoglobin measurement is one of the most frequent invasive laboratory measurements in the world, and is often measured as part of a complete blood count (CBC), which measures multiple other blood components. A low hemoglobin status is a condition called anemia. As a chronic disorder, anemia can be treated by iron supplements, diet changes or drugs that increase the production of RBCs. As an acute disorder resulting from bleeding, anemia requires either stoppage of the bleeding or a blood transfusion in order to sustain organ function and life.

SpHb® is available as a continuous or a spot-check measurement. Continuous SpHb® monitoring provides real-time visibility into hemoglobin levels and the changes, or lack of changes, in hemoglobin levels, which can otherwise only be measured through intermittent, invasive blood testing. SpHb® monitoring is not intended to be used as the sole basis for making diagnosis or treatment decisions, but continuous SpHb® monitoring may help clinicians to trend hemoglobin in real time between invasive blood samples.

SpOC™

The oxygen content of blood is a function of both oxygen saturation and hemoglobin levels. SpOC™ provides a more complete picture of a patient's oxygenation status by combining noninvasive and continuous measurements of both hemoglobin and oxygen saturation levels into a single calculation.

SpCO®

Carbon monoxide (CO) is a colorless, odorless and tasteless gas that is undetectable by humans and is often unknowingly inhaled from combustion fumes, or during fires by victims and first responders. CO poisoning is the leading cause of accidental poisoning death in the U.S. and is responsible for up to 50,000 emergency department visits and 500 unintentional deaths annually. CO, when bound to hemoglobin cells, prevents those cells from carrying oxygen. Elevated CO levels may cause severe neurological damage, permanent heart damage or death. Screening for elevated CO levels in the emergency department is critical, as symptoms of CO poisoning in patients may be misdiagnosed because such symptoms are similar to the flu.

CO levels in the blood can be measured using a laboratory CO-Oximeter, which requires a patient or a patient's blood sample to be transported to a hospital with laboratory CO-Oximetry capability. Additional delays occur if a patient needs hyperbaric oxygen therapy, which often requires transfer to yet another medical center with hyperbaric capability. Outside the hospital, laboratory measurements of carboxyhemoglobin are not considered feasible. Historically, this meant that CO levels in the blood could not be assessed in environments in which such assessment would be very useful, such as in the home or as part of the medical evaluation of first responders potentially exposed to CO at the scene of a fire.

We believe that the greatest opportunity for SpCO® monitoring is in the EMS, fire and hospital emergency department settings, since elevated SpCO® levels may help indicate a need for invasive testing in patients with headaches or other non-specific symptoms of CO poisoning. While SpCO® is not intended to replace invasive carboxyhemoglobin tests, when used with other clinical variables, SpCO® may help clinicians identify elevated CO levels and help determine additional test and treatment options. Over the past few years, multiple leading emergency first responder associations, including the National Association of Emergency Medical Technicians, the National Association of EMS Educators, the International Association of Fire Fighters and the International Association of Fire Chiefs, have

educated their members on the benefits of noninvasive CO measurement when exposure is suspected or when an individual presents symptoms that could indicate elevated CO levels. In 2015, the National Fire Protection Association (NFPA), one of the world's authoritative sources on fire prevention and public safety, released updated Fire Rehabilitation Standard 1584, Standard on the Rehabilitation Process for Members During Emergency Operations and Training Exercises, requiring firefighters exposed to smoke at incident scenes and during training to be assessed for elevated CO levels.

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SpMet®

Methemoglobin in the blood leads to a dangerous condition known as methemoglobinemia, which occurs as a reaction to some common drugs used in hospitals and outpatient procedures. Methemoglobinemia reduces the amount of oxygen bound to hemoglobin for delivery to tissues and forces normal hemoglobin to bind more tightly to oxygen, releasing less oxygen to the tissues. Methemoglobinemia may go unrecognized or be subject to delayed diagnosis, increasing risk to the patient. Commonly prescribed drugs can introduce methemoglobin into the blood and cause methemoglobinemia. Some of the 30 drugs that are known to cause methemoglobinemia include benzocaine, a local anesthetic routinely used in procedures ranging from endoscopy to surgery; inhaled nitric oxide, routinely used in the Neonatal Intensive Care Unit; nitroglycerin, used to treat cardiac patients, and dapsone, used to treat infections for immune-deficient patients such as Human Immunodeficiency Virus (HIV) patients. Warnings, cautions and alerts regarding the clinical significance and prevalence of methemoglobinemia have been generated by the FDA, the Veterans Administration, the Institute for Safe Medication Practices and the National Academy of Clinical Biochemistry. The American Academy of Pediatrics recommends monitoring methemoglobin levels in infants who receive nitric oxide therapy. While SpMet® is not intended to replace invasive methemoglobin tests, when used with other clinical variables, SpMet® may help clinicians identify elevated methemoglobin levels and help determine additional test and treatment options.

PVi®

PVi® is a measure of the dynamic changes in the Pi that occur during the respiratory cycle. The calculation is accomplished by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. PVi® is displayed as a percentage. The lower the number, the less variability there is in Pi over a respiratory cycle. PVi® may show changes that reflect physiologic factors such as vascular tone, circulating blood volume and intrathoracic pressure excursions. When used with other clinical variables, PVi® may help clinicians assess fluid responsiveness in surgical and intensive care patients who are mechanically ventilated, and help determine other treatment options.

RPVi™

Rainbow® Pleth Variability Index (RPVi)™ is a multi-wavelength version of PVi® that is designed to provide enhanced specificity to changes in fluid volume compared to PVi®. Similar to PVi®, RPVi™ is displayed as a percentage and is calculated by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. The lower the number, the less variability there is in Pi over a respiratory cycle, which indicates more fluid in the body. RPVi™ has received the CE Mark, but is not currently available for sale in the U.S.

RRp®

Respiration rate is defined as the number of breaths per minute. Changes in respiration rate provide an early warning sign of deterioration in patient condition. A low respiration rate is indicative of respiratory depression and high respiration rate is indicative of patient distress. Current methods of monitoring respiration rate include end tidal carbon dioxide ($EtCO_2$) monitoring, which requires a nasal cannula be inserted in the patient's nose or a mask to be worn, and therefore has low patient compliance; and impedance monitoring, which is considered unreliable and requires the placement of ECG electrodes on the chest. RRp® allows clinicians to noninvasively and continuously measure and monitor respiration rate using a standard Masimo SET® pulse oximetry sensor or rainbow® Pulse CO-Oximetry sensor. RRp® is determined by the variations in the plethysmograph waveform due to respiration, although the measurement is not possible in all patients or conditions and may not immediately indicate changes in respiration rate. RRp® has received the CE Mark, as well as FDA 510(k) clearance when used in healthcare settings with the MightySat® Rx fingertip SET® pulse oximeter. RRp® is also available in the U.S. for use by consumers for general health and wellness purposes as part of our MightySat® fingertip pulse oximeter.

RRa®

Our sound-based monitoring technology, rainbow Acoustic Monitoring® (RAM®), enables RRa® and provides continuous and noninvasive monitoring of respiration rate. For patients requiring accurate and sensitive respiration rate monitoring, we believe that RRa® better detects pauses in breathing than respiration rate measurements from other technologies such as $EtCO_2$ monitoring and RRp®. RRa® also provides an important visual indication of

breathing through a displayed acoustic waveform. Multiple clinical studies have shown that the noninvasive measurement of acoustic respiration rate provides as good or better respiration rate monitoring accuracy as $EtCO_2$ monitoring, and can reliably detect episodes of respiratory pause, defined as the cessation of breathing for 30 seconds or more. When used with other clinical variables, RRa® may help clinicians assess respiratory depression and respiratory distress earlier and more often to help determine treatment options and potentially enable earlier interventions.

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$SpfO_2$™

Prior to our debut of $SpfO_2$,™ pulse oximeters could only measure and display functional SpO_2 oxygen saturation. Therefore, when patients had elevated carboxyhemoglobin and/or elevated methemoglobin, the displayed functional SpO_2 oxygen saturation overestimated the actual oxygen saturation value. $SpfO_2$,™ or fractional oxygen saturation, allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to functional oxygen saturation, and may also allow earlier interventions and more timely therapeutic decisions. $SpfO_2$™ has received CE Mark, but is not currently available for sale in the U.S.

ORi™

ORi™ provides real-time visibility to oxygenation status in moderate hyperoxic range, which we define as a patient's oxygen "reserve". ORi™ can be trended and has optional alarms to notify clinicians of changes in a patient's oxygen reserve. When this technology is used with SpO_2 monitoring, ORi™ may extend the continuous and noninvasive visibility of a patient's oxygen status into ranges previously unmonitored in this fashion. ORi™ may also be of value in patients receiving supplemental oxygen, such as those in surgery, under conscious sedation or in the ICU, as ORi™ is represented as an "index" parameter with a unit-less scale between 0.00 and 1.00. Furthermore, ORi™ may provide an advance warning of an impending hypoxic state, or an indication of an unintended hyperoxic state, when evaluated in conjunction with the partial pressure of oxygen (PaO_2). In this way, ORi™ may assist in determining the need for proactive interventions to avoid hypoxia or unintended hyperoxia. ORi™ has received the CE Mark, but is not currently available for sale in the U.S.

Other Noninvasive Measurements and Technologies

Following the introduction of our rainbow SET™ platform, we have continued to expand our technology offerings by introducing additional noninvasive measurements and technologies to create new market opportunities in both hospital and non-hospital care settings.

SedLine® Brain Function Monitoring

Brain function monitoring is most commonly used during surgery to help clinicians avoid over-titration and under-titration of anesthesia and sedation. SedLine® brain function monitoring technology measures the brain's electrical activity by detecting EEG signals. In contrast to whole-scalp EEG monitoring, which is used for diagnostic purposes, this form of EEG monitoring is often referred to as processed EEG monitoring or brain function monitoring. Brain function monitors display the patient's EEG waveforms, but these may be difficult for clinicians to interpret. With SedLine® technology, EEG signals are processed and displayed as a single number called the Patient State Index (PSi), which gives a continuous quantitative indication of the patient's depth of anesthesia and sedation. SedLine® brain function monitoring technology also displays raw EEG waveforms, the PSi trend and a Density Spectral Array view, which allows clinicians to compare EEG power in both sides of the brain over time to facilitate the detection of asymmetrical activity and agent-specific effects on the EEG signal.

SedLine® brain function monitoring technology is available on Root™ through the use of a Masimo Open Connect® (MOC-9®) connectivity port. The Root™ patient monitoring and connectivity platform integrates rainbow® and SET® measurements with measurement technologies, such as SedLine®.

NomoLine® Capnography and Gas Monitoring

We offer a portfolio of capnography and gas monitoring products ranging from external "plug-in-and-measure" capnography and gas analyzers, integrated modules, handheld capnograph and capnometer devices, and capnography sampling lines. These products have the ability to measure multiple expired gases, such as carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2) and other anesthetic agents. In addition, respiration rate is calculated from the CO_2 waveform. These measurements are possible through either mainstream monitoring, which samples gases from a ventilated patient's breathing circuit, or sidestream monitoring, which samples gases from a breathing circuit in mechanically ventilated patients or through a cannula or mask in spontaneously breathing patients. These capnography and gas measurements are standard-of-care in many hospital environments, such as operating rooms and ICUs, during procedural sedation.

In November 2017, we released the full family of NomoLine® capnography sampling lines to the U.S. market. NomoLine® sampling lines are available in more than 40 configurations of airway adapter sets and cannulas for use 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. NomoLine® capnography sampling lines are compatible with both Masimo and many third-party OEM monitors facilitating easy to use sidestream capnography and gas monitoring. NomoLine® capnography sampling lines have received FDA 510(k) clearance.

