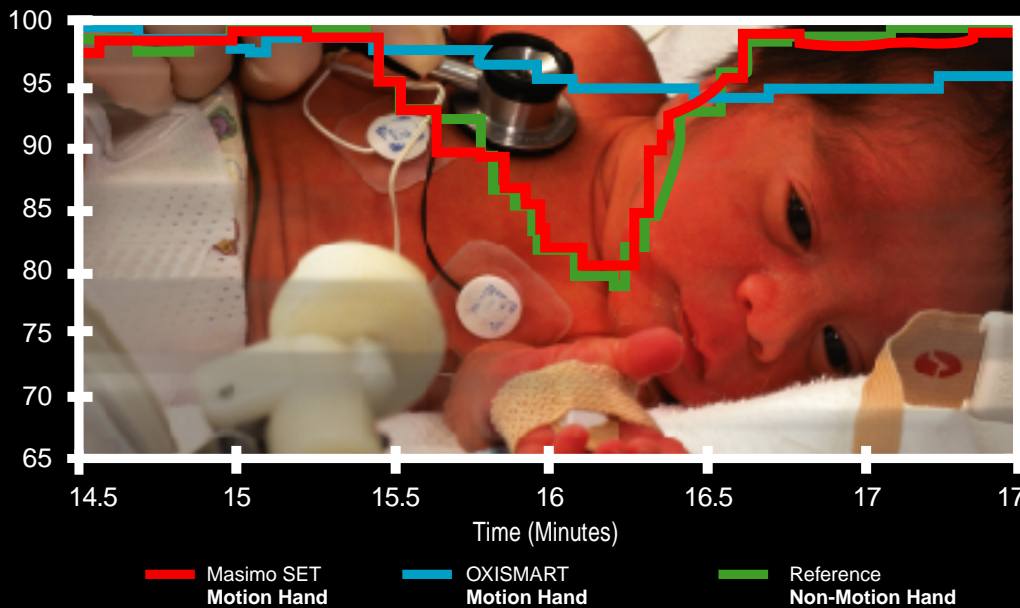


Saturation Recorded During Rubbing Motion
Masimo SET accurately tracks the desaturation and resaturation,
while the Oxismart product misses the hypoxemic event.
This study was performed on adult volunteers.
Data courtesy of Steven Barker Ph.D., M.D., Professor and Chairman,
Department of Anesthesiology, University of Arizona



the proof is in the
performance

Prove it to yourself — take Masimo SET pulse oximetry to your toughest patients and perform a confirming CO-Oximeter ABG. If the Masimo SET pulse oximeter measurement is further from the CO-Oximeter measurement than any other non-Masimo SET pulse oximeter, we will reimburse the cost of your test.*

 **MASIMO SET**[®]
Signal Extraction Pulse Oximetry

Masimo SET is the only pulse oximetry technology that has received FDA clearance during motion and low perfusion on all patients



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For Immediate Release

Masimo Corporation Receives FDA Clearance for Performance Claims During Motion and Low Perfusion on All Patients, from Neonates to Adults

Masimo SET Becomes the Only Pulse Oximetry Technology Cleared by the FDA to Specify Accuracy During Motion and Low Perfusion Conditions

Irvine, CA, June 9, 1999 - Masimo Corporation announced that it has today received clearance from the FDA to expand the indications for use for its Signal Extraction Technology pulse oximetry system to include conditions of patient motion and low perfusion, on all patient populations. In addition, Masimo SET was also cleared for accuracy specifications under these conditions. No other pulse oximetry technology can make these claims.

Pulse oximetry is the noninvasive measurement of arterial oxygen saturation and pulse rate. It is widely used and is considered a standard of care to monitor critically ill patients at risk of respiratory distress. Despite its promise, pulse oximetry has been plagued by its inability to remain accurate and reliable during patient motion or when the patient's pulse is weak (low perfusion). The result has been a high rate of false alarms and failures, which reduces the usefulness of pulse oximetry when monitoring critically ill patients.

