K033998

MAR 1 9 2004

510(k) SUMMARY

MASIMO®
2852 Kelvin Avenue
Irvine, CA 92614
Tel: 949-250-9688
Fax: 949-250-9686

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:	February 18, 2004
Trade Name	Masimo SET® Rad-5v Pulse Oximeter
Common Name	Pulse Oximeter
Classification Name	Oximeter (74DQA) (870.2700)
Substantially Equivalent Devices	Masimo SET Radical Pulse Oximeter with SatShare™ and LNOP series of Sensors and Cables 510(k) Number - K031330 Nonin Model 2500 Pulse Oximeter – 510(k) Number – K001930

The Masimo SET® Rad-5v Handheld Pulse Oximeter is noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-5v features a multicolored LED display that continuously displays numeric values for SpO2 and pulse rate, as well as LED indicator bars for Pulse Amplitude Index (PAI) and Signal Quality (SQ).

Features and Benefits

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and pulse amplitude index displays
- SQ for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 36 hours on 4 "AA" alkaline batteries
- Audible Alarm for sensor-off and low battery

Intended use

The Masimo SET® RAD-5v Pulse Oximeter is intended for non-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 mobile environments.

510(k) SUMMARY

Indications for use

The Rad-5v Handheld Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Rad-5v Handheld Pulse Oximeter is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Principles of Operation

The principles of operation of the Masimo SET® Rad-5v 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® Rad-5v 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 into the Masimo SET® Rad-5v 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® Rad-5v 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 Rad-5v pulse oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. 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® Rad-5v pulse oximeter is powered by 4 AA batteries with an operating time of 36 hours[4].

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

510(k) SUMMARY

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

Internally powered by 4 "AA" Alkaline batteries

Isolation

No external power or ground connection, internally powered only

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
Operating Altitude	500 mbar to 1060 mbar pressure -1,000 ft to 18,000 ft (-304 m to 5,486 m)

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of parameters
Automatic alarm messages

Display	
Type	LED, 7-segment
Data Displayed	Pulse Rate, SpO2 %, Alarm status, alarm silenced status, Pulse Amplitude Index Bar, Signal Quality Bar, and Battery Status.

Audio indicators

Adjustable volume audible pulse: OFF and 33% to 100% in 3 steps
Adjustable volume audible alarm tone: levels and 33% to 100% in 3 steps
Alarm silence (120 seconds): all mute (continuous silence)
Sensor condition alarms
System failure and battery low alarms

510(k) SUMMARY

Physical characteristics	
Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.32 kg)
Modes	
Averaging mode:	8 seconds
Sensitivity	Normal

1 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

2 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

3 The specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on adult volunteers and 1% was added to account for the properties of fetal hemoglobin to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates to be within ± 3 digits during no motion and ± 5 digits during motion conditions when compared to the ECG.. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

4 The Masimo SET Technology 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 which encompasses 68% of the population.

5 This represents approximate run time at lowest indicator brightness, using a new, fully charged battery.

Environmental Testing

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

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo SET® Rad-5v Pulse Oximeters 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® Rad-5v Pulse Oximeters 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® technology 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® technology 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.

Clinical studies were performed using the Masimo SET® technology 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.

510(k) SUMMARY

Clinical studies were performed using the Masimo SET® technology 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® technology 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 specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on adult volunteers and 1% was added to account for the properties of fetal hemoglobin to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates 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® Rad-5vPulse Oximeter **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **bench testing** demonstrates that the Masimo SET® Rad-5v Pulse Oximeters **met** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® technology **meets** 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® Rad-5v Pulse Oximeters is safe, effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2004

Mr. James Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
2852 Kelvin Ave.
Irvine, CA 92614-5826

Re: K033998
Trade/Device Name: Masimo SET Rad 5v Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DPZ
Dated: December 22, 2003
Received: December 24, 2003

Dear Mr. Cronin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 - Indications for Use

510(k) Number (if known):

Device Name: Masimo SET Rad 5v Pulse Oximeter

Indications For Use:

The Masimo SET® Rad5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Rad 5v Pulse Oximeter is 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, mobile, and home environments..

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K033998

0020

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2004

Mr. James Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
2852 Kelvin Ave.
Irvine, CA 92614-5826

Re: K033998
Trade/Device Name: Masimo SET Rad 5v Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DPZ
Dated: December 22, 2003
Received: December 24, 2003

Dear Mr. Cronin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 - Indications for Use

510(k) Number (if known):

Device Name: Masimo SET Rad 5v Pulse Oximeter

Indications For Use:

The Masimo SET® Rad5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Rad 5v Pulse Oximeter is 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, mobile, and home environments..

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K033998

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0020

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 31, 2003

MASIMO CORP.
2852 KELVIN AVE.
IRVINE, CA 92614
ATTN: JAMES J. CRONIN

510(k) Number: K033998
Received: 30-DEC-2003
Product: MASIMO SET RAD-5V PULSE OXIMETER, MODEL RAD-5V

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 24, 2003

MASIMO CORP.
2852 KELVIN AVE.
IRVINE, CA 92614
ATTN: JAMES J. CRONIN

510(k) Number: K033998
Received: 24-DEC-2003
Product: MASIMO SET RAD-5V
User Fee ID Number: 12415ETER,
MODEL RAD-5V

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier (e.g., Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at http://www.fda.gov/oc/mdufma.

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Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

K033998

MASIMO®
2852 Kelvin Avenue
Irvine, CA 92614
Tel: 949-250-9688
Fax: 949-250-9686

December 22, 2003

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: Masimo SET Rad-5v Pulse Oximeter

Dear Document Control Clerk:

This is to notify you of the intention of Masimo Corporation to commercially distribute the Masimo SET Rad-5v pulse oximeter which is a modification of Masimo's predicate device, the Masimo SET Radical Pulse Oximeter with Satshare:

Trade Name:	Masimo SET® Rad-5v Pulse Oximeter
Common Name:	Pulse Oximeter
Classification Name and Product Code:	Oximeter (74DQA) (870.2700)
Establishment Registration Number:	2031172
Address of Manufacturing Facility:	2852 Kelvin Ave. Irvine, CA 92614-5826
Classification:	Class II
Reason for Premarket Notification:	Device Modification
Substantially Equivalent Devices:	Masimo SET® Radical Pulse Oximeter with SatShare™ and LNOP® series of Sensors and Cables 510(k) Number - K031330 Nonin Model 2500 Pulse Oximeter – 510(k) Number K001930
Performance Standards:	To the best of our knowledge and as of this writing, no performance standards for the above device has been promulgated pursuant to Section 514.

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In response to the requirements addressed by the SMDA of 1990, I am enclosing **a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.**

All proprietary and confidential information will be identified as such.

For the benefit of the reviewer the information has been organized according to the Reviewer Guidance for Premarket Notification Submissions for Respiratory Devices dated November 1993.

If there are any questions regarding this submission, please contact Jim Cronin, Vice President, Regulatory Affairs/Quality Assurance at (949) 250-9688 or FAX (949) 250-9686.

Sincerely,

James J. Cronin
Vice President, Regulatory Affairs/Quality Assurance

Enclosures

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER (b) (4) [redacted]
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

MASIMO CORPORATION
2852 KELVIN AVENUE
IRVINE, CA 92614

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
330368882

2. CONTACT NAME
JAMES CRONIN

2.1 E-MAIL ADDRESS
jcronin@masimo.com

2.2 TELEPHONE NUMBER (Include Area Code)
949-250-9688

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
949-250-9686

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

$3,480.00

Form FDA 3601 (08/2003)

MASIMO®
2852 Kelvin Avenue
Irvine, CA 92614
Tel: 949-250-9688
Fax: 949-250-9686

December 22, 2003

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: Masimo SET Rad-5v Pulse Oximeter

Dear Document Control Clerk:

This is to notify you of the intention of Masimo Corporation to commercially distribute the Masimo SET Rad-5v pulse oximeter which is a modification of Masimo's predicate device, the Masimo SET Radical Pulse Oximeter with Satshare:

Trade Name:	Masimo SET® Rad-5v Pulse Oximeter
Common Name:	Pulse Oximeter
Classification Name and Product Code:	Oximeter (74DQA) (870.2700)
Establishment Registration Number:	2031172
Address of Manufacturing Facility:	2852 Kelvin Ave. Irvine, CA 92614-5826
Classification:	Class II
Reason for Premarket Notification:	Device Modification
Substantially Equivalent Devices:	Masimo SET® Radical Pulse Oximeter with SatShare™ and LNOP® series of Sensors and Cables 510(k) Number - K031330 Nonin Model 2500 Pulse Oximeter – 510(k) Number K001930
Performance Standards:	To the best of our knowledge and as of this writing, no performance standards for the above device has been promulgated pursuant to Section 514.

0001

In response to the requirements addressed by the SMDA of 1990, I am enclosing **a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.**

All proprietary and confidential information will be identified as such.

For the benefit of the reviewer the information has been organized according to the Reviewer Guidance for Premarket Notification Submissions for Respiratory Devices dated November 1993.

If there are any questions regarding this submission, please contact Jim Cronin, Vice President, Regulatory Affairs/Quality Assurance at (949) 250-9688 or FAX (949) 250-9686.

Sincerely,

James J. Cronin
Vice President, Regulatory Affairs/Quality Assurance

Enclosures

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Table of Contents

Masimo Corporation
510(k) Notification - Masimo SET® Rad 5v Pulse Oximeter

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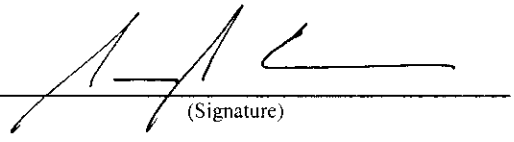
PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(j)]

I certify, in my capacity as Vice President Regulatory Affairs/Quality Assurance of Masimo Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

James J. Cronin

(Typed Name)

12/22/03

(Dated)

(Premarket Notification (510k) Number)

SD

0004

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: 12/22/03	FDA Document Number

Section A — Type of Submission

☒ 510(k)	☐ IDE	☐ PMA	☐ PMA Supplement - Regular
☐ 510(k) Add'l information	☐ IDE Amendment	☐ PMA Amendment	☐ PMA Supplement - Special
☐ Special 510(k): Device Modification	☐ IDE Supplement	☐ PMA Report	☐ PMA Supplement - 30 day
	☐ IDE Report		☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

☒ New Device
☐ Additional or expanded indications
☐ Change in technology, design, materials, or manufacturing process
☐ Other reason (specify):

Section B2 — Reason for Submission — PMAs Only

☐ New Device
☐ Withdrawal
☐ Additional or expanded indications
☐ Licensing agreement
☐ Labeling change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)

☐ Change in ownership
☐ Change in correspondent
☐ Other reason (specify):

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Other (specify below)

☐ Process Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing Site

☐ Location change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Report submission:
- ☐ Annual or periodic
- ☐ Post-approval study
- ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment

Section B3 — Reason for Submission — IDEs Only

☐ New Device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect

☐ Licensing agreement
☐ Change in ownership
☐ Change in correspondent
☐ Other reason (specify):

☐ Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report submission
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approved
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension of time to respond to FDA
- ☐ Request meeting

☐ IOL submissions only:
- ☐ Change in IOL style
- ☐ Request for protocol waiver

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	FDA Document Number

Section C — Product Classification

Product Code:	C.F.R. Section	Device Class:
74DQA	**870.2700**	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: **Cardiovascular**		

Section D — Information on 510(k) Submissions

Product Codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning Safety and effectiveness data:
1 **74DQA**	2 DQA 870.2710	3	4	☒ 510(k) summary attached
5	6	7	8	☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 **K031330**	1 **Masimo SET® Radical Pulse Oximeter with SatShare**	1 **Masimo Corporation**
2	2	2
3	3	3

Section E — Product Information — Applicable to All Applications

Common or usual name or classification name: **Pulse Oximeter (74DQA)**

Trade or proprietary or model name	Model Number
1 **Masimo SET® Rad-5v Pulse Oximeter ™**	1 **Rad-5v**

FDA document numbers of all prior related submissions (regardless of outcome):

1 K000126	2 K992340	3 K002477	4 K002574	5 K002682	6 K002751
7 K002939	8 K003167	9 K003244	10 K010419	11 K011851	12 K013792

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☒ Human trials

Indications (from labeling):

The Masimo SET® Rad-5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Rad-5 Pulse Oximeter is indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments

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	FDA Document Number

Section F — Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2031172	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler

Company / Institution name:
Masimo Corporation

Division name (if applicable):	Phone number (include area code): **(949) 250-9688**
Street address: **2852 Kelvin Ave.**	FAX number (include area code): **(949) 250-9686**

City:	State / Province:	Country:	ZIP / Postal Code
Irvine	**CA**	**USA**	**92614-5826**

Contact name:
James J. Cronin

Contact title:
Vice President, Regulatory Affairs/Quality Assurance

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler

Company / Institution name:

Division name (if applicable):	Phone number (include area code):
Street address:	FAX number (include area code):

City:	State / Province:	Country:	ZIP / Postal Code

Contact name:

Contact title:

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler

Company / Institution name:

Division name (if applicable):	Phone number (include area code):
Street address:	FAX number (include area code):

City:	State / Province:	Country:	ZIP / Postal Code

Contact name:

Contact title:

	FDA Document Number

Section G Applicant or Sponsor

Company / Institution Name:	FDA establishment registration number:
Masimo Corporation	
Division name (if applicable):	Phone number (include area code):
	(949) 250-9688
Street address:	FAX number (include area code):
2852 Kelvin Ave	**(949) 250-9686**

City:	State / Province:	Country:	ZIP / Postal Code
Irvine	**CA**	**USA**	**92614-5826**

Signature:

Name:
James J. Cronin

Title:
Vice President, Regulatory Affairs/Quality Assurance

Section H Submission correspondent (if different from above)

Company / Institution Name:	
Division name (if applicable):	Phone number (include area code):
Street address:	FAX number (include area code):

City:	State / Province:	Country:	ZIP / Postal Code

Signature:

Name:

Title:

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638 - 2041 or (301) 443 - 6597.