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O3® Regional Oximetry

O3® regional oximetry, also known as tissue or cerebral oximetry, uses near-infrared spectroscopy (NIRS) to provide continuous measurement of tissue oxygen saturation (rSO_2) to help detect regional hypoxemia, or oxygen deficits in specific tissues such as the brain, that pulse oximetry alone cannot detect under certain conditions. In addition, O3® sensors, in conjunction with our Root™ monitor, can automate the differential analysis of regional to central oxygen saturation derived from SET® pulse oximeters. O3® monitoring involves applying O3® regional oximetry sensors to the forehead and connecting the O3® MOC-9® module to a Root™ monitor through one of its three MOC-9® ports. O3® regional oximetry has received CE Mark and FDA 510(k) clearance for use in adult and pediatric patients.

Patient SafetyNet

Patient SafetyNet, our patient surveillance, remote monitoring and clinician notification solution, works in concert with our bedside and ambulatory monitoring devices to facilitate the supplemental monitoring of the oxygen saturation, pulse rate, perfusion index, hemoglobin, methemoglobin, and respiration rate of up to 200 patients simultaneously from a single server. Patient SafetyNet offers an intuitive and powerful user interface with trending, real-time waveform capability at a central station, as well as remote clinician notification via pager, Voice-over-IP phone or smart-phones. Patient SafetyNet also features an Adaptive Connectivity Engine™ (ACE) that enables two-way, HL-7 based connectivity to clinical/hospital information systems. The ACE significantly reduces the time and complexity to integrate and validate custom HL-7 implementations, and demonstrates our commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture.

Patient SafetyNet Series 5000™, along with Iris® Connectivity, Iris Gateway®, Kite®, UniView™ and MyView® through the Root™ patient monitoring and connectivity platform, offers a new level of interoperability designed to enhance clinician workflows and reduce the cost of care in a variety of hospital settings, including operating rooms and the general care floors. Patient SafetyNet Series 5000™ with Iris® enables Root™ to assimilate data from all devices connected to the patient, thereby acting as a comprehensive in-room patient monitor and connectivity hub. Alarms and alerts for all devices are seamlessly forwarded to the patient's clinician and device data can be transferred to the patient's electronic medical record (EMR). The patient-centric user interface of the Patient SafetyNet Series 5000™ displays near real-time data from all devices with Kite®, providing a single unified dashboard of patient information. To simplify documentation of patient data, Root™ enables clinicians to easily verify and send patient vitals and Early Warning Scores (EWS), as well as all connected medical device information data, to the EMR directly from Root.™ An interface between the Patient SafetyNet Series 5000™ and the hospital admission, discharge and transfer (ADT) system allows clinicians to receive ADT information on Root™ for positive patient identification at the bedside. Clinicians can also manually enter additional data on the Root™ device, including temperature, blood pressure, level of consciousness, pain score and urine output.

In an article published in 2010 by Dartmouth-Hitchcock Medical Center, clinicians using Masimo SET® and Patient SafetyNet identified patient distress earlier, which decreased rapid response team activations, ICU transfers and ICU days. Hospitals and other care centers may determine that they can reduce their costs by moving less critically ill patients from the ICU to the general care floors where they can be continuously and accurately monitored in a more cost-effective manner. We believe that the advanced performance of the Masimo SET® platform coupled with reliable, cost-effective and easy-to-use wireless remote monitoring will allow hospitals to create continuous surveillance solutions on general care floors where patients are at risk of avoidable adverse events and where direct patient observation by skilled clinicians is considered cost prohibitive.

MyView®

MyView® is a wireless, presence-detection system that enables the display of customized clinical profiles on Masimo devices, such as Root,™ Radical-7® and the Patient SafetyNet View Station. When a clinician approaches the device, a clinician-worn MyView® badge signals the device to display a preselected set of parameters and waveforms tailored to the individual clinician's preferences. MyView® gives clinicians the ability to receive and review medical device information in a manner that is most conducive to optimizing their workflow, while the presence mapping data collected by all the Masimo devices can provide insight into how clinicians spend time with patients. This provides nursing leadership and management the opportunity to examine analytical data on patient-clinician interactions and

optimize workflows across the unit, hospital and hospital system.

Patient SafetyNet Surveillance

Patient SafetyNet Surveillance is a software option that provides real-time video images of a patient's room, including the patient and connected monitoring devices, adding existing communication technology to central monitoring. Two-way audio is available to allow the caregiver to listen to and communicate with the patient. The system utilizes the existing hospital information technology network, precluding the installation of additional infrastructure.

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Trace™

Trace™ is a patient data visualization and reporting software designed for Masimo Root™ and Radical-7® monitors. Trace™ is the first data visualization and 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 O3® regional oximetry.

Third-Party Device Connectivity

Despite medical technology advances, the lack of device communication and integration creates risks to patient safety in hospitals around the world. Without device interoperability, critical patient information can go unnoticed, leaving clinicians unaware and patients at risk. Existing approaches for device interoperability require separate hardware, software and/or network infrastructure, which can clutter the patient room, increase complexity, burden IT management and increase costs. To address these challenges, we introduced Iris® connectivity in our Root™ patient monitoring and connectivity platform. Iris® connectivity enables multiple standalone third-party devices such as intravenous pumps (IV), ventilators, hospital beds and other patient monitors to connect through Root,™ enabling display, notification and documentation to the EMR through Masimo Patient SafetyNet.

The addition of Iris® connectivity to Root™ and Patient SafetyNet provides multiple advantages to hospitals, such as allowing standalone device information to be remotely viewed at a Patient SafetyNet view station, transmitted through notification systems to clinicians regardless of location or sent to electronic health record systems. This may enhance patient assessment, clinical workflows and decision support. In addition, bringing data from disparate devices together facilitates more integrated patient care, and provides a flexible and cost-effective platform, avoiding installation of separate costly systems and potentially reducing costs by leveraging existing network infrastructure.

Our Strategy

Our mission is to develop technologies that improve patient outcomes and reduce the cost of patient care. We intend to continue to grow our business and improve our market position by pursuing the following strategies:

- Continue to Expand our Market Share in Pulse Oximetry. We grew our product revenue to $829.9 million in 2018 from $599.3 million in 2015, representing a three-year compound annual growth rate of 11.5%. This growth can be attributed to continued expansion of our core SET® pulse oximeter customer base, higher revenues from rainbow® Pulse CO-Oximetry, NomoLine® capnography and other new technologies, and our expanding list of OEM partners. We supplement our direct sales to hospitals and other low-acuity healthcare facilities through various U.S. and international distributors. Combined sales through our direct and distributor sales channels increased to $718.6 million, or 86.6% of product revenue in 2018, from $508.2 million, or 84.8% of product revenue, in 2015. As the healthcare industry shifts toward hospitals, physicians and providers being rewarded by payers based on the quality and value of the services (as opposed to the volume of fee-for-service transactions), we expect to see more hospitals gravitate towards technologies like Masimo SET® that have a proven track record of improving patient care.
- Expand the Pulse Oximetry Market to Other Patient Care Settings. Many patients die due to unintended opioid overdoses after surgery while on general care floors. We believe the ability to continuously and accurately monitor patients outside of critical care settings, including the general, medical and surgical floors of the hospital, is currently an unmet medical need that has the potential to significantly improve patient care and increase the size of the pulse oximetry market. In addition, we believe the ability of Masimo SET® to accurately monitor and address the limitations of conventional pulse oximetry has enabled us, and will continue to enable us, to expand into non-critical care settings, and therefore, significantly expand the market for our products. To further support our expansion into the general care areas, we market Patient SafetyNet, which enables continuous monitoring of up to 200 patients' oxygen saturation, pulse rate and with rainbow SET,™ noninvasive hemoglobin and respiration rate. We believe that Patient SafetyNet, when combined with Masimo SET® pulse oximetry and RAM® or capnography, offers a clinically proven and cost-effective approach to continuous post-operative monitoring. Outside of the hospital setting, patients could die due to unintentional opioid overdose, even when opioids are being taken for short duration, such as after surgery, and as prescribed by a physician. We believe that in the home setting, accurate monitoring with Masimo SET® may help reduce the risk of opioid overdose by alerting family members and others when opioids have slowed a

patient's breathing and caused a significant drop in oxygen saturation.

- Expand the Use of rainbow® Technology in Hospital Settings. We believe the noninvasive measurement of rainbow® Pulse CO-Oximetry (SpHb®, SpCO®, SpMet®, PVi®, $SpfO_2$,™ SPOC™ and ORi™), rainbow Acoustic Monitoring® (RRa®), and the Halo Index,™ as well as future measurements, provide an excellent opportunity to help our customers improve patient care while reducing their overall cost of care.

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- Expand the Use of rainbow® Technology in Non-Hospital Settings. We believe the noninvasive measurement of hemoglobin, SpHb®, creates a significant opportunity in markets such as the physician office, emergency departments and blood donation centers; and the noninvasive measurement of carboxyhemoglobin, SpCO®, creates a significant opportunity in the fire/alternate care market.
- Expand the Use of Root™ in Hospital Settings. We believe Root™ represents a powerful new paradigm in patient monitoring because it enhances our rainbow® and SET® measurements with multiple specialty parameters, including SedLine® brain function monitoring, O3® regional oximetry, and NomoLine® capnography and gas monitoring, and enables open-architecture connectivity in an integrated, clinician-centric hub. Our Iris® integration platform for Root™ provides a conduit to the patient's EMR for a range of clinical devices that may otherwise remain disconnected, and therefore, unable to communicate their information. Iris® offers clinical utility and flexibility by collecting device information from multiple sources and making it available to clinicians in one networked place, akin to an airplane cockpit. Complementary innovations like the Radius-7® wearable, wireless monitor foster an environment of safety without sacrificing patient mobility or comfort. Radius-7® provides patients in medical-surgical units with mobility, allowing them to visit common areas and labs, all while being continuously monitored around the clock. Root™ is acuity-adaptable, meaning it can be configured for any care area, and is competitively priced.
- Utilize our Customer Base and OEM Relationships to Market Masimo rainbow SET™, O3®, SedLine® and Capnography Products Incorporating Licensed rainbow® Technology. We currently sell rainbow SET™ products through our direct sales force and distributors. We include our MX circuit boards in our pulse oximeters and also sell them to our OEM partners. Our MX circuit boards are equipped with circuitry to support rainbow® Pulse CO-Oximetry measurements that can be activated at time of sale or through a subsequent software upgrade. We believe that, over time, the clinical need for these measurements, along with our installed customer base, will help drive the adoption of our rainbow® Pulse CO-Oximetry products.
- Continue to Innovate and Maintain Our Technology Leadership Position. We invented and pioneered the first pulse oximeter to accurately measure arterial blood oxygen saturation level and pulse rate in the presence of motion artifact and low perfusion. In addition, we launched our rainbow SET™ platform that enabled what we believe is the first noninvasive monitoring of carboxyhemoglobin, methemoglobin and hemoglobin, as well as PVi®, all of which were previously only available with invasive and/or complicated testing. Furthermore, we believe that our introduction of RRa® with rainbow Acoustic Monitoring® technology represented the first platform to enable noninvasive and continuous respiration monitoring through an easy-to-use single-patient adhesive acoustic sensor. Finally, we believe that our recent introduction of ORi™ may provide advance warning of an impending hypoxic state, or an indication of an unintended hyperoxic state.

We plan to continue to innovate and develop new technologies and products, internally and through our collaboration with Cercacor, from whom we currently license certain rainbow® technologies.

