Final Test Report For Oxitone Medical, Ltd
Results of the SpO2 Accuracy Validation of Oxitone 1000 Pulse Oximeter via Reference CO-Oximetry
Study ID# PR 2016-192

Protocol Title:
"Accuracy Validation of the Oxitone SpO2 System"

Protocol No.:
PR 2016-192

Investigational Device:
Oxitone 1000 Pulse Oximeter

Commercial Sponsor:
Oxitone Medical, Ltd. Kfar Saba, Israel

Document Ownership:

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This study was conducted in accordance to CFR for Non-Significant Risk Medical Device Study

Origination Date: August 18, 2016 **Revised Date:** August 18, 2016

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Summary

Clinical Investigation Plan: "Accuracy Validation of the Oxitone SpO2 System"
Clinimark Study ID# PR 2016-192

Study Dates: August 9 – 11, 2016.

Introduction:
An SpO2 accuracy comparison was conducted as part of the final Pulse Oximetry validation for the Oxitone 1000 Pulse Oximeter. The study was conducted in accordance to Code of Federal Regulations (CFR) for Non-Significant Risk (NSR) investigational studies, following ISO 14155:2011 as appropriate and the pulse oximetry guidelines of ISO 80601-2-61:2011 applicable sections, and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance For Industry and Food and Drug Administration Staff (issued: March 4, 2013)

Purpose:
The purpose of this study was to evaluate the SpO_2 accuracy performance of Oxitone 1000 Pulse Oximeter placed on the left wrist during non-motion conditions over the range of 70-100% SaO2, arterial blood samples, assessed by CO-Oximetry. It was expected that the Accuracy Root Mean Square (A_{RMS}) performance of the oximetry system would meet the required specification of A_{RMS} of 3% or less in non-motion conditions for the range of 70 – 100% SaO2.

Subjects:
Following Institutional Review Board (IRB) approval Title: "Accuracy Validation of the Oxitone SpO2 System" (Rev 1, 26 Jul 2016), Clinimark Study ID# PR 2016-192, twelve healthy adult volunteer subjects were enrolled into the study. Once the study was started, two subjects were withdrawn. One subject was withdrawn following the initial blood draw collection due to total hemoglobin levels measuring less than 10g/dl. The 2nd subject was withdrawn at the end of the study due to the inability to synchronize the Oxitone data collection with the Clinimark control system clock. The demographics of subjects included the study included four males and six females (age: 20-46yrs, weight: 100-220lbs, height: 60-74", BMI: 19.5-32.4). For race and ethnicity, the subject pool included one Black / African-Americans, three Asians, and six White with One subjects of Hispanic ethnicity and nine of Non-Hispanic / Non-Latino ethnicity. The skin pigmentation / tones ranged from light to dark meeting the requirement of at least 2 darkly pigmented or 15 % of the subject pool whichever is larger. All subjects completed the study without incidence. There were no significant adverse events, device effects or other, observed during the study.

Methods:
Testing was conducted under normal office environment conditions. The Oxitone 1000 Pulse Oximeter was placed on the left wrist of the subject to evaluate the SpO2 accuracy performance during steady state non-motion conditions. A Clinimark Control Pulse Oximetry system was also placed on the subject to evaluate the stability of the draws. The subject was in a reclined position and connected to a breathing circuit, for administering medical grade oxygen and nitrogen. The gas flow delivery was adjusted for subject comfort. The gas mixture was controlled to various levels of induced hypoxia resulting in stable oxygen saturation plateaus

between 100% and 67% SaO_2. Arterial blood samples were drawn during simultaneous data collection from the control pulse oximeter and the test device. The blood was immediately analyzed by Reference CO-Oximetry providing functional SaO_2 for the basis of the SpO_2 accuracy comparison.

Results:
The SpO_2 accuracy performance results showed the following A_{RMS} values for a range of 70-100%.