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PREMARKET NOTIFICATION 510(k)
CHECKLIST FOR ACCEPTANCE DECISION

K Number		Device Name	Masimo SET® Rad 5 Pulse Oximeter

Division/Branch:	Cardiovascular Devices
Administrative Reviewer Signature:	Date: _____
Supervisory Signature:	Date: _____
Did the firm request expedited review:	_____ Yes ____x____ No
Did we grant expedited review?	_____ Yes ____x____ No
Truthful and accurate statement enclosed?	____x____ Yes _____ No

_____ Accepted

_____ Refuse to Accept

	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
I. CRITICAL ELEMENTS		
A. Is the product a device?	☒	☐
B. Is the device exempt from 510(k) by regulation or policy?	☒ No. It is a Class II Device	☐
C. Is the device subject to review by CDRH?	☒	☐
D. (i) Are you aware that this device has been the subject of a previous NSE decision?	☒ No. It is an initial Submission	☐
(ii) If Yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	☒ Not Applicable	☐
E. (i) Are you aware of the submitter being the subject of an integrity investigation?	☒ Masimo has not been subject to an integrity investigation.	☐
If yes, consult the ODE Integrity Officer.		
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	☒ Not Applicable	☐
F. Does the submission contain the information required under sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and subpart E of Part 807 in Title 21 of the Code of Federal Regulations?	☒	☐
1. Device Trade or Proprietary Name	☒	☐
2. Device Common or Usual Name or Classification Name	☒	☐
3. Establishment Registration Number (Only applies if establishment is registered)	☒	☐
4. Class into which the device is classified under (21 CFR Parts 862 to 892)	☒	☐
5. Classification Panel	☒	☐

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PREMARKET NOTIFICATION 510(k)
CHECKLIST FOR ACCEPTANCE DECISION

	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
6. Action taken to comply with section 514 of the Act	☒	☐
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	☒	☐
8. A 510(k) Summary of Safety and Effectiveness or a 510(k) Statement that Safety and Effectiveness information will be made available to any person upon request.	☒	☐
9. For Class III devices only, a Class III Certification and a Class III summary.	☒ Not Applicable. Class II Device	☐
10. Photographs of the device	☒	☐
11. Engineering drawings for the device with dimensions and tolerances	☒	☐
12. The marketed devices to which equivalence is claimed including labeling and description of the device	☒	☐
13. Statement of similarities and/or differences with marketed device(s)	☒	☐
14. Data to show consequences and effects of a modified device(s)	☒ New Device	☐
15. Truthful and Accurate Statement	☒	☐
II. Additional information that is necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	☒	☐
B. Contact person, telephone number and FAX number	☒	☐
C. Representative/consultant if applicable	☒	☐
D. Table of contents with pagination	☒	☐
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	☒ Device is to be sold non-sterile	☐
III. Additional information that maybe necessary under 21 CFR 807.87(h)		
A. Comparison table of the new device to the marketed device(s)	☒	☐
B. Action taken to comply with voluntary standards	☒	☐
C. Performance Data	☒	☐
Marketed Device:	☒	☐
Bench testing	☒	☐
Animal testing	☒ Bench and Clinical Data Included- Animal Testing Not Required	☐
Clinical data	☒	☐
New Device:	☒	☐
Bench testing	☒	☐
Animal testing	☒ Bench and Clinical Data Included - Animal Testing Not Required	☐
Clinical Data	☒	☐
D. Sterilization information	☒ Device is to be sold non-sterile	☐

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PREMARKET NOTIFICATION 510(k)
CHECKLIST FOR ACCEPTANCE DECISION

	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
E. Software information	☒	☐
F. Hardware information	☒	☐
G. If this 510(k) is for a kit, has the Kit Certification Statement been provided?	☒ Device is not a kit	☐
H. Is this device subject to issues that have been addressed in specific guidance document(s)?	☒	☐
If yes, continue review with checklist from any appropriate guidance documents.	☒	☐
If no, is 510(k) sufficiently complete to allow substantive review?	☒ Not Applicable	☐
I. Other (Specify)	☒ None	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

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ARDB PREMARKET NOTIFICATION 510(k)
REVIEWER'S CHECKLIST

K Number		TIER	

DATE:	
REVIEWER:	
PRODUCT NAME	Masimo SET® Rad 5v Pulse Oximeter
COMPANY NAME	Masimo Corporation
COMPANY CONTACT	James J. Cronin, Vice President Regulatory Affairs/Quality Assurance, (949) 250-9688

PRESENT	NEEDED		NECESSARY INFORMATION
☒ Yes ☐ NO	☒ Yes ☐ NO	1.	**Executive Summary** (Reviewer Guidance (RG) - Page 3)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Reason for 510(k) submission (new device or modification)
☒ Yes ☐ NO	☒ Yes ☐ NO		b. General description of the device & indications
☒ Yes ☐ NO	☒ Yes ☐ NO		c. Description of device configurations, components, size, accessories
☒ Yes ☐ NO	☒ Yes ☐ NO	2.	**Intended Use** (RG - Page 3)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Purpose and function of device
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Intended patient population
☒ Yes ☐ NO	☒ Yes ☐ NO		c. Intended environment of use
☒ Yes ☐ NO	☒ Yes ☐ NO		d. Device claims
☒ Yes ☐ NO	☒ Yes ☐ NO		e. Identification of legally marketed predicate device & applicable 510(k) with similar indications for use.
☒ Yes ☐ NO	☒ Yes ☐ NO		f. Explanations to how differences in indications do not adversely affect safety & effectiveness.
☒ Yes ☐ NO	☒ Yes ☐ NO	3.	**Device Description** (RG - Page 4)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Precise description of device, components, accessories
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Device specifications and materials
☒ Yes ☐ NO	☒ Yes ☐ NO		c. Method of operation
☒ Yes ☐ NO	☒ Yes ☐ NO		d. Engineering drawings, device pictures
☒ Yes ☐ NO	☒ Yes ☐ NO	4.	**Table of Comparison to Legally Marketed Device** (RG - Page 4)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Identification of predicate device, model, & manufacturer
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Predicate device 510(k) number or documentation of pre-Admendment status
☒ Yes ☐ NO	☒ Yes ☐ NO	5.	**Discussion of Similarities & Differences** (RG - Page 4)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Explanation of differences with supporting rationale
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Device Modification or enhanced version
☒ Yes ☐ NO	☒ Yes ☐ NO		1) Detailed description of each modification made to the predicate device for the development of the device under review.
☒ Yes ☐ NO	☒ Yes ☐ NO		2) Rationale for each modification
☒ Yes ☐ NO	☒ Yes ☐ NO		3) Explanation as to how each modification affects safety & effectiveness
☒ Yes ☐ NO	☒ Yes ☐ NO	6.	**Environmental Testing** (RG - Page 5)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Electrical
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Electromagnetic Compatibility
☒ Yes ☐ NO	☒ Yes ☐ NO		c. Mechanical
☒ Yes ☐ NO	☒ Yes ☐ NO		d. Leakage Current

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ARDB PREMARKET NOTIFICATION 510(k)
REVIEWER'S CHECKLIST

PRESENT	NEEDED		NECESSARY INFORMATION
☒ Yes ☐ NO	☒ Yes ☐ NO		e. Testing procedures and protocols
☒ Yes ☐ NO	☒ Yes ☐ NO		f. Explanation as to how testing simulates the intended environment
☒ Yes ☐ NO	☒ Yes ☐ NO		g. Comparison of testing procedures to that described in the Reviewer Guidance for Premarket Notification Submission (Appendix A)
☒ Yes ☐ NO	☒ Yes ☐ NO		h. Test results and analysis of results
☒ Yes ☐ NO	☒ Yes ☐ NO	7.	**Comparative Performance Evaluations** (RG - Page 5)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Testing procedures and protocols
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Test results and analysis of results
☒ Yes ☐ NO	☒ Yes ☐ NO	8.	**Clinical Performance Evaluations** (RG - Page 6)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Testing procedures and protocols
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Test results and analysis of results
☒ Yes ☐ NO	☒ Yes ☐ NO		c. Documentation demonstrating testing performed in accordance with 21 CFR parts 50, 56, and 812
☒ Yes ☐ NO	☒ Yes ☐ NO		1) Documentation of the institutional review board determination (significant risk or non-significant risk)
☒ Yes ☐ NO	☒ Yes ☐ NO		2) Documentation demonstrating that subject informed consent was obtained
☒ Yes ☐ NO	☒ Yes ☐ NO	9.	**Software Information** (RG - Page 6) Information in accordance with the Reviewer Guidance for Computer Controlled Medical Devices
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Description of the software and device performance requirements
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Description of potential system hazards and software and/or hardware functions implemented as a result of potential hazards
☒ Yes ☐ NO	☒ Yes ☐ NO		c. Description of software development activities, including the performance of hazard and fault-tree (or similar) analyses, verification and validation activities, and software maintenance activities after the device is on the market
☒ Yes ☐ NO	☒ Yes ☐ NO		d. Description of the most recent verification and validation protocols, and identification of which activities were performed prior to and after software/hardware integration
☒ Yes ☐ NO	☒ Yes ☐ NO		e. Documentation of verification and validation results and analyses showing that specifications were met at each appropriate level of software development
☒ Yes ☐ NO	☒ Yes ☐ NO		f. Written affirmation stating that the described software was developed and tested according to the stated procedure/method and tests showed requirements were met
☒ Yes ☐ NO	☒ Yes ☐ NO		g. Identification of the software version level featured in the final design of the device
☐ Yes ☒ NO	☐ Yes ☒ NO	10.	**Biocompatibility Information** (RG - Page 7)
☐ Yes ☒ NO	☐ Yes ☒ NO		a. Identification of predicate device (& applicable 510(k) file) with similar indications for use utilizing the exact same materials
☐ Yes ☒ NO	☐ Yes ☒ NO		b. Testing information in accordance with ISO 10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests
☐ Yes ☒ NO	☐ Yes ☒ NO		c. Test protocol and pass/fail criteria
☐ Yes ☒ NO	☐ Yes ☒ NO		d. Test results and analysis of results
☐ Yes ☒ NO	☐ Yes ☒ NO	11.	**Applicable Voluntary Standards** (RG - Page 7)
☐ Yes ☒ NO	☐ Yes ☒ NO		a. Identification of applicable standards (i.e. AAMI, ASTM, IEC, etc.) to which

ARDB PREMARKET NOTIFICATION 510(k) REVIEWER'S CHECKLIST

PRESENT	NEEDED		NECESSARY INFORMATION
			the device complies
☐ Yes ☒ NO	☐ Yes ☒ NO		b. Explanation as to how each standard requirement is met
☐ Yes ☒ NO	☐ Yes ☒ NO		c. For performance requirements, testing procedures and protocols, test results, and analysis of results
☐ Yes ☒ NO	☐ Yes ☒ NO	**12.**	**Sterility Information** (RG - Page 7) Information in accordance with the 510(k) Sterility Reviewer Guidance
☒ Yes ☐ NO	☒ Yes ☐ NO	**13.**	**Reusable or Single Use Devices** (RG - Page 7)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Testing information (i.e., procedures, results, analysis demonstrating that the function of the device is not comprised by repeated use and disinfection/resterilization processes)
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Labeling identifying the maximum number of resterilization processes to be performed and performance tests/inspections that have to be passed after each process
☒ Yes ☐ NO	☒ Yes ☐ NO		c. Labeling identifying device as single use only
☒ Yes ☐ NO	☒ Yes ☐ NO	**14.**	**Labeling, Instructions for Use, Promotional Material** (RG Pages 7 & 18-21)
☒ Yes ☐ NO	☒ Yes ☐ NO		a. Device claims
☒ Yes ☐ NO	☒ Yes ☐ NO		b. Prescription statement (21 CFR 801.109(b)(1))
☐ Yes ☒ NO	☐ Yes ☒ NO	**15.**	**Kit Information** (RG - Page 8)
☐ Yes ☒ NO	☐ Yes ☒ NO		a. Kit certification
☐ Yes ☒ NO	☐ Yes ☒ NO		b. Identification of each kit component and applicable 510(k) number or documentation of pre-Amendment status
☐ Yes ☒ NO	☐ Yes ☒ NO		c. Device information on components not cleared through the 510(k) process
☐ Yes ☒ NO	☐ Yes ☒ NO		d. Glove certification
☒ Yes ☐ NO	☒ Yes ☐ NO	**16.**	**510(k) Summary or Statement** (RG - Page 8)
☐ Yes ☒ NO	☐ Yes ☒ NO	**17.**	**Class III Certification and Summary** (RG - Page 9)

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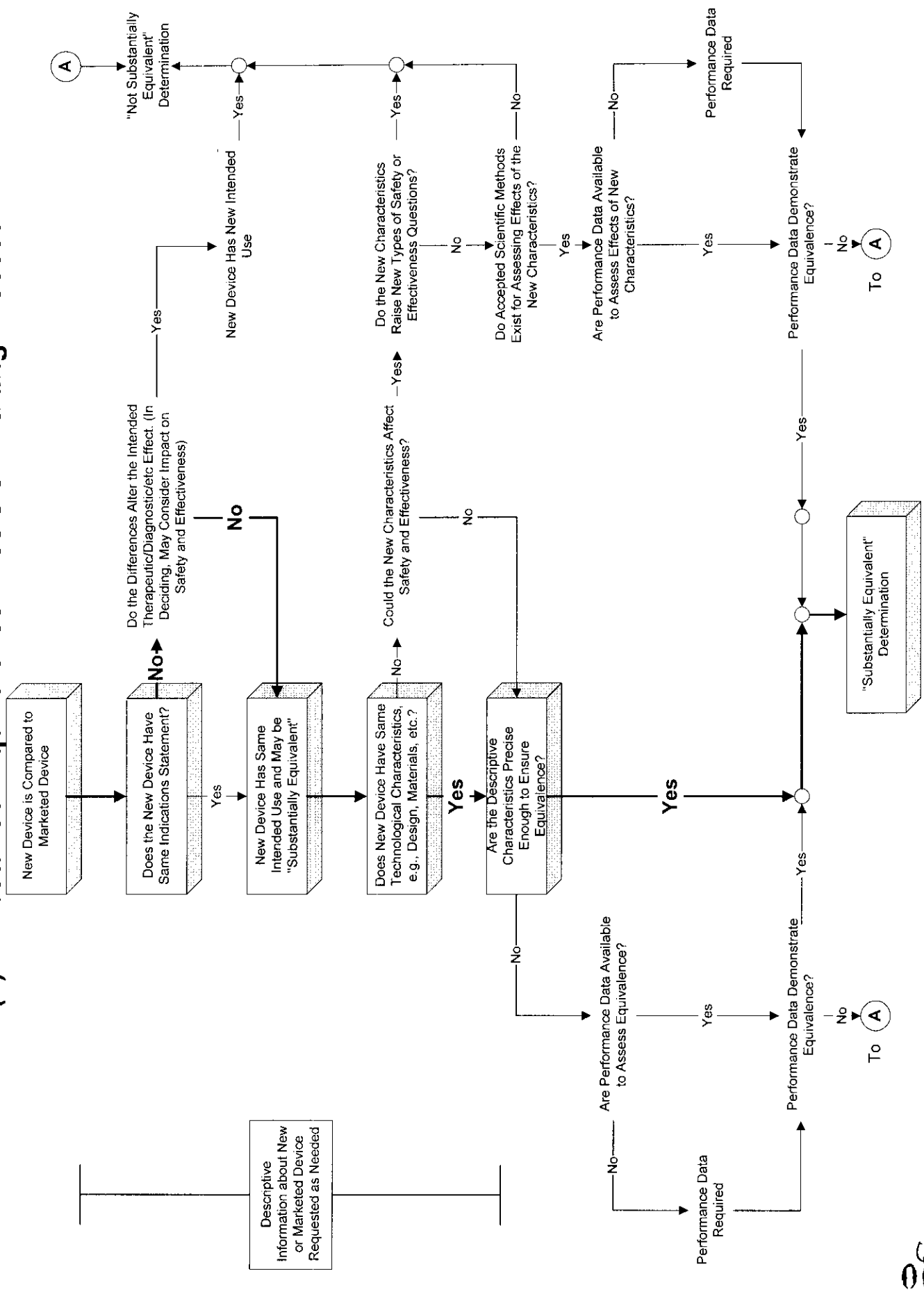