Our future growth strategy is also closely tied to our focus on international expansion opportunities. Since 2007, we have continued to expand our sales and marketing presence in Europe, Asia, Asia Pacific, Middle East, Canada and Latin America. We have accomplished this by both additional staffing and adding or expanding sales offices in many of these territories. By centralizing a portion of our international operations, including sales management, marketing, customer support, planning, logistics and administrative functions, in Neuchâtel, Switzerland, we believe we have developed a more efficient and scalable international organization that is capable of being even more responsive to the business needs of our international customers under this centralized management structure.

Our Products and Markets

We develop, manufacture and market patient monitoring technologies that incorporate a monitor or circuit board and sensors, including proprietary single-patient-use and reusable sensors and patient cables. In addition, we offer remote alarm/monitoring solutions, software and connectivity solutions.

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The following chart summarizes our principal product components and principal markets and methods of distribution:

Patient Monitoring Solutions:		
Description:	Use:	Distribution Channel:
Circuit Boards and Modules (e.g., MX-3 (shown below), MX-5(shown below), MS-2011, MS-2013, MS-2040, uSpO2®, SedLine®, ISA™ and IRMA™)	• Signal processing apparatus for all Masimo technology platforms • Mainstream and sidestream capnography and gas monitoring	• Incorporated and sold to OEM partners who incorporate our circuit boards into their patient monitoring systems
Monitors and Devices (e.g., Radical-7®, Rad-97™ (both shown below), Rad-67™, Rad-87®, Rad-57®, Pronto-7®, Root™, Rad-8®, Rad-5® and Radius-7®)	• Bedside, handheld and wireless monitoring devices that incorporate Masimo SET® with and without licensed Masimo rainbow SET™ technology, noninvasive blood pressure and capnography.	• Sold directly to end-users and through distributors and in some cases to our OEM partners who sell to end-users

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Description:	Use:	Distribution Channel:
Patient Monitoring and Connectivity Platform (e.g., Root™, Radius-7® and Root™ with NIBP (shown below))	• Displays measurements from Masimo's Radical-7® (connected or hand carried) or Radius-7® (patient-worn) • Provides additional specialty measurements from Masimo or third-party-developed applications through Masimo Open Connect® (MOC-9®) • Integrates noninvasive blood pressure (NIBP) and temperature • Connects third-party devices such as IV pumps, ventilators, beds and other patient monitors to automate data transfer to the EMR	• Sold directly to end-users and through distributors
Sensors (e.g., SET®, rainbow® Pulse CO-Oximetry, rainbow Acoustic Monitoring® Sensors, RD SedLine®, TFA-1®, RD rainbow SET™ O3® Pediatric, RD rainbow Lite SET®, rainbow® DCI®-Mini (last four shown		

below))

- Extensive line of both single-patient, reusable and rainbow® sensors
- Patient cables, as well as adapter cables that enable the use of our sensors on certain competitors' monitors

- Sold directly to end-users and through distributors and to OEM partners who sell to end-users

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Description:	Distribution Channel:
Line Filters and Mainstream Adapters for Capnography and Gas Monitoring. (e.g., NomoLine® Cannula with EMMA® Capnograph with disposable adapter (shown below))	
• Line of disposables to measure gas parameters using mainstream and sidestream capnography	• Sold directly to end-users and through distributors and to OEM partners who sell to end-users
Remote Alarm and Supplemental Monitoring Solutions (e.g., Patient SafetyNet)	
• Network-linked, wired or wireless, multiple patient floor monitoring solutions	• Sold directly to end-users
• Standalone wireless alarm notification solutions	
Proprietary Measurements (e.g., SpHb®, SpCO®, SpMet®, PVi®, RRa®, ORi™, 3D Alarms® and	

Adaptive Threshold Alarm)

- rainbow® measurements and other proprietary features

- Sold directly to end-users and through OEM partners who sell to new and existing end-users

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Description:	Distribution Channel:
Connectivity (e.g., Iris® Connectivity, Connectivity Solutions and UniView™ (Shown below))	
• Software and hardware enabling third-party devices to connect through Patient SafetyNet and to document data in the EMR	• Sold directly to end-users

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Consumer Monitoring Solutions:

Devices (e.g. iSpO2®, MightySat® with PVi® and RRp®(shown below))	
• Fingertip pulse oximeter, or pulse oximeter cable and sensor for use with an iPhone, iPad, iPod touch and select Android smart phones	• Sold directly to consumers and through consumer retailers

Circuit Boards

Masimo SET® MS Circuit Boards. Our Masimo SET® MS circuit boards perform all signal processing and other pulse oximetry functions incorporating the Masimo SET® platform. Our MS circuit boards are included in our proprietary monitors or sold to our OEM partners for incorporation into their monitors. Once incorporated into a pulse oximeter, the MS circuit boards perform all data acquisition processing and report the pulse oximetry measurements to the host monitor. The circuit boards and related software interface directly with our proprietary sensors to calculate SpO_2, PR and Pi. Our latest generation boards include the MS-2003, MS-2011, MS-2013 and MS-2040, with a typical power consumption of less than 45 milliwatts.

Masimo rainbow SET™ MX Circuit Boards. Our next-generation circuit board is the foundation for our Masimo rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring® platform, utilizing certain technology that is licensed from Cercacor. The MX circuit boards offer full the functionality of our rainbow® technology, which includes noninvasive measurements for SpHb®, SpOC™, SpCO®, SpMet®, PVi® and RRa®, in addition to providing Measure-through Motion and Low Perfusion® SET® pulse oximetry measurements SpO_2, PR and Pi measurement capabilities of Masimo SET® pulse oximetry. Customers can choose to purchase additional measurements beyond SpO_2, PR and Pi at the time of sale or at any time in the future through a field-installed software upgrade.

Our MX-5 OEM circuit board deploys a technology platform that utilizes approximately half the power of previously available rainbow® circuit boards to deliver rainbow® Pulse CO-Oximetry noninvasive measurement performance. In addition to its lower power demands, the MX-5 adds dynamic power utilization to scale the MX-5's power draw based upon the combination of parameters being monitored to permit even longer battery run-times.

$uSpO_2$® Cable/Board. Our SET® technology-in-a-cable contains the low power (MS-2040) technology in a reduced size, allowing it to be embedded into patient cables as part of the sensor connector. This allows the $uSpO_2$® cable/board to interface with monitoring devices externally via an existing communications port in instances where internal integration of a traditional Masimo SET® technology board is not feasible. The $uSpO_2$® cable/board provides the same Masimo SET® Measure-through Motion and Low Perfusion® pulse oximetry found in our other products, with a typical power consumption of less than 45 milliwatts.

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Monitors / Devices

Root™. Root™ is a powerful patient monitoring and connectivity platform that integrates our rainbow® and SET® measurements with multiple additional specialty measurements through MOC-9® open architecture technology in an integrated, clinician-centric platform. The first MOC-9® technologies developed by Masimo were SedLine® brain function monitoring, NomoLine® capnography and gas monitoring and O3® regional oximetry. Root™ with NomoLine® capnography, SedLine® brain function monitoring, wireless communication and Iris® connectivity for third-party medical devices has received FDA 510(k) clearance. O3® regional oximetry has received CE Mark and FDA 510(k) clearance.

EWS for Root™ aggregates information from multiple vital signs and clinical observations to generate a score that represents the potential degree of patient deterioration. There are several EWS protocols, such as the Pediatric Early Warning Score (PEWS), Modified Early Warning Score (MEWS) and National Early Warning Score (NEWS). These various scores require vital signs contributors such as oxygen saturation, pulse rate, respiration rate, body temperature and systolic blood pressure along with contributors input by clinicians, 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 for various predefined EWS protocols, or hospitals can configure their own set of required contributors, and their relative weights, to create an EWS unique to their care environment.

Our MOC-9® partnerships enable third parties to utilize Root's™ open architecture and built-in connectivity to independently develop, obtain regulatory approvals, and commercialize their own external MOC-9® module. Alternatively, third parties can develop Masimo Open Connect Control (MOC-C)™ applications for Root™ using the MOC-9® software development kit (SDK). While we support the development efforts of our MOC® partners as needed, and help increase awareness of the availability of non-Masimo MOC-9® modules and MOC-C™ applications, our MOC-9® partners use their existing distribution channels to sell their MOC-9® modules or MOC-C™ applications to customers.

In July 2018, we announced the Vital Signs Check application for Root™. Vital Signs Check is an integrated patient data collection and workflow application that augments Root's™ versatility by helping to streamline hospital vital signs testing and optimize patient data management through automated patient association, centralized data collection, and immediate electronic charting at the bedside.

Radical-7®. The Radical-7® Pulse CO-Oximeter® is a wireless touchscreen device that incorporates our MX circuit board to allow upgradable rainbow SET™ measurements and offers three-in-one capability. The Radical-7® can be used as:

- a standalone device for bedside monitoring;
- a detachable, battery-operated handheld unit for easy portable monitoring;
- an integrated device as part of the Root™ patient monitoring and connectivity platform; and
- a monitor interface via SatShare®, a proprietary technology allowing our products to work with certain competitor products, to upgrade existing conventional multiparameter patient monitors to Masimo SET® while displaying rainbow® measurements on the Radical-7® itself.

With its wide-ranging flexibility, Radical-7® can continuously monitor a patient from the ambulance, to the emergency room, to the operating room, to the general floor and beyond, until the patient is discharged. Radical-7® delivers the accuracy and reliability of Masimo rainbow SET™ with multi-functionality, ease of use and the availability of measurement upgrades for existing monitors.

Radius-7®. Radius-7® for the Root™ patient monitoring and connectivity platform is the first and only wearable, wireless monitor with rainbow SET™ technology, enabling continuous monitoring and early identification of clinical deterioration while still allowing patients the freedom of movement. With Bluetooth® and Wi-Fi wireless connectivity, Radius-7® with Root™ can alert clinicians at the bedside or remotely, through Masimo Patient SafetyNet, of critical changes in a patient's SpO_2 and PR, even during states of motion and low perfusion, as well as RRa® and additional rainbow SET™ measurements. Radius-7® with Root™ has received both CE Mark and FDA 510(k) clearance.

Rad-97™. Rad-97™ is a versatile standalone Pulse CO-Oximeter® that features a 1080p HD color display with user-friendly multi-touch navigation and Measure-through Motion and Low Perfusion® SET® that can be used to

measure SpO_2, PR, PVi® and Pi. rainbow SET™ measurements such as SpHb®, SpOC™, SpCO®, SpMet® and RRa® can also be enabled. Rad-97™ is the smallest Masimo bedside device currently capable of monitoring the full rainbow SET™ platform. Rad-97™ has received CE Mark. In September 2017, we announced FDA 510(k) clearance and full market release of Rad-97™, including an additional Rad-97™ configuration with integrated NomoLine® capnography. Rad-97™ has also received FDA 501(k) clearance for home use, bringing hospital-grade technology to the home in a single integrated device that is a monitoring, connectivity and telecommunications hub.

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An optional integrated camera allows remote clinicians to interact with patients at home over live audio and video. With its built-in enterprise Wi-Fi capability, Rad-97™ has the ability to connect wirelessly from the home to supplemental patient monitoring systems, including Patient SafetyNet, facilitating automatic data transfer to hospital EMR systems.

Rad-97™ NIBP. Rad-97™ NIBP includes an integrated port that allows clinicians to connect a blood pressure cuff inflation hose directly to the device. Designed for reliability and patient comfort, Rad-97™ NIBP is compatible with both disposable and reusable cuffs for a variety of patient types. Rad-97™ NIBP enables clinicians to measure arterial blood pressure for adult, pediatric and neonatal patients, with three measurement modes: spot-check, automatic interval (which measures blood pressure routinely, at a desired interval) and stat interval (which continually measures blood pressure for a desired duration). In March 2017, we announced the CE Mark of the Rad-97™ NIBP. In September 2017, we announced FDA 510(k) clearance and full market release of Rad-97™ NIBP.

