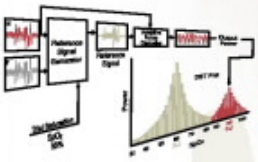
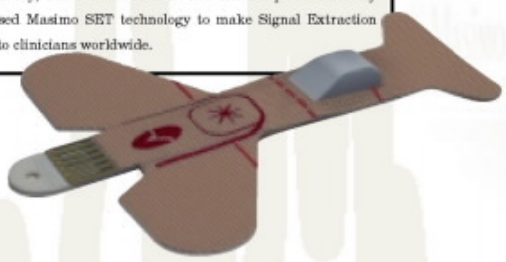
MASIMO®

Signal Extraction Technology®



1998

Masimo SET® In 1989, Diab and Kiani at Masimo Corporation invent Signal Extraction Pulse Oximetry, which enables the use of adaptive filter technology to separate the arterial signal from the non-arterial noise (e.g. venous blood movement during motion). The result is the only pulse oximetry technology that has been scientifically and clinically proven to be accurate during patient motion, and low perfusion. In 1998, Masimo unveiled this breakthrough technology to the clinicians. As of today, more than 60% of the world's pulse oximetry manufacturers have licensed Masimo SET technology to make Signal Extraction Pulse Oximetry available to clinicians worldwide.



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accurate pulse oximetry when you need it™

accurate during patient movement

•

accurate during low perfusion

•

designed for accurate monitoring during

intense ambient light and electrocautery interference

•

substantially eliminates false alarms

without sacrificing true alarms

•

reduces cost of care through reliable monitoring

and durable adhesive sensors

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clinically proven

Masimo Corporation has developed Signal Extraction™ pulse oximetry. This remarkable new technology enables the use of adaptive filters to separate the arterial signal from the non-arterial noise. The result is the only pulse oximetry technology that has been scientifically and clinically proven to be accurate during patient motion and low perfusion. This technology is also designed to deliver superior performance during conditions of intense ambient light and electrocautery interference. As of today, more than 60% of the world's pulse oximetry manufacturers have licensed Masimo SET® technology to make Signal Extraction pulse oximetry available to clinicians worldwide. Over 40 clinical studies have been published and presented in internationally respected forums documenting the significantly superior performance of Masimo SET Pulse Oximetry.

motion and low perfusion study

Oximeter	SpO_2 Sensitivity	SpO_2 Specificity	Drop Out
Masimo SET	99%	97%	0.0%
Agilent Viridia 24 C	78%	90%	1.6%
Agilent CMS Rev B	70%	83%	3.7%
Nellcor N-395	70%	73%	4.0%
Novametrix MARS	40%	42%	2.4%

Barker SJ. Presented at the Society for Technology in Anesthesia Annual Meeting, January 2001.

"Pulse oximetry has been, at best, a fair weather friend. With Masimo SET, pulse oximetry can become a foul weather friend, providing useful clinical information during times of crisis and when you need it most."

H.J.C. Swan, Ph.D., M.D.

Professor of Medicine, Emeritus
University of California, Los Angeles

"I saw and was conquered. I was not able to defeat the Masimo SET pulse oximeter using all the motion and low pulse tricks I know. This technology is most impressive and should be valuable in all oximeters."

John Severinghaus, M.D.

Professor of Anesthesiology, Emeritus
University of California, San Francisco

"Masimo SET should become the 'Dolby' of pulse oximeters."

Kevin K. Tremper, Ph.D, M.D.

Chairman, Department of Anesthesiology
University of Michigan

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technology

How is Masimo SET® technology different?

Conventional "red-over-infrared" based technologies attempt to treat the symptoms; i.e., mask or manage the problem of false alarms via a decision matrix aimed at detecting the presence of corrupt incoming information. Masimo SET technology, on the other hand, addresses the core problem, not the symptom, by truly identifying and removing the noise contribution in the detected red and infrared signals.

Masimo Signal Extraction Technology® begins with a new understanding of how motion affects the tissue and venous blood. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, which causes conventional pulse oximeters to under-read because they can not distinguish between the arterial and venous blood. Masimo SET signal processing identifies the venous blood signal, isolates it, and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation.

Masimo SET consists of a breakthrough Discrete Saturation Transform™ algorithm and a revolutionary Low Noise Optical Probe™ sensor design.