510(k) "Substantial Equivalence" Decision Making Process

K Number		Device Name	Masimo SET® Rad 5v Pulse Oximeter

Question?	Answer	Justification
New Device Compared to Marketed Device?	☒ Yes ☐ No	Compared to Masimo SET Radical K031330 And Nonin Model 2500 Pulse Oximeter
Does the new device have the same Indication Statement?	☒ Yes ☐ No	Same as Nonin 2500 Pulse Oximeter See Section 3
New device has same intended use and may be "Substantially Equivalent"?	☒ Yes ☐ No	Same as Nonin 2500 Pulse Oximeter. See Section 2
Does new device have same technological characteristics, e.g., Design, Materials, etc.?	☒ Yes ☐ No	Same as Masimo SET Radical. See Sections 5 and 6
Are the descriptive characteristics precise enough to ensure equivalence?	☒ Yes ☐ No	Same as parts of Masimo SET Radical. See Sections 4, 5 and 6.
Are performance data available to assess equivalence?	☒ Yes ☐ No	Bench and Clinical data provided. See Sections 8 and 9.
Performance data demonstrate equivalence?	☒ Yes ☐ No	Bench and Clinical data provided. See Sections 8 and 9.
"Substantially Equivalent" determination	☒ Yes ☐ No	Substantially Equivalent to Masimo SET Radial; Nonin Model 2500

Section 1 — Executive Summary

Masimo SET® Rad 5v Pulse Oximeter

510(k) Summary

Submitted By:	Masimo Corporation 2852 Kelvin Ave Irvine, CA 92614-5826 (949) 250-9688 FAX (949) 250-9686
Contact:	James J. Cronin Vice President, Regulatory Affairs/Quality Assurance
Trade Name:	Masimo SET® Rad 5v Pulse Oximeter
Common/Classification Name:	Oximeter (74DQA)
Substantially Equivalent Devices:	Masimo SET Radical Pulse Oximeter with Satshare and accessories 510(k) Number – K031330 Nonin Model 2500 Pulse Oximeter – 510(k) Number K001930

Reason for Submission

Premarket notification for Masimo SET® Rad 5v Pulse Oximeter, a New Device, seeking authority to market the device under Section 510(k) as a device that is substantially equivalent to the Masimo SET® Radical Pulse Oximeter with Satshare and accessories, Nonin's Model 2500 Pulse Oximeter.

Intended Use of Device

The Masimo SET® Rad 5v is intended for non-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, mobile, and home environments.

Indications for Use

The Masimo SET® Rad 5v is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Rad 5v is 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, mobile, and home environments.

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Contraindications For Use:

The Masimo SET® Rad 5v is contraindicated for use as apnea monitors.

Device Description

The Masimo SET Rad 5v Handheld Pulse Oximeter is a non-continuous noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-5v features a multicolored LED display that continuously displays numeric values for SpO2 and pulse rate, as well as LED indicator bars for Perfusion Index (PI) and Signal Identification and Quality Indicator (Signal IQ™). The Masimo SET Rad 5 Handheld Pulse Oximeter is intended to be used with Masimo's LNOP series of oximetery sensors and patient cables.

Features and Benefits

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and perfusion index displays
- Signal IQ™ for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 36 hours on 4 "AA" alkaline batteries
- Audible Alarm for sensor-off and low battery

Configurations

The Masimo SET® Rad 5v Pulse Oximeter is available in only one configurations:

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Section 2 — Intended Use

INTENDED USE

The Masimo SET® Rad 5v Pulse Oximeter is intended for non-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, mobile, and home environments.

Section 3 - Indications for Use

510(k) Number (if known):

Device Name: Masimo SET Rad 5v Pulse Oximeter

Indications For Use:

The Masimo SET® Rad5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Rad 5v Pulse Oximeter is 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, mobile, and home environments..

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 4 — Device Description

Description of Device

The Masimo SET® Rad-5v Handheld Pulse Oximeter is noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-5v features a multicolored LED display that continuously displays numeric values for SpO2 and pulse rate, as well as LED indicator bars for Perfusion Index (PI) and Signal Identification and Quality Indicator (Signal IQ™).

Features and Benefits

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and perfusion index displays
- Signal IQ™ for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 36 hours on 4 "AA" alkaline batteries
- Audible Alarm for sensor-off and low battery

Intended use

The Masimo SET® RAD-5v Pulse Oximeter is intended for non-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 mobile environments.

Indications for use

The Rad-5v Handheld Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Rad-5v Handheld Pulse Oximeter is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Principles of Operation

The principles of operation of the Masimo SET® Rad-5v 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® Rad-5v 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 into the Masimo SET® Rad-5v 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® Rad-5v 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 Rad-5v pulse oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. The practitioner can then use the information that is continuously displayed on the monitor 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.

Section 4 — Device Description

Power Source

The Masimo SET® Rad-5v pulse oximeter is powered by 4 AA batteries with an operating time of 36 hours[5].

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

Internally powered by 4 "AA" Alkaline batteries

Isolation

No external power or ground connection, internally powered only

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

Section 4 — Device Description

Operating Altitude	500 mbar to 1060 mbar pressure -1,000 ft to 18,000 ft (-304 m to 5,486 m)

Circuitry

- Microprocessor controlled
- Automatic self-test of oximeter when powered on
- Automatic setting of parameters
- Automatic alarm messages

Display

Type	LED, 7-segment
Data Displayed	Pulse Rate, SpO2 %, Alarm status, alarm silenced status, Perfusion Index Bar, Signal IQ Bar, Battery Status, APOD, FastSat.

Audio indicators

- Adjustable volume audible pulse: OFF and 33% to 100% in 3 steps
- Adjustable volume audible alarm tone: levels and 33% to 100% in 3 steps
- Alarm silence (120 seconds); all mute (continuous silence)
- Sensor condition alarms
- System failure and battery low alarms

Section 4 — Device Description

Physical characteristics

Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.32 kg)

Modes

Averaging mode:	2, 4, 8, 10, 12, and 16 seconds
Sensitivity	Normal, APOD, and MAX

1 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

2 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

3 The Masimo SET Technology 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 which encompasses 68% of the population.

4 The Masimo SET Technology 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 which encompasses 68% of the population.

5 This represents approximate run time at lowest indicator brightness, using a new, fully charged battery.

Section 4 — Device Description

Answers to questions in Reviewer Guidance for Premarket Notification Submissions:

a. Is the device life-supporting or life-sustaining?

No.

b. Is the device an implant (short-term or long-term)?

No.

c. Is the device sterile?

No.

d. Is the device for single use?

No.

e. Is the device for prescription use?

Yes. All required labeling indicates the following:

"Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician."

See Section 15 of this filing.

f. Is the device for use in hospital, home, or mobile environments?

The device is intended for use in a hospital, home, and mobile environments.

See Section 7 of this filing for the environmental testing performed.

g. Does the device contain a drug or biological product as a component?

No.

h. Is the device a kit?

No.

i. Is the device software driven?

Yes. See Section 10 for software information.

j. Is the device electrically operated?

Yes. See Section 7 for the environmental/electrical testing performed.

k. Are there applicable voluntary standards for this device to which conformance has been demonstrated?

Yes, See Section 12 for the applicable voluntary standards for which the device conforms.

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Section 11 — Biocompatibility Information

This section does not apply because the Masimo SET Rad 5v does not have any patient contacting materials.

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Section 12 — Applicable Voluntary Standards

The Masimo SET® Rad 5v Pulse Oximeter is designed to comply with the applicable portions of the following voluntary standards.

- The FDA's Reviewer Guidance for Computer Controlled Medical Devices undergoing 510(k) Review
- Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1, Part 1 and Amendment 1
- IEC 60601-1-1, Part 1
- IEC 60601-1-2, Part 2
- IEC 60601-1-4, Part 1
- ISO 9919 (1992)
- EN-865
- UL 60601-1

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Section 13 — Sterility Information

This section does not apply because the Masimo SET® Rad 5v Pulse Oximeter is supplied and used non-sterile.

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Section 14 — Reusable or Single Use Devices

The Masimo SET® Rad 5v Pulse Oximeter is a reusable devices. The device is supplied and used non-sterile.

The outer surface of the Masimo SET® Rad 5v Pulse Oximeter can be cleaned with a soft cloth dampened with a mild detergent and warm water solution. Do not allow liquids to enter the interior of the instrument:

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Rad-5v™

Signal Extraction Pulse Oximeter

OPERATOR'S MANUAL

The Rad-5v Operating Instructions intend to provide the necessary information for proper operation of all Rad-5v pulse oximeter models. There may be information provided in this manual that is not relevant for your pulse oximetry system.

General knowledge of pulse oximetry and an understanding of the features and functions of the Rad-5v Pulse Oximeter are prerequisites for proper use.

Do not operate the Rad-5v Pulse Oximeter without completely reading and understanding these instructions.

NOTICE

Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION:

FEDERAL LAW (U.S.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

For further information contact:

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EC REP

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Tel.: +49-511-62 62 86 30
Fax.: +49-511-62 62 86 33

MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601-1/CAN/CSA C22.2 No. 601.1

USA Patents and international equivalents. 5337744, 5452717, 5482036, 5490505, 5632272, 5638818, 5645440, 5685299, 5758644, 5769785, 5782757, 6002952, 6067462, 6157850 and 6206830. Other patents pending.
Manufactured in USA

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SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

The Rad-5v Handheld Pulse Oximeter is designed to minimize the possibility of hazards from errors in the software program by following sound engineering design processes, Risk Analysis and Software Validation.

- Explosion hazard. Do not use the Pulse Oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- The Pulse Oximeter is NOT intended for use as an apnea monitor.
- A Pulse Oximeter should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.
- The Pulse Oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Do not open the pulse oximeter cover except to replace the batteries. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient. Do not lift the pulse oximeter by the patient cable.
- 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 blood pigmentation may cause erroneous readings.
- Severe anemia may cause erroneous SpO_2 readings.
- Do not use the pulse oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.
- Do not place the pulse oximeter where the controls can be changed by the patient.
- Do not place the pulse oximeter face against a surface. This will cause the alarm to be muffled.
- Do not place the pulse oximeter on electrical equipment that may affect the pulse oximeter, preventing it from working properly.
- Do not expose the pulse oximeter to excessive moisture such as direct exposure to rain. Excessive moisture can cause the pulse oximeter to perform inaccurately or fail.
- Do not place containers containing liquids on or near the pulse oximeter. Liquids spilled on the pulse oximeter may cause it to perform inaccurately or fail.
- Failure of Operation - If the pulse oximeter fails any part of the setup procedures remove the pulse oximeter from operation until qualified service personnel have corrected the situation.

SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- The pulse oximeter can be used during defibrillation, but the readings may be inaccurate for a short time.
- This equipment has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1994, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving device.
  - Increase the separation between the equipment.
  - Consult the manufacturer for help.

About this Manual

This manual explains how to set up and use the Rad-5v Handheld Pulse Oximeter. Important safety information relating to general use of the Rad-5v Pulse Oximeter appears before this introduction. Other important safety information is located throughout the manual where appropriate.

Read the entire safety information section before you operate the monitor.

In addition to the safety section, this manual includes the following sections:

SECTION 1	OVERVIEW gives a general description of pulse oximetry.
SECTION 2	SYSTEM DESCRIPTION describes the Rad-5v Handheld Pulse Oximeter system and its functions and features.
SECTION 3	SETUP describes how to setup the Rad-5v Handheld Pulse Oximeter for use.
SECTION 4	OPERATION describes the operation of the Rad-5v Pulse Oximetry system.
SECTION 5	ALARMS AND MESSAGES describes the alarm system messages.
SECTION 6	TROUBLESHOOTING gives troubleshooting information.
SECTION 7	SPECIFICATIONS gives the detailed specifications of the Rad-5v Handheld Pulse Oximeter.
SECTION 8	SENSORS AND PATIENT CABLES outlines how to use and care for the Masimo SET LNOP sensors and Masimo SET patient cables.
SECTION 9	SERVICE AND MAINTENANCE describes how to maintain, service and obtain repair for the Rad-5v Handheld Pulse Oximeter.

Warnings, cautions and notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels are as follows:

A **WARNING** is provided when actions may result in a serious outcome (i.e., injury, serious adverse affect, death) to the patient or user. Look for text in a gray shaded box.

Sample of Warning:

WARNING: THIS IS A SAMPLE OF A WARNING STATEMENT.

A **CAUTION** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device or damage to other property.

Sample of Caution:

CAUTION: THIS IS A SAMPLE OF A CAUTION STATEMENT.

A ***NOTE*** is provided when extra general information is applicable.

Sample of Note:

NOTE: *This is a sample of a Note.*

Product Description

The Rad-5v Handheld Pulse Oximeter is a noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-5v features a multicolored LED display that continuously displays numeric values for SpO_2 and pulse rate, as well as LED indicator bars for Perfusion Index (PI) and Signal Identification and Quality Indicator (Signal IQ™).

The Rad-5 family consists of two models: the full-featured Rad-5 and the Rad-5v entry-level spot checker. Both units are built on the same motion tolerant pulse oximetry technology, with the Rad-5 adding parameter alarming, three sensitivity settings and adjustable averaging times.

FEATURES AND BENEFITS

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and perfusion index displays
- Signal IQ™ for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 48 hours on 4 "AA" alkaline batteries
- Audible Alarm for sensor-off and low battery

INDICATIONS FOR USE

The Rad-5v and accessories are indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor).

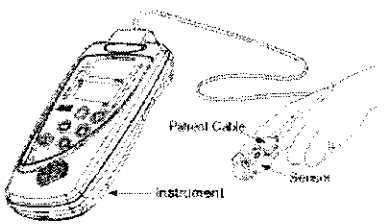
WARNING: THE RAD-5v IS NOT INTENDED FOR CONTINUOUS PATIENT MONITORING.

The Rad-5v Handheld Pulse Oximeter and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Pulse Oximetry

GENERAL DESCRIPTION

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor connects to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two ways: 1) as a percent value for arterial oxygen saturation (SpO_2), and 2) as a pulse rate (PR). The following figure shows the general monitoring setup.

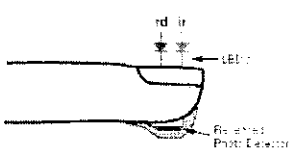


PRINCIPLE OF OPERATION

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Rad-5v Handheld Pulse Oximeter uses a two-wavelength pulsatile system to distinguish between oxygenated and deoxygenated blood. Signal data is obtained by passing red (rd) (660 nm wavelength) and infrared (ir) (905 nm wavelength) light through a capillary bed (for example a fingertip, a hand, a foot) and measuring changes in light absorption during the pulsatile cycle. See figure below. The Rad-5v utilizes a sensor with red and infrared light-emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). The photodetector receives the light, converts it into an electronic signal and sends it, via a patient cable, to the Rad-5v for calculation.



Once the Rad-5v receives the signal from the patient sensor, it utilizes Masimo SET signal extraction technology for calculation of the patient's functional oxygen saturation and pulse rate.