Rad-67™. Rad-67™, our handheld Pulse CO-Oximeter®, is a compact, portable spot-check device that offers Measure-through Motion and Low Perfusion® SET® pulse oximetry and upgradeable rainbow® noninvasive monitoring technology. With the universal reusable rainbow® DCI®-mini sensor, Rad-67™ features Next Generation SpHb® technology. In June 2017, we announced the limited market release of the Rad-67™. The Rad-67™ with next generation SpHb® technology has received the CE Mark, but is not currently available for sale in the U.S.

Rad-57®. Rad-57® is a fully featured handheld Pulse CO-Oximeter® that provides continuous, noninvasive measurement of SpO_2, PR, PVi® and Pi with the ability to upgrade to SpHb®, SpCO®, SpMet® and SpOC. Its rugged and lightweight design makes it applicable for use in hospital and field settings, specifically for fire departments and emergency medical service units.

Rad-8®. Rad-8® is a bedside pulse oximeter featuring Masimo SET® (without the ability to update to rainbow® technology) in a low cost design and with a streamlined feature set.

Rad-5®/Rad-5v®. Rad-5® and Rad-5v® were Masimo's first dedicated lightweight, user-configurable, handheld pulse oximeters to provide Masimo SET® SpO_2, PR and Pi measurement (without the ability to upgrade to rainbow® technology).

Rad-G™. Rad-G™ is a low-cost, rugged, handheld pulse oximetry device with a rechargeable battery and LCD display. It uses Measure-through Motion and Low Perfusion® SET® pulse oximetry technology to measure SpO_2, PR, Pi and RRp®. Rad-G™ was designed primarily for use in pneumonia screening and spot-checking of SpO_2 in low-resource settings. Rad-G™ is not currently available for sale in the U.S.

Pronto®. Pronto® is a handheld noninvasive multiparameter testing device that uses Masimo rainbow SET™ technology to provide spot-check measurement of SpO_2, PR, Pi and SpHb® in both hospitals (i.e., emergency departments) and remote settings such as physician offices.

SatShare®. Our SatShare® technology enables a conventional monitor to receive continuous measurement updates using Masimo SET® through a simple cable connection from the back of Radical-7® to the sensor input port on the conventional monitor. No software upgrades or new modules are necessary for the upgrade, which can be completed in minutes. SatShare® allows hospitals to standardize the technology and sensors used throughout the hospital while allowing them to gain the more accurate monitoring capabilities using Masimo SET®, as well as other additional functionality, in a cost-effective manner. SatShare® technology has facilitated many hospital-wide conversions of previously installed competitor monitors to Masimo SET®. In addition, Masimo rainbow SET™ measurements such as SpHb® are available to clinicians on the Radical-7® itself while the device is being used in SatShare® mode.

MightySat® Rx. MightySat® Rx is a fingertip pulse oximeter that incorporates Masimo Measure-through Motion and Low Perfusion® SET® technology, which measures and displays SpO_2, PR and Pi with the option to add PVi® and RRp®. The MightySat® Rx (without RRp®) has received CE Mark and FDA 510(k) clearance. In February 2017, we announced the CE Mark of the RRp® measurement on the MightySat® Rx fingertip pulse oximeter.

$iSpO_2$ Rx™. The $iSpO_2$ Rx™ pulse oximeter combines a fingertip sensor, cable and pulse oximeter in a lightweight, portable device that connects directly to a smart device for displaying measurements. $iSpO_2$ Rx™ uses Measure-through Motion and Low Perfusion® SET® technology to measure SpO_2, PR and Pi. The Masimo Professional Health app, available for both iOS® and Android devices, allows clinicians to track, trend and download patient data. $iSpO_2$ Rx™

has received the CE Mark, but is not currently available for sale in the U.S.

SedLine® MOC-9® Module. Our SedLine® MOC-9® module for Root™ is an EEG-based continuous brain function monitor that provides information about a patient's response to anesthesia. Our Next Generation SedLine® enhances PSi to make it less susceptible to EMG interference and to improve performance in low-power EEG cases.

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O3® MOC-9® Module. Our O3® MOC-9® module for Root™ uses NIRS to detect regional hypoxemia by continuously measuring tissue oxygen saturation (rSO_2), automating the differential analysis of regional to central oxygen saturation.

NomoLine® Capnography and Gas Monitoring. Our gas analyzers, IRMA™ and ISA,™ are available through Root™ MOC-9® modules via OEM integration or through an emergency capnometer (EMMA®). These analyzers enable our customers to benefit from CO_2, N_2O, O_2 and anesthetic agent monitoring in many hospital environments.

uSpO_2® Cable/Board. Our SET® technology-in-a-cable contains our low power (MS-2040) technology in a reduced size, allowing it to be embedded into patient cables as part of the sensor connector.

Sensors

Sensors and Cables. We have developed one of the broadest lines of single-patient-use (disposable), reusable and rainbow® sensors and cables. In total, we have over 100 different types of sensors designed to meet virtually every clinical need. Masimo SET® sensors are uniquely designed to reduce interference from physiological and non-physiological noise. Our proprietary technology platforms operate only with our proprietary sensor lines. However, through the use of adapter cables, our sensors can be connected to certain competitor pulse oximetry monitors. We sell our sensors and cables to end-users directly or through our distributors and OEM partners.

Our single-patient-use sensors offer several advantages over reusable sensors, including improved performance, cleanliness, increased comfort and greater reliability. Our reusable sensors are primarily used for short-term, spot-check monitoring.

RD SET,™ RD rainbow SET,™ and RD rainbow Lite SET®. Our RD family of sensors is designed to maximize patient comfort, optimize clinician workflow and reduce material waste. RD sensors are lightweight with no moving parts and a flat, soft cable with smooth edges. RD sensors are available in fold-over and wrap-around styles for a variety of patient types and clinical scenarios.

SofTouch™ Sensors. SofTouch™ sensors are designed with less or no adhesive for patients with compromised skin conditions. SofTouch™ sensors are available as single-patient sensors for newborns and multi-site reusable sensors for pediatrics and adults.

Trauma and Newborn Sensors. We have developed two specialty sensor lines, for trauma and resuscitation situations, as well as for newborns. These sensors contain an identifier that automatically sets the pulse oximeter to its maximum sensitivity and fastest settings, and allow for quick application, even in wet and slippery environments. Additionally, we introduced low-profile sensors LNCS® and M-LNCS® Neo, NeoPt and Inf sensors to monitor oxygen saturation in newborns. These sensors are smaller and thinner, making them significantly more comfortable for patients and easier for clinicians to apply.

Blue® Sensors. We believe our Blue® Sensors are the first FDA-cleared sensors to accurately monitor arterial blood oxygen saturation levels in cyanotic infants and children with abnormally low oxygen saturation levels.

E1® Ear Sensor. We believe that our E1® Ear Sensor is the first single-patient-use ear sensor that can be placed securely in the ear conchae, allowing clinicians to combine Masimo SET® performance and central monitoring to provide quick access and responsive assessment of oxygenation. The E1® Ear Sensor is designed for field emergency medical services utilization.

TFA-1® Adhesive Forehead Sensor. We designed our TFA-1® forehead sensor for hospitals desiring forehead monitoring using a disposable sensor. TFA-1® combines Masimo SET® performance with quick access and responsive oxygenation assessment, and has received FDA 510(k) clearance.

rainbow® Sensors. We developed these proprietary, multi-wavelength sensors for use with our rainbow® Pulse CO-Oximetry products. In contrast to traditional sensors that only have the capability to monitor SpO_2, and PR, our rainbow® sensors can also monitor SpCO®, SpMet® and SpHb®. Our licensed rainbow SET™ sensors are the only sensors that are compatible with our licensed rainbow SET™ products. Rainbow® sensors are available in single-patient-use, and reusable spot-check sensor types.

The rainbow® DCI®-mini is the first noninvasive hemoglobin spot-check sensor for infants and small children (weight 3 to 30 kg). Paired with our handheld Pronto® or Rad-67™ devices, the rainbow® DCI®-mini sensors are designed to help clinicians quickly and easily spot-check hemoglobin levels in infants and small children, which may facilitate the

identification of anemia. When paired with Rad-67,™ the rainbow® DCI®-mini enables Next Generation SpHb® measurements. The rainbow® DCI®-mini has received CE Mark in Japan and Europe, but is not currently available for sale in the U.S. The rainbow® Super DCI®-mini sensor allows for the ability to measure SpHb®, SpCO®, SpMet® and SpO_2 on the same noninvasive reusable sensor. The rainbow® Super DCI®-mini has received CE Mark in Japan and Europe, but is not currently available for sale in the U.S.

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rainbow Acoustic® Sensors. We believe we were the first to market a continuous respiration rate monitoring technology based on an acoustic sensor placed on the patient's neck. Our rainbow Acoustic® sensors detect the sounds associated with breathing and convert the sounds into continuous respiration rate using proprietary signal processing that is based on Masimo SET®. RAS-45, our single-use acoustic respiration sensor for RAM®, is designed to facilitate placement on and improve attachment to the neck. RAS-45 operates with Masimo MX circuit boards to measure RRa® and display an acoustic respiration wave form. Like the RAS-125c sensor, RAS-45 operates with Masimo MX technology boards to measure RRa®, display the acoustic respiration wave form and optionally allow clinicians to listen to the sound of breathing. Both the RAS-45 and RAS-125c are available in CE marked countries and the U.S. for adult and pediatric patients who weigh more than 10 kg. In September 2018, we received FDA 510(k) clearance for the RAS-45 for infant and neonatal patients. With this new clearance, acoustic respiration rate measurement is now available for all patients, including neonates, in the U.S. The RAS-45 for infant and neonatal patients has not received CE mark.

SedLine® Sensor. Used with the SedLine® MOC-9® module for the Root™ patient monitoring and connectivity platform, the SedLine® sensor is a disposable sensor that collects EEG data for our SedLine® monitor. In 2017, we introduced RD SedLine® sensors, which feature a repositioned, color-coded sensor-cable connection that lies comfortably on the patient's head and soft foam pads to reduce discomfort upon application to the patient.

O3® Sensors. Used with the O3® MOC-9® module for the Root™ patient monitor, each O3® sensor contains four light-emitting diodes and two detectors to continuously measure rSO_2. In May 2017, we announced FDA 510(k) clearance for our pediatric application of O3® regional oximetry with the O3® pediatric sensor, making O3® regional oximetry monitoring available in the U.S. for both adult patients and pediatric patients weighing more than 5 kg (11 lbs) and less than 40 kg (88 lbs).

Reprocessed Sensors. We offer customers the option of using Masimo reprocessed sensors, the only sensor reprocessing solution that maintains new Masimo sensor performance specifications.

Remote Alarm and Monitoring Solutions

Masimo Patient SafetyNet. Patient SafetyNet is a supplemental remote monitoring and clinician notification system that routes bedside-generated alarms through a server to a qualified clinician's handheld paging device in real-time. Each system can support up to 200 bedside monitors and can either be integrated into a hospital's existing IT infrastructure or operate as a stand-alone wireless network. In March 2018, we announced Replica,™ an application for smart phones and tablets that works in conjunction with Patient SafetyNet.™ Replica™ allows clinicians to view continuous monitoring data for multiple patients, as well as view and respond to alarms and alerts, all from their smart phones, regardless of location.

Proprietary Measurements and Features

All of our monitors shipped since January 2006, including Radical-7® and certain future OEM products, that incorporate the MX circuit board will allow purchases of software for rainbow® measurements, as well as other future measurements. Our current rainbow® measurements include SpHb®, SpCO®, SpMet®, SpOC™ ORi,™ Pi, PR, PVi®, RPVi,™ RRp® and $SpfO_2$,™ as well as rainbow Acoustic Monitoring®, RRa®.

