

BETA Biomed Services, Inc.

NEW PRODUCT INFORMATION

CENTRAL SpO2 SENSOR PROBES (Patents Pending)

INTRODUCTION

The probes described, and referred to in this document, were designed to function interchangeably with present OEM SpO2 sensor probes and special instruments developed by BETA Biomed Services, Inc. They are as accurate as the OEM sensor probes (as shown in the enclosed validation studies and will provide the same information (SpO2 and Pulse Rate); however, they are more convenient when connecting to the patient. In addition, the monitoring location of the Central SpO2 Sensors will allow the medical staff to utilize the arms of the patient for other monitoring procedures without interfering with the SpO2 monitoring procedure.

The most important advantage of the CENTRAL SpO2 SENSOR PROBES is the displayed data originates from major branches of the Carotid Artery supplying the medical staff consistently with the desired data. The central location supplies a much greater signal to noise ratio resulting in more responsive data from signals that are two to ten times greater than that received from the finger. The response time of the Central Probes to physiological events, is much more desirable and acceptable compared to peripheral probes (see enclosed paper and graphs). Many of these events are undetectable from finger sensor probes.

We are now introducing this exciting technology. The following sensor (Cheek) is our first central device to become available. Others will follow during the year (2005).

CHEEK SpO2 SENSOR PROBE

The Reusable Adult Cheek SpO2 Sensor Probe is the first version of our central probes. The problem that triggered the device was the need to allow the medical staff to monitor burn patients in the ICU, especially those patients that have damaged extremities. After verifying the prototype units on burn patients, it became obvious to the ICU personnel that had many cases in the ICU requiring a number of IV procedures making vital sign monitoring difficult. We verified that central monitoring of the SpO2 and Pulse Rate resulted in the same conclusions found with burn patients. This research has triggered the development of additional central sensors and significant technological conclusions.

The CHEEK SpO2 SENSOR PROBE is typically placed on the left side of the mouth; however, it will function as well on the right side. Place a disposable sheath over the probe before inserting the probe over the patient's cheek. Then place the probe at an angle, with the cable running over the ear. This should place the LED over the Facial Artery and indicate a very strong pleth.

It is recommended that this sensor be used in surgery or other departments where the patient is sedated or anesthetized.

CONFIDENTIAL



Peripheral Perfusion and Response Time

Nasal Lip and Cheek Units vs. Standard Finger Clip

Introduction:

The knowledge of a patient's oxygen saturation during critical care or in the operating room remains an invaluable tool for anesthesiologists, physicians and critical care RNs. A patient's SpO₂ may indicate a problem in respiratory, cardiovascular, and neuromuscular systemic areas as well as more broad ranges issues like patient core temperature and general well being.

There is no questioning the necessity for the health care field to accurately monitor and control a patient's oxygen saturation. However, current technology can be limiting. The response time for most SpO₂ units is poor at best. Oxygenated red blood cells have to travel all the way to the capillary beds in a patient's finger or toe. This could not only cause a dramatic delay in accurately determining the SpO₂ but may even act as a poor marker for systemic oxygen levels. During anesthesia and extended bed rest the peripheral perfusion of a patient can be compromised. The blood flow to the extremities is restricted and recording patient information from the fingers and toes may only serve to give false information to the physician or RN.

Currently, there is no accurate way to measure the peripheral perfusion rate and response time for change in a patients blood oxygen levels. Luckily, Beta Bio Med Services Inc. has developed a new way of monitoring blood oxygen levels that may not only help to dramatically improve response time for blood oxygen changes but to serve as an indicator for peripheral perfusion, an invaluable – yet unavailable – tool for anesthesiologists monitoring in the operating room. By taking measurements of arterial oxygen saturation levels through the capillary beds of the interior nasal septum or the inferior coronary artery around the lips and cheek Beta Bio Med Services Inc. can more accurately measure changes in a patients SaO₂. The nasal, lip, and cheek monitoring systems monitor the blood gas levels of capillary beds only 2-3 branches away from the carotid artery, the main ascending branch of the cardiovascular system. Unlike measuring from the extremities these areas are not as affected by loss in peripheral perfusion due to anesthesia and can indicate changes in alveoli gas exchange of the lungs with more accuracy and speed than in the extremities.

