

## Contents

<b>1.0 Masimo SET Overview</b> .....	<b>2</b>
1.1 Summary .....	2
1.2 Value Proposition.....	2
1.4 “Product Solution” Elements: .....	3
<b>2.0 Breakthrough Technical and Clinical Innovation</b> .....	<b>4</b>
2.1 Clinical Outcomes .....	4
2.2. Safety Profile .....	4
2.3. Consumer Satisfaction.....	4
2.4 <i>Cost Savings</i> .....	5
2.5 Clinical References .....	7
2.6 Non-clinical Improvements and Outcomes Profile .....	7
<b>3.0 Masimo SET Oximetry Features &amp; Benefits</b> .....	<b>8</b>
3.1 Important Features and Benefits: .....	8
<b>4.0 Supplier Viability</b> .....	<b>11</b>
4.1 Quality Control.....	11
4.2 Distribution/Field Support:.....	11
<b>5.0 Product Classification and Regulatory Issues</b> .....	<b>11</b>
5.1 Classification: .....	11
5.2. Regulatory Status:.....	11
5.3 Intellectual Property Status:.....	11

## List of Exhibits

- **Hospital References**
- **Clinical Studies**
  - Masimo Peer Reviewed Literature (1 - 61)
  - Masimo Sponsored Literature (M1 – M6)
  - Nellcor Peer Review Literature (N1-N2)
- **Masimo Partners**
- **Awards**
- **FDA Claims**
- **N-595**
- **ECRI Report**
- **Clinical Testimony**
- **Miscellaneous**
- **Product Sheets**
- **Audie Lewis Report**

## 1.0 Masimo SET Overview

### 1.1 Summary

Masimo SET<sup>®</sup> performance is the new standard of care and provides a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. Masimo SET uses four proprietary algorithms in parallel (all patented by Masimo), which, along with the conventional red over infrared algorithm, allows for unprecedented:

1. Fidelity – precision;
2. Sensitivity – the ability to detect true saturation events; and
3. Specificity – the ability to not false alarm

Patient data is presented to the set of algorithms, and each algorithm's unique strengths are leveraged to ensure accurate readings through all patient conditions.

Due to its unique use of 5 parallel processing engines, Masimo SET substantially eliminates the problems of:

1. Motion artifact [3,4,5, 6,8,13,21,58];
2. Low peripheral perfusion [3,4,5,24]; and
3. Most low signal-to-noise situations

This greatly extends the utility of SpO<sub>2</sub> in high motion, low signal and noise intensive environments, and ensures accurate performance on the sickest patients where it is needed most. [11,21,34,36,38,41,49,55,57]

### 1.2 Value Proposition

Masimo SET's unmatched performance improves clinical outcomes by more accurately tracking the patient's true physiology when it is needed most, during periods of motion and low perfusion. Masimo SET's documented, unprecedented sensitivity in detecting true alarms and unprecedented specificity in rejecting false alarms [3,4,5,6,8, 27,52], improves response time to patient distress [43,49], and can result in better patient outcomes [35,41,44,46,47,50]. Masimo's superior accuracy is documented in the included Bibliography of published studies, the ECRI Report on Masimo SET and our FDA 510k clearance "Indications for Use". Many of the studies compare Masimo SET to Nellcor's very latest technology.

Masimo SET's unprecedented performance impacts three distinct areas:

1. **Improved Patient Care.** Due to the proven accuracy, fidelity and reliability of Masimo SET pulse oximetry, clinicians utilize better patient data to make better clinical decisions, which leads to improved patient care [42,44,46,47,50,52,53,54].
2. **Reduced Medical Errors.** Medical errors are reduced due to more accurate and trusted readings being provided to the clinician, thus enabling appropriate clinical intervention [46,47,52].
3. **Reduced Cost of Care.** With proven accuracy and reliability, clinicians can shift their focus from managing equipment (false alarms and inaccurate readings) to managing patient care [46,47]. This will result in lower sensor consumption, reduction in arterial blood gas tests, reduction in oxygen requirements and shorter length of stay [41,44,46, 47,51,56]. Masimo routinely guarantees hospitals a 10% - 30% reduction in hospital sensor consumption.

