K992238

OCT 8 1999

510(k) SUMMARY

MASIMO®
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Submitted by:	Masimo Corporation 2852 Kelvin Ave Irvine, CA 92614-5826 (714) 250-9688 FAX (714) 250-9686
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	September 27, 1999
Trade Name	Masimo SET® Radical Pulse Oximeter and accessories
Common Name	Pulse Oximeter and Sensor
Classification Name	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900)
Substantially Equivalent Devices	Masimo SET 2000 Pulse Oximeter and accessories 510(k) Number - K990966

Description of Masimo SET® Radical Pulse Oximeter

The Masimo SET® Radical pulse oximeter and accessories is a device consisting of the Masimo SET technology, connecting cable, and oximetry sensors to noninvasively calculate the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It features an easy-to-read display that presents patient data and status information: a LCD (liquid crystal display) display that shows the SpO_2, pulse rate values, and a plethysmographic waveform, the current high and low SpO_2 and pulse rate limit setting, and messages as appropriate.

Features

- Ability to perform as a stand alone monitor and a portable monitor
- Several types of Masimo LNOP® sensors for flexibility.
- An automatic self-test at start-up.
- Backlit display for excellent visibility in subdued lighting conditions.
- Direct access to user-selectable high and low alarm limits for SpO_2 and pulse rate.
- An audible pulse indicator with an adjustable volume
- Visual and audible (adjustable volume) alarms.
- An alarm-silence feature; silences audible alarms continuously until deactivated.
- Status and alarm informational messages appear on the LCD.
- 8, 12, or 16 second SpO_2 response averaging modes.
- Trend data storage of up to 8 hr.
- Automatic scaled plethysmographic waveform
- Large SpO_2 digital display for clear differentiation from the pulse rate value.

510(k) SUMMARY

The PC series of connecting cables connects the monitor to the oximetry sensors and transfers LED drive power to the oximetry sensors from the monitor and the monitor receives the detector signals from the oximetry sensor.

The LNOP® series of oximetry sensors measure the light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently than unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

Intended use

The Masimo SET® Radical Pulse Oximeter and accessories is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, and home environments.

Indications For Use:

The Masimo SET® Radical Pulse Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Radical Pulse Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and home environments.

Principles of Operation

The principles of operation of the Masimo SET® Radical pulse oximeter are that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography), and that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET® Radical pulse oximeter decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the SpO_2 saturation in an empirically derived equation in the Masimo SET® Radical's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and non-motion conditions.

Method of Operation

The Masimo SET® Radical pulse oximeter is turned on. An oximetery sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the Masimo SET® Radical pulse oximeter module.

The monitor will begin continuously displaying the patient's pulse plethysmographic waveform, pulse rate, and SpO_2 value. The practitioner can adjust the high and low alarm limits to their desired value, if required. The practitioner can then use the information that is continuously displayed on the monitor, and hear if an alarm limit is reached, to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

Power Source

The Masimo SET® Radical pulse oximeter is powered either with a voltage input of 100-230 Vac, 47 – 63 Hz. The detachable portable monitor operates on 4 AA batteries with and operating time of 2 hours.

510(k) SUMMARY

Specifications and Operating Ranges

Range

Saturation (% SpO_2)	1% - 100%
Pulse Rate (bpm)	25 – 240
Perfusion	0.02% - 20%

Accuracy

Saturation (% SpO_2) - During No Motion Conditions[1]

Adults, Pediatrics	70% - 100% ± 2 digits
	0% - 69% unspecified
Neonates	70% - 100% ± 3 digits
	0% - 69% unspecified

Saturation (% SpO_2) - During Motion Conditions[2,3]

Adults, Pediatrics[2]	70% - 100% ± 3 digits
	0% - 69% unspecified
Neonates[3]	70% - 100% ± 3 digits
	0% - 69% unspecified

Pulse Rate (bpm) - During No Motion Conditions[1]