Research:

The following study shows the dramatic difference between measuring SpO₂ from the peripheral extremities as opposed to the nasal and lip/cheek perfusion sites. With this knowledge, an understanding of how this type of monitoring can be used in

conjunction with standard extremity SpO₂ monitoring to help determine a patient's peripheral perfusion rate, an important patient monitoring tool that is currently unavailable to health care professionals.

Three different pulse oximeters and three different probes were used for this project. An OEM Ohmeda finger probe was attached to an Ohmeda 3740 pulse oximeter while a Beta Bio Med Services Inc. nasal and lip/cheek unit was attached to either a Nellcor N-200 or N-180. All three probes were attached to the same subject and tested three times. A stable signal was obtained from all three units and the displayed SpO₂ was recorded at 5-second intervals for 90 seconds. At the tenth second self-induced Hypoxia was initiated for a period of 40 seconds. Self-induced hypoxia is caused from the subject's forced denial of the urge to breathe. After a period of adjustment, this should elicit a decrease in blood oxygen levels followed by an increase as the subject reverses the hypoxic result through deep breathing and increased oxygen intake.

Results:

After 30-40 seconds of self-induced hypoxia the SpO₂ readings for the nasal and lip/cheek unit indicate a dramatic decrease in SpO₂ of 5 to 8 percent. Typically SpO₂ levels below 90 elicit an alarm for physicians and RN's to check and adjust the patient. Levels below 90 were recorded on 5 of 6 of the trials for both Beta Bio Med Services Inc. probes. This period of low saturation levels in the Beta Bio Med Services Inc. probes lasted for 20-40 seconds until fully recovered.

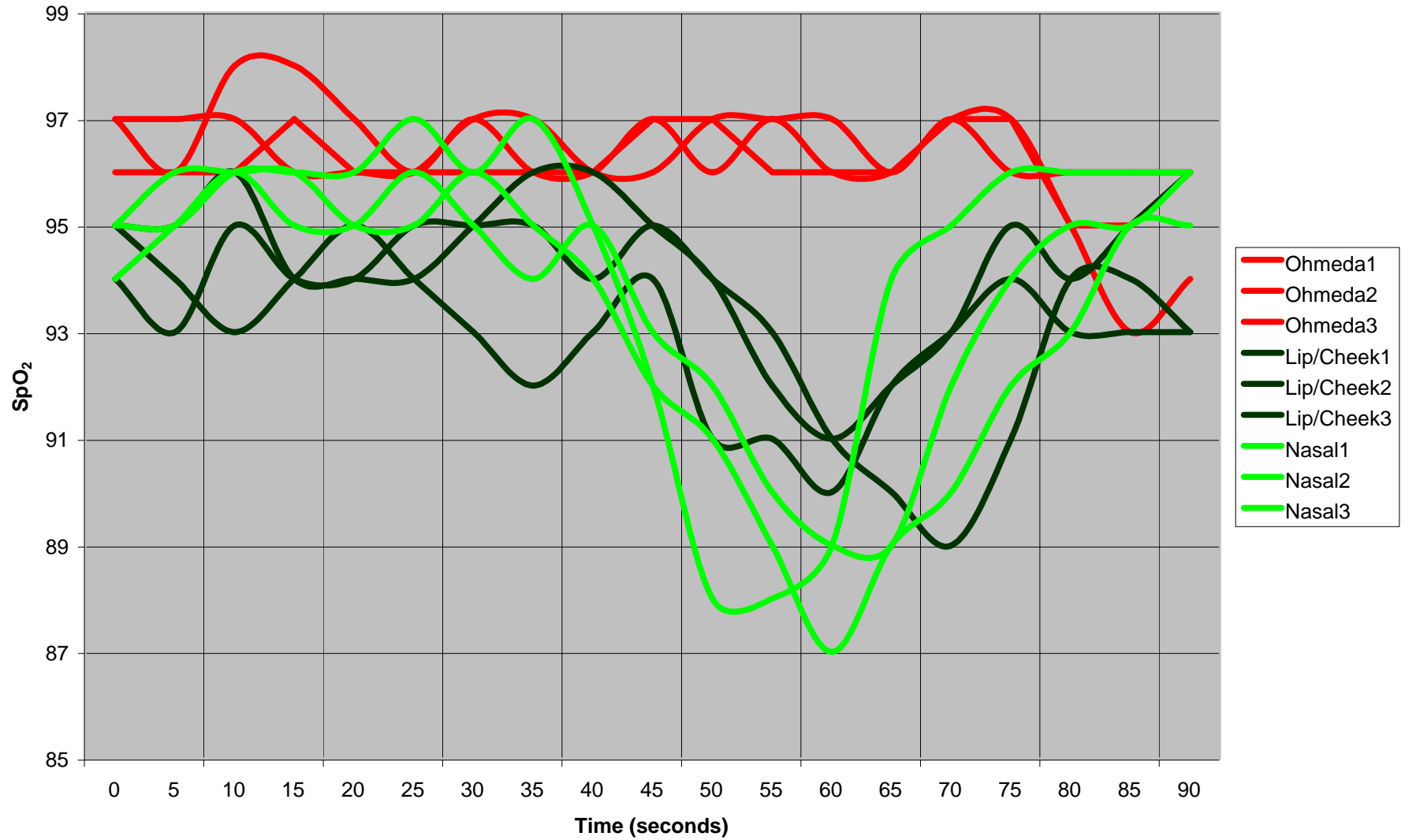
The Ohmeda pulse oximeter finger probe showed very little change in signal during and after the self-induced hypoxic period. At 75-80 seconds a slight decrease was obtained of less than 2 percent.