Halo Index.™ Currently, clinicians monitor multiple clinical parameters on each patient and interpret each measurement independently. Halo Index™ is a dynamic indicator that facilitates continuous global trending and assessment of multiple physiological measurements within a single index to quantify changes in patient status that can be displayed on the Patient SafetyNet view stations. Halo Index™ has received CE Mark, but is not currently available for sale in the U.S. In the future, subject to receipt of regulatory clearance, we expect Halo Index™ will also be available as part of our standalone devices and OEM boards. As more clinical evidence is collected on Halo Index,™ its clinical utility in a variety of care areas and patient types will become more specific.

Eve,™ our newborn screening software application for our Radical-7® Pulse CO-Oximeter®, is designed to help clinicians more effectively and efficiently screen newborns for CCHD. In the Radical-7® Pulse CO-Oximeter®, Eve™ automates the screening steps with animated instruction, including sensor application, measurement selection and screening result determination. Eve™ is intended to provide consistent application of the screening protocol to reduce method-and operator-induced variability and improve efficiency by automating the data capture and comparison

between readings. Eve™ has received CE Mark, but is currently not available for sale in the U.S.

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X-Cal®

Sensor and cable failures can prevent pulse oximeters from providing the patient safety advantages that continuous pulse oximetry monitoring is intended to provide. Our X-Cal® technology enhances patient safety and improves clinician efficiency by preserving system quality, performance and reliability and reducing the chances of bad or inferior sensors and cables being used on patients. X-Cal® technology enhances the benefits of Masimo's pulse oximetry by incorporating the means to track the expected monitoring life of our sensors and cables and provides appropriate user messaging on the host monitor.

X-Cal® addresses three common problems experienced by clinicians using an integrated Masimo system, including:

- Patient safety may be compromised by using imitation Masimo sensors and cables because they are not produced with comparable components, do not provide proper shielding from ambient interferences, create electrostatic noise caused by motion, do not have our quality and performance controls, and are not tested or warranted to work within a Masimo system;
- We design our sensors and cables to last well beyond their warranty period and customer feedback indicates our sensors and cables last significantly longer than competing products, but cable and sensor reliability may still be compromised when used beyond their intended life, affecting patient care and causing clinicians and biomedical engineers to spend time troubleshooting intermittent cable and sensor issues; and
- We believe that third-party reprocessed pulse oximetry sensors introduce challenges in the clinical environment due to potential quality issues. In fact, we believe that most third-party reprocessed sensors do not indicate that they are capable of performing in the same conditions as Masimo Measure-through Motion and Low Perfusion® sensors or in neonatal applications, key performance requirements available with Masimo SET® sensors. To the best of our knowledge, no third-party company has attempted to reprocess rainbow SET™ sensors.

Connectivity

Iris® connectivity on Root™ allows third-party devices, such as intravenous pumps and ventilators, to connect to Root™ enabling display of measurements and notification on the Root™ monitor, with the ability to document results in the EMR through Masimo Patient SafetyNet.

Iris Gateway® bridges the gap between device data generated at the patient bedside and documentation in patient data management systems by automatically transferring data from medical devices to EMRs, improving productivity and reducing the likelihood of transcription errors.

Kite® provides a supplemental display of data from a Masimo device on a compatible smart television and allows clinicians to configure the display differently than that of the connected Masimo device. Kite® integrates into existing hospital infrastructures where a supplementary display may be beneficial, such as the operating room.

UniView™ provides a supplemental, integrated display of real-time data and alarms from multiple Masimo and third-party devices. UniView™ is designed to reduce clinician cognitive overload and promote data sharing among multiple clinicians, helping them to spot trends and coordinate care.

Data Analysis & Reporting

Trace™ is the first data visualization and reporting software compatible with the full capabilities of the 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, ISA™ and ISA™ OR+ capnography, and O3® regional oximetry. Trace™ can create insightful, easy-to-read patient reports that include parameter trends, histograms, event annotations, and key statistics. Trace™ can communicate with Masimo devices via high-speed wired or wireless connections, with the ability to transfer up to 96 hours of patient data.

Consumer Products

MightySat®, our fingertip pulse oximeter for personal use provides SpO_2, PR and Pi measurements for health and wellness applications. MightySat®, which is also available with RRp® and PVi®, provides measurements in a compact, battery-powered design with a large color screen that can be rotated for real-time display of the measurements. Bluetooth® wireless functionality enables measurement display via a free, downloadable Masimo Personal Health application on iOS® and Android mobile devices, as well as the ability to trend and communicate

measurements, including the Apple Health Kit. MightySat® is available through consumer retailers and directly from Masimo, and is intended for general health and wellness use only. MightySat® is not intended for medical use.

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$iSpO_2$® is a personal use pulse oximeter that combines a fingertip sensor, cable and pulse oximeter in a lightweight, portable device that connects directly to a smart device for displaying measurements. $iSpO_2$® uses Measure-through Motion and Low Perfusion® SET® technology to measure SpO_2, PR and Pi. The Masimo Personal Health app, available for both iOS® and Android devices, allows users to track, trend and download their data, as well as share it with the Apple Health app. $iSpO_2$® is available through consumer retailers and directly from Masimo and is intended for general health and wellness use only. $iSpO_2$® is not intended for medical use.

Cercacor Laboratories, Inc.

Cercacor is an independent entity spun-off from us to our stockholders in 1998. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Cercacor. We are a party to a cross-licensing agreement with Cercacor, which was amended and restated effective January 1, 2007 (the Cross-Licensing Agreement), which governs each party's rights to certain intellectual property held by the two companies.

The following table outlines our rights under the Cross-Licensing Agreement relating to specific end user markets and the related technology applications of specific measurements.

Measurements	End User Markets Professional Caregiver and Alternate Care Market	Patient and Pharmacist
Vital Signs[1]	Masimo (owns)	Cercacor (non-exclusive license)
Non-Vital Signs[2]	Masimo (exclusive license)	Cercacor (owns or exclusive license)

(1) Vital Signs measurements include, but are not limited to, SpO_2, peripheral venous oxygen saturation, mixed venous oxygen saturation, fetal oximetry, sudden infant death syndrome, ECG, blood pressure (noninvasive blood pressure, invasive blood pressure and continuous noninvasive blood pressure), temperature, respiration rate, CO_2, pulse rate, cardiac output, EEG, perfusion index, depth of anesthesia, cerebral oximetry, tissue oximetry and/or EMG, and associated features derived from these measurements, such as 3D alarm®, PVi® and other features.

(2) Non-Vital Signs measurements include the body fluid constituents other than vital signs measurements and include, but are not limited to, carbon monoxide, methemoglobin, blood glucose, hemoglobin and bilirubin.

Our License to Cercacor. We granted Cercacor an exclusive, perpetual and worldwide license, with sublicense rights, to use our Masimo SET® technology, including all improvements, for the monitoring of non-vital signs measurements and to develop and sell devices incorporating Masimo SET® for monitoring non-vital signs measurements in the "Cercacor Market". The Cercacor Market consists of any product market in which a product is intended to be used by a patient or pharmacist rather than a professional medical caregiver regardless of the particular location of the sale, including sales to doctors, hospitals, alternate care market professionals or otherwise, provided the product is intended to be recommended, or resold, for use by the patient or pharmacist. We also granted Cercacor a non-exclusive, perpetual and worldwide license, with sublicense rights, to use Masimo SET® for the measurement of vital signs in the Cercacor Market. In exchange, Cercacor pays us a 10% royalty on the amount of vital signs sensors and accessories sold by Cercacor.

Cercacor's License to us. We exclusively license from Cercacor the right to make and distribute products in the "Masimo Market" that utilize rainbow® technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation, and hemoglobin, which includes hematocrit. The Masimo Market consists of any product market where the product is intended to be used by a professional medical caregiver, including hospital caregivers, surgicenter caregivers, paramedic vehicle caregivers, doctors' offices caregivers, alternate care facility caregivers and vehicles where alternative care services are provided. We also have the option to obtain exclusive licenses to make and distribute products in the Masimo Market that utilize rainbow® technology for the monitoring of

other non-vital signs measurements, including blood glucose. We have 180 days after proof of feasibility to exercise the above-referenced option to obtain a license for the measurement of blood glucose for an additional $2.5 million and licenses for other non-vital signs measurements for an additional $0.5 million each. The licenses are exclusive until the later of 20 years from the grant of the applicable license or the expiration of the last patent included in the rainbow® technology related to the applicable measurements. To date, we have developed and commercially released devices that measure carbon monoxide, methemoglobin and hemoglobin using licensed rainbow® technology. We also make and distribute products that monitor respiration rate via rainbow Acoustic Monitoring®, which is a Masimo-developed rainbow® technology and, therefore, is not required to be licensed from Cercacor.

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Our license to use rainbow® technology for these measurements in these markets is exclusive on the condition that we continue to pay Cercacor royalties on our products incorporating rainbow® technology, subject to certain minimum aggregate royalty thresholds, and that we use commercially reasonable efforts to develop or market products incorporating the licensed rainbow® technology. The royalty is up to 10% of the rainbow® royalty base, which includes handhelds, tabletop and multiparameter devices. Handheld products incorporating rainbow® technology carry a 10% royalty rate. For other products, only the proportional amount attributable to that portion of our devices used to monitor non-vital signs measurements, rather than to monitor vital signs measurements, and sensors and accessories for measuring only non-vital sign parameters are included in the 10% rainbow® royalty base. For multiparameter devices, the rainbow® royalty base includes the percentage of the revenue based on the number of rainbow®-enabled measurements. For hospital contracts where we place equipment and enter into a sensor contract, we pay a royalty to Cercacor on the total sensor contract revenue based on the ratio of rainbow®-enabled devices to total devices. During the year ended December 29, 2018 and going forward, we are subject to certain specific annual minimum aggregate royalty payment obligations of $5.0 million per year.

Change in Control. The Cross-Licensing Agreement provides that, upon a change in control:

- if the surviving or acquiring entity ceases to use “Masimo” as a company name and trademark, all rights to the “Masimo” trademark will be assigned to Cercacor;
- the option to license technology developed by Cercacor for use in blood glucose monitoring will be deemed automatically exercised and a $2.5 million license fee for this technology will become immediately payable to Cercacor; and
- the minimum aggregate annual royalties payable to Cercacor for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, hemoglobin and/or glucose will increase to $15.0 million per year until the exclusivity period of the agreement ends, plus up to $2.0 million for each additional measurement with no maximum ceiling for non-vital sign measurements.

For purposes of the Cross-Licensing Agreement, a change in control includes any of the following with respect to us or Cercacor:

- the sale of all or substantially all of either company’s assets to a non-affiliated third-party;
- the acquisition by a non-affiliated third-party of 50% or more of the voting power of either company;
- Joe Kiani, our Chief Executive Officer and the Chief Executive Officer of Cercacor, resigns or is terminated from his position with either company; or
- the merger or consolidation of either company with a non-affiliated third-party.

Ownership of Improvements. Any improvements to Masimo SET® or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third-party that relates to non-vital signs monitoring, and any new technology acquired by Cercacor, is and will be owned by Cercacor. Any improvements to the Masimo SET® platform or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third-party that relates to vital signs monitoring, and any new technology acquired by us, is and will be owned by us. However, for both non-vital signs and vital signs monitoring, any improvements to the technology, excluding acquired technology, will be assigned to the other party and will be subject to the terms of the licenses granted under the Cross-Licensing Agreement. Any new non-vital signs monitoring technology utilizing Masimo SET® that we develop will be owned by Cercacor and will be subject to the same license and option fees as if it had been developed by Cercacor. Also, we will not be reimbursed by Cercacor for our expenses relating to the development of any such technology.