#### **1.4 “Product Solution” Elements:**

Masimo SET pulse oximetry is used wherever blood oxygenation monitoring is a standard of care or required for patient assessment throughout the hospital and at subacute care centers, outpatient clinics, surgicenters, sleep centers or home use. Masimo SET pulse oximetry can be used under the most demanding conditions [8,10,11,25,27,29,30,31,32,33,34,35,36,37,40,41,42,43,44,45,49,51,57], where accurate monitoring [26,33,38,54] and fast response (fidelity) [1,9,12,28,48] to changing conditions are critically required.

Masimo SET performance is applicable for the entire range of patients: adult, pediatric and neonatal.

Masimo offers its Masimo SET pulse oximetry technology through:

1. Masimo Radical<sup>®</sup> and Masimo Rad-9<sup>™</sup> Standalone Pulse Oximeters
2. Manufacturers of Single and Multiparameter Monitors, Defibrillators, Infusion Pumps, Incubators/Warmers and Ventilators (OEM partners)

More than 35 OEM patient monitoring companies, including Alaris, Datascope, GE Medical Systems (Marquette, Critikon, and others), Medtronic Physiocontrol, Welch Allyn and Zoll, market Masimo SET technology in over 40 different products. These companies combine to provide more than 1,000 sales representatives and 150 clinical specialists that can support Masimo SET in clinical settings. Please refer to the “Partner Companies” tab in this binder for an up-to-date listing of Masimo SET licensees.

Masimo employs its own sales force of 12 field key account managers and 9 clinical specialists who provide in-house training and support for clinical users.

Masimo provides in-service videos as well as operator manuals and machine-side quick reference guides for operational questions. Masimo also provides web-enabled, on-line training. This consists of self-paced learning with reportable testing, as well as troubleshooting and education on sensors and systems.

Masimo offers its technology through a variety of cost advantaged acquisition programs including no-capital-cost/sensor usage programs.

## 2.0 Breakthrough Technical and Clinical Innovation

### 2.1 Clinical Outcomes

Masimo SET pulse oximetry has been shown to more accurately track true SpO<sub>2</sub> and Pulse Rate compared to conventional pulse oximetry as well as Nellcor Oxismart (N3000, N290, N295 and MP 304 OEM boards) and Oxismart XL (N395 and MP 404 OEM Boards) pulse oximetry, thus ensuring appropriate patient care and lower overall costs [1,6,3,4,5,8,9,10,11,13,21,23,24,27,28, 29,31,32,33,34,35,36,38,40,41,42,43,45,46,47,48,49,54,57,58]. Based on independent clinical evaluations and our own internal studies, we believe that Masimo SET not only outperforms the Nellcor N595 [22], but also that the N595 does not perform as well as its predecessor, the N395.

Masimo SET has been shown in neonatal, pediatric and adult critically ill patients to decrease false alarms and increase the duration of reliable monitoring time. Increased monitoring reliability results in increased caregiver confidence in monitoring technology and thus better patient care [40,43,44,49,50,51]. This has translated to:

1. Decreased weaning time from high oxygen concentrations [25,47,55];
2. Decreased weaning time from mechanical ventilation [44];
3. Decreased length of stay in the PACU and the ICU [43,44];
4. Fewer blood gas samples to confirm oxygenation status [30,38]; and
5. Greater stability of oxygenation status (leading to a decrease risk of oxygen's toxic effects such as ROP, and pulmonary fibrosis) [7,30,55].

Additionally, Masimo SET has been shown to improve diagnostic accuracy in both sleep and exercise-stress testing [1,9,12,42,45,44].

In addition to the cost savings resulting from changes in caregiver practices described above, hospitals also realize significant cost reductions in sensor-related expenditures due to the durability, longevity and better performance of Masimo LNOP sensors [32,51,56]. As a result, Masimo routinely guarantees hospitals switching to Masimo SET technology a 10% - 30% reduction in sensor utilization and costs or Masimo will pay for the difference.

