

Memorandum

To: Bob Terranova **Date:** July 10, 2001

From: Raj Rajagopalan

Subject: OSI 2100 Pulse Oximeter

Copy: Eric Kinast, Gordon Neff

The OSI Medical 2100 Pulse Oximeter non-invasively calculates the functional saturation of arterial hemoglobin (SpO₂) and pulse rate. It has a display that presents patient data and status information: an LCD display that shows the SpO₂, pulse rate values, a plethysmographic waveform, the current high and low SpO₂ and pulse rate limit settings, and other messages as appropriate. The unit uses an FFT based signal processing technique. The Dolphin Sensor used in the 2100 system digitizes light intensity information at the point of the probe. A key benefit of the device's digital signal processing technology claimed by OSI is the ability to provide readings with lower interference from nearby electronic signals than that which is experienced when using a typical system. The claim of increased EMI immunity was however not tested during this evaluation. The published specifications of this monitor are as follows:

Measurement Range:

SpO ₂ (functional)	0% - 100%
Pulse Rate (bpm)	30 - 240 bpm
Perfusion	0.02% - 0.2%
Low Perfusion	0.02% - 0.2%

Where perfusion = $(AC/DC)_{90s} \times 100\%$

Resolution:

Saturation (% SpO ₂)	1%
Pulse Rate (bpm)	1

Accuracy:

SpO ₂ (functional)	Adult	No Motion and	70 - 100	± 2 %
	Pediatric > 30 kg	Normal Perfusion	0 - 69	Unspecified

Pulse Rate (bpm)	Adult Pediatric > 30 kg	No Motion and Normal Perfusion	30 – 240	± 3 bpm
SpO2 (functional)	Adult Pediatric > 30 kg	Motion or Low Perfusion < 0.2%	70 – 100 0 – 69	± 3 % Unspecified
Pulse Rate (bpm)	Adult Pediatric > 30 kg	Motion or Low Perfusion < 0.2%	30 – 240	± 5 bpm

The OSI 2100 was evaluated using simulators and on volunteers with and without added motion artifacts (specific movements of the arm). The effect of varying ambient light was also tested. The performance of the OSI 2100 was compared to a Passport 2 with Massimo SpO2. The details of the instrument tested and the test equipment used are indicated in the following table and the results are discussed briefly in what follows.

DESCRIPTION	MAKE	MODEL	SERIAL NO.	CALIBRATION DUE DATE
Patient Monitor	OSI Medical	2100	M0111-006	
SpO2 Simulator	BioTek	Index	7391	06 / 2002
Passport 2 Monitor	Datascope Corp	0996-00-045-0001	C401024-K9	

You might want to change the first sentence describing the third set of tests, so that the purpose of the recorder paper is clearer. For example, " In a third set of tests, the units were tested under weak signal conditions, by wrapping layers of recorder paper around the finger to attenuate the light. "

GENERAL COMMENTS:

The monitor is fairly small in size, but it is quite heavy. The fonts used are good and the numbers are large. However, the pleth signal display is rather poor. Instead of a line depicting the signal, the bottom half of the screen (below the signal line) is white while the top half is black. Access to menu items is fairly obvious. The probe is very similar to those used by Datascope Corp, and a Texas Instruments light to frequency converter chip is to be found in the probe.

SUMMARY OF TESTS:

In the first part of the tests, the OSI 2100 was compared to a Passport 2 Massimo using signals from a simulator (BioTek INDEX). The 2100 was found to perform as well as the Passport 2 Massimo except for the following:

- The 2100 took longer to indicate a reading when switched from one mode to another
- The 2100 stopped beeping on every cycle when the simulator was set to obese patient
- The 2100 was unable to measure when the ambient light setting on the simulator was set to SUN.
- At heart rates above the specified upper limit, the OSI 2100 was found to indicate a lower value while the Passport 2 correctly indicated over range.

The work sheet entitled "Simulator Test" in the attached spread sheet contains details of the results from this test.

performance in noisy environments because of the digitization of the signal at the sensor. Overall, within the limitations of the tests, the OSI 2100's performance was quite impressive.

REFERENCES:

The following are references to a couple of articles that talk about the OSI 2100 technology and performance.

- Predictors of Pulse Oximetry Failure. D.L. Reich, A. Timcenko, C.A. Bodian, J. Kraidin, J. Hofman, M. DePerio, S.N. Konstadt, T. Kurki, J.B. Elsenkraft. Anesthesiology 1996; B4:859-64.
- Signal Processing Methods for Pulse Oximetry T.L. Rusch, R. Sankar, J. E. Scharf. Computer Biological Medicine 1996 Vol. 26, No. 2: 143-159.