Adults, Pediatric, Neonates	25 to 240 ± 3 digits

Pulse Rate (bpm) - During Motion Conditions[2,3]

Adults, Pediatric, Neonates	25 to 240 ± 5 digits

Resolution

Saturation (% SpO_2)	1%
Pulse Rate (bpm)	1

Low Perfusion Performance[4]

> 0.02% Pulse Amplitude	Saturation (% SpO_2) ± 2 digits
and % Transmission > 5%	Pulse Rate ± 3 digits

Interfering Substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Power

Voltage Input Range	100-230 Vac, 47-63 Hz
Maximum AC Power Consumption:	55 VA

Fuses

1ASB, Metric, (5x20mm), 250V

510(k) SUMMARY

Isolation

Chassis Leakage Current	Less than 100 μAmp
Ground resistance	Less than 1.0 Ω

Environmental

Operating Temperature	41°F to + 104°F (5°C to +40°C)
Storage Temperature	-40°F to + 158°F (-40°C to +70°C)
Relative Humidity	5% to 95% noncondensing

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of default parameters
Automatic alarm messages
Trend data output of SpO2, pulse rate - up to 8 hours of stored data

Display

Type	Backlit LCD
Pixels	480 x 160 dots
Dot Pitch	0.24 mm
Data Displayed	Pulse Rate, SpO2 %, Pleth wave, Alarms, Trends, Status messages

Audio indicators

Adjustable volume audible pulse: OFF and 25% to 100% in 4 steps
Adjustable volume audible alarm tone: levels and 25% to 100% in 4 steps
Alarm silence (120 seconds); all mute (continuous silence)
Pulse rate out-of-limits alarm
SpO_2 level out-of limits alarm
Sensor condition alarms
System failure and battery low alarms

Modes

Averaging mode:	8, 12, and 16 seconds
Sensitivity	Normal and High

Audible Volumes

Alarm	25% to 100% in 4 steps
Pulse Beep	OFF and 25% to 100% in 4 steps

510(k) SUMMARY

COM 1: A digital interface for network communication.

Data output every second; SpO_2, and pulse rate	
9600 Baud bidirectional	
Number of bits per character:	8
Parity	None
Bits	1 start, 1 stop
Handshaking	None
Connector type	9-pin standard D, female
Connector pin functions:	
1	No Connection
2	Receive data – RS-232 ±9 V (±5 Vmin)
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground Reference for COM 1 signals
6	No Connection
7	Request to send – Not used
8	Clear to send – Not used
9	No Connection

PRINTER: A connection for optional printer.

Connector pin functions:	
1	No Connection
2	Receive data – Not used
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground – Reference for Printer signals
6	No Connection
7	Request to send – Not used
8	Clear to send – RS-232 ±9 V (±5 Vmin)
9	No Connection

Dimensions

Docking Station	
Height	3.5 in (8.9 cm)
Width	10.5 in (26.7 cm)
Depth	7.7 in (19.6 cm)
Weight	4.7 lbs (2.14 kg)
Portable	
Height	8.9 in (22.6 cm)
Width	3.3 in (8.4 cm)
Depth	2.1 in (5.3 cm)
Weight	1.3 lbs (0.59 kg)

[1] The Masimo SET® Radical pulse oximeter with LNOP•Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo SET® Radical pulse oximeter with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 - 100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[3] The Masimo SET® Radical pulse oximeter with LNOP-Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm

against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

- The Masimo SET® Radical pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Technological characteristics of the Masimo SET® Radical Pulse Oximeter compared to the Masimo SET® 2000 Pulse Oximeter.

The technological characteristics of the Masimo SET® Radical Pulse Oximeter and accessories and the Masimo SET® 2000 Pulse Oximeter both have the same or similar technological characteristics in design, materials, and energy source.

The design of both devices is the similar in that both devices are stand alone devices that monitor the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by a SpO_2 sensor) for adult, pediatric, and neonatal patients. The Masimo SET® Radical Pulse Oximeter also has fully functional detachable portable monitor. The principles of operation and methods of operation for both devices is the same.

