510(k) SUMMARY

K973887

JAN - 8 1998

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:	October 10, 1997
Trade Name	Masimo SET® MS-1P 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 MS-1 Pulse Oximeter and accessories 510(k) Number - K962603

Description of Masimo SET® MS-1P Pulse Oximeter

The Masimo SET® MS-1P pulse oximeter and accessories is a device consisting of the Masimo SET technology in an Ohmeda 4000 monitor, connecting cable, and oximetry sensors to nonivasively calculate the functional or fractional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It features two easy-to-read displays that present patient data and status information: a numeric LED (light-emitting diode) display that shows the SpO_2 and pulse rate values, and a plethysmographic LCD (liquid crystal display) that shows the waveform, the current high and low SpO_2 and pulse rate limit setting, and messages as appropriate.

Features

- Several types of Masimo LNOP® sensors for flexibility.
- An automatic self-test at start-up.
- Automatic tiered alarm messages.
- Backlit and adjustable viewing-angle 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; the automatic pitch modulation reflects changing SpO_2 level.
- 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.
- Short, medium, or long SpO_2 response averaging modes.
- Adult or neonatal patient modes for default pulse rate alarm settings.
- Fractional or functional SpO_2 calibration modes.

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- Automatic storage of up to 12 hours of SpO2, pulse rate, and alarm limit violations in trend memory, which can be output through the RS-232 serial connector.
- Automatic scale plethysmographic waveform to provide a relative indication of sensor site perfusion level.
- Larger SpO_2 digital display for clear differentiation from the pulse rate value.

The PC series connecting cables connects the monitor to the oximetry sensors and transfers LED drive power and the calibration drive to the oximetry sensors from the monitor and the monitor receives the detector signal 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 as compared to 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 intended use of the Masimo SET® MS-1P pulse oximeter is the continuous noninvasive monitoring of functional or fractional saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by a SpO_2 sensor) for adult, pediatric, and neonatal patients in a hospital and mobile environment.

Indications For Use:

Masimo SET® MS-1P Pulse Oximeter and the LNOP® Series of Sensors and PC Series of Patient Cables are indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rates during both no motion and patient motion conditions for adult, pediatric, and neonatal patients in a hospital and mobile environment.

Principles of Operation

The principles of operation of the Masimo SET® MS-1P pulse oximeter is 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® MS-1P 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 a look-up table built into the Masimo SET® MS-1P'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.

Method of Operation

The method of operation of the Masimo SET® MS-1P pulse oximeter is to turn on the monitor. 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 MS-1P pulse oximeter module.

The monitor will begin continuously displaying the patient's pulse plethysmographic waveform, pulse signal strength, 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 heard 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.

Specifications and Operating Ranges

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Range

Saturation (% SpO_2)	1% - 100%
Pulse Rate (bpm)	25 - 240

Accuracy

Saturation (% SpO_2) - During No Motion Conditions*

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

Saturation (% SpO2) - During Motion Conditions**

Adults	70% - 100% ± 3 digits
	0% - 69% unspecified
~~Neonates~~	~~70% - 100% ± 3 digits~~

Pulse (bpm) - During No Motion Conditions*

25 to 240 ± 3 digits

Pulse (bpm) - During Motion Conditions**

Adults	25 to 240 ± 5 digits

Resolution

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

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

Consumption	15 watts typical
Voltage Range	120 VAC at 60 Hz
Current approximately:	0.1 ampere at 120 V

Fuses

T2.0A/250V, 5 mm (OD) x 20 mm(L)

Isolation

Chassis Leakage Current	Less than 100 µAmp
Ground resistance	Less than 0.2 Ω

Environmental

Operating Temperature	-4°F to + 104°F (-20°C to +40°C)
Storage Temperature	-4°F to + 140°F (-20°C to +60°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, and alarm messages via RS-232 serial port - up to 12 hours of stored data

Display

Graphic display (Liquid Crystal Display)
- Plethysmographic waveform
- High and low SpO_2 alarm limits setting
- High and low pulse rate alarm limits setting
- Sensor condition alarms
- System operational status messages
- Alarm messages
- Contrast adjustment for best viewing

Numeric display (light emitting diodes)
- Arterial oxygen saturation (SpO_2) reading
- Pulse rate reading

Audio indicators
- Adjustable volume audible pulse: OFF and levels 1 through 5
- Adjustable volume audible alarm tone: levels 1 through 5
- Pitch modulation reflects changing SpO_2 levels
- 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 recharge-battery alarms

Modes

Averaging mode:	Long (16 secs); Medium (8 secs - default), Short (6 secs)
Patient mode:	Adult (default), Neonatal
SpO_2 calibration mode	Fractional (default), Functional
Language mode	English (default), French, German, Italian, Japanese, Spanish
EMI line frequency	60 Hz (default), 50 Hz