### 2.2. Safety Profile

Masimo SET pulse oximetry provides greatly improved patient safety due to the increased fidelity of monitoring. Clinical studies in neonatal, pediatric and adult patients have demonstrated greatly improved reliability in detection of heart rate variability and bradycardia episodes [7,10,27,33, 45,57] as well as significantly improved reliability of detection of hypoxemic events [7,11,27, 39]. Masimo SET monitoring technology now provides accurate and reliable oxygen saturation and pulse rate monitoring during patient episodes and in environments (transport/bright lights/electrical interference) when such monitoring was previously unavailable due to the low signal to noise ratio and thereby greatly increases patient safety [50,52]. This includes patients being transported [36], newborn infants in the delivery room [29], patients with low perfusion [36,40,57] and patients experiencing extreme motion conditions [45]. Additionally, because of significantly reduced false alarm rate due to Masimo SET technology, patient safety has been increased due to increased caregiver efficiency and the reduction of latent errors due to caregiver distractions [46,47,52].

### 2.3. Consumer Satisfaction

**Company/Product Awards.** Since its introduction, Masimo SET technology has been reviewed in many peer- reviewed journals, posters and other forums. Masimo has also received numerous awards (<http://www.masimo.com/awards/awards.htm>), including the Society for Critical Care Medicine's Technology Excellence Award, the American Electronics Association's award for

innovative product/technology in the medical area, and the 2001 Medical Design Excellence Award for the Radical pulse oximeter. Please see the “Awards” tab in this binder for a complete listing of Masimo’s awards.

**Customer Satisfaction Study.** Masimo SET has been shown to provide significant end-user satisfaction, in a recently published survey, 83% of clinicians stated “they would recommend Masimo SET oximetry if they were transferred to another work location” [52].

**Masimo Technology/Customer Satisfaction Audit.** Audie Lewis Consulting, Inc, a consulting organization serving hospitals, published an audit report in November 2001 on Masimo Signal Extraction Technology (Masimo SET). In this audit report, Masimo received the Audie Lewis Mark of Excellence™, the only pulse oximetry company receive this distinction. This Mark was given to Masimo after an extensive audit, a large majority of which was conducted prior to Masimo being made aware that it was taking place. The audit report concluded that none of the other pulse oximetry technologies matched the quality and clinical benefits of Masimo SET, and provided an overall assessment of “Outstanding.” Masimo also received high grades for Masimo SET’s cost reduction impact to hospitals, and Audie Lewis’ highest rating ever for customer satisfaction following direct interviews with 21 Masimo clients throughout the USA. The Audie Lewis audit is provided in the inside back cover of this binder.

**Masimo References.** Also included in this binder in the “Hospital References” tab is a list of clinical references with contact names and telephone numbers. Any of these contacts could provide additional feedback on their experiences with the Masimo SET technology.

**Independent Agency Assessment.** ECRI, a nonprofit agency, reported in Health Devices (10/2000, Volume 29, Number 10) “We rated Masimo SET *Preferred* over conventional pulse oximetry. Our laboratory testing, literature review, and user interviews show that SET performs better than conventional technology under conditions of low perfusion.” ECRI further stated that Masimo SET performance in motion, light, and low perfusion was “excellent.” They also stated sensor comfort and durability was excellent compared to conventional sensors. Overall, ECRI said that Masimo SET performance was an improvement over conventional pulse oximetry, surpassing conventional technology in most motion and light interference studies. The ECRI report is included with this binder.

## **2.4 Cost Savings**

Many cost savings have been mentioned and referenced throughout this binder including:

1. Sensor savings due to durability/longevity: 49% - 58% reduction versus current costs
2. Arterial blood gas test savings (greater than 50% reduction in ABG’s) due to increased reliability:
3. Savings related to moving patients to lower acuity areas faster
4. Savings related to lower O<sub>2</sub> administration
5. Soft savings related to productivity gains due to fewer false alarms

Cost savings are detailed below in Sections 2.4.1 – 2.4.3.