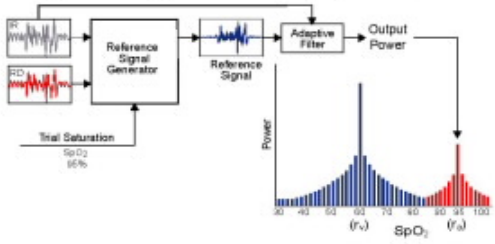
Discrete Saturation Transform Algorithm

The DST™ algorithm has three facets: Reference Signal Generator, Adaptive Filter, and Peak Picker. The Reference Signal Generator builds a noise reference from the incoming red and infrared signals for each percent SpO_2, from 1 to 100 percent. The Reference Signal Generator signal is passed through the Adaptive Filter, which cancels the correlated frequencies between the reference signal and the incoming infrared signal. If the frequencies between the two inputs are all similar, the entire signal cancels and a low energy output occurs. If they are dissimilar, a minimal amount of signal cancels and a high-energy output is obtained. Energy output from the Adaptive Filter is measured and plotted for all possible saturations from 1 to 100 percent in 0.5 percent increments every 0.4 seconds. During no motion, the DST

algorithm generates one energy output peak, but generates several during motion. Because arterial blood has the highest oxygen saturation the Peak Picker algorithm displays the highest saturation peak as the percent SpO_2 when the Masimo SET model is met.

Masimo SET pulse oximetry accurately calculates percent SpO_2 without first referencing the pulse rate, whereas recognition of a stable pulse is a prerequisite to conventional pulse oximetry. For more information on Discrete Saturation Transform, see Masimo's Technical Bulletin #1.

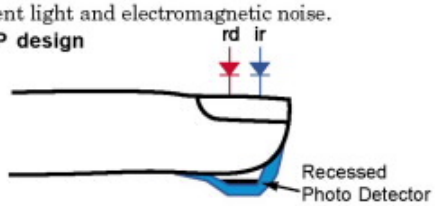
DST plot during motion at SpO_2 of 95%



Low Noise Optical Probe (LNOP®)

The LNOP sensors are uniquely designed to assume that noise, both physiological and non-physiological, will be present. Unlike conventional pulse oximetry sensor design, the photodetector is recessed in a cavity to minimize optical path length changes during motion. The cavity is covered by a conformable adhesive that allows the fleshy part of the digit to move in and out of the cavity during motion, similar to shock absorbers in automobiles. In comparison, conventional sensors place the photodetector directly on the tissue. The LNOP design also minimizes the effects of venous blood movement at the monitored site due to motion. Another advantage of the recessed photodetector and the overall shielded design is that it is better protected from ambient light and electromagnetic noise.

LNOP design



"Masimo SET is the first significant advancement in pulse oximetry since the introduction of pulse oximetry. Masimo SET should clearly become the new standard for pulse oximetry."

Steven Barker, Ph.D, M.D.

Professor and Chairman, Dept. of Anesthesiology
University of Arizona

what is Masimo SET pulse oximetry?

Masimo SET pulse oximetry is a fundamentally advanced method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. Combining proprietary signal processing algorithms with innovative sensor design, Masimo SET pulse oximetry enables adaptive filters to work in real time to accurately report human physiology. Masimo SET pulse oximetry systems have been clinically proven to virtually eliminate the problems of motion artifact, low peripheral perfusion and most weak signal-to-noise situations.

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LNOP® sensors... reducing cost of care

durable adhesive sensors

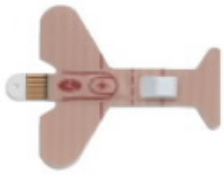
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sensor rejuvenation feature

•

competitive sensor pricing

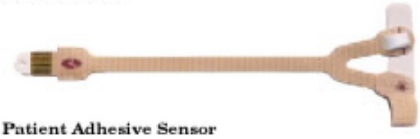
LNOP products



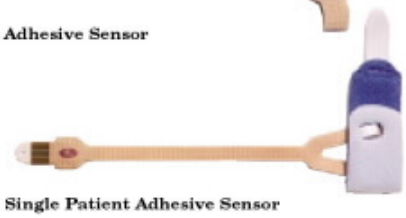
LNOP Adt
Adult Single Patient Adhesive Sensor