Audible alarms

Alarm	1 through 5 (default = 3)
Pulse Beep	OFF and 1 through 5 (default = 2)
Volume setting of 1	55 decibels (minimum)
Volume setting of 5	85 decibels (maximum)

Serial output, RS-232

Data output every 2 seconds; SpO_2, pulse rate, alarm limit violation messages and displayed alarm/error messages

9600 Baud

Full duplex

Number of bits per character:	8
Parity	None
Bits	1 start, 1 stop
Handshaking	CTS/RTS
Connector type	9-pin standard D, female

Connector pin functions:

1	chassis ground
2	receive data by the oximeter
3	transmit data from the oximeter
5	signal ground
7	RTS
8	CTS

Dimensions

Height	3.7 in (9.4 cm)
Width	9.53 in (24.4 cm)
Depth	8.86 in (22.5 cm)
Weight	4.92 lbs (2.23 kg)

* The Masimo MS-1P 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.

** The Masimo MS-1P 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.

Technological characteristics of the Masimo SET® MS-1P Pulse Oximeter compared to the Masimo SET® MS-1 Pulse Oximeter.

The technological characteristics of the Masimo SET® MS-1P Pulse Oximeter and accessories and the Masimo SET® MS-1P Pulse Oximeter both have the same or similar technological characteristics in design, materials, and energy source.

The design of both devices is the same 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 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.

Masimo SET® MS-1P Pulse Oximeter operates under 120 VAC 60Hz while the Masimo SET® MS-1P Pulse Oximeter operates under 85 - 265 VAC 47-63 Hz. The Masimo SET® MS-1P Pulse Oximeter can also operate under 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.

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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® MS-1P 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 both the Masimo SET® MS-1P 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® MS-1P 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 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® MS-1P Pulse Oximeter saturation accuracy values within ± 2 digits during no motion conditions and ± 4 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.

Conclusions

The results of the **environmetal testing** demonstrated that the Masimo SET® MS-1P 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® MS-1P Pulse Oximeter **meets** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® MS-1P Pulse Oximeter and accessories **meet** its performance requirements during no motion and motion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo SET® MS-1P Pulse Oximeter and accessories is safe, effective, and performs as well as the predicate device, the Masimo SET® MS-1P Pulse Oximeter, and therefore, it is substantially equivalent to the Masimo SET® MS-1P Pulse Oximeter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 1998

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

Re: K973887
Masimo SET® MS-1P Pulse Oximeter and the LNOP®
series of Sensors and Cables
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: October 10, 1997
Received: October 14, 1997

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 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/dsmamain.html".

Sincerely yours,

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): K973887

Device Name: Masimo SET® MS-1P Pulse Oximeter and the LNOP® Series of Sensors and Cables

Indications For Use:

Masimo SET® MS-1P Pulse Oximeter and the LNOP® Series of Sensors and PC Series of Patient Cables are indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rates during both no motion and patient motion conditions for adult, pediatric, and neonatal patients in a hospital and mobile environment.

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 greater than 2,000 gms
A single use oximetry sensor intended for neonates less than 2,000 gms
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® MS-1P Pulse Oximeter.

Contraindications For Use:

The Masimo SET® MS-1P Pulse Oximeter and the LNOP® Series of Sensors and PC Series of Patient Cables are contraindicated for use as apnea monitors.

The Masimo LNOP® Series of Disposable Sensors are contraindicated for patients that exhibit allergic reactions to adhesive tape. The sensors must be removed and repositioned every eight (8) hours and if indicated by circulatory condition or skin integrity reapplied to a different monitoring site.

The Masimo LNOP® Reusable sensor is contraindicated for use for prolonged periods of use. It is not intended for long-term monitoring. It must be removed and repositioned every 4 hours and if indicated by circulatory condition or skin integrity reapplied to a different monitoring site.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vol Sapurstein
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973087

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Prescription Use _____ **or** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

0019

(Optional Format 1-2-96)

Section 3 — Indications for Use

510(k) Number (if known): K973887

WARNINGS

Explosion hazard. Do not use the Masimo SET® MS-1P Pulse Oximeter in the presence of flammable anesthetics.

A pulse oximeter should NOT be used as an apnea monitor.

A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

If an alarm condition occurs while the alarm silence period is set to off, only alarm indications will be visual displays and symbols related to the alarm condition.

The Masimo SET® MS-1P Pulse Oximeter is to be operated by qualified personnel only.

Electric shock hazard. Covers to be removed only by technically qualified service personnel. There are no user-serviceable parts.

To ensure patient electrical isolation, connect only to other equipment with electronically isolated circuits.

Note: Do not connect to an electrical outlet controlled by a wall switch.

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Do not place the monitor or external power supply in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable, use only the handle on the monitor.

Do not use the Masimo SET® MS-1P Pulse Oximeter or Masimo LNOP® series of sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Masimo SET® MS-1P Pulse Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-The-Counter Use** _____ 0020

(Per 21 CFR 801.109) (Optional Format 1-2-96)