### **2.4.1 Direct Medical Care Savings:**

Masimo SET reduces overall oximetry monitoring costs in the following direct ways:

- Less adhesive sensors are used with Masimo SET because the pulse oximetry technology is more robust and reliable. Many times clinicians waste multiple Nellcor sensors in order to acquire a SpO<sub>2</sub> reading.
- Masimo LNOP adhesive sensors are made from a durable tape material, allowing multiple applications for a single patient, for up to 30 days. In addition, simply wiping the sensor with an alcohol swab can rejuvenate the adhesive. Fewer adhesive sensors are required overall [41,51,56].
- Masimo LNOP adhesive sensors are made from a non-absorbent material. This material will not absorb odors as other sensors on the market have a tendency to do. Therefore, their use-life is longer – many competitive sensors are changed due to odor problems, even though they are working fine.

Masimo SET, by decreasing erroneous low and high oxygen saturation and pulse rate values and increasing monitor uptime, offers these benefits:

- Reduced instances of investigating causes of artifactual hypoxemia [46]
- Decreased arterial blood gases (commonly performed to “verify” incorrect SpO<sub>2</sub> values) [44,47,46]
- Decreased time on ventilator [44]
- Decreased sensor usage [41,51,56]
- Decreased over prescription of O<sub>2</sub> [44,43,46,52]
- Decreased ROP (retinopathy of prematurity) [see Clinical Testimonial]
- Less staff time required to investigate and “treat” false desaturations (distraction due to “cry wolf” phenomenon) [44,46,47,50,51,52, 53,21]
- Reduce length of stay in ICU [44]

### **2.4.2 Indirect Care Cost Savings – Reduced Medical Errors**

Masimo SET performance is the new standard of care. Hospital-wide use of Masimo SET via monitors with Masimo SET, Radical and SatShare can reduce a facility’s liability through improved performance, and a common standard of care throughout the institution. Two examples:

- The Hospital for Sick Children, a world-renowned children’s hospital in Toronto, Canada lost a 12-year old girl who had been admitted to the hospital with a severe ankle injury. The patient monitors were turned off due to false alarms and the girl, having been placed on a morphine drip, expired due to overmedication. Without proper feedback, her condition was not responded to until it was too late. Following this tragedy, the hospital undertook a two-year evaluation of monitoring technologies and ultimately converted to completely new technology, including Masimo SET.
- A similar tragedy was reported in the Los Angeles Times on May 11, 2002, where Community Hospital of San Bernardino settled with a family for \$43.5 million because the monitors were turned off on a 4-month old boy who subsequently suffered hypoxic brain damage [copy of article supplied behind the “Miscellaneous” tab].

In addition, implementation of Masimo SET technology offers an opportunity to standardize sensors across the entire hospital, thus offering savings in materials management by eliminating the need to carry two brands of sensors from two different manufacturers.

### **2.4.3 Self Care Cost Savings (Patient Savings)**

With faster weaning times and better patient outcomes, patients leave the hospital sooner (removing costs from the greater healthcare system) and thereby return to work sooner (potentially improving the patient's personal financial situation). Additionally, proper diagnosis and treatment of Obstructive Sleep Apnea (OSA) has been shown to reduce the number of missed workdays for patients [1,9,12,28,48].

## **2.5 Clinical References**

See "Hospital References" tab provided in this binder.

## **2.6 Non-clinical Improvements and Outcomes Profile**

In addition to providing superior outcomes in terms of achieving what pulse oximeters were designed to do – report accurate SpO<sub>2</sub> measurement without false alarming – Masimo SET pulse oximetry has been clinically proven to increase caregiver efficiencies by changing their behavior. These improved efficiencies contribute to increased staff satisfaction, while enabling care givers to focus more on the patient and other important tasks [46,47,52].

**Continuous product improvements** result in an ever expanding value proposition to Masimo SET users: As updates are developed for Masimo SET technology, upgrades have been provided to the health care facilities at no additional charge via simple, efficient software field updates. This has resulted in postponing obsolescence of the installed base – a significant cost savings while providing the latest improvements to the clinician.