Discussion:

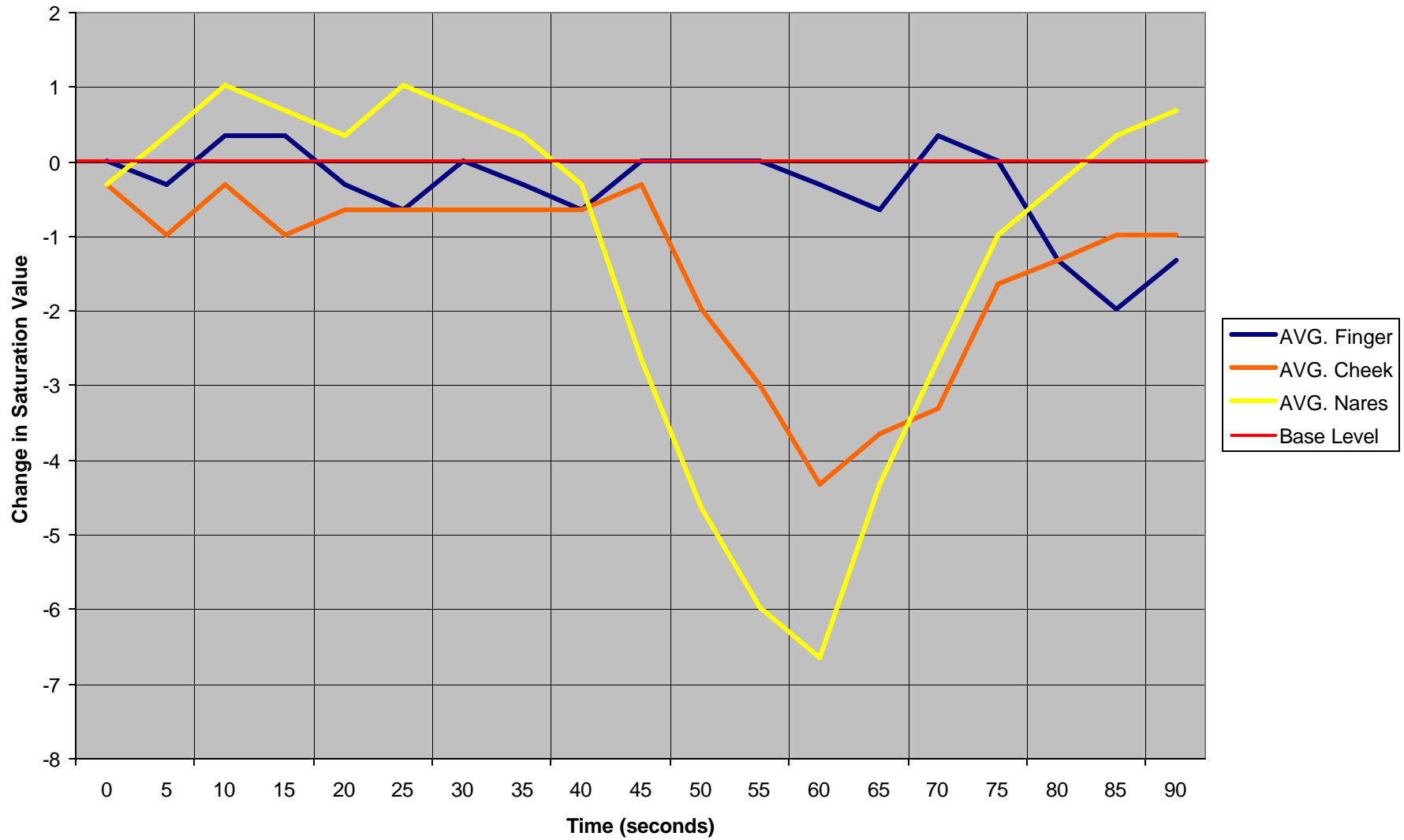
As a tool for improving response time for patients SpO₂ levels both Beta Bio Med Services Inc. units appear to have a successful future. Not only did they indicate the change in SpO₂ at a much earlier time, the change they indicated was dramatic enough to elicit an alarm for most monitoring situations. This means that the physicians and RN's will have more time to help improve the patient's well-being and prevent further damage. Further study has indicated that the response time for the standard finger probe may take 90-120 seconds to first elicit a response. If hypoxia had continued during this time period the patient could have already been placed into a critical condition due to poor oxygen levels before any pulse oximeter response indication.