Masimo Corporation has created Signal Extraction pulse oximetry for the express purpose of solving these problems. Masimo's proprietary signal processing and sensor technology, Masimo SET, is the only pulse oximetry technology which has been clinically proven accurate under conditions of motion and low perfusion. To date, there have been 16 independent, peer reviewed clinical studies published in prestigious journals which all conclude that Masimo SET pulse oximetry exhibits far fewer false alarms and failures (e.g., drop outs or zero outs), while being more reliable in detecting true alarms. This improvement is due to Masimo SET's ability to accurately monitor under these difficult conditions.

"This is one more reassurance for those who are ready to adopt Masimo SET as the new performance standard for pulse oximetry," stated Joe E. Kiani, President and Chief Executive Officer of Masimo Corporation. "We have had many published studies from leading clinical researchers like Dr. Steven Barker, Dr. William Hay, Dr. Christian Poets and Dr. Kevin Tremper showing Masimo SET's superior performance. We have had numerous accounts by clinicians of Masimo SET's ability to work whenever needed, which has resulted in their ability to better care for their patients. And now, we have FDA clearance for accuracy during motion and low perfusion on all patient populations. Our licensees are offering this technology worldwide; and the real beneficiaries will be the patients. I am proud of what our Team has accomplished."

Masimo Corporation is a privately-held medical technology company that designs, develops and licenses advanced medical signal processing and sensor technology for the noninvasive monitoring of vital parameters. Masimo has created a fundamentally unique method to measure arterial oxygen saturation. Masimo Signal Extraction pulse oximetry is the only technology that provides accurate readings during motion and low perfusion and is designed for accuracy during motion and low perfusion. Masimo has licensed its Signal Extraction

Section 3 — Indications for Use

510(k) Number (if known): K990966

Device Name: **Masimo SET® 2000 Pulse Oximeter and the LNOF® Series of Sensors and Cables**

Indications For Use:

The Masimo SET® 2000 Pulse Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). The Masimo SET® 2000 Pulse Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

clinically proven



accuracy specification

Parameter	No Motion and Normal Perfusion	Low Perfusion†	Motion†
Saturation (70% to 100% SpO ₂)			
Adults and Pediatrics	2 digits	2 digits	3 digits
Neonates	3 digits	3 digits	3 digits
Pulse Rate (25-240 bpm)			
Adults, Pediatrics and Neonates	3 digits	3 digits	5 digits

Low Perfusion Performance: >0.02% Pulse Amplitude and % Transmission > 5 %

low perfusion study

SpO ₂ System	Masimo SET	OXISMART	N-200
Drop Out Rate	0.8%	9.9%	17.8%
True Hypoxemias Missed	0%	33.3%	33.3%

Source: Barker SJ, Novak S, Morgan S. The Performance of Three Pulse Oximeters During Low Perfusion in Volunteers. *Anesthesiology* 1997;87(3A):A409.

motion study

SpO ₂ System	Masimo SET	OXISMART	N-200
False Alarms	0%	36%	30%
True Hypoxemias Missed	0%	16%	1%

Source: Barker SJ, Shah NK. The Effects of Motion on the Performance of Pulse Oximeters in Volunteers. *Anesthesiology* 1997;86(1):101-108.

NICU true alarm reliability study

SpO ₂ System	Masimo SET	OXISMART	N-200
True Hypoxemias Missed	1%	8%	8%
True Bradycardias Missed	7%	69%	31%

Source: Bohnhorst B, Peter CS, Poets CF. Pulse Oximeters' Reliability in detecting Hypoxemia and Bradycardia: Comparison between Nellcor N-200, N-3000 and Masimo SET. *Pediatric Pulmonology*. 1998;26:444.