**ISO 9001/13485 (TUV) certified facility:** Masimo has embraced ISO standards to ensure the highest quality in its products and services. All incoming materials are quality inspected, 100% of finished goods are quality inspected.

**Web-based E-learning modules:** Masimo has a partnership with Saba, the leader in Learning Management Systems, to create and evolve high-quality e-learning programs for its customers. Masimo's e-learning programs improve the response time to training needs while being able to measure the results of the training through web-enabled testing.

**SatShare™:** This feature/improvement allows facility-wide implementation of Masimo SET technology, even on existing multi-parameter monitors, thus creating a standard for the entire facility. This, in turn, leads to cost savings in materials management, and improved patient care.

**Signal IQ™:** With conventional pulse oximetry, visual inspection of the plethysmograph was an indication of data integrity. If the plethysmograph looked corrupt (due to motion or low signal-to-noise ratio), clinicians questioned the reliability of the oximetry measurements. Masimo pioneered motion tolerant pulse oximetry, so even if the plethysmograph is corrupt, the oximeter is capable of making accurate oximetry and pulse rate measurements under most conditions. At times, however, even the Masimo SET pulse oximeter may report erroneous data. Therefore, clinicians need a robust and accurate means to evaluate the data integrity of the displayed measurements. Signal IQ, is the only solution available today, which allows clinicians to know when to trust and when to question the "Next Generation Pulse Oximeter" measurements [15,16,55].

### 3.0 Masimo SET Oximetry Features & Benefits

Masimo SET Radical<sup>®</sup> represents an innovative pulse oximetry system offering a unique, three-in-one platform. Radical can be used as a standalone system or, a portable/handheld system, or it can replace existing pulse oximeters in multiparameter monitors via SatShare<sup>®</sup>, a novel method of linking Masimo SET Radical technology to the facility's existing monitoring devices.

Not only is Masimo SET the only clinically proven motion and low perfusion tolerant pulse oximetry technology delivering on the promise of dramatically reduced false alarms and increased detection of true events, but via Radical, it is the only "Next Generation Pulse Oximetry" technology that can be implemented hospital wide.

Masimo also has an extensive line of adhesive disposable, single patient adhesive, reusable ear, reusable multi-site and reusable finger clip sensors, as well as wide range of patient cables and other accessories. With these products, Masimo SET can be used on the widest range of patients.

#### 3.1 Important Features and Benefits:

**Feature: The only hospital-wide solution.** Masimo's motion- and low perfusion-tolerant pulse oximetry technology is integrated in over 40 devices from over 35 patient monitoring companies. The Masimo Radical with its SatShare feature, is the only available motion- and low perfusion-tolerant technology that can be deployed throughout the entire hospital because it interfaces into existing multiparameter monitors. In addition it is the only "Next Generation" technology available as a handheld monitor.

**Benefit:** Hospitals can quickly and inexpensively convert to a consistent standard of care for pulse oximetry throughout the hospital – all patients receive the same improved standard of care.

**Feature: Patented Parallel Processing Engines.** Masimo SET uses 5 parallel engines (algorithms) for SpO<sub>2</sub> calculation. Of the 4 proprietary parallel algorithms, Masimo SET's most powerful algorithm is DST<sup>®</sup>. All algorithms depend upon assumptions, and the more assumptions, the weaker the algorithm. DST makes only one assumption – that arterial blood has a higher oxygen level than venous blood and surrounding tissue – making it the most powerful pulse oximetry algorithm. This allows Masimo SET instruments to accurately and quickly calculate the patient's SpO<sub>2</sub> through more conditions than any other pulse oximeter in the market.

