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:

SpO2 (functional)	0% - 100%
Pulse Rate (bpm)	30 - 240 bpm
Perfusion	0.02% - 0.2%
Low Perfusion	0.02% - 0.2%

Where perfusion = $(AC/DC)_{905} \times 100$ %

Resolution:

Saturation (% SpO2)	1%
Pulse Rate (bpm)	1

Accuracy:

SpO2 (functional)	Adult Pediatric > 30 kg	No Motion and Normal Perfusion	70 – 100 0 – 69	± 2 % 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 arounf 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 form this test.

The performance of the 2100 in the presence of specific motion artifacts was then compared that of a Passport 2. Specific repeatable movements of the arm, and finger on which the SpO2 sensor was attached were used. It was found that both monitors were unaffected by violent and sudden movements and continued to indicate the correct oxygen saturation and pulse rate. When more gentle and subtler movements were used, it was possible to affect the performance of both monitors.

- Rubbing the hands together did not affect either unit.
- When the fingers (including that with the sensor) were used in a drumming motion, the Passport remained unaffected, but the 2100 locked on to this movement if the drumming rate was close to the pulse rate. Once this happened, the saturation and pulse rates were easy to change and depended on the amplitude and rate of the drumming.
- Gentle curling and uncurling of the finger affected both units and they could both be made to lock on to the spurious signal produced by this motion. It was easier to get the units to malfunction if the motion artifact was introduced during the pulse search phase.
- Using one hand the end of the sensor with the hinge was lifted up a mm or two and lowered at a rate close to the pulse rate measured in the absence of motion. This affects both the OSI 2100 and the Passport 2 but it was found that the OSI 2100 was a bit more stable than the Passport in the presence of this artifact.

For details of the results from this phase of testing please refer to the work sheet entitled "Motion-1".

In a third set of tests, the units were tested for performance under weak signal conditions by wrapping layers of strip chart recorder paper around the finger to attenuate the light. The 2100 was unable to measure with more than 3 layers of paper on the finger while the Passport 2 Massimo unit stopped measuring only after 6 layers of paper were wrapped around the finger. All the motion artifacts cases tested above were repeated with layers of recorder paper around the finger. The results are to be found in the work sheet "Light&Motion". The performance of the units in the presence of motion with layers of paper wrapped on the finger was very similar to performance without paper on the finger attenuating the light. However, it was sometimes easier to get the units to lock on to the artifact under conditions of reduced signal intensity.

In a final set of tests, performance was verified under increased ambient lighting. It was found that the Passport 2 Massimo worked at much higher levels of ambient light than the OSI 2100. The results from these tests are detailed in the work sheet entitled "AmbientLight".

CONCLUSIONS:

The tests used to evaluate the OSI 2100 pulse oximeter and to compare its performance to a Passport 2 Massimo unit were somewhat limited. The OSI 2100 was found to perform very well and was comparable to the performance of the Passport 2 except under certain conditions like increased ambient light. It was in fact better than the Passport 2 in a very narrow band of tests (artifact created by moving the sensor up and down at the hinge). It was found that the 2100 was more vulnerable to motion artifacts during the pulse search phase when compared to the post pulse search phase when a stable signal had been acquired. The following important aspects were not tested because the means to do so were not available.

- Performance during desaturation with and without the addition of other factors like motion, decreased light intensity, increased ambient light etc.
- Performance on real patients with weak pulses.
- Ability to respond to dynamic saturation changes in the presence of artifacts.
- Performance in the presence of electrosurgical noise since one of the claims of OSI is good

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; 84:859-64.

- Signal Processing Methods for Pulse Oximetry T.L. Rusch, R. Sankar, J. E. Scharf. Computer Biological Medicine 1996 Vol. 26, No. 2: 143-159.