Table 1: Summary of SpO_2 Accuracy Results

Comparison to Reference CO-Oximetry (functional SaO_2)	**A_{RMS} SpO_2 70-100%**	**A_{RMS} Spec 3% for a range of 70-100%**
Oxitone 1000 Pulse Oximeter	1.9 (240 pts)	Pass

Note: The range of 70% to 100% includes reference data down to 67%.

Conclusions:
The results of the study provide supporting evidence that the SpO_2 accuracy performance of Oxitone 1000 Pulse Oximeter placed on the left wrist pass an A_{RMS} specification of 3% under steady state / non-motion conditions for the range 70-100%. Additionally, the SpO2 performance meets an A_{RMS} specification of 2 or 2.5 and could be labeled as such.

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1. Introduction

Pulse oximetry monitoring is considered a standard physiological measurement and is used by clinicians in everyday situations to estimate arterial oxygen saturation. A pulse oximeter is a device that measures the oxygen saturation of arterial blood non-invasively. In general, pulse oximeters use two wavelength absorption spectrophotometry to measure oxygen saturation based on the amount of reflected or scattered radiation. The wavelengths are selected to provide the best separation of absorbencies of oxy-hemoglobin (O2Hb) and deoxy-hemoglobin (HHb) states. The ratio of the two absorbencies is used to calculate the oxygen saturation (SpO_2) value. Because an arterial sample of blood is not required to make the measurement, the pulse oximeter can provide non-invasive real time information. The clinical use of pulse oximeters has reduced the frequency and necessity of invasive arterial blood sampling, and has helped to improve patient safety by providing information to clinicians about patients' oxygenation status.

The purpose of this study was to evaluate the SpO_2 accuracy performance of Oxitone 1000 Pulse Oximeter placed on the left wrist during non-motion conditions over the range of 70-100% SaO2 to arterial blood samples assessed by CO-Oximetry for SpO_2 validation.

The goal, in its entirety, was to show the SpO_2 accuracy performance for the investigational device below.

It was expected that the Accuracy Root Mean Square (A_{RMS}) performance would meet the required specification of A_{RMS} 3% in non-motion conditions for the range of 70 – 100% SaO2 thereby demonstrating an acceptable SpO2 accuracy performance specification.

No risks or adverse device effects were expected. There were no contraindications for use in the proposed study / study population.

The study was conducted in accordance to the code of federal regulations for non-significant medical device studies and applicable ISO 14155 (2nd edition 2011-02-01), applicable sections of ISO80601-2-61 (1st edition 2011-04-01), and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance For Industry and Food and Drug Administration Staff (issued: March 4, 2013).

2. Investigational Device And Methods

2.1 Device Description:

The Oxitone 1000 by Oxitone Medical, Ltd. is a wrist-worn pulse oximeter.

Watch: Oxitone 1000, version: 1.0.2, s/n 1624017

Android Phone: HTC desire 510

Android Application: Version 2.0.63 build #72

The dedicated application was used in order to collect the clinical data recorded by the Oxitone 1000 device during the clinical trial. It consists of a smartphone application on an android based smartphone that was supplied to the investigational team by the sponsor, before the trial. It passively collects the Oxitone 1000 SpO2 and the Pulse Rate values, throughout the trial.
The data digitally collected served as a database for off-line statistical analyses.

The investigational device is intended to be used in spot checking monitoring of functional oxygen saturation levels on the intended population for humans. There were no modifications to the test devices during the study data collection.

2.2 Gas Delivery & Monitoring System with data collection

Desaturation Study Gas Delivery System
The Clinimark proprietary Desaturation Fixture with Automated Data Collection is a single limb blow by system used to deliver medical grade oxygen and nitrogen gas mixtures to induce various hypoxic levels in subjects at a slow steady rate allowing an automatic marking and collection of the Control or secondary Transfer reference Pulse Oximeter and other pulse oximetry systems at 1 second intervals.
Description of Clinimark Desaturation Fixture with Automated Data Collection:

- Computer with desaturation gas control software and automated data collection system
- Sealink Mux box – 8 channel, communication cables
- Gas control fixture
- Medical grade oxygen and nitrogen cylinders

Control Oximetry System
The Control Pulse Oximeter, an FDA cleared device, is used to monitor the oxygen saturation levels real time throughout the study for subject safety and to target stable plateaus. This device is used to assess the stability of the data.