**Benefit:** Independent clinical studies demonstrate Masimo SET captures substantially more true desaturation events (up to over 110% more, depending on the clinical environment) [1,9,12,24,25,45] with up to 90% fewer false alarms [3,4,5,6,8,10,13,23,27,30,31,32,39,44,46,52,58], when compared to competing products (even the very latest generation technologies), ensuring patient safety [46,52] and proper caregiver response [29,46,47]. Masimo SET's accurate and reliable SpO<sub>2</sub> [26,38,54] measurement has also been clinically proven to result in less Arterial Blood Gases (ABGs) (improved patient care, less costs), lower prescription O<sub>2</sub> requirements (improved care/reduced incidence of Retinopathy of Prematurity (ROP), reduced cost), faster weaning (reduced cost, improved care), and significantly lower sensor utilization (multiple sensors are not placed on the patient in attempts to get a reading) [7,35,41,44,46,47,51,54,56].

**Feature: FastSat<sup>™</sup>** ensures the fastest response time of any pulse oximeter on the market (including the Tyco-Nellcor N-595), and highest fidelity oximetry on the market, independent of sensor or site selection.

**Benefit:** When fast response times are desired, or when the caregiver wishes to see very quick, brief desaturations as with sleep disordered breathing or critically ill patients, Masimo SET with FastSat gives the highest fidelity in measurement. Masimo's ear sensor with FastSat has been shown to provide the fastest response times to desaturation events when compared to Nellcor's forehead reflectance sensors.



**Feature: Signal IQ™** signal identification and quality indicator [53].

**Benefit:** Powerful feature that notifies the caregiver when they should not have confidence in the signal and thus take other precautionary measures. With Masimo SET's unprecedented sensitivity, specificity, and Signal IQ, researchers have shown that closed loop oxygenation is even possible [15,16,55].

**Feature: Adjustable averaging times down to two seconds**

**Benefit:** Allows for higher-fidelity pulse oximetry performance for applications which require it, such as the sleep laboratory [1,9,12,28,48]. Nellcor's current oximeters do not offer adjustable averaging time, let alone the 2 second averaging time, causing an internationally recognized researcher to conclude: "The sensitivity and motion artifact rejection characteristics of the Nellcor N-395 oximeter are not adequate for a pediatric sleep laboratory setting." [9]. Their subsequent generation oximeter (N-595) also does not have adjustable averaging times.

**Feature: SatShare** - allows replacement (upgrade) of older or non-Masimo SET multiparameter monitors.

**Benefit:** Enables hospitals to upgrade their multiparameter monitors to Masimo SET and provide all of their patients with the safest SpO<sub>2</sub> monitor available. In addition to SatShare, Masimo has jointly created a variety of upgrade modules (e.g., HP/Philips Vuelink, Spacelabs Flexport).

**Feature: Tear-resistant sensor tape**

**Benefit:** Independent clinical studies have demonstrated that Masimo's LNOP sensors last over twice as long as the competitors [32,56]. Fewer sensors are used during a patient's stay, dramatically reducing hospital sensor consumption costs [51].

**Feature: Adhesive Rejuvenation**

**Benefit:** Masimo's LNOP sensors have been designed with a unique rejuvenation feature, which enables caregivers to rejuvenate the adhesiveness of LNOP sensor with an alcohol swab when changing the sensor site, thus ensuring sensors lasting longer and ultimately lowering costs. The LNOP sensors' durable adhesive with its rejuvenation feature has proven to be far more cost effective and simpler to implement than competitor's sensor recycling program.

**Feature: Patented Electronic and Ambient Light Shielded Sensor**

**Benefit:** Masimo's LNOP sensors are fully shielded against ambient and electro-magnetic frequencies. They outperform competitors' sensors under conditions of electrical/electrosurgical interference and/or ambient light. Masimo SET pulse oximetry monitoring can be effectively accomplished under the most intense light, including Bilirubin lamps and sunlight, and during use of electrocautery devices.

**Feature: CleanShield™ Multi-Site Wrap**

**Benefits:** ECRI surveys show most hospitals do not routinely clean their reusable sensors. Cross contamination is a leading cause of medical errors, and CleanShield enables hospitals to gain the cost benefit of reusable sensors with less risk of cross contamination.