FUNCTIONAL VS. FRACTIONAL SATURATION

The Rad-5v measures and displays functional saturation: the amount of oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. The Rad-5v does not measure fractional saturation: oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin. To convert fractional saturation to functional saturation, the fractional saturation measurements must be converted according to:

$$\text{Functional saturation} = \frac{\text{Fractional saturation}}{100 - (\%\ \text{carboxyhemoglobin} + \%\ \text{methemoglobin})} \times 100$$

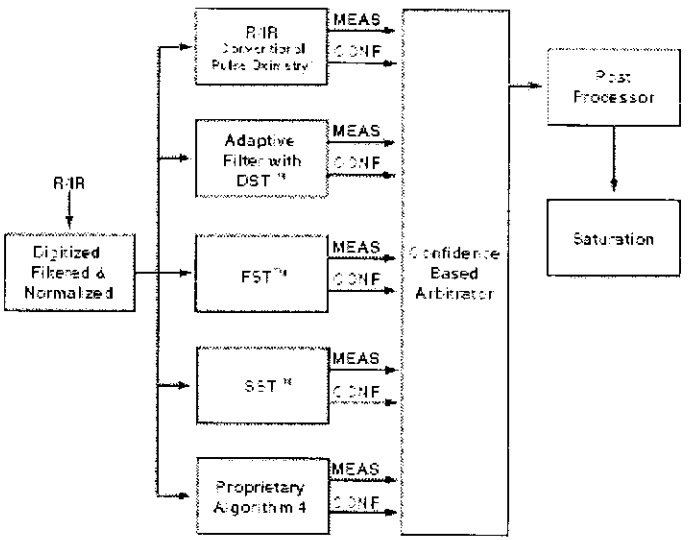
MEASURED VS. CALCULATED SATURATION

Oxygen saturation measurements obtained from a pulse oximeter are commonly compared to saturations calculated from the partial pressure of oxygen (PO_2) obtained from an arterial blood gas sample. When comparing the two measurements and interpreting values, caution should be used, as the calculated value obtained from the blood gas sample may differ from the SpO_2 measurement of the pulse oximeter. Different results are usually obtained from the blood gas sample if the calculated saturation is not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. Also, as blood gas samples are usually taken over a period of 20 seconds (the time it takes to draw blood) a meaningful comparison can only be achieved if the core oxygen saturation of the patient is stable and not changing over the period of time that the blood gas sample is taken.

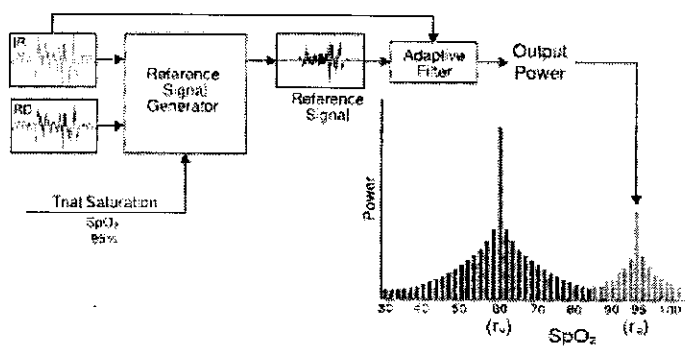
MASIMO SET SIGNAL EXTRACTION TECHNOLOGY

Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the non-arterial blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform™ (DST), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor. Although venous saturation is not displayed, Masimo SET measures and calculates the values of both the arterial and venous oxygen saturation. This is referred to as stereo saturation measurement, since it separates the arterial from the venous information instead of mixing them together, as is done with conventional pulse oximeters.

MASIMO SET PARALLEL ENGINES



MASIMO SET DST



Introduction

The Rad-5v Handheld Pulse Oximeter is designed for ease of operation. All pulse oximetry measurement information, as well as device status data, is displayed on the front panel of the device. All user input is handled by control buttons on the front panel and the sensor cable connection is located at the top edge of the device.

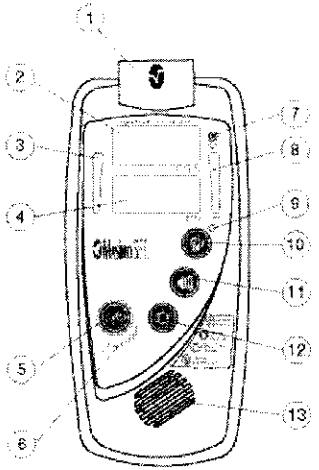
The Rad-5v is powered by 4 "AA" alkaline batteries, which provide over 48 hours of battery life.

- Rad-5v offers full Masimo SET technology in a small, hand held device
- Rad-5v supports the full line of Masimo sensors and patient cables (see Section 8, *sensors and patient cables*).
- Rad-5v supports standardization of sensors and pulse oximetry technology throughout the hospital
- Rad-5v provides essential pulse oximetry features

A LNOP DCSC Sensor or Masimo Patient Cable and Masimo sensor attach to the connector on the top of the Rad-5v unit. The Rad-5v can be used either as a transport monitor or as a handheld pulse oximeter for spot checks.

WARNING: THE RAD-5v IS NOT INTENDED FOR CONTINUOUS PATIENT MONITORING.

Rad-5v front panel controls

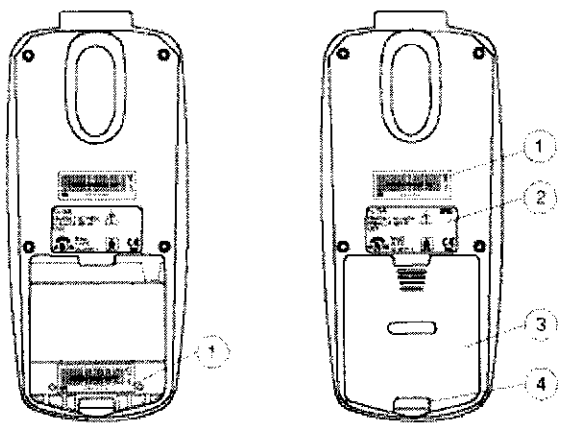


Rad-5v

	CONTROL / INDICATOR	DESCRIPTION
①	Patient Cable Connector	Connects to LNOP DCSC sensor or Masimo Patient Cable
②	Saturation Display	The functional arterial hemoglobin oxygen saturation is displayed in units of SpO_2. When searching for a saturation and pulse, it will flash dashed lines.
③	Perfusion Index	The Perfusion Index provides an indication of the percentage of pulsatile signal to non pulsatile signal. The bar is highest when the quality of the perfused site is best.
④	Pulse Rate Display	The pulse rate in beats per minute (bpm). When searching for a saturation and pulse, it will flash dashed lines.
⑤	Power On / Off	Used to turn the unit on and off.
⑥	Battery Level Indicator	Four LED's indicate the status of the battery. When the final indicator begins flashing, replace the batteries.
⑦	Visual Alarm Indicator	Illuminates when any alarm condition exists. This indicator may not be turned-off or otherwise over-ridden.

	CONTROL / INDICATOR	DESCRIPTION
⑧	Signal IQ / Pulse Bar	The Signal IQ provides an indication of the quality of the acquired signal as well as the timing of the pulse. A green vertical LED bar rises and falls with the pulse, where the height of the bar indicates the quality of the signal.
⑨	Alarm Silenced Indicator	Flashes to indicate the alarm is temporarily silenced (by pushing the Alarm Silence Button once) or is illuminated solid to indicate the alarms have been permanently muted (by pushing the Alarm Silence Button twice) .
⑩	Alarm Silence Button	Push to silence the audible alarm. While monitoring a patient, the Alarm Silenced Indicator will continue to flash as long as alarm condition exists.
⑪	Pulse Tone Volume	Provides control of the pulse tone volume. Cycles through three volume levels, and mute. At the loudest level, pressing the Pulse Tone Volume button will return the volume to mute.
⑫	Display Brightness	Provides control of the front panel indicator brightness. Cycles through four brightness levels. At the brightest level, pressing the Display Brightness button will return the display to the lowest brightness setting.
⑬	Speaker	Provides audible indication of alarm conditions, pulse tone and feedback for key-presses. Ensure the speaker is not covered or the unit is placed face-down on bedding or other sound absorbing surface.

Rad-5v rear panel



CONTROL / INDICATOR		DESCRIPTION
①	Serial Number Label	Second serial number label located inside battery compartment
②	Agency Approvals Label	
③	Battery Cover	
④	Battery Cover Release	Press down and slide the battery cover off the bottom of the oximeter

Introduction

Before the Rad-5v Handheld Pulse Oximeter can be used in a clinical setting, it needs to be inspected, properly setup and the batteries need to be installed.

Unpacking and inspection

Remove the instrument from the shipping carton and examine for signs of shipping damage. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.

If anything is missing or damaged, contact the Technical Service Department. The contact address and phone numbers are listed in Section 9, *Service and Repair.*

Preparation for monitoring

The following sections of the manual describe the preparation, set-up and initial installation of the Rad-5v Handheld Pulse Oximeter.

POWER REQUIREMENTS

The Rad-5v is powered by 4 "AA" alkaline batteries. Do not use any other type of batteries or power source to run the device. The battery compartment is accessed from the back of the device. To install the batteries first remove the battery cover by depressing the Battery Cover Release at the bottom of the cover, and sliding the Battery Cover down off the bottom of the device. Install the batteries in the directions indicated by the battery icons inside the battery compartment. Replace the battery cover by sliding it back up from the bottom of the device until the Battery Cover Release snaps back into position.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.

Battery charge level is indicated by four LED indicators at the bottom of the front panel. All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge. When less than ten (10) percent battery life remains, the final battery indicator will begin to flash and an audible alarm will sound.

Monitor setup

INITIAL SETUP

1. Inspect the oximeter case for damage.
2. Install 4 (four) new AA alkaline batteries.
3. Verify unit powers-up immediately after installing batteries.
4. Turn unit off

5. Turn the unit on, verify all indicators illuminate and speaker sounds a brief tone.

No other setup is required. Refer to Section 4, *General Setup and Use* for additional steps to verify proper functioning of the unit.

Introduction

To operate the Rad-5v Pulse Oximeter effectively, the operator must:

- Know how the oximeter derives its readings (see Section 1, *Pulse Oximetry*)
- Be familiar with its controls and operation.
- Understand its status and alarm messages (see Section 5, *Messages* and Section 6, *Troubleshooting*).

Basic operation

GENERAL SETUP AND USE

1. Inspect the oximeter case for damage.
2. Ensure that the batteries are correctly installed.
3. Connect an LNOP DCSC Sensor or patient cable to the Patient Cable connector of the oximeter. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
4. Select a sensor that is compatible with the oximeter before connecting it to the patient cable. See *Section 8, Sensors and Patient Cables.* If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the photodetector are properly aligned. If using a reusable sensor, make sure it opens and closes smoothly. Remove any substances that may interfere with the transmission of light between the sensor's light source and photodetector.
5. Attach the sensor to the patient. Refer to the Directions for Use of the sensor.
6. Connect the sensor to the patient cable with the logos lining up; make sure it is a firm connection (does not apply for LNOP DCSC Sensor).
7. Press the Power button to turn the oximeter on.
8. Verify all front-panel indicators momentarily illuminate and a brief tone is heard.
9. Verify the front panel display is free of alarm and system failure messages (see Section 5, *Alarms and Messages*) and the battery indicator shows sufficient charge (see Section 4, *Battery Level Indicator*)
10. On the display, verify the readings for SpO_2 and pulse rate.

    NOTE: *"- - - " will flash on the numeric display until the SpO_2 and pulse rate readings have stabilized (approximately 10 seconds).*
11. Verify the sensor alarms are functional by removing the sensor from the sensor site.
    - "SEn OFF" message appears on the display.
    - The alarm tone sounds.
    - The Visual Alarm Indicator flashes.

- Disconnect the sensor from the patient cable or oximeter.
- Confirm that "NO SEn" message appears on the display.

Note: *"NO SEn" and "SEn OFF" will only generate an alarm if the Rad-5v was actively monitoring a patient when the sensor was disconnected.*

12. To begin patient monitoring:
    - Adjust the pulse beep volume.
    - Adjust the display brightness.
15. Verify the sensor is applied correctly and that the measured data is appropriate, see Section 4, *Successful SpO_2 Monitoring.*
16. Monitor the patient.
17. After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules. See the Directions for Use of the sensor.
18. Press and hold the Power/Standby Button for 2 seconds to turn the oximeter off.

Note: *turn the oximeter off between patients so that it can re-calibrate in order to interpret new physiological data and to conserve battery life.*

Successful SpO_2 monitoring

The following general points will aid in ensuring oximetry monitoring success.

- Place the sensor on a site that is not too thick, has sufficient perfusion and provides proper alignment of the LED's and photodetector.
- Place the sensor on a site that has unrestricted blood flow.
- Do not constrict the monitoring site when securing a sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor Directions for Use for proper sensor application.

NUMERIC DISPLAY - SpO_2

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and PR.

Inaccurate measurements may be caused by:

- Significant levels of dysfunctional hemoglobin (e.g., carboxyhemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous pulsations at the frequency of the patient's arterial pulse.
- Very low hemoglobin levels.

NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Rad-5v may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can be additive to the pulse rate displayed on the pulse oximeter .

SIGNAL IQ AND PULSEBAR

The Rad-5v display provides a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO_2 values are not based on adequate signal quality. The signal quality indicator displayed on the Rad-5v is called the Signal IQ. The Signal IQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement.

The Signal IQ is shown as a "bouncing bar" indicator, where the peak of the bar coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Rad-5v locates the arterial pulsation. The pulse tone (when enabled) coincides with the peak of the Signal IQ bar.

The height of the Signal IQ bar indicates the quality of the measured signal. A high vertical bar indicates that the SpO_2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO_2 measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO_2 measurement may be compromised. A "Low Signal IQ" is indicated by a bar height of two bars or less and the bars turn red. When this occurs, proceed with caution and do the following:

- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the Rad-5v to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or a spell of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. For example, as may occur while lifting or crossing their legs, during a diaper change.

After performing the above, if the "Low Signal IQ" indication occurs frequently or continuously, obtaining an arterial blood specimen for CO-oximetry analysis may be considered to verify the oxygen saturation value.

LOW PERFUSION

The Rad-5v indicates perfusion on a 10-bar LED indicator. The lower two segments of the bar will turn red when the amplitude of the arterial pulsations is very low (low perfusion).

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation[1]. This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

CAUTION: IF THE LOW PERFUSION INDICATION IS FREQUENTLY DISPLAYED, FIND A BETTER-PERFUSED MONITORING SITE. IN THE INTERIM, ASSESS THE PATIENT AND, IF INDICATED, VERIFY OXYGENATION STATUS THROUGH OTHER MEANS.

[1] Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction. Anesthesiology 1990; 73:532-537

ACTIONS TO BE TAKEN

If the SpO_2 readings show significant differences, do the following:

- Make sure the emitter and photodetector are aligned directly opposite each other.
- Select a site where the distance between the emitter and photodetector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds. Strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical units or other electrical/electronic equipment.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient light. Although the Rad-5v Handheld Pulse Oximeters with integrated Masimo SET technology have significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.

CAUTION: IF ANY MEASUREMENT SEEMS QUESTIONABLE, FIRST CHECK THE PATIENT'S VITAL SIGNS BY ALTERNATE MEANS AND THEN CHECK THE PULSE OXIMETER FOR PROPER FUNCTIONING

BATTERY LEVEL INDICATOR

Four LED indicators provide information on the remaining battery capacity. The operator should monitor these indicators periodically to determine remaining battery life and if the batteries should be replaced. Battery capacity is indicated in the following chart.