The additional time period it takes to display a difference in SpO₂ for the finger probes can vary from patient to patient and condition to condition. This variance can be used to help show specific peripheral perfusion during that time period. If the time difference is shorter and the percent change is closer to the percent change of nasal/lip/cheek probes that it can be shown that that patient's peripheral perfusion is high. Likewise, if the time difference is extended and the percent change in SpO₂ is much smaller than the percent change in the lip/cheek/nasal probe this could be an indication that the peripheral perfusion is poor and some adjustments should be made in order to improve the patient's well-being.

Response Time



Deviation from Initial Saturation as Hypoxic Conditions Increase

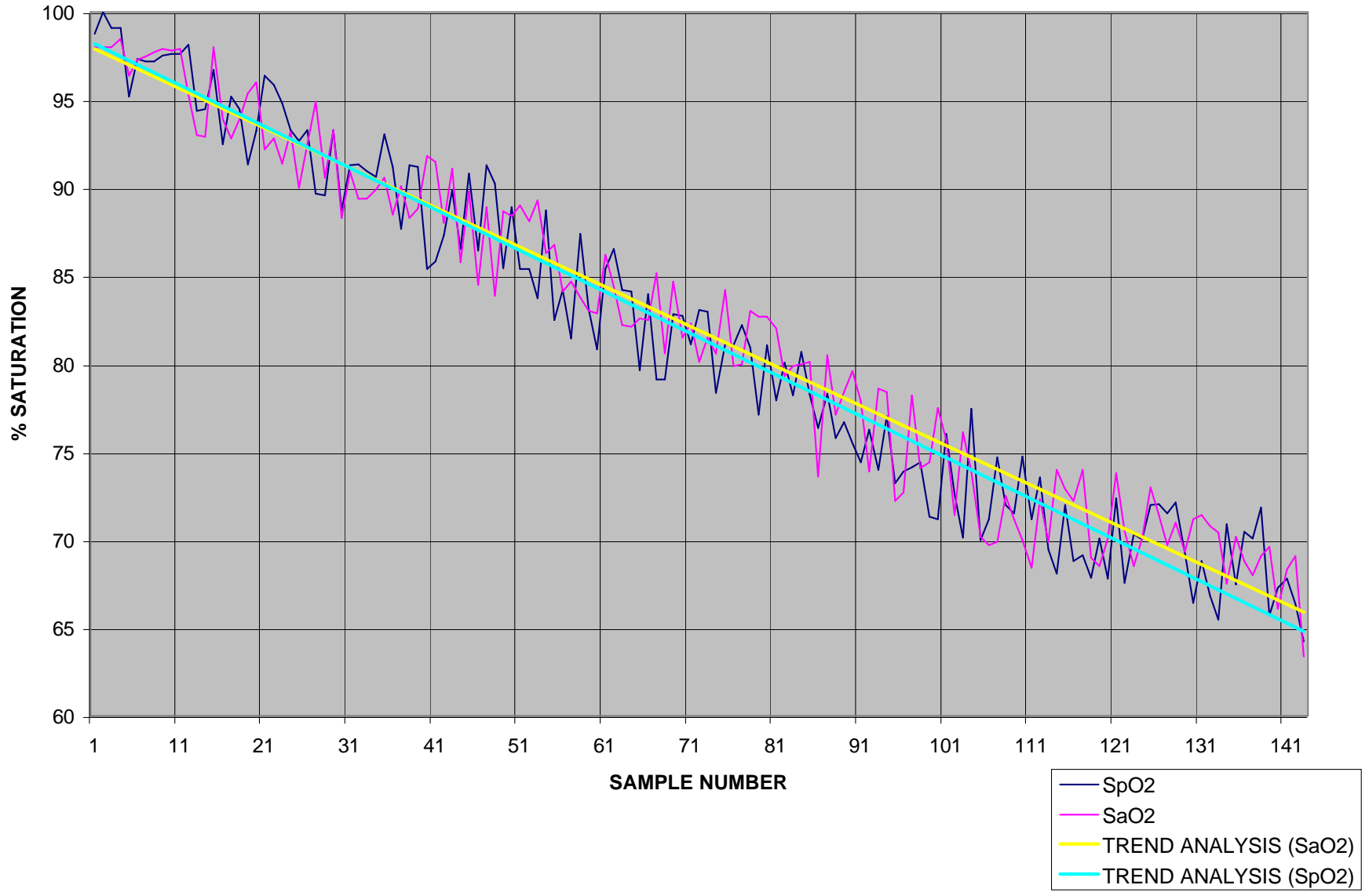


75.79	78.60	10.1	1.2	1.2	7.46/38/43	34.28	41.78	80.84	43
75.50	78.40	11.0	1.1	1.0	7.47/34/40	32.73	40.65	80.25	40
74.75	72.20	11.6	1.2	1.4	7.47/33/34	30.98	35.09	73.81	34
74.68	72.70	12.8	1.4	0.9	7.47/32/35	31.56	39.21	79.00	35
74.40	78.20	11.2	1.0	1.2	7.48/32/39	31.03	40.35	80.59	39
74.40	74.10	11.7	1.1	1.5	7.50/30/36	28.86	34.74	74.48	36
74.14	74.40	13.1	1.2	0.9	7.50/29/35	29.49	34.48	73.68	35
73.99	77.50	11.9	1.4	1.3	7.50/32/37	29.20	35.40	74.96	37