- GE Healthcare (Datex-Ohmeda) 3900 TruTrak+ / OxyTip+ Oxy-F-UN or Oxy-AF Sensor and Oxy-OL3 cable

Safety Equipment
Multi-parameter monitor used during the study to observe a subject's vital signs including ECG tracing, heart rate, respiratory rate, end-tidal CO_2 with capnograph, secondary monitor for the oxygen concentration being delivered to the subject. This device will also serve as the pulse rate reference.

- GE Healthcare S5 Compact Monitor, M-NESTPR module with ECG
- Portable oxygen tank, mask and ambu bag

2.3 Reference Equipment

Reference CO-Oximeters
A whole blood analyzer (CO-Oximeter) is used as the reference standard device for obtaining the functional SaO_2 value from arterial blood samples obtained during the study.

- Instrumentation Laboratories IL682 and associated supplies: ID# 80500734 (ILK), 70900664 (ILG)
- Radiometer ABL 80 Flex OSM and associated supplies ID#: 307205, 313093

2.4 Study Procedure / Clinical Investigative Plan (CIP) Summary:
This study was a comparative, single-center, non-randomized study conducted to evaluate the SpO_2 accuracy per standards and guidelines identified above for SpO2 accuracy for pulse oximetry equipment over the range of 70-100% SaO_2 under non-motion conditions. Arterial blood sampling measured by functional SaO_2 CO-Oximetry, was used as the basis for comparison. Testing was conducted under normal office environment conditions.

Subjects were provided with an IRB approved Informed Consent form. For subject enrollment, the subject needed to understand the study, provide consent to participate by signing the Informed Consent Form and satisfactorily completing a health assessment form, meet the inclusion criteria and none of the exclusion criteria prior to starting the test.

Inclusion Criteria

- Subject must have the ability to understand and provide written informed consent
- Subject is 18 to 50 years of age
- Subject must be willing and able to comply with study procedures and duration
- Subject is a non-smoker or who has not smoked within 2 days prior to the study.
- Male or female of any race
- Subject demographics include a range of skin pigmentations, including at least 2 darkly pigmented subjects or 15% of the subject pool, whichever is larger.

Exclusion Criteria

- Subject is considered as being morbidly obese (defined as BMI >39.5)
- Compromised circulation, injury, or physical malformation of fingers, toes, hands, ears or forehead/skull or other sensor sites which would limit the ability to test sites needed for the study. (Note: Certain malformations may still allow subjects to participate if the condition is noted and would not affect the particular sites utilized.)
- Females who are pregnant, who are trying to get pregnant, or have a urine test positive for pregnancy on the day of the study
- Subjects with COHb levels >3% as assessed with a Masimo Radical 7 (Rainbow)
- Subjects with known respiratory conditions such as: (self-reported), uncontrolled / severe asthma, flu, pneumonia / bronchitis, shortness of breath / respiratory distress, respiratory or lung surgery, emphysema, COPD, lung disease
- Subjects with known heart or cardiovascular conditions such as: (self-reported, except for blood pressure and ECG review): hypertension: systolic >140mmHg, Diastolic >90mmHg on 3 consecutive readings. have had cardiovascular surgery, Chest pain (angina), heart rhythms other than a normal sinus rhythm or with respiratory sinus arrhythmia, previous heart attack, blocked artery, unexplained shortness of breath, congestive heart failure (CHF), history of stroke, transient ischemic attack, carotid artery disease, myocardial ischemia, myocardial infarction, cardiomyopathy
- Self-reported health conditions as identified in the Health Assessment Form (self-reported) diabetes, thyroid disease, kidney disease / chronic renal impairment, history of seizures (except childhood febrile seizures), epilepsy, history of unexplained syncope, recent history of frequent migraine headaches, recent head injury, cancer / chemotherapy
- Subjects with known clotting disorders (self-reported) history of bleeding disorders or personal history of prolonged bleeding from injury, history of blood clots, hemophilia, current use of blood thinner: prescription or daily use of aspirin
- Subjects with severe contact allergies to standard adhesives, latex or other materials found in pulse oximetry sensors, ECG electrodes, respiration monitor electrodes or other medical sensors (self-reported)
- Unwillingness or inability to remove colored nail polish from test digits.
- Other known health condition, should be considered upon disclosure in health assessment form