INDICATION	BATTERY CAPACITY
4 LED'S	100% to 75%
3 LED'S	75% to 50%
2 LED'S	50% to 25%
1 LED	25% to 10%
1 FLASHING LED WITH AUDIBLE ALARM	10% to 0%

LOW BATTERY AUDIBLE ALARM

If a low battery condition occurs during patient monitoring, a low priority alarm will sound and can be silenced by pressing the Alarm Silence Button. The last battery indicator light and the Alarm Indicator light will continue to flash.

If a low battery condition occurs while not monitoring a patient, pressing the Alarm Silence Button will silence the the alarm until the power is cycled or patient monitoring begins.

If a low battery condition occurs, immediatly discontinue patient monitoring and replace the batteries.

WARNING: FAILURE TO REPLACE BATTERIES PROMPLTY AFTER A LOW BATTERY ALARM MAY RESULT IN THE OXIMETER SHUTTING DOWN LEAVING THE PATIENT IN AN UN-MONITORED CONDITION.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.

Normal patient monitoring

During normal operation, the Rad-5v display shows oxygen saturation (as % SpO_2) on the upper number and Pulse Rate (in beats per minute) on the lower number.

The following sections describe the function of the Rad-5v front panel controls during normal patient monitoring.

RAD-5v FRONT PANEL CONTROL OPERATION

BUTTON	FUNCTION
	Front panel indicator brightness. Pressing this button will cycle the brightness through the full range, then back to the lowest setting to begin the cycle again.
	Alarm Silence. Pressing this button will acknowledge and permanently silence an alarm (until power is cycled or patient monitoring begins).
	Pulse Tone Volume. Pressing this button will cycle the pulse tone volume through the full range, then back to the 'silence' setting to begin the cycle again.
	Power On/Off. Press to turn unit on. Press and hold for 2 seconds to turn unit off.

Alarm Indication

An alarm condition is indicated by:

- Audible alarm tone
- Visual Alarm Indicator

"SEn OFF" and "nO SEn" will only generate an alarm condition after a pulse has been found.

ALARM SILENCE

Audible alarms may be suspended, while visual alarms may not.

Power-On – Alarms are active and Alarm Silenced Indicator is off.

Push Once – Alarm is silenced and Alarm Silenced Indicator flashes.

Push Twice – Return to Audible Alarm Active.

ALARM SILENCED INDICATOR

The Alarm Silenced Indicator provides visual feedback when illuminated, the Rad-5v audible alarms are silenced.

While monitoring a patient, acknowledging an alarm condition by pressing the Alarm Silence Button (one time) will silence the alarm tone and the Alarm Silenced Indicator will flash until the alarm condititon is resolved or until the power is cycled.

Should the alarm condition be created by low batteries, replace the batteries before monitoring a patient.

MESSAGES

The Rad-5v will indicate other data or system errors as indicated below:

DISPLAY	TYPE	SOLUTION
NO SEN	No Sensor Connected	Connect sensor to cable.
SEN OFF	Sensor off patient	1. Reattach sensor to patient. 2. Verify proper sensor placement.
LEDS FLASH HORIZONTAL BARS	Pulse Search	Wait for found pulse. (This Search should occur whenever a sensor is first applied to a patient).
PULSE BAR TURNS RED (Bottom two LEDs only.)	Low Signal IQ	1. Rule out occlusion of blood flow. 2. Verify placement of sensor.
PERFUSION BAR TURNS RED (Bottom two LEDs only.)	Low Perfusion	1. Rule out occlusion of blood flow. 2. Attempt to warm patient. 3. Move sensor to better perfused site. ***Note:*** *Masimo recommends using an adhesive sensor whenever low perfusion is expected or evident.*
SINGLE BATTERY LEVEL INDICATOR FLASHES (WITH AUDIBLE ALARM)	Battery level too low	Replace batteries immediatly.
Err 12	System Fault	Return for service

Troubleshooting

The following chart describes what to do if the Rad-5v system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
UNIT DOES NOT POWER ON	Low battery	Check / replace battery
CONTINUOUS SPEAKER TONE	Internal Failure	Unit requires service. Press the Alarm Silence button. If alarm continues to sound, power down unit and remove batteries.
NO SPEAKER TONE	Pulse tone set to "mute"	Press Alarm Volume Adjust.
	Alarm Suspend Enabled	Inspect Alarm Silenced Indicator. See Section 4, *Alarm Silence*. Press Alarm Silence button until Alarm Silenced Indicator is no longer illuminated or flashing.
BUTTONS DON'T WORK WHEN PRESSED	Internal Failure	Return for service.

Rad-5v family specifications

PERFORMANCE

measurement range

SpO_2:	1-100%
Pulse Rate:	25-240 beats per minute (bpm)
Perfusion:	0.02% - 20%

ACCURACY

Saturation	70% to 100%
No Motion[1]	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Motion	
Adults[2], Pediatrics[2]	±3 digits
Neonate[3]	±3 digits
Low Perfusion[4]	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Pulse Rate Accuracy	
Pulse rate:	25-240 bpm
No Motion[1]	
Adults, Pediatrics, Neonate	±3 digits
Motion[2,3]	
Adults, Pediatrics, Neonate	±5 digits
Low Perfusion[4]	
Adults, Pediatrics, Neonate	±3 digits

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

ELECTRICAL

batteries

Type:	4 "AA" Alkaline[6]
Capacity:	over 48 hours[5]

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)[6]
Operating Humidity:	5% to 95%, non-condensing
Operating Altitude:	500 mbar to 1060 mbar pressure, -1000 ft to 18,000 ft (-304 m to 5,486 m)

PHYSICAL CHARACTERISTICS

Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.32 kg)

Alarms

Audible and visual alarms for sensor condition, system failure and low battery alarms

Display/Indicators

Data display: %SpO_2, pulse rate, alarm status, alarm silenced status,
Signal IQ / pleth bar, perfusion index bar, battery status

Type:	LED

Compliance

EMC Compliance:	EN60601-1-2, Class B
Equipment Classification:	IEC 60601-1-1 / UL 2601-1
Type of Protection:	Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type BF-Applied Part
Mode of Operation:	Spot Check

1 Masimo SET technology 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 which encompasses 68% of the population.

2 Masimo SET technology 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 which encompasses 68% of the population.

3 Masimo SET technology 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 which encompasses 68% of the population.

4 Masimo SET technology 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 which encompasses 68% of the population.

5 This represents approximate run time at lowest indicator brightness, using a new, fully charged battery.

6 If alkaline batteries are to be stored for extended periods of time, it is recommended that they be stored between -0°C to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

Introduction

This section covers the use and cleaning of Masimo LNOP sensors and Masimo SET patient cables.

Masimo LNOP® sensors

Before use, carefully read the LNOP sensor Directions for Use.

Use only Masimo oximetry sensors for SpO_2 measurements. Other oxygen transducers or sensors may cause improper Rad-5v Handheld Pulse Oximeter performance.

Tissue damage can be caused by incorrect application or use of an LNOP sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity and correct positioning and adhesion of the sensor.

CAUTIONS:

- DO NOT USE DAMAGED LNOP SENSORS. DO NOT USE AN LNOP SENSOR WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS. DO NOT IMMERSE THE SENSOR IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO LNOP SENSORS.
- DO NOT USE DAMAGED PATIENT CABLES. DO NOT IMMERSE THE PATIENT CABLES IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE PATIENT CABLE CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE.

SELECTING A MASIMO LNOP SENSOR

When selecting a sensor, consider, the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following table or contact your Sales Representative. Use only Masimo SET sensors and sensor cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

SENSOR/CABLE	USAGE	PATIENT WEIGHT
LNOP Adt	Single	Adult > 30 kg
LNOP Adt Long	Single	Adult > 30 kg
LNOP Pdt	Single	Pediatrics and slender adults >10 kg < 50 kg
LNOP Neo	Single	Neonate < 10 kg
LNOP NeoPt	Single	Neonate < 1 kg or with poor skin integrity
LNOP Neo-L	Single	Neonate < 10 kg
LNOP NeoPt-L	Single	Neonate < 1 kg or with poor skin integrity
LNOP Inf-L	Single	Neonate > 3 kg < 10 kg
NR7	Resuable	Adult > 30 kg
LNOP DCI	Resuable	Adult > 30 kg
LNOP DCSC	Resuable	Adult and Pediatrics, >30kg
LNOP DCIP	Resuable	Pediatrics and slender adults >10 kg < 50 kg
LNOP YI Multisite	Resuable	Adults, Pediatrics, and Neonates > 1 kg
LNOP EAR	Resuable	Adults > 30kg. Accuracy: SpO_2 is ± 3.5 digits
NR125	Resuable	Adults > 30kg
PC04 Patient Cable	Resuable	All
PC08 Patient Cable	Resuable	All
PC12 Patient Cable	Resuable	All
PC04-Ext Cable	Resuable	All, EXTENSION CABLE

SENSOR ACCURACY

Refer to Section 7, Specifications for SpO2 and pulse rate accuracy, unless otherwise specified in the table above.

Accuracy specified when used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules using PC series patient cables, during no motion. Numbers represent ± 1 standard deviation. Plus or minus one standard deviation represents 68% of the patient population. SpO2 accuracy from 70% to 100%. Pulse Rate accuracy from 25 to 240bpm.

CLEANING AND REUSE OF MASIMO LNOP SENSORS

Reusable sensors can be cleaned per the following procedure:

- Remove the sensor from the patient.
- Disconnect the sensor from the monitor.
- Wipe the entire sensor clean with a 70% isopropyl alcohol pad.
- Allow the sensor to air dry before returning it to operation.

REATTACHMENT OF SINGLE USE ADHESIVE SENSORS

- LNOP single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.
- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

NOTE: *If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.*

CAUTIONS:

- DO NOT REPROCESS ANY LNOP SINGLE USE SENSORS.
- DO NOT SOAK OR IMMERSE THE SENSOR IN ANY LIQUID SOLUTION. DO NOT STERILIZE ANY MASIMO SENSOR BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE.

Masimo SET patient cables

Reusable patient cables of various lengths are available. All cables that display the Masimo SET logo are designed to work with any Masimo LNOP sensor and with any pulse oximeter or multiparameter instrument displaying the Masimo SET logo.

Only use Masimo oximetry patient cables for SpO_2 measurements. Other patient cables may cause improper Rad-5v pulse oximeter performance.

CLEANING AND REUSE OF MASIMO SET PATIENT CABLES

Patient cables can be cleaned per the following procedure:

- Remove the cable from the sensor.
- Disconnect the cable from the monitor.
- Wipe clean with a 70% isopropyl alcohol pad.
- Allow the cable to dry before returning it to operation.

CAUTIONS:

- CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.
- DO NOT SOAK OR IMMERSE PATIENT CABLES IN ANY LIQUID SOLUTION. DO NOT STERILIZE PATIENT CABLES BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO PATIENT CABLES.
- DO NOT REPROCESS ANY MASIMO SET PATIENT CABLES.

Introduction

This chapter covers how to test the operation of the Rad-5v how to properly clean the Rad-5v pulse oximeter, how to replace the batteries and how to obtain service.

Under normal operation, no internal adjustment or recalibration is required.

WARNING: BEFORE CLEANING THE OXIMETER, ALWAYS TURN IT OFF AND REMOVE THE BATTERIES.

Cleaning

To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

To clean the outer surface of the oximeter, use a soft cloth dampened with a mild soap and water. Do not allow liquids to enter the interior of the instrument.

CAUTIONS:

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THIS OXIMETER.
- DO NOT SOAK OR IMMERSE THE MONITOR IN ANY LIQUID.
- USE THE CLEANING SOLUTION SPARINGLY. EXCESSIVE SOLUTION CAN FLOW INTO THE MONITOR AND CAUSE DAMAGE TO INTERNAL COMPONENTS.
- DO NOT TOUCH, PRESS, OR RUB THE DISPLAY PANELS WITH ABRASIVE CLEANING COMPOUNDS, INSTRUMENTS, BRUSHES, ROUGH-SURFACE MATERIALS, OR BRING THEM INTO CONTACT WITH ANYTHING THAT COULD SCRATCH THE PANEL.
- DO NOT USE PETROLEUM-BASED OR ACETONE SOLUTIONS, OR OTHER HARSH SOLVENTS, TO CLEAN THE OXIMETER. THESE SUBSTANCES ATTACK THE DEVICE'S MATERIALS AND DEVICE FAILURE CAN RESULT.

Refer to Section 8, Cleaning and Reuse of Masimo LNOP Sensors for cleaning instructions of the sensor.

Performance verification

To test the performance of the Rad-5v pulse oximeter following repairs or during routine maintenance, follow the procedure outlined in this section. If the Rad-5v fails any of the described tests, discontinue its use and correct the problem before returning the unit back to the user.

Before performing the following tests verify or install new batteries into the Rad-5v Handheld. Also disconnect any patient cables or pulse oximetry probes or serial cables from the instrument.

Power-On Self-Test:

1. Turn the monitor on by depressing the Power Button. For about 5 seconds all available LEDs are illuminated and a brief beep tone sounds.
2. The oximeter begins normal operation.

Key Press Button Test:

1. With the exception of the Power Button, press each button and verify that the oximeter acknowledges each key-press with an audible beep tone or by indicating a change on the display.

LED Brightness:

1. Push the Display Brightness key several times to cycle through all four brightness levels

Testing Rad-5v with Masimo SET Tester (Optional):

1. Turn the Oximeter off and then on again.
2. Connect the Masimo SET Tester to the Patient Cable Connecter.
3. Verify that within 20 seconds a Signal IQ/pulsebar is displayed.
4. Verify that the SpO_2 measurement is between 79% and 84%.
5. Verify that the pulse rate measurement is between 55 bpm and 65 bpm.
6. Press the Pulse Tone Volume button several times and verify that the loudness of the pulse beep tone increases, then is turned off, then repeats the cycle
7. Disconnect the Masimo Set Tester from the Rad-5v.
8. Verify that an audible alarm occurs, that the front panel displays "nO SEn" and the Alarm indicator is flashing.
8. Press the Alarm Silence button once and verify that the alarm is silenced and the Alarm Silence Indicator is off.

Service and repair

REPAIR POLICY

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the unit repaired.

Please clean contaminated/dirty equipment before returning, following the cleaning procedure described in Section 9, Cleaning. Make sure it is fully dry before packing the equipment.

To return the Rad-5v unit for service, please follow the Return Procedure.

WARNING: DO NOT REMOVE THE COVER OF THE MONITOR EXCEPT FOR BATTERY REPLACEMENT. AN OPERATOR MAY ONLY PERFORM MAINTENANCE PROCEDURES SPECIFICALLY DESCRIBED IN THIS MANUAL. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TRAINED IN THE REPAIR OF THIS EQUIPMENT.

RETURN PROCEDURE

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Package the equipment securely – in the original shipping container if possible – and enclose the following information and items:

- Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number.
- A letter describing in detail any difficulties experienced with the pulse oximeter. Please include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the oximeter is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the oximeter has been decontaminated for bloodborne pathogens.