73.91	75.70	13.8	0.6	0.8	7.44/38/41	36.71	41.88	79.23	41
73.56	71.40	13.1	6.4	0.9	--	30.24	36.64	76.45	--
73.20	76.10	13.0	1.2	1.0	7.46/38/37	35.64	37.18	75.40	37
72.61	73.90	10.2	1.5	1.0	7.47/36/39	34.80	37.00	73.81	39
72.36	70.20	11.3	1.3	0.8	7.49/32/33	32.37	34.90	74.65	33
72.13	69.70	12.9	1.5	1.0	7.49/30/33	29.48	34.74	74.16	33
72.03	69.90	13.0	1.4	1.0	7.48/31/33	30.51	36.84	76.56	33
72.00	72.50	13.4	1.1	1.0	7.53/31/32	30.99	31.80	70.29	32
72.00	71.20	11.9	1.3	1.2	7.47/34/34	31.98	34.74	72.74	34
72.00	70.00	12.9	1.5	0.9	7.46/33/34	32.41	36.96	75.75	34
71.84	68.40	13.5	1.3	1.0	7.46/35/37	34.74	35.99	72.26	37
71.52	72.30	10.0	1.3	1.0	7.47/36/38	33.75	36.93	73.36	38
71.50	69.90	13.9	1.0	1.0	7.52/30/33	30.87	33.22	72.79	33
71.30	74.00	14.4	1.2	1.0	7.47/34/35	33.07	36.65	75.92	35
71.20	72.90	10.1	1.3	1.1	7.46/37/40	34.59	38.01	75.25	40
71.20	72.20	12.8	1.4	1.2	7.47/37/35	34.29	37.39	76.38	35
71.17	74.00	13.4	1.3	0.9	7.49/29/35	29.81	36.30	77.06	35
70.87	69.00	11.8	1.2	1.3	7.48/32/32	30.73	32.71	70.06	32
70.46	68.50	12.8	1.1	1.1	7.58/26/29	26.52	30.76	71.28	29
70.32	70.10	14.3	1.2	1.0	7.45/36/34	33.27	34.23	71.22	34
70.12	73.80	13.6	1.1	0.9	7.51/33/33	32.26	33.78	72.84	33
70.10	70.50	14.0	1.4	1.2	7.50/33/32	32.53	35.02	73.81	32
70.08	68.50	12.9	1.2	0.9	7.46/38/32	35.92	33.84	70.08	32
70.02	70.10	11.7	1.2	1.3	7.48/34/33	31.82	34.46	72.36	33
