

This paper explains the concept, implementation, and use of Masimo SET®, Radical®, and Radical SatShare™ products.

Background

Hospital facilities that want to standardize all of their pulse oximetry to the latest technology available in the marketplace must consider both their standalone pulse oximeters and their multi-parameter patient monitors. Standalone pulse oximeters can easily be replaced, however, replacement of technology in multi-parameter monitors is often a more costly and difficult undertaking. To help address the complications of upgrading multi-parameter monitors, Masimo has developed a cost effective alternative known as SatShare. Using Masimo's unique and patented SatShare interface, Radical pulse oximeters can be integrated with the hospital's existing multi-parameter monitors, enabling measurements using Masimo SET technology to be displayed on the host patient monitor. The SatShare interface is a cost effective, reliable and, sometimes necessary approach for implementing Masimo SET technology in legacy systems from the more than 35 patient monitor companies.

Introduction to Masimo SET

Since the commercial introduction of Masimo SET in 1998, pulse oximeter failures (false alarms) are no longer tolerated. Hospitals that want to standardize all of their pulse oximeters, including the multi-parameter patient monitors, to the new standard in pulse oximetry performance, can do so simply and safely by integrating a Radical pulse oximeter using the SatShare interface.

Masimo SET pulse oximetry is a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. Masimo SET technology utilizes parallel processing engines and enables the power of adaptive filters to be applied to real-time physiologic monitoring utilizing proprietary techniques, enabling direct calculation of arterial oxygen saturation and pulse rate. Because it is not bound by a conventional "red over infrared" ratio approach, the Masimo SET system substantially eliminates the problems of motion artifact, low peripheral perfusion and most low signal-to-noise situations. This greatly expands the utility of SpO₂ in high motion, low signal and noise intensive environments.

The superior performance of Masimo SET pulse oximetry has been validated in over 100 independent clinical studies. The table below summarizes the results of two such studies.¹

Machine and Self Generated Motion					
Device		Missed Event	Sensitivity	False Alarm	Specificity
 Masimo Radical (v5.0)	MG	0/20	100	4/60	93
	SG	1/20	95	2/60	97
Nellcor N-600 (v1.1.2.0)	MG	7/20	65*	20/60	67*
	SG	10/20	50*	14/60	77*
Datex-Ohmeda TruSat	MG	16/20	20*	10/60	83*
	SG	17/20	15*	11/60	82*

Introduction to Radical

Masimo's Radical signal extraction pulse oximeter, when combined with a SatShare interface, provides three powerful options:

1. A standalone device for bedside monitoring,
2. A detachable handheld that facilitates both transport and spot check monitoring, and
3. A monitor interface that permits the Radical signal extraction pulse oximeter to become the default SpO₂ technology in multi-parameter monitors.

With multi-function capability, ease of use, and economical sensor standardization, users can provide continuous and reliable SpO₂ monitoring anywhere within the continuum of care. The Radical delivers the unsurpassed accuracy and reliability of Masimo SET technology, virtually eliminating false alarms without sacrificing the ability to detect true alarms.

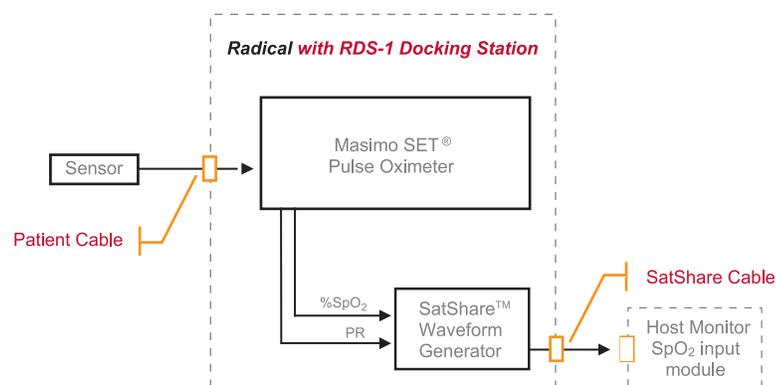
SatShare Concept

A SatShare cable provides an interface from the standalone Radical signal extraction pulse oximeter to the SpO₂ input of a multi-parameter patient monitor, instantly upgrading its existing pulse oximetry to Masimo SET pulse oximetry (see Figure 1). SatShare cables attach to the back of the Radical Docking Station (RDS-1), and are available to interface with most multi-parameter monitors.

- Radical measures physiological patient data from the Masimo sensor through the patient cable.
- Radical's integrated Masimo SET technology reads through noise and extracts two numbers: SpO₂ and pulse rate.
- The two numbers are then passed to the SatShare Waveform Generator.
- The SatShare Waveform Generator produces a non-physiological waveform of the proper characteristics to enable the older pulse oximeter to display the same SpO₂ and pulse rate numbers measured by Radical.

The patient's actual physiologic waveform is shown on the Radical display. Because older monitors cannot effectively monitor through motion, sensor data cannot be transmitted to the older pulse oximeter being upgraded. Since the older pulse oximeter is not receiving sensor data, it is no longer functioning as a pulse oximeter. The Radical signal extraction pulse oximeter performs all the pulse oximetry calculations, and simply passes a signal to the older pulse oximeter that enables it to display the proper Masimo SET pulse oximetry measurements.