Return Rad-5v pulse oximeter to the following shipping address:

Masimo Corporation
2852 Kelvin Ave
Irvine, California 92614
949-250-9688
FAX 949-250-9686

Warranty

Masimo warrants to the initial purchaser that each new pulse oximeter will be free from defects in workmanship or materials for a period of three (3) years from the date of purchase. Masimo's sole obligation under this warranty is to repair or replace any product that Masimo deems to be covered under warranty with a repaired or a replacement pulse oximeter.

Batteries are not warrantied.

To request a replacement under warranty, contact Masimo for a returned goods authorization. If Masimo determines that a product must be replaced or repaired under warranty, it will be replaced or replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of the purchaser.

Exclusions

This warranty does not extend to any product that has been subject to misuse, neglect or accident; that has been damaged by causes external to the Product; that has been used in violation of the operating instructions supplied with the product. The warranty does not extend to any product that has been connected to an unlicensed instrument system, modified accessories or any unit that has been disassembled or reassembled by anyone but an authorized Masimo agent.

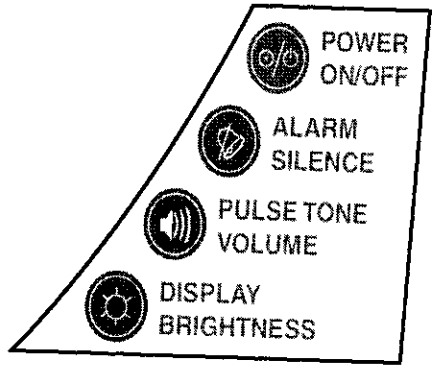
THIS WARRANTY, TOGETHER WITH ANY OTHER EXPRESS WRITTEN WARRANTY THAT MAY BE ISSUED BY MASIMO IS THE SOLE AND EXCLUSIVE WARRANTY AS TO MASIMO'S PRODUCTS. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MASIMO SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM THE USE OR LOSS OF USE OF ANY PRODUCTS.

End-user license agreement

THIS DOCUMENT IS A LEGAL AGREEMENT BETWEEN YOU, THE "PURCHASER," AND Masimo Corporation ("MASIMO"). IF YOU DO NOT AGREE TO THE TERMS OF THIS AGREEMENT, PROMPTLY RETURN THE ENTIRE PACKAGE, INCLUDING ALL ACCESSORIES, IN THEIR ORIGINAL PACKAGE, WITH YOUR SALES RECEIPT TO MASIMO FOR A FULL REFUND.

1. Grant of License: In consideration of payment of the license fee, which is part of the price paid for this product, MASIMO grants to Purchaser a nonexclusive, nontransferable license, without right to sublicense, to use the copy of the incorporated software/firmware and documentation in connection with Purchaser's use of the Masimo Products for their labeled purpose. MASIMO reserves all rights not expressly granted to Purchaser.

2. Ownership of Software/Firmware: Title to, ownership of, and all rights and interests in, any MASIMO software and/or firmware and the documentation, and all copies thereof, remain at all times vested in MASIMO Corporation, licensor to MASIMO, and they do not pass to Purchaser.
3. Assignment: Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise, without MASIMO's prior written consent; any attempt without such consent, to assign any rights, duties or obligations arising hereunder shall be void.
4. Copy Restrictions: The software/firmware and the accompanying written materials are copyrighted. Unauthorized copying of the software, including software that has been modified, merged, or included with other software, or other written materials is expressly forbidden. You may be held legally responsible for any copyright infringement that is cause or incurred by your failure to abide by the terms of this license. Nothing in this license provides any rights beyond those provided by 17 U.S.C. §117.
5. Use Restriction: As the Purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not electronically transfer the software/firmware from the products to any other device. You may not disclose, publish, translate, release or distribute copies of the software/firmware or accompanying written materials to others. You may not modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the software/firmware. You may not modify, adapt, translate, or create derivative works based on the written materials without the prior written consent of MASIMO.
6. Transfer Restrictions: The software/firmware is licensed to the Purchaser, and may not be transferred to anyone, except other end-users, without the prior written consent of MASIMO. In no event may you transfer, assign, rent, lease, sell, or otherwise dispose of the software/firmware or the products on a temporary basis.
7. Beneficiary: Masimo Corporation is a Beneficiary of this Agreement and has the right to enforce its provisions.
8. U.S. Government Rights: If you are acquiring software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the software is deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this agreement.



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Section 16 — Kit Information

This section does not apply because the Masimo SET® Rad 5v Pulse Oximeter is not a kit.

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510(k) SUMMARY

MASIMO®
2852 Kelvin Avenue
Irvine, CA 92614
Tel: 949-250-9688
Fax: 949-250-9686

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:	December 22, 2003
Trade Name	Masimo SET® Rad-5v Pulse Oximeter
Common Name	Pulse Oximeter
Classification Name	Oximeter (74DQA) (870.2700)
Substantially Equivalent Devices	Masimo SET Radical Pulse Oximeter with SatShare™ and LNOP series of Sensors and Cables 510(k) Number - K031330 Nonin Model 2500 Pulse Oximeter – 510(k) Number – K001930

The Masimo SET® Rad-5v Handheld Pulse Oximeter is noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-5v features a multicolored LED display that continuously displays numeric values for SpO2 and pulse rate, as well as LED indicator bars for Perfusion Index (PI) and Signal Identification and Quality Indicator (Signal IQ™).

Features and Benefits

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and perfusion index displays
- Signal IQ™ for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 36 hours on 4 "AA" alkaline batteries
- Audible Alarm for sensor-off and low battery

Intended use

The Masimo SET® RAD-5v Pulse Oximeter is intended for non-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 mobile environments.

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Indications for use

The Rad-5v Handheld Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Rad-5v Handheld Pulse Oximeter is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Principles of Operation

The principles of operation of the Masimo SET® Rad-5v 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® Rad-5v 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 into the Masimo SET® Rad-5v 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® Rad-5v 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 Rad-5v pulse oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. 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® Rad-5v pulse oximeter is powered by 4 AA batteries with an operating time of 36 hours[5].

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

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510(k) SUMMARY

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

Internally powered by 4 "AA" Alkaline batteries

Isolation

No external power or ground connection, internally powered only

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
Operating Altitude	500 mbar to 1060 mbar pressure -1,000 ft to 18,000 ft (-304 m to 5,486 m)

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of parameters
Automatic alarm messages

Display

Type	LED, 7-segment
Data Displayed	Pulse Rate, SpO2 %, Alarm status, alarm silenced status, Perfusion Index Bar, Signal IQ Bar, Battery Status, APOD, FastSat.

Audio indicators

Adjustable volume audible pulse: OFF and 33% to 100% in 3 steps
Adjustable volume audible alarm tone: levels and 33% to 100% in 3 steps
Alarm silence (120 seconds); all mute (continuous silence)
Sensor condition alarms
System failure and battery low alarms

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Physical characteristics	
Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.32 kg)
Modes	
Averaging mode:	2, 4, 8, 10, 12, and 16 seconds
Sensitivity	Normal, APOD, and MAX

1 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

2 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

3 The Masimo SET Technology 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 which encompasses 68% of the population.

4 The Masimo SET Technology 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 which encompasses 68% of the population.

5 This represents approximate run time at lowest indicator brightness, using a new, fully charged battery.

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.

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo SET® Rad-5v Pulse Oximeters 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® Rad-5v Pulse Oximeters 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® technology 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® technology 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.

Clinical studies were performed using the Masimo SET® technology 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.

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510(k) SUMMARY

Clinical studies were performed using the Masimo SET® technology 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® technology 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 specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on neonates with saturations down to 83% combined with clinical studies on adults to show that the Masimo SET® technology to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates 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® Rad-5vPulse Oximeter **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **bench testing** demonstrates that the Masimo SET® Rad-5v Pulse Oximeters **met** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® technology **meets** 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® Rad-5v Pulse Oximeters is safe, effective.

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Section 18 — Class III Certification and Summary

This section does not apply because the Masimo SET® Rad 5v Pulse Oximeter is classified as a Class II devices and not a Class III devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Neel Patel

Subject: 510(k) Number K033998

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices. SE
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☑ YES	☐ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: DQA Oximeter 870.2700 class II,

Additional Product Code(s) with panel (optional): DPZ

Review: _____ (Branch Chief) ANDS (Branch Code) 3.17.04 (Date)

Final Review: _____ (Division Director) 3/19/04 (Date)

Revised:4/2/03

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review

K033998

Date: March 17, 2004
To: The Record
From: Neel Patel, Biomedical Engineer

Office: HFZ-480
Division: DAGID/ARDB

Company Name: Masimo Corp.
Device Name: Masimo SET Rad-5v Pulse Oximeter
Contact: James J. Cronin
Phone: 949.250.9688
Fax: 949.250.9686

I. Purpose

The sponsor intends to market a new device which is a modification of its previously cleared device.

II. Device Description

A. Intended Use/Indications for Use

"The Masimo SET Rad 5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by and SpO2 sensor). The Masimo SET Rad 5v Pulse Oximeter is 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, mobile, and home environments."

B. Summary

Life-supporting or life-sustaining?	☐Yes	☒No
Implant?	☐Yes	☒No
Sterile?	☐Yes	☒No
Single use?	☐Yes	☒No

Prescription use?	☒Yes	☐No
Home use?	☒Yes	☐No
Transportable?	☒Yes	☐No
Drug or biological combination product?	☐Yes	☒No
Kit?	☐Yes	☒No
Software driven?	☒Yes	☐No
Electrically Operated?	☒Yes	☐No
Patient Population		
Adult	☒Yes	☐No
Pediatric	☒Yes	☐No
Infant	☒Yes	☐No
Neonatal	☒Yes	☐No

C. Materials/Biocompatibility

The sponsor states that the Rad 5v does not have any patient contacting materials. The sensors intended to be used with this device are patient contacting and have been most recently cleared for use in K033296.

D. Design/Specifications

The Masimo SET Rad 5v is a handheld pulse oximeter intended for non-continuous use and is powered by 4 AA batteries. The Rad 5v does not include SatShare, which the predicate Radical oximeter has. The Radical allowed users to adjust alarm limits, data averaging period, alarm volume, and patient mode. The Rad 5v only allows the user to adjust the pulse tone volume and display brightness. The Rad 5v also only has an audible alarm for low battery conditions. It has visual indicators for no sensor connected, sensor off patient, pulse search, low signal IQ, low perfusion, and system faults. It has a multicolored LED display that continuously displays numeric values for SpO2 and pulse rate as well as indicator bars for Perfusion Index and Signal Identification and Quality Indicator. The Rad 5v keypad includes the following buttons: power on/off, alarm silence, pulse tone volume, and display brightness.

It is intended to be used with the following Masimo LNOP oximetry sensors and cables: Adt, Pdt, Neo, NeoPt, NR7, DCI, DCSC, DCIP, YI Multisite, EAR, TF-I, PC04 patient cable, PC08 patient cable, PC12 patient cable, and PC04 ext. cable. The SpO2 and pulse rate accuracy specifications were originally provided on page 22 of the submission and in the user manual. Upon request, the sponsor provided by email, dated 3/16/04, a table of saturation and pulse rate accuracy specifications for each sensor. This table will be included in the Rad 5v labeling.

E. Sterilization/Reuse

The Rad 5v is supplied and used non-sterile. Reusable and single use sensors intended to be used with the Rad 5v provided non-sterile. The device and the

reusable sensors may be cleaned with 70% isopropyl alcohol.

F. Labeling

The labeling includes the user manual, a device face label, a Serial Number label, and an Agency Approvals label. The user manual and face label were provided for review.

The user manual includes the following sections: Overview, System Description, Setup, Operation, Alarms/Messages, Troubleshooting, Specifications, Sensor & Patient Cables, Service and Maintenance. The user manual includes the instructions for use and appropriate cautions and warnings including the prescription caution. It also includes device specifications including SpO2 and pulse rate accuracy and cleaning instructions for the device and reusable accessories.

The device face label includes English text that identifies button on the face of the device.

Promotional claims were provided upon request.

Also, upon request, the sponsor will list individual sensor specifications in their labeling and change PI (perfusion index) to PAI (pulse amplitude index) and SIQ (signal identification and quality) to SQ (signal quality). These changes were also requested in submission K033296 (Rad 5 handheld oximeter).

G. Performance Testing

Clinical validation testing information for the Rad 5 oximeter was provided on page 297. This does not include motion accuracy testing; however, relevant motion accuracy testing was provided in submission K033296 (Rad 5 handheld oximeter)*.

Comparative simulator testing is provided on page 255. This testing includes low perfusion validation testing information. However, the testing provided is for the Rad 5 oximeter*.

Skin temperature testing was provided on page 241. The testing provided was for the Rad 5 oximeter, not the Rad 5v*.

* The Rad 5v and Rad 5 incorporate identical software and hardware used to determine saturation and pulse rate. Therefore additional information is not necessary.

H. Clinical Testing (see above)

Has the sponsor provide financial disclosure statements for the clinical validation with human subjects according to 21 CFR 54, http://forms.psc.gov/forms/FDA/fda3454.pdf? No

Has the sponsor provided a copy of the consent form used during the study? No

I. Software – Masimo SET

Version: MS-11 v4.1, System Board v1.0, Sound v1.0
Level of Concern: moderate
Software description: Section 10
Device Hazard Analysis: Section 10, appendix 1
Software Requirements Specifications: Section 10, appendix 2
Architecture Design Chart: Section 10, appendix 3
Design Specifications: Section 10, appendix 4
Traceability Analysis/Matrix: Section 10, appendix 5
Development: Section 10
V&VT: Section 10, appendix 6
Revision level history: Section 10, appendix 7
Unresolved anomalies: none

J. Environmental Testing (yes/no; pass/fail):

Electrical Safety:

Battery power	yes
Electrical power indicators	yes
Overcurrent protection	n/a
Dielectric Withstand	n/a
AC power grounding and polarity	n/a
Leakage current	n/a

Electromagnetic Compatibility: EMC testing performed for the Rad 5 oximeter (K033296) was provided. This information is located on page 38 of the submission and is acceptable to demonstrate the EMC of the Rad 5v.

Mechanical:

Shock	yes
Sinusoidal vibration	yes
Random vibration, wide band	yes
Fluid spill resistance	yes
High and low temp and humidity	yes
Surface temperature	yes
Drop	yes

K. Certifications/Statements/Standards Met

510(k) Summary	- email dated 3/18/04
Truthful and Accurate Statement	- page 4
Indications for Use	- page 20 (Section 3)

L. Predicate Devices

K031330, Masimo SET Radical Pulse Oximeter with SatShare and LNOP series of Sensors and Cables, Masimo Corp.
K001930, Nonin Model 2500 Pulse Oximeter, Nonin Medical Inc.

III. Correspondence

Conference Call – 3/15/04

A phone conversation to clarify issues regarding the Rad 5v took place between Jim Cronin (sponsor), Joanna Weitershausen, and I. During the conversation, the sponsor stated that the hardware and software used to calculate oxygen saturation and pulse rate are identical to the Rad 5 (K033296). The sponsor also stated that the housing of the Rad 5v was identical to the Rad 5.