Other Agreements with Cercacor. We have also entered into various other agreements with Cercacor, including an Administrative Services Agreement, a Consulting Services Agreement and a Sublease Agreement. See Note 3 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on these agreements and other transactions with Cercacor.

As a result of changes in the capital structure of Cercacor, as well as certain of its contractual relationships with us, we completed a re-evaluation of the authoritative consolidation guidance during the year ended December 31, 2016 and determined that, although Cercacor remains a variable interest entity, we are no longer its primary beneficiary. Based on such determination, we discontinued consolidating Cercacor within our consolidated financial statements effective

as of January 3, 2016. See Note 3 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information.

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Government Regulation

As a global medical technology company, we are subject to significant government regulation, compliance requirements, fees and costs, both in the U.S. and abroad. These regulatory requirements subject our products and our business to numerous risks that are specifically discussed within "Risks Related to Our Regulatory Environment" under Part I, Item 1A—"Risk Factors" within this Annual Report on Form 10-K. A summary of certain critical aspects of our regulatory environment is included below.

U.S. Food and Drug Administration (FDA) Premarket Clearance and Approval Requirements

The FDA and other federal, state and local authorities regulate our products and product-related activities. Pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA) and the regulations promulgated under that Act, the FDA regulates the design, development, clinical trials, testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices. We endeavor to ensure that our products and procedures remain in compliance with all applicable FDA regulations, but the regulations regarding the manufacture and sale of our products are subject to change. We cannot predict the effect, if any, that these changes might have on our business, financial condition and results of operations. Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive from the FDA either clearance of a 510(k) premarket notification, or approval of a premarket application (PMA). Alternatively, the device may be cleared by the FDA through the de novo classification process.

The FDA's 510(k) clearance process usually takes from four to nine months, but it can take longer. The process of obtaining PMA approval or de novo classification is much more costly, lengthy and uncertain than the process of obtaining 510(k) clearance. We cannot be sure that 510(k) clearance, PMA approval or de novo classification will be obtained for any product we propose to market on a timely basis or at all. In addition, if the FDA discovers that an applicant has submitted false or misleading information, the FDA may refuse to review submissions until certain requirements are met pursuant to its Application Integrity Policy.

Although an applicant may initially choose whether to submit a 510(k) notification for clearance, a PMA for approval or a de novo classification request, the FDA decides which pathway is appropriate based upon the classification of the device. Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's general regulatory controls (General Controls) for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation (QSR), facility registration and product listing, reporting of adverse medical events and malfunctions, reporting of corrections and removals, and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Only specified Class I devices, including devices with software, are subject to the design controls requirements of the QSR; other Class I devices are exempt from design control requirements. Some Class I devices are also exempt from many of the good manufacturing practice requirements of the QSR by regulation. While most Class I devices are exempt from the 510(k) premarket notification process, some Class I devices also require 510(k) clearance by the FDA.

Class II devices are subject to the FDA's General Controls, including the Design Control requirements of the QSR, and other special controls deemed necessary by the FDA to provide reasonable assurance of the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure, although some Class II devices are exempt from the premarket notification requirement. The majority of our current regulated devices are classified as Class II devices, while only a few are classified as Class I devices.

To obtain 510(k) clearance, a company must submit a premarket notification demonstrating substantial equivalence between the proposed device and a legally marketed "predicate" device. A "predicate device" is a legally marketed device that (i) was legally marketed prior to May 28, 1976, for which the FDA has not yet called for submission of a PMA application; (ii) has been reclassified by the FDA from Class III to Class II or Class I; (iii) has been cleared through the 510(k) premarket notification process; or (iv) previously has been determined to be exempt from the 510(k) process. The proposed device is substantially equivalent to the predicate device if the proposed device has the same intended use and the same technological characteristics as the predicate device, or, if the proposed device has different technological characteristics, the proposed device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness. After a device receives 510(k) clearance, any modification that could

significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, requires a new 510(k) clearance or, if the modified device is not substantially equivalent to the unmodified device, could require a PMA approval or de novo classification. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review this decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, PMA approval or de novo classification, the agency may retroactively require the manufacturer to seek 510(k) clearance, PMA approval or de novo classification. The FDA can also require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance, PMA approval or de novo classification is obtained.

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Class III devices are those deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or those devices deemed not substantially equivalent to a legally marketed predicate device. Due to the risk level associated with Class III devices, the FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of the device. These Class III devices must be approved through the PMA approval process during which the manufacturer must provide reasonable assurance of safety and effectiveness for the intended use(s) of the device to the FDA's satisfaction. A PMA application must be supported by valid scientific evidence, including extensive preclinical (including bench tests and laboratory and animal studies) and clinical studies as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. As part of the PMA application review, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the FDA's QSRs. If the FDA approves the PMA, it may place restrictions on the device or the labeling or require additional clinical studies, monitoring or other post-market requirements. If the FDA's evaluation of the PMA application or the manufacturing facility is not favorable, the FDA may deny approval of the PMA application or issue a "not approvable" letter. The FDA may also require additional clinical trials, which can delay the PMA approval process by several years or otherwise make obtaining PMA approval infeasible. None of our products are currently approved under a PMA.

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application or de novo classification request. Clinical trials involving a "significant risk" device require FDA approval of an Investigational Device Exemption (IDE) application, unless the proposed study is deemed to be exempt from the IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, protocols for the proposed clinical trials and other information demonstrating that the device is appropriate for use with humans in a clinical study. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards (IRBs) at the clinical trial sites. Submission of an IDE application does not give assurance that the FDA will issue the IDE. If the IDE application is approved, there can be no assurance the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. If the study meets the requirements for a non-significant risk study, it may be eligible for compliance with "abbreviated" IDE requirements, which include a subset of the requirements applicable to significant risk medical devices studies. Sponsors of non-significant risk studies must obtain IRB approval but are not required to obtain FDA approval of an IDE application. Sponsors of both significant risk and non-significant risk trials must comply with the FDA's regulations, including the requirement that informed consent be obtained from each subject, and with clinical trial reporting regulations that require submission of information about certain clinical trials to a public database maintained by the National Institutes of Health. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance, approval or classification of the device.

We believe that our OEM partners may be required to obtain 510(k) clearance from the FDA for certain of their products that incorporate Masimo SET® technology, Masimo rainbow SET™ technology, Masimo Board-in-Cable technology or Masimo sensors. In order to facilitate receipt of 510(k) clearance by our OEM partners for their products that incorporate Masimo SET® or Masimo rainbow SET™ boards and sensors, we grant our OEM partners a right to cross-reference the 510(k) submission files from our cleared Masimo SET® circuit boards, sensors, cables and notification systems.

We market our iSpO2® pulse oximeter and MightySat® fingertip pulse oximeter for general health and wellness use. We are marketing these products in accordance with the FDA's current policy and enforcement discretion which indicates that pulse oximeters that are not intended for medical purposes can be marketed directly to consumers without first obtaining 510(k) clearance. We cannot assure you that the FDA will not change its policy regarding the regulation of these products. If the FDA changes its policy, we may be required to seek 510(k) clearance to market

these pulse oximeters. We also may be required to cease marketing and/or recall the products until we obtain new 510(k) clearances.

The regulatory regime is subject to change by Congress or the FDA. For example, in December 2016, Congress enacted the 21st Century Cures Act (Cures Act), which contained several provisions related to the review and approval of new medical technologies. Along with other changes, the Cures Act established a statutory program for "breakthrough" devices, defined as devices intended to treat or diagnose a life-threatening or irreversibly debilitating disease that represents a breakthrough technology, devices that have no approved/cleared alternatives, devices that offer significant advantages over approved/cleared alternatives, or devices where the availability of such device is in the best interest of patients. The FDA will apply additional resources to help speed the approval or clearance of devices that are designated as breakthrough devices. The Cures Act also included provisions related to the "least burdensome" principle and expanded the number of patients that could be treated using a device approved under a Humanitarian Device Exemption, among other provisions. Furthermore, in August 2017, Congress enacted the FDA Reauthorization Act of 2017 (FDARA).

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Although FDARA principally reauthorized the FDA user fee programs, it also included, among other things, provisions that establish processes for the initial classification and reclassification of accessory devices, i.e., devices used with a parent device.

User Fees

Unless a specific exemption or waiver applies, 510(k) submissions, de novo classification requests, and PMA applications are subject to user fees. The PMA and de novo classification user fees are significantly higher than the user fees for 510(k) notifications. The FDA was reauthorized to assess medical device user fees through fiscal year 2022 pursuant to FDARA.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, it continues to be subject to the FDA's regulatory authority. The FDA regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- unique device identification (UDI) registration, which identifies medical devices through their distribution and use;
- QSRs and current good manufacturing practices (GMPs), which require manufacturers, including third-party manufacturers, to follow stringent design control, testing, change control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process, including requirements for packaging, labeling and record keeping, complaint handling, corrective and preventive actions and internal auditing;
- labeling control and advertising regulations, including FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses or indications;
- for 510(k)-cleared devices, clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change or modification in intended use of one of our cleared devices;
- for any future PMA approved products, approval of product modifications that affect the safety or effectiveness of the device;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- for any future PMA approved products, post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of its conditions of approval, governing laws and/or regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

We must register with the FDA as a medical device manufacturer, list all products placed in commercial distribution and obtain all necessary state permits, licenses or other authorizations to operate our business. As a manufacturer, we are subject to announced and unannounced inspections by the FDA to determine our compliance with the FDA's QSR and other regulations. Our OEM partners also are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements.

If the FDA finds that we or one of our OEM partners have failed to comply with the FDA's QSR, the agency can institute a wide variety of enforcement and other regulatory actions, including:

- an FDA Form 483, which is issued by the FDA at the conclusion of an inspection when an investigator has observed any conditions that may constitute potential violations of the FDCA and related Acts;
- a public warning letter that notifies a company of potential violations of the FDCA;
- fines and monetary civil penalties against us and/or OEM partners;
- delays in clearing or approving, or refusal to clear or approve, our products;
-

withdrawal or suspension of clearances and/or approvals of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

- product recall;

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- product detention or seizure;
- interruption of production;
- refusal to provide Certificates to Foreign Governments (CFGs), which may be necessary to permit the export of devices from the U.S. to other countries;
- operating restrictions;
- injunctions (including those agreed to in a consent decree); and
- criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device manufactured or distributed by us.

Advertising and Promotion

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission (FTC) and by federal and state regulatory and enforcement authorities, including the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and various state attorneys general. Although physicians are permitted to use their medical judgment to use medical devices for indications other than those cleared or approved by the FDA, we may not promote our products for such "off-label" uses and can only market our products for cleared or approved uses.

Other companies' promotional activities for their FDA-regulated products have been the subject of FTC enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. FTC enforcement actions often result in consent decrees that constrain future actions. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

Import and Export Requirements

To import a device, the importer must file an entry notice and bond with the United States Bureau of Customs and Border Protection (CBP). All devices are subject to FDA examination before release from CBP. Any article that appears to be in violation of the FDCA may be refused admission and a notice of detention and hearing may be issued. If the FDA ultimately refuses admission, the CBP may issue a notice for redelivery and, if a company fails to redeliver the goods or otherwise satisfy CBP and the FDA with respect to their disposition, may assess liquidated damages for up to three times the value of the lot. The CBP also imposes its own regulatory requirements on the import of our products, including inspection and possible sanctions for noncompliance.