The materials used in both devices are similar. The instrument cases are formed of thermoplastic materials. The electronics within the instruments are standard electronic parts (resistors, capacitors, integrated circuits, wiring, connectors, etc.). The sensors and cables for both devices are formed of thermoplastic materials, adhesives, wires, electrical contacts, light emitting diodes, and photodetectors.

The Masimo SET® Radical Pulse Oximeter and the Masimo SET® 2000 Pulse Oximeter operate under 100 - 230 VAC 47-63 Hz and battery power.

Environmental Testing

Applicable environmetal testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed.

Biocompatibility Testing

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days) as defined ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests. All patient contacting material **passed.**

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo SET® Radical Pulse Oximeter and accessories was subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of saturation and pulse rates that both devices specify.

The results of the bench testing showed that the Masimo SET® Radical Pulse Oximeter and accessories returned the same saturation accuracy values within ± 2 digits and pulse rate values within ± 3 digits when compared to the simulators used.

Clinical tests performed that support a determination of substantial equivalence.

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter on healthy adult volunteer subjects during no motion and motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter on neonates during no motion and motion conditions and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

510(k) SUMMARY

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter on healthy adult volunteer subjects who were subjected to low perfusion conditions and to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter on neonates with low perfusion conditions and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects and Part 56 - Institutional Review Boards.

The results from the clinical studies show that the Masimo SET® Radical Pulse Oximeter saturation accuracy values for adults and pediatrics within ± 2 digits during no motion conditions and ± 3 digits during motion conditions when compared to the CO-Oximeter and the pulse rate accuracy values within ± 3 digits during no motion conditions and ± 5 digits during motion conditions when compared to the ECG.

The results from the clinical studies also show that the Masimo SET® Radical Pulse Oximeter saturation accuracy values for neonates to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter and the pulse rate accuracy values to be within ± 3 digits during no motion and ± 5 digits during motion conditions when compared to the ECG.

Conclusions

The results of the **environmetal testing** demonstrated that the Masimo SET® Radical Pulse Oximeter and accessories **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **biocompatibility testing** demonstrates the all patient contacting material **met** the requirements of ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests for Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days).

The results of the **bench testing** demonstrates that the Masimo SET® Radical Pulse Oximeter **meets** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® Radical Pulse Oximeter and accessories **meet** its performance requirements during no motion and motion conditions and low perfusion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo SET® Radical Pulse Oximeter and accessories is safe, effective, and performs as well as the predicate device, the Masimo SET® 2000 Pulse Oximeter, and therefore, it is substantially equivalent to the Masimo SET® 2000 Pulse Oximeter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1999

Mr. James J. Cronin
Masimo Corporation
2852 Kelvin Avenue
Irvine, CA 92614-5826

Re: K992238
Masimo SET® Radical Pulse Oximeter and the LNOP® Series of Sensors and Cables
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: September 28, 1999
Received: September 29, 1999

Dear Mr. Cronin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 — Indications for Use

510(k) Number (if known): K992238

Device Name: Masimo SET® Radical Pulse Oximeter and the LNOP® Series of Sensors and Cables

Indications For Use:

The Masimo SET® Radical Pulse Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Radical Pulse Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and home environments.

The Masimo LNOP® Series of Sensors are indicated for the following:

A single use oximetry sensor intended for adults and pediatrics greater than 30 kg
A single use oximetry sensor intended for pediatrics and small adults greater than 10 kg and less than 50 kg
A single use oximetry sensor intended for neonates with good skin integrity less than 10 kg
A single use oximetry sensor intended for neonates with poor skin integrity less than 1 kg
A reusable oximetry sensor intended for adults and pediatrics greater than 30 kg

The Masimo PC Series of Patient Cables are indicated for use with the Masimo LNOP® Series of Sensors and the Masimo SET® Radical Pulse Oximeter.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992238

Prescription Use X **or** **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)