Due to inconsistencies in the submission, the sponsor was asked to describe the features of the device. The sponsor stated that the differences between the Rad 5v and Rad 5 were that the Rad 5v is for spot checking, doesn't have user selectable, hi/lo saturation and pulse rate alarms, doesn't have user selectable sensitivity modes, doesn't have Fastsat feature, and has a different keypad. The sponsor will provide us with a list of device features and a statement that the device does not include Fastsat and user selectable sensitivity modes.

The sponsor was asked to provide a list of claims they intend to make since no promotional literature was provided, to change perfusion index (PI) to pulse amplitude index (PAI) and signal IQ (SIQ) to signal quality (SQ), and to identify the saturation and pulse rate accuracies of each compatible sensor in its labeling. The sponsor stated that they will provide a list of claims and make the changes to their labeling.

Regarding the change of PI to PAI and SIQ to SQ, the sponsor believes that the original terms are correct. We believe these terms to be misleading and after discussion of the accuracy of the terms and what they represent, it was decided that they will provide their justification of using the terms, PI and SIQ, in a future pre-IDE submission. Until then, they have agreed, as stated above, to the recommended changes.

Response Inadequate: Mr. Jim Cronin, the sponsor, responded to issues raised in our phone March 15, 2004 phone conversation. Mr. Cronin stated, "The Rad

5v audible alarms are for low battery, Sensor Off, No sensor, System Fault, and System Error - All of which are in the Rad 5," and, "The Rad 5v does not have adjustable sensitivity levels, it's sensitivity level is normal." However, he did not state that the Rad 5v did not include the Fastsat feature. The sponsor also provided a table of sensor saturation and pulse rate accuracy specifications that will be included in the Rad 5v labeling, potential promotional claims, and revised labeling to show that they will change PAI (Pulse Amplitude Index) from PI (Perfusion Index) and SQ (Signal Quality) from Signal IQ (Signal Identification and Quality). Please see the March 16, 2004 deficiency email sent to the sponsor for issues that were not addressed or that resulted from this email response.

Additional Issues – sent by email on 3/16/04

After review of the March 15, 2004 response to issues raised in our March 15, 2004 conference call, the following issues were identified and need to be addressed.

1. In our March 15, 2004 phone conversation, we asked you to clarify what features are included in the Rad 5v. This included a discussion of the alarms, sensitivity modes, and features such as Fastsat. Your response dated March 15, 2004 stated, "The Rad 5v audible alarms are for low battery, Sensor Off, No sensor, System Fault, and System Error - All of which are in the Rad 5," and, "The Rad 5v does not have adjustable sensitivity levels, it's sensitivity level is normal." Although you stated during our phone conversation that the Rad 5v does not include Fastsat, your email response did not address whether or not the Rad 5v includes Fastsat. Due to inconsistencies in your submission, we recommend that you state in writing whether or not the Rad 5v includes the Fastsat feature. Please provide a statement that the Rad 5v does not include the Fastsat feature.

   Response Adequate: "The Rad 5v does not include the Fastsat feature."

2. In our March 15, 2004 phone conversation, we asked you to change Perfusion Index (PI) to Pulse Amplitude Index (PAI) and Signal Identification and Quality (SIQ) to Signal Quality (SQ) in the Rad 5v labeling just as you have done in the Rad 5 labeling. Your response dated March 15, 2004 stated, "We will change our labeling to PAI (Pulse Amplitude Index) from PI (Perfusion Index) and SQ (Signal Quality) from Signal IQ (Signal Identification and Quality) and I've attached a picture of the Label that will be added to the Rad 5v." However, the sample labeling you identifies Pulse Amplitude Index as P_AI rather than PAI. Please revise your labeling to identify Pulse Amplitude Index as PAI and provide the revised labeling for review.

   Response Adequate: Revised labeling identifying Pulse Amplitude Index as PAI was provided.

3. In our March 15, 2004 phone conversation, we asked you to list saturation and pulse rate accuracy specifications for all sensors intended to be used with the Rad 5v. Your March 15, 2004 response provided a table of sensor saturation and pulse rate accuracies that will be added to the manual. Please address the following items regarding this table and provide the revised table for review.

   a. This table does not include all the sensors listed on page 489 of the submission (page 8-2 of the Rad 5v user manual). The following sensors listed on page 489 are not listed in the provided table: LNOP Adt Long, LNOP Neo-L, LNOP NeoPt-L, LNOP Inf-L, and NR125. Please revise this table to include these sensors if they are intended to be used with the Rad 5v and have been clinically validated with the Rad 5v (please provide testing information including test methods, quantitative acceptance criteria, and a summary of results regarding the clinical validation of any of these sensors if it has not been provided previously). If any of these sensors have not been clinically validated or are not intended to be used with the Rad 5v, please ensure that they are not listed in your user manual.

      Response Adequate: The revised table was provided. "Additional sensors will be added after they have been clinically validated."

   b. This table does not include the low perfusion saturation and pulse rate accuracy specifications. Please revise this table to include low perfusion specifications.

      Response Adequate: The table was revised to include low perfusion specifications.

   c. This table includes motion and no motion saturation and pulse rate accuracy specifications for the LNOP YI - multisite sensor. However, this sensor was not clinically validated for no motion. Please provide testing information including test methods, quantitative acceptance criteria, and a summary of results for the clinical validation of this sensor for no motion conditions. Alternatively, you may remove the no motion saturation and pulse rate accuracy specifications for the LNOP YI sensor from your labeling.

      Response Adequate: The no motion specifications were removed from the table.

   d. The LNOP TF-I sensor was clinically validated for use with the Rad 5v (MS-11) under no motion conditions. Low perfusion testing was also provided. However, the table you have provided does not include the sensor. Please clarify if this sensor is intended to be used with the Rad 5v. If this sensor is intended to be used with the Rad 5v, you may choose

to include no motion and low perfusion saturation and pulse rate accuracy specifications for this sensor in your labeling.

Response Adequate: "The table has been modified to include the accuracy specification of the LNOP-TF-I sensor."

4. In our March 15, 2004 phone conversation, we asked you to list provide a list of claims you intend to make regarding the Rad 5v. Your March 15, response stated that you have "not yet developed any promotional claims" and that "claims will be based on claims submitted to the FDA in this 510(k)." You also stated that "claims may include the following: Masimo SET Technology, Long Battery Life, Ideal for Spot Checking, Uses Masimo's Sensors." We do not consider these phrases to be claims. Please provide sample statements of claims you intend to make regarding the Rad 5v.

   Response Inadequate: "The claims listed for the Rad 5v in the attached are the claims we intend to make for the Rad 5v and this is how they were presented in our last 510(k)'s that have been recently cleared (K033298, K033349, K032551)."

   Comment: We do not believe that the phrases provide represent actual promotional claims that may be made regarding the Rad 5v.

Conference Call – 3/17/04

A phone conversation to clarify issues regarding the Rad 5v took place between Jim Cronin (sponsor), Joanna Weitershausen, and I. During the conversation, one remaining issue was discussed. We do not consider the phrases the sponsor has provided as claims to be claims. We recommended to the sponsor that they provide actual promotional statement(s) that they intend to make concerning the Rad 5v. It was explained that this information is necessary for review. Section 513(i)(1)(E)(i) of the Federal Food, Drug, and Cosmetic Act states that "any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for a device under section 510(k)." Additionally, 21 CFR 807.87 states that "each premarket notification submission shall contain the following information: ... (e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use."

Response Adequate: The sponsor has provided the following claims:

"The Rad 5v Pulse Oximeter contains Masimo SET Technology.
The Rad 5v has a 48 hour Battery Life.
Ideal for Spot Checking.
Uses Masimo's Sensors."

IV. Substantial Equivalence

The subject device has been demonstrated to be substantially equivalent to the predicate devices.

V. Recommendation

I recommend that the file be found substantially equivalent to:

DQA Oximeter **870.2700 Class II (two)**

Additionally, the following product code applies:

DPZ Oximeter, Ear

Neel J Patel 3/17/04

Neel J Patel date

Patel, Neel

From: Jim Cronin [JCronin@masimo.com]
Sent: Thursday, March 18, 2004 2:10 PM
To: 'Patel, Neel '
Cc: 'Weitershausen, Joanna'
Subject: RE: K033998 Masimo SET Rad 5v

Dear Neel,

Per our conversation today please find the revised 510(k) summary with the changes that you requested.

Please let me know if you have any additional questions.

Regards

Jim Cronin

-----Original Message-----
From: Jim Cronin
Sent: Wednesday, March 17, 2004 11:16 AM
To: 'Patel, Neel '
Cc: 'Weitershausen, Joanna'
Subject: RE: K033998 Masimo SET Rad 5v

Dear Neel,

Per my conversation with Joanna today please find attached the revised promotional claims for the Rad 5v.

Please let me know if you have any additional questions.

Regards

Jim Cronin

-----Original Message-----
From: Jim Cronin
Sent: Tuesday, March 16, 2004 6:17 PM
To: 'Patel, Neel '; Jim Cronin
Cc: Weitershausen, Joanna
Subject: RE: K033998 Masimo SET Rad 5v

Dear Neel,

Per your request below:

1. The Rad 5v does not include the Fastsat feature.

510(k) SUMMARY

MASIMO
2852 Kelvin Avenue
Irvine, CA 92614
Tel: 949-250-9689
Fax: 949-250-9686

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:	February 18, 2004
Trade Name	Masimo SET® Rad-5v Pulse Oximeter
Common Name	Pulse Oximeter
Classification Name	Oximeter (74DQA) (870.2700)
Substantially Equivalent Devices	Masimo SET Radical Pulse Oximeter with SatShare™ and LNOP series of Sensors and Cables 510(k) Number - K031330 Nonin Model 2500 Pulse Oximeter – 510(k) Number – K001930

The Masimo SET® Rad-5v Handheld Pulse Oximeter is noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-5v features a multicolored LED display that continuously displays numeric values for SpO2 and pulse rate, as well as LED indicator bars for Pulse Amplitude Index (PAI) and Signal Quality (SQ).

Features and Benefits

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and pulse amplitude index displays
- SQ for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 36 hours on 4 "AA" alkaline batteries
- Audible Alarm for sensor-off and low battery

Intended use

The Masimo SET® RAD-5v Pulse Oximeter is intended for non-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 mobile environments.

510(k) SUMMARY

Indications for use

The Rad-5v Handheld Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Rad-5v Handheld Pulse Oximeter is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Principles of Operation

The principles of operation of the Masimo SET® Rad-5v 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® Rad-5v 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 into the Masimo SET® Rad-5v 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® Rad-5v 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 Rad-5v pulse oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. 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® Rad-5v pulse oximeter is powered by 4 AA batteries with an operating time of 36 hours[5].

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

510(k) SUMMARY

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

Internally powered by 4 "AA" Alkaline batteries

Isolation

No external power or ground connection, internally powered only

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
Operating Altitude	500 mbar to 1060 mbar pressure -1,000 ft to 18,000 ft (-304 m to 5,486 m)

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of parameters
Automatic alarm messages

Display

Type	LED, 7-segment
Data Displayed	Pulse Rate, SpO2 %, Alarm status, alarm silenced status, Pulse Amplitude Index Bar, Signal Quality Bar, and Battery Status.

Audio indicators

Adjustable volume audible pulse: OFF and 33% to 100% in 3 steps
Adjustable volume audible alarm tone: levels and 33% to 100% in 3 steps
Alarm silence (120 seconds); all mute (continuous silence)
Sensor condition alarms
System failure and battery low alarms

510(k) SUMMARY

Physical characteristics	
Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.32 kg)
Modes	
Averaging mode:	8 seconds
Sensitivity	Normal

1 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

2 The Masimo SET Technology 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% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

3 The specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on adult volunteers and 1% was added to account for the properties of fetal hemoglobin to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates to be within ± 3 digits during no motion and ± 5 digits during motion conditions when compared to the ECG.. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

4 The Masimo SET Technology 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 which encompasses 68% of the population.

5 This represents approximate run time at lowest indicator brightness, using a new, fully charged battery.

Environmental Testing

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

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo SET® Rad-5v Pulse Oximeters 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® Rad-5v Pulse Oximeters 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® technology 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® technology 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.

Clinical studies were performed using the Masimo SET® technology 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.

510(k) SUMMARY

Clinical studies were performed using the Masimo SET® technology 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® technology 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 specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on adult volunteers and 1% was added to account for the properties of fetal hemoglobin to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates 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® Rad-5vPulse Oximeter **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **bench testing** demonstrates that the Masimo SET® Rad-5v Pulse Oximeters **met** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® technology **meets** 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® Rad-5v Pulse Oximeters is safe, effective.

Patel, Neel

From: Jim Cronin [JCronin@masimo.com]
Sent: Wednesday, March 17, 2004 2:16 PM
To: 'Patel, Neel '
Cc: 'Weitershausen, Joanna'
Subject: RE: K033998 Masimo SET Rad 5v

Dear Neel,

Per my conversation with Joanna today please find attached the revised promotional claims for the Rad 5v.

Please let me know if you have any additional questions.

Regards

Jim Cronin

Promotional Claims

Masimo has not yet developed any promotional claims for our Rad 5v Pulse Oximeter

Promotional claims will be based on the claims submitted to the FDA in this 510(k) including intended use and indications for use. Promotional claims may include the following:

The Rad 5v Pulse Oximeter contains Masimo SET Technology.
The Rad 5v has a 48 hour Battery Life.
Ideal for Spot Checking.
Uses Masimo's Sensors.

Patel, Neel

From: Jim Cronin [JCronin@masimo.com]
Sent: Tuesday, March 16, 2004 9:17 PM
To: 'Patel, Neel '; Jim Cronin
Cc: Weitershausen, Joanna
Subject: RE: K033998 Masimo SET Rad 5v

Dear Neel,

Per your request below:

1. The Rad 5v does not include the Fastsat feature.

2. Attached is the revised labeling with PAI.

3a. Attached is the revised table that will be included in the Rad 5v manual. Additional sensors will be added after they have been clinically validated.

3b. The low perfusion saturation and pulse rate accuracy has been added to the attached table.

3c. The no motion saturation and pulse rate accuracy specification has been removed from the LNOP YI sensor.

3d. The table has been modified to include the accuracy specification of the LNOP-TF-I sensor.

4. The claims listed for the Rad 5v in the attached are the claims we intend to make for the Rad 5v and this is how they were presented in our last 510(k)'s that have been recently cleared (K033298, K033349, K032551).

Please let me know if you have any questions.

Regards,

Jim Cronin

The following table will be added to the Rad 5v Manual:

Sensor	Patient Weight	Saturation Accuracy (70%-100%)		Pulse Rate Accuracy (25-240 bpm)		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP-Adt	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP-Pdt	10-50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP-Neo	< 10 Kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP-NeoPt	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP-DC-I	> 30 Kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP-DC-IP	10-50 Kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP-DC-SC	>30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP-Y1	> 1 kg	N/A	± 3%	N/A	± 5 bpm	N/A	N/A
LNOP-Ear	> 30 kg	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
NR-7	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP-TF-I	> 30 kg	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm

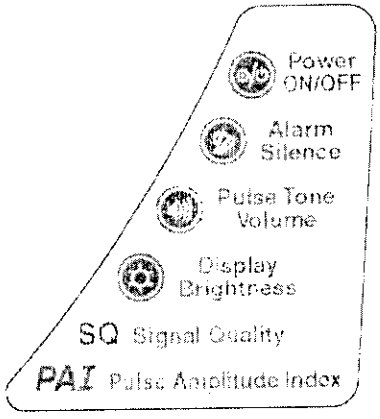
The LNOP-Ear and LNOP-TF-I sensors were not validated under motion conditions and the LNOP-Y1 was not validated under no motion conditions with the Rad 5v.