The host monitor, upon receiving the generated waveform, displays the accurate saturation values, which were determined by the Radical. These values have the capability of remaining within the continuum of the patient's record.

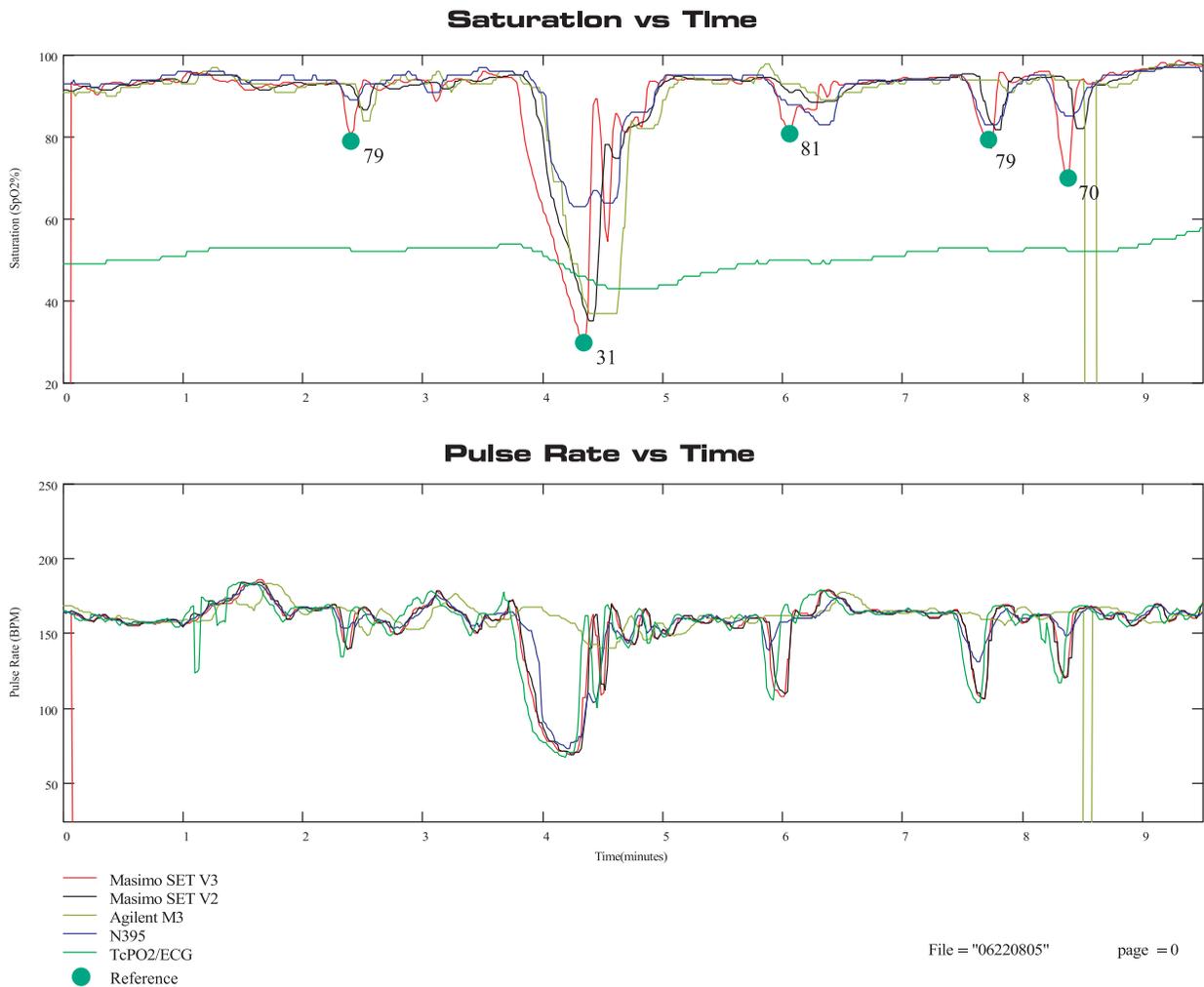


Masimo SET Performance

The Radical pulse oximeter has been designed to respond quickly and consistently to changes in a patient's physiology. Unlike other pulse oximeters, the Radical responds with high fidelity irrespective of patient motion conditions and perfusion level.