Subjects were instructed that they could terminate the test at any time. The principal investigator, clinician or gas controller could terminate the test based on such request or judgment of the well-being of the subject.

Following completion of the initial screening, a vascular assessment was conducted prior to cannulation of the artery to verify the presence of adequate collateral blood flow to the hand. Precautions to minimize discomfort were taken by including a small injection of Lidocaine (a numbing medicine) under the skin at the insertion site. A radial arterial line was then placed. Radial arterial line placement involves introduction of a standard arterial catheter or angiocath into the radial artery. Since the arterial catheter is placed into the artery using a needle, mild to moderate discomfort was expected. Blood samples were drawn to a 3cc arterial blood sample syringe with dry lithium heparin. The total amount of blood drawn during the procedure was less than 150cc.

Subjects were reclined for the study. The Oxitone Pulse Oximeters were placed the left wrist of each subject to evaluate the SpO2 accuracy performance.

Subjects were given medical grade mixtures of oxygen and nitrogen to induce stable plateaus across the range of 100% to 67%. The goal was to have an equal distribution of data by decade. The stable plateaus allowed data collection in the following SaO2 ranges 95-100, 90-95, 85-90, 80-85, 75-80, 67-75. In general, 4 to 8 discrete points were collected at each of the levels such that the overall data of the population was evenly distributed by decade and the minimum number of points was met for the data analysis. Fewer data points were expected in subjects that were unable to tolerate the duration of the lower hypoxic levels. Data was collected under non-motion conditions. Arterial blood samples were drawn simultaneously to SpO_2 data collection and measured immediately on the gold standard Reference CO-Oximeters.

After the test, the clinician reviewed final questions that might have been raised by the subject and the subject was released. Calls were made to subjects post study as a follow up for any questions regarding the study and status of the site where the arterial line was placed. There were no significant adverse events reported.

The endpoint comparator for data collection was a minimum of 200 points evenly distributed across the full range of 70-100% SaO_2 on a minimum of ten subjects as well as to document the accuracy for the specified range of 70-100%. The Accuracy Root Mean Square (A_{RMS}) calculation was used for statistical analysis comparison for the test device vs Reference CO-Oximetry, functional SaO2.

Data analysis results provide documentation showing SpO_2 accuracy performance of the Oxitone 1000 pulse oximetry system as compared to arterial blood samples measured by Reference CO-Oximetry.

3. Results

Institutional Review Board (IRB) approval[1] was obtained for testing. The study was conducted August 9-11, 2016, in the Clinimark Laboratories located in Avista Adventist Hospital Plaza in Louisville, CO in accordance with the study procedure[2]. There were no deviations to the study procedure. Twelve subjects were enrolled into the study. Two subjects were withdrawn prior to the data analysis due to low tHb levels and inability to synchronize the data collection for the test device. Each subject was cannulated with an indwelling catheter in the right radial artery. The control oximeter[3] was attached to the hand on the cannulated side to evaluate the stability of the SpO_2 level during the data collection process. All devices were tested under non-motion conditions. The device under test was the Oxitone 1000 Pulse Oximeter, Watch with Android phone.