Promotional Claims

Masimo has not yet developed any promotional claims for our Rad 5v Pulse Oximeter Transflectance Sensor.

Promotional claims will be based on the claims submitted to the FDA in this 510(k) including intended use and indications for use. Promotional claims may include the following:

Masimo SET Technology.
Long Battery Life
Ideal for Spot Checking
Uses Masimo's Sensors



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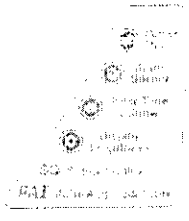


100% scale

Title: Label, Rad-5v Keypad Legend 2/04

Patel, Neel

From: Patel, Neel
Sent: Tuesday, March 16, 2004 3:16 PM
To: 'Jim Cronin'
Cc: Weitershausen, Joanna
Subject: RE: K033998 Masimo SET Rad 5v

Dear Jim,

After review of the information you have submitted by email, we have identified the following items that need to be addressed:

1. In our March 15, 2004 phone conversation, we asked you to clarify what features are included in the Rad 5v. This included a discussion of the alarms, sensitivity modes, and features such as Fastsat. Your response dated March 15, 2004 stated, "The Rad 5v audible alarms are for low battery, Sensor Off, No sensor, System Fault, and System Error - All of which are in the Rad 5," and, "The Rad 5v does not have adjustable sensitivity levels, it's sensitivity level is normal." Although you stated during our phone conversation that the Rad 5v does not include Fastsat, your email response did not address whether or not the Rad 5v includes Fastsat. Due to inconsistencies in your submission, we recommend that you state in writing whether or not the Rad 5v includes the Fastsat feature. Please provide a statement that the Rad 5v does not include the Fastsat feature.

2. In our March 15, 2004 phone conversation, we asked you to change Perfusion Index (PI) to Pulse Amplitude Index (PAI) and Signal Identification and Quality (SIQ) to Signal Quality (SQ) in the Rad 5v labeling just as you have done in the Rad 5 labeling. Your response dated March 15, 2004 stated, "We will change our labeling to PAI (Pulse Amplitude Index) from PI (Perfusion Index) and SQ (Signal Quality) from Signal IQ (Signal Identification and Quality) and I've attached a picture of the Label that will be added to the Rad 5v." However, the sample labeling you identifies Pulse Amplitude Index as P_AI rather than PAI. Please revise your labeling to identify Pulse Amplitude Index as PAI and provide the revised labeling for review.

3. In our March 15, 2004 phone conversation, we asked you to list saturation and pulse rate accuracy specifications for all sensors intended to be used with the Rad 5v. Your March 15, 2004 response provided a table of sensor saturation and pulse rate accuracies that will be added to the manual. Please address the following items regarding this table and provide the revised table for review.

   a. This table does not include all the sensors listed on page 489 of the submission (page 8-2 of the Rad 5v user manual). The following sensors listed on page 489 are not listed in the provided table: LNOP Adt Long, LNOP Neo-L, LNOP NeoPt-L, LNOP Inf-L, and NR125. Please revise this table to include these sensors if they are intended to be used with the Rad 5v and have been clinically validated with the Rad 5v (please provide testing information including test methods, quantitative acceptance criteria, and a summary of results regarding the clinical validation of any of these sensors if it has not been provided previously). If any of these sensors have not been clinically validated or are not intended to be used with the Rad 5v, please ensure that they are not listed in your user manual.

   b. This table does not include the low perfusion saturation and pulse rate accuracy specifications. Please revise this table to include low perfusion specifications.

   c. This table includes motion and no motion saturation and pulse rate accuracy specifications for the LNOP YI - multisite sensor. However, this sensor was not clinically validated for no motion. Please provide testing information including test methods, quantitative acceptance criteria, and a summary of results for the clinical validation of this sensor for no motion conditions. Alternatively, you may remove the no motion saturation and pulse rate accuracy specifications for the LNOP YI

sensor from your labeling.

d. The LNOP TF-I sensor was clinically validated for use with the Rad 5v (MS-11) under no motion conditions. Low perfusion testing was also provided. However, the table you have provided does not include the sensor. Please clarify if this sensor is intended to be used with the Rad 5v. If this sensor is intended to be used with the Rad 5v, you may choose to include no motion and low perfusion saturation and pulse rate accuracy specifications for this sensor in your labeling.

4. In our March 15, 2004 phone conversation, we asked you to list provide a list of claims you intend to make regarding the Rad 5v. Your March 15, response stated that you have "not yet developed any promotional claims" and that "claims will be based on claims submitted to the FDA in this 510(k)." You also stated that "claims may include the following: Masimo SET Technology, Long Battery Life, Ideal for Spot Checking, Uses Masimo's Sensors." We do not consider these phrases to be claims. Please provide sample statements of claims you intend to make regarding the Rad 5v.

Please address these issues by 4:00 pm EST on March 17, 2004. Also, please contact me if you need further clarification of any issues presented above.

Regards,

Neel Patel

Patel, Neel

From: Jim Cronin [JCronin@masimo.com]
Sent: Monday, March 15, 2004 8:51 PM
To: 'Patel, Neel '
Cc: Weitershausen, Joanna
Subject: RE: K033998 Masimo SET Rad 5v

Dear Neel

Per our phone conversation today, the following are the items that we discussed concerning K033998 Masimo SET Rad 5v pulse Oximeter:

1. The Rad 5v audible alarms are for low battery, Sensor Off, No sensor, System Fault, and System Error - All of which are in the Rad 5

2. The Rad 5v does not have adjustable sensitivity levels, it's sensitivity level is normal.

3. The attached table will be added to the manual for Sensor Saturation and Pulse Rate Accuracy

4. Attached are our potential promotional claims.

5. We will change our labeling to PAI (Pulse Amplitude Index) from PI (Perfusion Index) and SQ (Signal Quality) from Signal IQ (Signal Identification and Quality) and I've attached a picture of the Label that will be added to the Rad 5v.

Please let me know if you require any additional information.

Regards

Jim Cronin
Vice President Regulatory Affairs/Quality Assurance

The following table will be added to the Rad 5 Manual:

Sensor	Patient Weight	Saturation Accuracy (70%-100%)		Pulse Rate Accuracy (25-240 bpm)	
		No Motion	Motion	No Motion	Motion
LNOP-Adt	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-Pdt	10-50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-Neo	< 10 Kg	± 3%	± 3%	± 3 bpm	± 5 bpm
LNOP-NeoPt	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm
LNOP-DC-I	> 30 Kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-DC-IP	10-50 Kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-DC-SC	>30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-Y1	> 1 kg	± 2%	± 3%	± 3 bpm	± 5 bpm
LNOP-Ear	> 30 kg	± 3.5%	N/A	± 3 bpm	N/A
NR-7	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm

The LNOP-Ear sensor was not validated under motion conditions

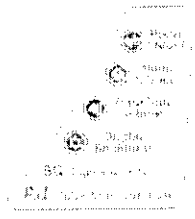
This table was removed, see 3/16 email from S. m Crow

Promotional Claims

Masimo has not yet developed any promotional claims for our Rad 5v Pulse Oximeter Transflectance Sensor.

Promotional claims will be based on the claims submitted to the FDA in this 510(k) including intended use and indications for use. Promotional claims may include the following:

Masimo SET Technology.
Long Battery Life
Ideal for Spot Checking
Uses Masimo's Sensors



Title: Label, Rad-5v Keypad Legend 2/04
LAB-3387
Rev. B
DRO-9020

Patel, Neel

From: Patel, Neel
Sent: Monday, March 15, 2004 12:38 PM
To: 'Jim Cronin'
Cc: Weitershausen, Joanna
Subject: K033998 Masimo Rad 5v

Dear Jim,

Per our phone conversation today, I am sending you information on providing a declaration of conformity to a standard and to our reviewer guidance found at http://www.fda.gov/cdrh/ode/guidance/638.pdf. To declare conformity to the reviewer guidance, you may sign and provide the attached "Reviewer Guidance Certification" (or relevant sections of the attached certification).

When providing a declaration of conformity or a statement that the device will comply prior to marketing may be provided in lieu of data when using a standard to demonstrate equivalence. Please refer to our document, titled Use of Standards in Substantial Equivalence Determinations located at http://www.fda.gov/cdrh/ode/guidance/1131.pdf for additional guidance. In order to declare conformance with an FDA recognized consensus standard, a declaration of conformity information sheet should be provided that:

a. Identifies the applicable recognized consensus standards that were met;

b. Specifies, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations that should be noted below in the declaration of conformance;

c. Identifies for each consensus standard any way(s) in which the standard may have been adapted for application to the device under review, e.g., identifies which of an alternative series of tests were performed;

d. Identifies, for each consensus standard, any requirements that were not applicable to the device;

e. Specifies any deviations from each applicable standard that were applied (e.g. deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70)).

f. Specifies what differences exist, if any, between the tested device and the device to be marketed and justifies the use of test results in these areas of difference; and

g. If a test laboratory or certification body was employed, provide the name and address of each laboratory or certification body that was involved in determining the conformance of the device with the applicable consensus standards and a reference to any accreditation of those organizations.

Additionally, each recognized standard includes an extent of recognition. Therefore, each standard declaration of conformity should provide information in a manner consistent with the extent of recognition. For example, if conformance to IEC 60601-1-2, (First Edition, 1993-04), Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests (General) is claimed, then any declaration of conformance to the EMC aspects of the IEC standard should be accompanied by the following documentation: 1) a summary of the testing that was done, 2) the requirements of the standard that were meet, 3) the pass/fail criteria used, 4) the performance of the device during each immunity test (i.e., degradation observed) 5) identification of and justification for any of the standard's allowances that were used, and 6) a description of and justification for any deviations from the requirements of the standard. However, it should be noted that the recommendations of the November 1993 Reviewer Guidance for Premarket Notification Submission supersede

the IEC recommendations. Furthermore, additional testing should be supplied to conform to the Reviewer Guidance for Premarket Notification Submissions.

Therefore, to assert conformance, a review of the extent of recognition should be performed for each standard to ensure that that the declaration of conformance is consistent with the scope of agency's recognition of the specific standard. A list of the recognized standards along with the extent of recognition may be located at the internet web site "http://www.fda.gov/cdrh/modact/recstand.html"

For any testing that is necessary for establishing the safety and effectiveness or equivalence that is not covered in a recognized standard, then the complete test protocol, pass/fail criteria, test results and an analysis explaining the significance of the results should be provided.

Please contact me if you need further clarification.

Regards,

Neel Patel
Biomedical Engineer
Anesthesiology and Respiratory Devices Branch
FDA / CDRH / ODE / DAGID
p: 301.443.8611x3
f: 301.480.4204
e: nep@cdrh.fda.gov

Reviewer Guidance Certificatio...

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K033998

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☒ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard**, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ___√___ Yes _____ No

Reviewer:_____

Concurrence by Review Branch:_____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 033998

Reviewer: Neel Patel

Division/Branch: DAGID / ARDB

Device Name: Masimo SET Rad 5V Pulse Oximeter

Product To Which Compared (510(K) Number If Known): K031330, K001930, K033296

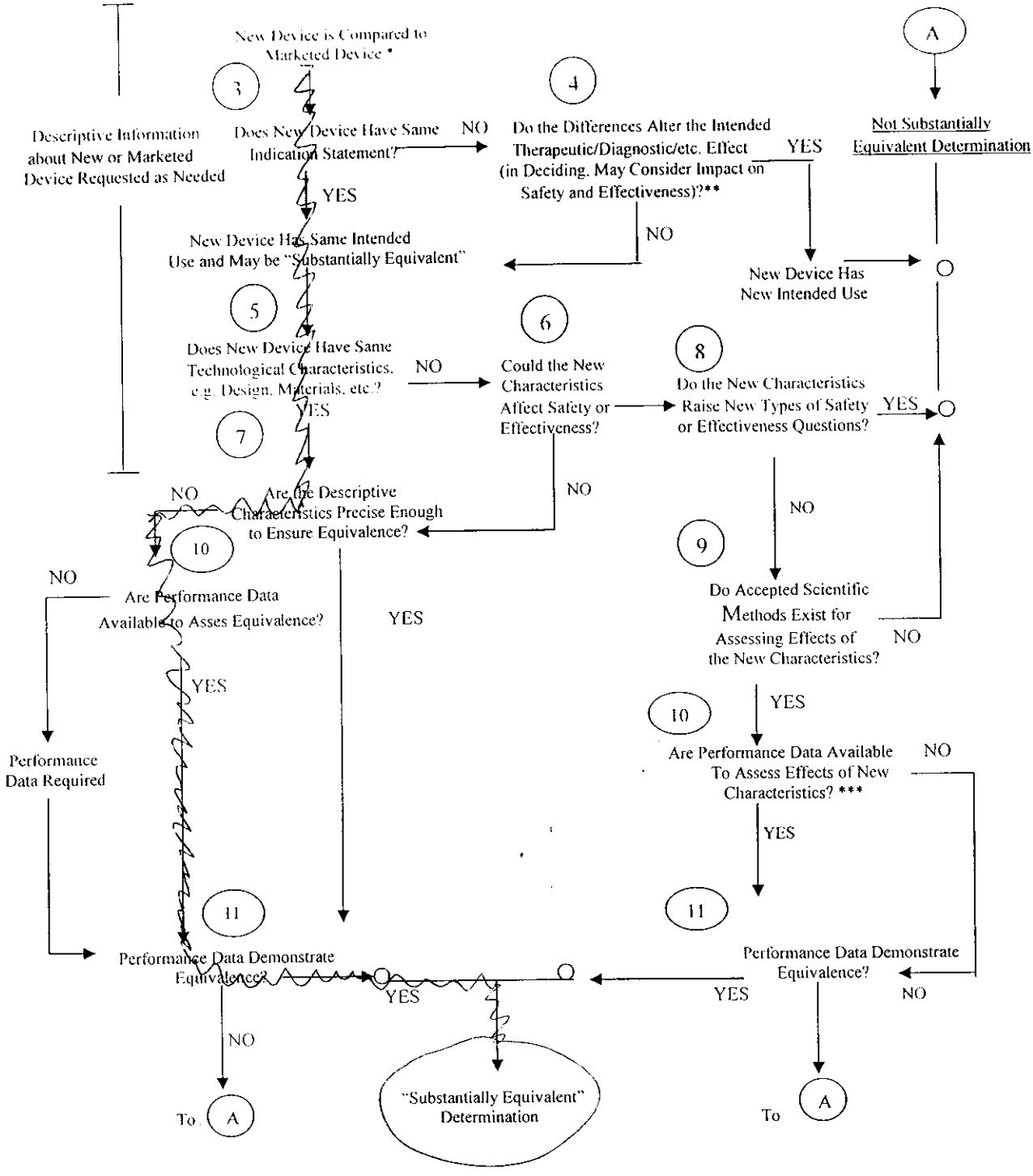
	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		✓
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.