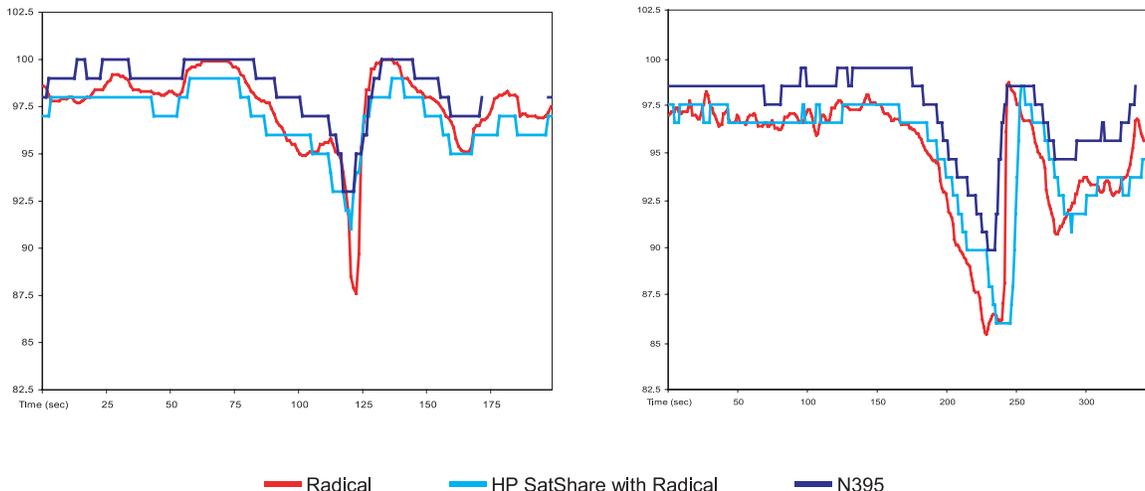
With user selectable averaging times, in the range of 2, 4, 8, 10, 12, 14 and 16 seconds for normal operation, and 2, 4 and 8 seconds in the SatShare mode, Radical gives users maximum flexibility in determining how the Radical shall be configured to measure and display changes in saturation and pulse rate measurements.

The figure below displays clinical data collected in the NICU. It shows that Masimo SET responds faster to significant changes in physiology than the Agilent Viridia or the Nellcor N395. Note that the Agilent Viridia misses some of the bradycardias that accompanied the desaturations, implying that the desaturations - although true - may be artifactual. Also note that the N395 does not follow the patient saturation to 30%; instead it steadies at approximately 60%. The Masimo SET device correctly captures all of the changes in physiology, both saturation and pulse rate. Looking closely at the deep desaturation (t = 4 min.), Masimo SET (v2 and v3) tracks the desat more closely than either Nellcor or Agilent, but notice how v3 desats first ahead of the other pulse oximeters, reaches 30%, resats to 90%, desats to 55%, resats to 80% and resats to 90%. Remarkably, the ECG heart rate and Masimo SET pulse rate mimics the change in saturation fluctuations that are missed by the other pulse oximeters.



SatShare Performance

With the Radical interfaced to the host monitor via SatShare, the response of the overall system is slightly delayed. Notice, however, that the Radical via a SatShare interface still delivers a faster response to changes in physiology than that of the Nellcor N395 standalone pulse oximeter.



Further testing characterized the response times of the Radical, interfaced via SatShare, and the Nellcor N395, reporting a step change in saturation. The following chart shows the response time test results. From this table it is clear that, despite a slight delay in the overall response, Radical interfaced via SatShare still responds faster to changes in physiology than the Nellcor N395.

Instrument	Pulse Rate (BPM)	100% Step Change (SpO ₂ = 80%)
Masimo SET Radical ³	75	11.0
SLM ⁴ via SatShare	75	20.2
H-P Omnicare ⁵ via SatShare	75	22.8
H-P Viridia ⁶ via SatShare	75	24.0
NPB-395 ⁷	75	25.0
Masimo SET Radical ³	120	11.4
SLM ⁴ via SatShare	120	20.3
H-P Omnicare ⁵ via SatShare	120	17.6
H-P Viridia ⁶ via SatShare	120	25.0
NPB-395 ⁷	120	25.3

SatShare Approvals

The Radical signal extraction pulse oximeter, with its unique SatShare feature, has been extensively tested for safety and performance to the latest applicable national and international standards. The Radical Signal Extraction pulse oximeter meets or exceeds all of the requirements and has received FDA clearance (510(k): K000126, K002477, K002574, K002682, K002751, K002939, K003167, K003244, K010419, K011851), Canadian Approval, UL, CUL, CE and Shonin (Japan) approval for the safe and effective use of the SatShare feature with multi-parameter devices.

To ensure that the Radical signal extraction pulse oximeter operates safely when being used with a multi-parameter device without violating any safety requirements or IEC/ISO standards, the multi-parameter device must be EN 60601-1-1 compliant.

To perform properly, the Radical pulse oximeter must be connected to the multi-parameter device using the proper SatShare interface cable. To date, Masimo has validated interface cables for many of the multi-parameter monitors on the market. Check with your Masimo representative, or www.masimo.com for the latest list of validated monitors.

Selected References and Web site information

1. Shah N, Estanol L. Comparison of three new generation pulse oximeters during motion and low perfusion in volunteers. *Anesthesiology*. 2006; A929.
2. Radical System software release 2.0 and later.
3. Masimo Radical with Masimo SET V3 set to 4 second averaging.
4. Spacelabs Medical monitor set to 4 second averaging.
5. HP Omnicare Model 1204 monitor set to 5 second averaging.
6. HP Viridia Model 24C monitor set to 5 second averaging.
7. Nellcor N395 pulse oximeter default settings.

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