The facts about Masimo SET:

The only pulse oximetry technology clinically proven accurate during motion and low perfusion

Virtually eliminates false alarms

More reliable in detecting true alarms

Continuous monitoring (no freezing or alarm management)

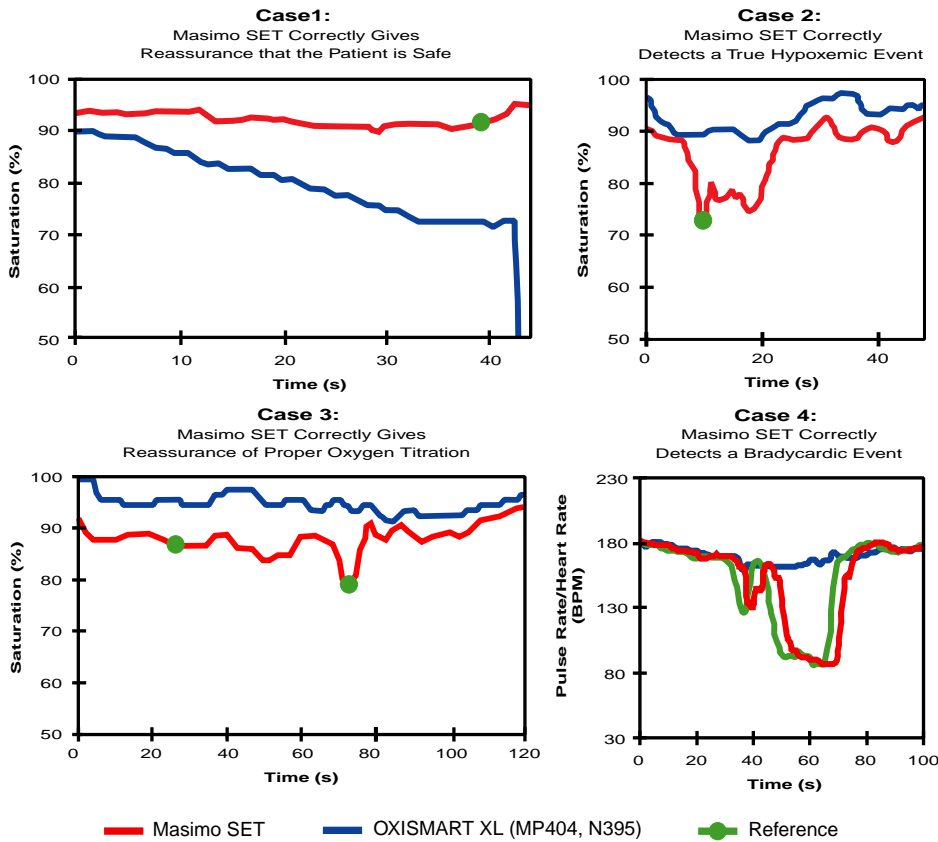
“Masimo SET pulse oximeter detected hypoxemia reliably, despite a 93% reduction in alarms in the neonatal intensive care unit”

Christian F. Poets, MD
Professor, Pediatric Pulmonary,
Hanover Medical School, Germany

Masimo SET vs. OXISMART XL

Data reflects results of clinical studies performed on NICU infants.

Masimo's
announced partners:



Often imitated, never replicated

In 1989, Masimo invented Signal Extraction Pulse Oximetry, which enabled the use of adaptive filter technology to extract the arterial signal from noise. In 1998, Masimo unveiled this breakthrough technology to the world. And in June 1999, Masimo SET became the first and only technology to receive FDA clearance for accuracy during motion and low perfusion conditions on all patients.

Prior to the introduction of Masimo SET, pulse oximeters could only be relied upon for accurate measurement during ideal conditions. Today, after 5 years of clinical research, over 20 published clinical studies have shown that Masimo SET reliably and continuously tracks changes in oxygen saturation and pulse rate, giving you accurate monitoring when you need it most.


Over the past two years, approximately 40% of the world's pulse oximetry suppliers have adopted Masimo SET as their pulse oximetry solution. Already, more than twenty patient monitors are available from leading patient monitoring companies with Masimo SET pulse oximetry. Prove it to yourself, take Masimo SET pulse oximetry to your toughest patients.



1-877-4-MASIMO • www.masimo.com

* CO-Oximeter test must be performed on a calibrated CO-Oximeter with four or more wavelengths (e.g., IL 482 or Radiometer OSM3). Certain other rules and restrictions apply. Contact Masimo for more details.

† For test protocols contact Masimo Corporation.

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