[1] IRB approval: Salus Independent Review Board, Board 2 #IRB00006834, Approval 01 Aug 2016
[2] Clinical Investigation Test Plan for: "Accuracy Validation of the Oxitone SpO2 System", (Rev 1, 26 Jul 2016), Clinimark Study ID# PR 2016-192
[3] Control Oximeter: Datex-Ohmeda 3900 TruTrak®+ Pulse Oximeter. TruTrak+ is a registered trademark of Datex-Ohmeda Inc., now GE Healthcare.

Each subject was presented with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 67% SaO_2. Arterial blood draws were collected under non-motion conditions. SpO_2 values from the pulse oximeters were collected electronically at one second intervals simultaneously to blood drawn from the indwelling catheter. Four to eight arterial blood samples were collected, approximately 20-40 seconds apart for each stable level. The blood was immediately analyzed by the Reference CO-Oximeter[4] to measure the arterial oxygen saturation (Functional SaO_2).

All subjects completed the study without incidence. The stable data from each system for all twelve subjects was included for analysis. There were no serious adverse events or adverse device effects during the study.

3.1 Subject Demographics

Table 2: Summary of Subject Demographics Record

Sex	Male	40%	(4/10)
	Female	60%	(6/10)
Race	Black / African-American	10%	(1/10)
	Asian	30%	(3/10)
	White	60%	(6/10)
Ethnicity	Hispanic or Latino	10%	(1/10)
	Not Hispanic or Latino	90%	(9/10)
Skin Tone	Light	0%	(0/10)
	Medium Light	60%	(6/10)
	Medium	20%	(2/10)
	Medium Dark	10%	(1/10)
	Dark	10%	(1/10)
Age	Mean +/-SD (N)	30.0 +/- 8.5	10
	Median	26.5	
	Range (min, max)	(20, 46)	
Weight	Mean +/-SD (N)	155.5 +/- 37.0	10
	Median	159	
	Range (min, max)	(100, 220)	
Height	Mean +/-SD (N)	67.2 +/- 4.3	10
	Median	65.5	
	Range (min, max)	(60, 74)	
BMI	Mean +/-SD (N)	24.0 +/- 4.4	10
	Median	22.8	
	Range (min, max)	(19.5, 32.4)	

[4] Reference CO-Oximeter: ABL80 Flex OSM, Radiometer and IL 682 CO-Oximeter, Instrumentation Laboratories

3.2 Equipment Record:

Table 3: Equipment Record

	Unit/Rev.	Unit S/N	Sensor	Site
Control	3900P TT+ 9.000/11.000	FBZ200195	Oxy-FUN ABS010804-12 Lot # 36303 Oxy-OL3 Cable 07104	Finger
Safety	Nellcor N-600X V 1.6.0.0	G08817962	NellcorMAX-Fast DOC-10 Cable	Forehead
Safety	Datex-Ohmeda S5	Monitor 5014850 MNESTPR 3645308 M-CAiO 3611324	3 lead ECG 891402-1.0 1997-01-09 RR / FiO2 EtCO2	Chest
Oxitone 1	Oxitone 1000 Pulse Oximeter	Watch 1624017	Android Phone 02	Left Wrist

4. Data Analysis

Excel was used as the data analysis tool. Data analysis follows ISO80601-2-61:2011, Annex EE and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance For Industry and Food and Drug Administration Staff (issued: March 4, 2013). The reference guidance documents clearly define the study, number of subjects, data points needed for the analysis and handling of missing data or data that is removed from the analysis. Complying with the standards was achieved through more than 200 paired observations of Test and Reference values equally distributed over the specified SpO_2 accuracy range (70-100%) of the device under test. The data was collected on healthy adult volunteer subjects who range in age, gender and skin tone with at least two subjects having deep skin pigmentation tones. Controls for the study were maintained by using a control oximeter to assess the stability of the plateaus for data collection and a Reference Standard Pulse Oximetry value for oxygen saturation level of the subject during the study. An Accuracy Root Mean Square (A_{RMS}) calculation was used to determine SpO_2 Accuracy as compared to "gold standard" measurements of blood SaO_2 by Reference CO-Oximetry.