70.00	73.00	14.0	1.3	1.0	7.44/37/37	34.52	36.66	75.20	37
69.48	71.40	14.2	1.3	0.7	7.43/38/37	28.73	43.26	84.37	37
69.27	69.70	12.9	1.4	1.3	7.48/35/33	33.31	35.15	73.58	33
69.15	71.00	11.1	1.2	0.9	7.51/30/35	29.40	33.76	72.64	35
68.82	69.30	13.1	1.2	1.0	7.50/29/33	28.94	31.66	69.24	33
68.81	71.20	14.0	1.3	1.2	7.51/31/32	31.24	34.62	73.88	32
68.10	71.40	10.2	1.3	1.0	7.47/36/37	33.26	57.88	75.76	37
67.87	70.80	11.0	1.2	1.0	7.50/30/33	30.16	33.80	72.22	33
67.78	70.40	14.5	0.9	0.9	7.50/31/32	29.81	33.35	72.68	32
67.78	67.50	13.0	1.4	0.9	7.48/30/31	30.14	34.98	74.10	31
67.54	70.20	10.2	1.1	1.2	7.48/36/36	34.84	37.32	75.05	35
67.46	68.80	12.8	1.3	0.9	7.48/36/32	32.49	34.85	73.52	32
67.30	68.00	14.2	1.2	1.0	7.44/37/33	32.44	36.10	74.46	33
66.84	69.10	11.2	1.3	0.9	7.50/31/32	30.44	33.58	71.60	32
66.40	69.60	13.8	1.2	1.2	7.50/34/31	33.32	35.72	74.44	31
66.35	66.10	14.1	1.3	1.2	7.50/33/30	32.77	33.61	71.34	30
65.71	68.30	14.1	0.9	0.9	7.52/28/30	25.96	32.48	73.62	30
65.46	69.10	14.1	1.2	0.9	7.44/37/35	32.24	35.60	73.89	35
64.24	63.40	10.3	1.2	1.1	7.51/33/32	26.31	32.9	72.22	32

RMS ERROR (within 1 SD of all data points) = 2.04

FDA Standard of Error = 3.00

CHEEK SpO₂/SaO₂ COMPARISON



VARIANCE OF SpO2 FROM SaO2 VALUES AS HYPOXIC CONDITIONS INCREASE AS MEASURED BY CHEEK SENSOR (B1700-1011, sn PDT008)