**Feature: Uniquely Designed Ear Sensor**

**Benefits:** Some clinicians prefer a sensor attached to the ear, but traditional ear sensors have suffered from low signal-to-noise problems due to the small capillary blood flow in the ear. In addition, the problem has been exacerbated due to conventional ear sensor designs, which apply excessive force on the monitoring site to keep the sensor in place. Masimo's ear sensor is designed to minimize this force, through a combination of proprietary features, including an ear hanger, wide measurement surface area and adhesive squares.

**Feature: Choice of Stand Alone Pulse Oximeter Configuration- Radical, Rad-9 and/or VitalSat**

**Radical** is a three-in-one pulse oximeter that allows for maximum flexibility and portability. Radical incorporates a very small handheld pulse oximeter component that can be detached from the docking station (Radical Docking Station-RDS1 or RDS2), and with its long life battery (up to 8 hours), can be moved with the patient for continuous monitoring during transport. The handheld piece can then be attached to another docking station upon reaching the destination. Radical, with its docking station, also represents a lightweight pulse oximeter that can be moved with the patient if so desired.

**Rad-9** is a stand-alone pulse oximeter with bright display and a very simple user interface that clinicians will quickly adapt to.

**VitalSat** is a standalone pulse oximeter manufactured by one of Masimo's licensees. VitalSat incorporates both an LCD display for the plethysmograph, and a bright LED display for the SpO<sub>2</sub> and PR values – offering a highly visible display.

**Benefits:** Clinicians have a choice.

**Features: Radical Rotational Screen** – The Radical can be positioned either vertically or horizontally. The display orients automatically.

**Benefits:** Radical can more flexibly fit into locations that clinicians desire because the display rotates automatically based on the position (horizontal or the space-saving vertical position). In addition, the display's orientation can be controlled manually to up, down, right or left.

**Feature: 30 Day trending.** The saturation, pulse rate, and signal IQ can be stored in memory of the handheld piece of the Radical and printed or viewed on the Radical display.

**Benefits:** This is useful for long-term patients and patients at home. Competing products can only trend for 3 days.

**Feature: Long battery life.** Up to 8 hours standard with optional docking station battery providing up to 18 hours of operation

**Benefits:** This is useful for transport and emergency situation. Competing products' battery life is 2 hours.

**Feature: Electronic Upgradability.** Masimo pioneered pulse oximetry upgradability. Masimo's earliest OEM boards and Radicals can be upgraded with new software, so hardware does not need to be changed.

**Benefits:** Hospitals can get the latest software on equipment purchased years ago. The latest Masimo SET software is V3.1.

## **4.0 Supplier Viability**

### **4.1 Quality Control**

Masimo has a full quality control system that is certified to ISO-9001/13485, EN-46001 and the Medical Device Directive and is in compliance with the FDA's Quality System Regulation 21 CFR 820.

### **4.2 Distribution/Field Support:**

Masimo distributes end user products directly or through our distributors (Nationwide-Allegiance, Owen & Minors, Datascope and Regional Distributors-numerous) to the GPO members or through our 35+ OEM partners such as Datascope and GE. In addition, Masimo can SatShare interface our pulse oximetry solution with most major patient monitoring companies.

## **5.0 Product Classification and Regulatory Issues**

### **5.1 Classification:**

Class II product - Product Code 74DQA for Oximeter and 74DSA for Sensors and Cables.

### **5.2. Regulatory Status:**

*This section describes the current **regulatory status** of the product.*

510(k) clearance for Masimo SET OEM boards, Masimo SET Radical, Rad-9, VitalSat and LNOP Series of Sensors and Patient Cables: Latest 510(k) is 992340, cleared 10/8/99.

Masimo Products are Class II devices and no IDE's or Phase I or Phase II clinical trials are required.

### **5.3 Intellectual Property Status:**

Masimo SET is a breakthrough technology that has been protected with an extensive patent portfolio developed over the past 13 years. There are more than 70 patents issued and over 100 patent applications pending worldwide. Masimo has invested a tremendous amount of resources into the creation of its intellectual property and follows a policy of aggressively defending it. Masimo SET has been carefully designed to respect the intellectual property rights of others.