Products exported from the United States are subject to foreign countries' import requirements and the exporting requirements of the FDA or European regulating bodies, as applicable. In particular, international sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Foreign countries often require, among other things, a CFG for export. To obtain a CFG, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities were in compliance with the FDA's QSR regulations at the time of the last FDA inspection.

Foreign Regulation Regarding Clearance and Approval

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance and the requirements may differ.

In particular, marketing of medical devices in the European Union (EU) is subject to compliance with the Medical Devices Directive 93/92/EEC (MDD). A medical device may be placed on the market within the EU only if it conforms to certain "essential requirements" and bears the CE Mark. The most fundamental and essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the essential performance(s) intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

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Manufacturers must demonstrate that their devices conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. The classification rules are mainly based on three criteria: the length of time the device is in contact with the body, the degree of invasiveness and the extent to which the device affects the anatomy. Conformity assessment procedures for all but the lowest risk classification of device involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Manufacturers usually have some flexibility to select a notified body for the conformity assessment procedures for a particular class of device and to reflect their circumstances, e.g., the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer's quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE Mark. Application of the CE Mark allows the general commercializing of a product in the EU. The product can also be subjected to local registration requirements depending on the country. We maintain CE Marking on all of our products that require such markings as well as local registrations as required.

In May 2017, the EU adopted a new Medical Devices Regulation (EU) 2017/745 (MDR), which will repeal and replace the MDD with effect from May 26, 2020. The MDR clearly envisages, among other things, stricter controls of medical devices, including strengthening of the conformity assessment procedures, increased expectations with respect to clinical data for devices and pre-market regulatory review of high-risk devices. The MDR also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2020 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU.

Medical Device Tax

The Affordable Care Act (ACA) also imposed a significant new tax on medical device makers in the form of a 2.3% excise tax on U.S. medical device sales, with certain exemptions (MDET). For the year ended January 2, 2016, we recorded $6.9 million in medical device taxes that were included in selling, general and administrative expenses. The MDET is currently suspended through December 31, 2019. The tax may be reimposed on medical device makers beginning on January 1, 2020 if the suspension is not re-extended or the medical device tax is not permanently repealed.

Conflict Minerals and Supply Chain

We are subject to certain SEC rules adopted pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act concerning "conflict minerals" (generally tin, tantalum, tungsten and gold) and similar rules are under consideration by the EU. Certain of these conflict minerals are used in the manufacture of our products. Although the rules are being challenged in court, in their present form they require us to investigate the source of any conflict minerals necessary to the production or functionality of our products. If any such conflict minerals originated in the Democratic Republic of the Congo or adjoining countries (the DRC region), we must undertake comprehensive due diligence to determine whether such minerals financed or benefited armed groups in the DRC region. Since our supply chain is complex, our ongoing compliance with these rules could affect the pricing, sourcing and availability of conflict minerals used in the manufacture of our products.

We are also subject to disclosure requirements regarding abusive labor practices in portions of our supply chain under the California Transparency in Supply Chains Act.

Environmental

Our manufacturing processes involve the use, generation and disposal of solid wastes, hazardous materials and hazardous wastes, including silicone adhesives, solder and solder paste, sealants, epoxies and various solvents such as methyl ethyl ketone, acetone and isopropyl alcohol. As such, we are subject to stringent federal, state and local laws relating to the protection of the environment, including those governing the use, handling and disposal of hazardous

materials and wastes. Products that we sell in Europe are subject to regulation in EU markets under the Restriction of Hazardous Substances Directive (RoHS). RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in EU member states. In addition, the EU's Regulation-Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products.

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Future environmental laws may require us to alter our manufacturing processes, thereby increasing our manufacturing costs. We believe that our products and manufacturing processes at our facilities comply in all material respects with applicable environmental laws and worker health and safety laws; however, the risk of environmental liabilities cannot be completely eliminated.

Health Care Fraud and Abuse

In the U.S., there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. For example, the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the referral of patients for, or the purchase, order or recommendation of, health care products and services reimbursed by a federal health care program, including Medicare and Medicaid. Recognizing that the federal anti-kickback law is broad and potentially applicable to many commonplace arrangements, Congress and the Office of Inspector General (OIG) within the Department of Health and Human Services have created statutory “exceptions” and regulatory “safe harbors”. Exceptions and safe harbors exist for a number of arrangements relevant to our business, including, among other things, payments to bona fide employees, certain discount and rebate arrangements, and certain payment arrangements involving Group Purchasing Organizations (GPOs). Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the law, but the OIG or other government enforcement authorities may examine the practice to determine whether it involves the sorts of abuses that the statute was designed to combat. Violations of this federal law can result in significant penalties, including imprisonment, monetary fines and assessments, and exclusion from Medicare, Medicaid and other federal health care programs. Exclusion of a manufacturer, like us, would preclude any federal health care program from paying for its products. In addition to the federal anti-kickback law, many states have their own laws that are analogous to the federal anti-kickback law, but may apply regardless of whether any federal or state health care program business is involved. Federal and state anti-kickback laws may affect our sales, marketing and promotional activities, educational programs, pricing and discount practices and policies, and relationships with health care providers by limiting the kinds of arrangements we may have with hospitals, alternate care market providers, GPOs, physicians, payers and others in a position to purchase or recommend our products.

Federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payers that are false or fraudulent. For example, the Federal Civil False Claims Act (31 U.S.C. § 3729 et seq.) imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and Medicare. Some suits filed under the False Claims Act, known as “qui tam” actions, can be brought by a “whistleblower” or “relator” on behalf of the government and such individuals may share in any amounts paid by the entity to the government in fines or settlement. Manufacturers, like us, can be held liable under false claims laws, even if they do not submit claims to the government, where they are found to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements or off-label promotion with customers that file claims. A number of states also have false claims laws, and some of these laws may apply to claims for items or services reimbursed under Medicaid and/or commercial insurance. Sanctions under these federal and state fraud and abuse laws may include civil monetary penalties and criminal fines, exclusion from government health care programs and imprisonment.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created new federal crimes, including health care fraud and false statements related to health care matters. The health care fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program, including those offered by private payers. The false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of either statute is a felony and may result in fines, imprisonment and other significant penalties.

The Physician Payment Sunshine Act (Sunshine Act), which was enacted by Congress as part of the ACA, requires medical device companies to track and publicly report, with limited exceptions, all payments and transfers of value to physicians and teaching hospitals in the U.S. Companies are required to track payments made and to report such payments to the government by March 31 of each year. Several states have similar requirements.

The Foreign Corrupt Practices Act of 1977 and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

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Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect many of the arrangements we have with customers and physicians. Therefore, our risk of being found in violation of these laws is increased by the fact that some of these laws are broad and open to interpretation.

Privacy and Security of Health and Other Personal Information

Numerous federal, state and international laws and regulations, including HIPAA and General Data Protection Regulation (GDPR), govern the collection, use and disclosure of patient-identifiable, protected health information (PHI) and other personal information. In the U.S., HIPAA applies to covered entities, which include most healthcare facilities that purchase and use our products, and their business associates. The HIPAA Privacy Rule restricts the use and disclosure of PHI, and requires covered entities and their business associates to safeguard that information and to provide certain rights to individuals with respect to that information. The HIPAA Security Rule establishes detailed requirements for safeguarding PHI transmitted or stored electronically. Although we are not a covered entity, we are sometimes deemed to be a business associate of covered entities due to activities that we perform for or on behalf of covered entities, such as training customers on the use of our products or investigating product performance. As business associates, we are subject to many of the requirements of HIPAA and could be directly subject to HIPAA civil and criminal enforcement and the associated penalties for violation of the Privacy, Security and Breach Notification Rules.

The HIPAA standards also apply to the use and disclosure of PHI for research and generally require the covered entity performing the research to obtain the written authorization of the research subject (or an appropriate waiver) before providing that subject's PHI to sponsors like us for purposes related to the research. These covered entities also typically impose contractual limitations on our use and disclosure of the PHI they disclose to us. We may be required to make costly system modifications to comply with the privacy and security requirements that will be imposed on us and our failure to comply may result in liability and adversely affect our business.

Numerous other federal and state laws protect the confidentiality of PHI, including state medical privacy laws and federal and state consumer protection laws. These various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability.

Other countries also have, or are developing, laws governing the collection, use and transmission of health information, and these laws could create liability for us or increase our cost of doing business.

Third-Party Reimbursement

Health care providers, including hospitals, that purchase our products generally rely on third-party payers, including the Medicare and Medicaid programs and private payers, including indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of the products and the procedures in which they are used. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payers. No uniform coverage or reimbursement policy for medical technology exists among all third-party payers, and coverage and reimbursement can differ significantly from payer to payer.

The Centers for Medicare & Medicaid Services (CMS) is the federal agency responsible for administering the Medicare program. Along with its contractors, CMS establishes the coverage and reimbursement policies for the Medicare program. Because a large percentage of our products are used in the treatment of elderly or disabled individuals who are Medicare beneficiaries, Medicare's coverage and reimbursement policies are particularly significant to our business. In addition, private payers often follow the coverage and reimbursement policies of Medicare.

In general, Medicare will cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage. For example, several Medicare local

contractors have issued policies that restrict coverage for pulse oximetry in hospital inpatient and outpatient settings to a limited number of conditions, including limiting coverage to patients who (i) exhibit signs of acute respiratory dysfunction, (ii) have chronic lung disease, severe cardiopulmonary disease or neuromuscular disease involving the muscles of respiration, (iii) are under treatment with a medication with known pulmonary toxicity, or (iv) have sustained multiple trauma or complaints of acute chest pain.

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Reimbursement for our products may vary not only by the type of payer involved but also based upon the setting in which the product is furnished and utilized. For example, Medicare payment may be made, in appropriate cases, for patient stays in the hospital inpatient and outpatient settings involving the use of our products. Medicare generally reimburses hospitals based upon prospectively determined amounts. For hospital inpatient stays, the prospective payment generally is determined by the patient's condition and other patient data and procedures performed during the inpatient stay, using a classification system known as Medicare Severity Diagnosis-Related Groups (MS-DRGs). Prospective rates are adjusted for, among other things, regional differences, co-morbidity and complications. Hospitals generally do not receive separate Medicare reimbursement for the specific costs of purchasing our products for use in the inpatient setting. Rather, Medicare reimbursement for these costs is deemed to be included within the prospective payments made to hospitals for the inpatient services in which the products are utilized.

In contrast, some differences may be seen in the reimbursement for use of our products in hospital outpatient departments. In this setting, Medicare payments also are generally made under a prospective payment system based on the ambulatory payment classifications (APCs) under which individual items and procedures are categorized. Hospitals receive the applicable APC payment rate for the procedure regardless of the actual cost for such treatment. Some outpatient services such as oximetry services do not receive separate reimbursement. Rather, their reimbursement is deemed packaged into the APC for an associated procedure and the payment for that APC does not vary whether or not the packaged procedure is performed. Some procedures also are paid through composite APCs, which are APCs that establish a payment rate that applies when a specific combination of services is provided. Reimbursement for certain pulse oximetry monitoring services, including those using our products, may be separately payable when they are the only service provided to the patient on that day, packaged if provided with certain critical care services, or reimbursed through a composite APC when provided in connection with certain other services. Because payments through the Prospective Payment System in both the hospital inpatient and outpatient settings are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, hospitals have incentives to lower their operating costs by utilizing products that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs. If hospitals cannot obtain adequate coverage and reimbursement for our products, or the procedures in which they are used, we cannot be certain that they will purchase our products, despite the clinical benefits and opportunity for cost savings that we believe can be derived from their use.