LNOP Pdt
Pediatric/Slender Digit
Single Patient Adhesive Sensor



LNOP Neo
Neonatal Single Patient Adhesive Sensor



LNOP NeoPt
Sensitive Skin Neonatal Single Patient Adhesive Sensor



LNOP DCI
Reusable Finger Sensor



LNOP DCIP
Pediatric Reusable Finger Sensor



Masimo Sensor Patient Cable

A complete selection of single patient use, latex free adhesive sensors is available for all patients from adults to neonates. Reusable Adult and Pediatric finger clip sensors are also available for short-term spot checking. In addition to improved performance and competitive pricing, the single patient adhesive sensors have the following advantages that further helps to reduce costs:

Durability

The tape material used in Masimo LNOP adhesive sensors is much more durable than that used in the Nellcor disposable sensors. The result is a sensor that can be removed and reapplied multiple times during a patient's stay.

Rejuvenation Feature

The adhesive used in the Masimo LNOP sensors has a unique rejuvenation feature. Using an isopropyl alcohol pad, the adhesive can be rejuvenated and the effectiveness restored.

Increased Sensor Longevity

As shown below, longevity studies have been conducted and the results show a nearly two-fold increase in durability with Masimo LNOP sensors compared to Nellcor disposable sensors.

Test Sensor	Masimo SET LNOP-Neo	Nellcor N-25
Average Sensor Life	11.1 days	5.7 days
% of Sensors Lasting Throughout Patient Stay	81%	6%

Source: Alison Thomas BSN, RN, Michael Holmes BS, RRT, John Vogt MD, Ernesto Gangitano, MD, Carolina Stephenson MD, Richarde Liberman MD, Dept. of Neonatology, Huntington Memorial Hosp., Pasadena, CA. Useful Life of Pulse Oximeter Sensors in a NICU, *Respiratory Care* 1998.

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Radical™ signalextraction™ pulse oximeter

Radical as a Standalone Pulse Oximeter

Radical's lightweight and rugged design, provides continuous and reliable arterial oxygen saturation monitoring anywhere throughout the continuum of care: in the ER, OR, ICU and recovery room, in any specialty clinic, the general floor and home.

Radical as a Handheld Pulse Oximeter

The Handheld pulse oximeter easily detaches from the standalone unit as a full-featured Handheld pulse oximeter to travel with the patient during hospital transport providing continuous, seamless Masimo SET performance.

Radical with SatShare™ as an Upgrade to Your Existing Validated* Monitor

Radical with SatShare interface upgrades existing monitors to Masimo SET pulse oximetry. This unique upgrade capability gives clinicians a quick, easy and affordable way to upgrade their existing conventional pulse oximeters to Masimo SET performance.



[1]Contact Masimo for a list of the latest SatShare validated multiparameter monitors which include Datascope, Datex-Ohmeda, GE Medical Systems, Hewlett-Packard/Agilent/Philips, Siemens Medical Systems and Spacelabs Medical.

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1935

Matthes develops first 2-wavelength ear O_2 saturation meter with red and green filters, later switched to red and infrared filters. First device to measure O_2 saturation.



1949

Wood adds pressure capsule to squeeze blood out of ear to obtain zero setting in an effort to obtain absolute O_2 saturation value when blood was readmitted. Concept similar to today's conventional pulse oximetry but suffered due to unstable photocells and light sources. Not used clinically.



1981

In 1972, Aoyagi at Nihon Kohden invents conventional Pulse Oximetry. Using the ratio of red to infrared light absorption of the pulsating components (assumed to be only arterial blood) within the measuring site, he could calculate O_2 saturation without calibration. It was commercialized by Nellcor and Ohmeda in 1981, who introduced smaller probes utilizing light emitting diodes (LEDs). However, motion, low perfusion, electrocautery interference and ambient light limited the effectiveness of conventional pulse oximetry.

Civilization took 10 Thousand Years to Evolve...Pulse Oximetry only took 60.

1942

Millikan develops optical blood oxygen saturation method because Air Force fighter pilots were blacking out at high "G" forces. Arterialized blood in ear by heating, coined the term "oximeter".



1964

Shaw assembles first absolute-reading ear oximeter by using eight wavelengths. Commercialized by Hewlett Packard, use was limited to pulmonary function and sleep laboratories due to cost and size.



Instruments and sensors containing Masimo SET technology are identified with the Masimo SET logo. Look for the Masimo SET designation on both the sensors and monitors to ensure accurate pulse oximetry when needed most. Masimo SET.

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