Our success with rainbow SET™ technologies in U.S. settings of care with reimbursable monitoring procedures, such as hospital emergency departments, hospital procedure labs, and the physician office may largely depend on the ability of providers to receive reimbursement for such procedures. While private insurance payers often follow Medicare coverage and payment, we cannot be certain of this and, in many cases, cannot control the coverage or payment rates that private insurance payers put in place. In addition, the potential amendment, repeal or judicial invalidation of the ACA, and/or the enactment of other legislation or regulations, could affect future payment for services involving the use of our products.

Our success in non-U.S. markets depends largely upon the availability of coverage and reimbursement from the third-party payers through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payer government managed systems, as well as systems in which private payers and government managed systems exist side-by-side. Our ability to achieve market acceptance or significant sales volume in international markets we enter will be dependent in large part on the availability of reimbursement for procedures performed using our products under health care payment systems in such markets.

Other U.S. and Foreign Regulation

We and our OEM partners also must comply with numerous federal, state and local laws, as well as laws in other jurisdictions, relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substance disposal. We cannot be sure that we will not be required to incur significant costs to comply with these laws and regulations in the future or that these laws or regulations will not hurt our business, financial condition and results of operations. Unanticipated changes in existing regulatory requirements or adoption of new requirements could hurt our business, financial condition and results of operations.

Competition

The medical device industry is highly competitive and many of our competitors have substantially greater financial, technical, marketing and other resources than we do. While we regard any company that sells pulse oximeters as a potential customer, we also recognize that the companies selling pulse oximeters on an OEM basis and/or pulse oximetry sensors are also potential competitors. Our primary competitor, Medtronic plc (Medtronic, formerly Covidien Ltd.), currently holds a substantial share of the pulse oximetry market.

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Medtronic sells its own brand of Nellcor pulse oximeters to end-users, sells pulse oximetry modules to other monitoring companies on an OEM basis, and licenses to certain OEMs the right to make their pulse oximetry platforms compatible with their sensors. We also face substantial competition from larger medical device companies, including companies that develop products that compete with our proprietary Masimo SET® and our OEM partners. We believe that a number of companies have announced products that claim to offer motion-tolerant accuracy. Pursuant to the terms of the Third Amendment to Settlement Agreement and Release of Claims effective September 2016, Medtronic discontinued paying royalties to us for its sales after October 6, 2018. In addition, some of our patents have expired and other will expire over time in accordance with the laws of the jurisdiction in which they were issued.

We believe that the principal competitive factors in the market for pulse oximetry products include:

- accurate monitoring during both patient motion and low perfusion;
- ability to introduce other clinically beneficial measurements related to oxygenation and respiration, such as noninvasive and continuous oxygen reserve index and hemoglobin;
- competitive pricing, including bundling practices;
- brand recognition and perception of innovation abilities;
- sales and marketing capability;
- access to hospitals which are members of GPOs;
- access to integrated delivery networks;
- access to OEM partners; and
- patent protection.

Sales and Marketing

We have sales and marketing employees in the U.S. and abroad. We expect to moderately increase our worldwide sales and sales support organizations as we continue to expand our presence throughout both the U.S. and the world, including Europe, the Middle East, Asia, Latin America, Canada and Australia. We currently sell all of our medical products both directly to hospitals and the alternate care market via our sales force and certain distributors. We sell our non-medical/consumer products through e-commerce Internet sites such as www.masimopersonalhealth.com and www.amazon.com.

The primary focus of our sales representatives is to facilitate the conversion of competitor accounts to our Masimo SET® pulse oximetry and rainbow SET™ Pulse CO-Oximetry® products, to expand the use of Masimo SET® and Patient SafetyNet on the general floor and to create and expand the use of rainbow® measurements in both critical care and non-critical care areas. In addition to sales representatives, we employ clinical specialists to work with our sales representatives to educate end-users on the benefits of Masimo SET® and assist with the introduction and implementation of our technology and products to their sites. Our sales and marketing strategy for pulse oximetry has been and will continue to be focused on building end-user awareness of the clinical and cost-saving benefits of our Masimo SET® platform. More recently, we have expanded this communication and educational role to include our Masimo rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring® products, including hemoglobin, carboxyhemoglobin, methemoglobin, PVi®, acoustic respiration rate and Halo Index.™

For the year ended December 29, 2018, two just-in-time distributors, Owens & Minor and Cardinal Health, represented approximately 10.0% and 12.5%, respectively, of our total revenue. These were the only two customers that represented 10% or more of our revenue for the year ended December 29, 2018. Importantly, these two distributors take and fulfill orders from our direct customers, many of which have signed long-term sensor purchase agreements with us. As a result, in the event a specific just-in-time distributor is unable to fulfill these orders, the orders would be redirected to other distributors or fulfilled directly by us.

Additionally, we sell certain of our products through our OEM partners who both incorporate our boards into their monitors and resell our sensors to their customers' installed base of Masimo SET® products. Our OEM agreements allow us to expand the availability of Masimo SET® through the sales and distribution channels of each OEM partner. To facilitate clinician awareness of Masimo SET® installations, all of our OEM partners have agreed to place the Masimo SET® logo prominently on their instruments.

In order to facilitate our U.S. direct sales to hospitals, we have signed contracts with what we believe to be the five largest national GPOs in the U.S., based on the total volume of negotiated purchases. In return for the GPOs putting our products on contract, we have agreed to pay the GPOs a percentage of our revenue from their member hospitals. In 2018 and 2017, revenue from the sale of our pulse oximetry products to hospitals that are associated with GPOs amounted to $470.5 million and $417.0 million, respectively.

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Our marketing efforts are designed to build end-user awareness through digital and print advertising, direct mail and trade shows. In addition, we distribute published clinical studies, provide product education for doctors, nurses, biomedical engineers and respiratory therapists and assist with product evaluations.

Intellectual Property

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect our intellectual property.

We have developed a patent portfolio internally, and, to a lesser extent, through acquisitions and licensing, that covers many aspects of our product offerings. As of December 29, 2018, we had 644 issued patents and 353 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. Our patents expire in accordance with the laws of the particular jurisdiction in which they were issued, which sometimes change. Additionally, as of December 29, 2018, we owned 81 U.S. registered trademarks and 248 foreign registered trademarks, as well as trade names that we use in conjunction with the sale of our products. Our trademarks are perpetually renewable.

Under the Cross-Licensing Agreement, we and Cercacor have agreed to allocate proprietary ownership of technology developed based on the functionality of the technology. We will have proprietary ownership, including ownership of all patents, copyrights and trade secrets, of all technology related to the noninvasive monitoring of vital signs measurements, and Cercacor will have proprietary ownership of all technology related to the noninvasive monitoring of non-vital signs measurements. We also rely upon trade secrets, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with consultants, vendors and employees, although we cannot be certain that the agreements will not be breached or that we will have adequate remedies for any breach.

There are risks related to our intellectual property rights. For further detail on these risks, see “Risks Related to Our Intellectual Property” under Item 1A—“Risk Factors” in this Annual Report on Form 10-K.

Research and Product Development

We believe that ongoing research and development efforts are essential to our success. Our research and development efforts focus primarily on continuing to enhance our technical expertise in pulse oximetry, expanding our noninvasive monitoring of other measurements and developing remote alarm and monitoring solutions.

Although we and Cercacor each have separate research and development projects, we collaborate with Cercacor on multiple research and development activities related to rainbow® technology and other technologies. Under the Cross-Licensing Agreement, the parties have agreed to allocate proprietary ownership of technology developed by either party based on the functionality of the technology. We will have proprietary rights to all technology related to the noninvasive measurement of vital signs measurements, and Cercacor will have proprietary ownership of all technology related to the noninvasive monitoring of non-vital signs measurements.

Manufacturing

Our strategy is to manufacture products in-house when it is efficient and cost-effective for us to do so. We currently manufacture our bedside and handheld pulse oximeters, our full line of disposable and reusable sensors and most of our patient cables in-house or through captive contract maquiladora operations. We maintain an approximate 70,700 square foot manufacturing facility in Irvine, California, and two separate manufacturing facilities in Mexicali and San Luis Rio Colorado, Mexico that have combined square footage of approximately 216,900 square feet, all three of which are International Organization for Standardization (ISO) 13485:2016 certified. We also maintain an approximate 86,500 square foot facility in Hudson, New Hampshire, a portion of which is used to manufacture advanced light emitting diodes and other advanced component-level technologies. In addition, we maintain an ISO 13485:2016 certified facility approximating 16,400 square feet in Danderyd, Sweden, a portion of which is used to manufacture ultra-compact mainstream and sidestream capnography and gas monitoring technologies. We will continue to utilize third-party contract manufacturers for products and subassemblies that can be more efficiently manufactured by these parties, such as our circuit boards. We monitor our third-party manufacturers and perform inspections and product tests at various steps in the manufacturing cycle to ensure compliance with our specifications.

We also do full functional testing of our circuit boards.

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For raw materials, we and our contract manufacturers rely on sole source suppliers for some components, including digital signal processor chips and analog-to-digital converter chips. We and our contract manufacturers have taken steps to minimize the impact of a shortage or stoppage of shipments of digital signal processor chips or analog to digital converter chips, including maintaining a safety stock of inventory and designing software that may be easily ported to another digital signal processor chip. We believe that our sources of supply for components and raw materials are adequate. In the event of a delay or disruption in the supply of sole source components, we believe that we and our contract manufacturers will be able to locate additional sources of these sole source components on commercially reasonable terms and without experiencing material disruption in our business or operations.

We have agreements with certain major suppliers and each agreement provides for varying terms with respect to contract expiration, termination and pricing. Most of these agreements allow for termination upon specified notice, ranging from four to twelve months, to the non-terminating party. Certain of these agreements with our major suppliers allow for pricing adjustments, each agreement provides for annual pricing negotiation, and one agreement also guarantees us the most favorable pricing offered by the supplier to any of its other customers.

Employees

As of December 29, 2018, we had approximately 1,500 full-time employees and approximately 3,000 dedicated contract personnel worldwide.

Address

Our principal executive offices are located at 52 Discovery, Irvine, California 92618, and our telephone number at that address is (949) 297-7000. Our website address is www.masimo.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, proxy statements, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge at www.masimo.com as soon as reasonably practicable after electronically filing such reports with the SEC. Any information contained on, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way a part of, this Annual Report on Form 10-K.

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ITEM 1A. RISK FACTORS

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the following risks come to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Revenues

We currently derive the majority of our revenue from our Masimo SET® platform, Masimo rainbow SET™ platform and related products. If these technologies and related products do not continue to achieve market acceptance, our business, financial condition and results of operations would be adversely affected.

We are highly dependent upon the continued success and market acceptance of our proprietary Masimo SET® technology that serves as the basis of our primary product offerings. Continued market acceptance of products incorporating Masimo SET® will depend upon us continuing to provide evidence to the medical community that our products are cost-effective and offer significantly improved performance compared to conventional pulse oximeters. Health care providers that currently have significant investments in competitive pulse oximetry products may be reluctant to purchase our products. If hospitals and other health care providers do not believe our Masimo SET® platform is cost-effective, safe or more accurate or reliable than competitive pulse oximetry products, they may not buy our products in sufficient quantities to enable us to generate revenue growth from the sale of these products. In addition, allegations regarding the safety and effectiveness of our products, whether or not substantiated, may impair or impede the acceptance of our products.

Some of our products are in development or have been recently introduced into the market and may not achieve market acceptance, which could limit our growth and adversely affect our business, financial condition and results of operations.

Many of our noninvasive measurement technologies are considered disruptive. These technologies have performance levels that we believe are acceptable for many clinical environments but may be insufficient in others. In addition, these technologies may perform better in some patients and settings than others. Over time, we hope to continue to improve the performance of these technologies and educate the clinical community on how to properly evaluate them. If we are successful in these endeavors, we expect these technologies will become m