4.1 Control Oximeter Stability handling:

The data was analyzed in the following manner. The Control Oximeter SpO_2 data was reviewed for Stability. The data points are considered unstable and removed prior to the analysis:

- if the Control Oximeter SpO_2 value varies by >2% during the draw
- if the combined minimum and maximum deviations of the Control Oximeter SpO_2 value are > 3% during the review period of 20-30 sec prior to draw period as defined by ISO 80601-2-61:2011.

4.2 Test SpO2 Data handling:

Since the SpO_2 data from the test device does not record values >99.5%, data recorded over this level was removed prior to the analysis for this criteria.

4.3 CO-Oximeter Data handling:

The third step in the process was to review the CO-Oximetry data for outliers or anomalous readings prior to pairing of the CO-Oximeter value with the test device SpO_2 value.

The CO-Oximeter data was reviewed for outliers or anomalous readings from which these plateaus were subject to removal. The functional oxygen saturation value was used for the basis of comparison to SpO_2

value collected from the pulse oximeter. Subjects with elevated COHB (>3%), MetHb (>2%) and/or tHb (<10g/dl) levels were excluded from the data collection. The tHb, COHb, MetHb values were reviewed for consistency to the other draws for each subject. If those values were found to not be similar in readings for a given subject, then it is determined that the reference value was unstable and the point was to be removed from the analysis.

Draws with CO-Oximeter data that were<67%were excluded from the analysis for the evaluation of the accuracy specification claim. Overall stable data 70-100% SaO_2 is presented in the statistics for each graph. Summary statistics includes data for claims only.

A rationale was provided for data that was excluded from the data analysis due to the Control Oximeter Stability, the Test Device and the Reference CO-Oximetry values. Please refer to the attached Line Listing for the rational of excluded data.

4.4 Description of Statistics

The final step was to pair the remaining CO-Oximeter functional SO_2 value with the Test device SpO_2.
Ref = Reference CO-Oximetry SO_2
DUT = Device Under test SpO_2,

- Oxitone 1000 pulse oximeter

The data was plotted and analyzed through the following statistics, using the Reference CO-Oximetry SO_2 value for the x value and the Device Under Test SpO_2 value for the y value.

SpO_2 accuracy was evaluated for root-mean-square (rms) difference between the DUT and the reference for the overall range and by decade.

$$Arms = \sqrt{\frac{\sum_{i=1}^{n}(DUT_i - \mathrm{Re}\, f_i)^2}{n}}$$

The average difference was calculated to show the bias of the device under test as compared to the reference. The bias is calculated for the overall range and by decade.

$$Bias = \frac{\sum_{i=1}^{n}(DUT_i - \mathrm{Re}\, f_i)}{n}$$

A least squares line was generated for the overall range.
The minimum and maximum deviations of the test device were calculated from the reference.

Bland-Altman graphical plots, error (SpO_2 – SaO_2) versus average SaO_2 +SpO2 were generated with linear regression fit, mean, and upper 95% and lower 95% limits of agreement according to Section 3 of “Agreement Between Methods Of Measurement With Multiple Observations Per Individual“ by Bland and Altman in 2007 Journal of Biopharmaceutical Statistics. Individual test subjects were color coded in the Bland-Altman graphical plot.

Error plots were generated showing the difference of SpO_2 – SaO_2 versus the Reference SaO_2.

Pass / Fail Criteria:

The statistical results of the data were reviewed for the following pass/fail criteria.

Over 70 – 100% an A_{RMS} 3% in non-motion conditions – Pass result

4.5 SpO2 Accuracy Results:

Table 4: Comparison to Reference CO-Oximetry

Comparison to Reference CO-Oximetry					
Oxitone 1000 Pulse Oximeter	70—100	90--100	80--<90	67--<80	A_{RMS} Spec 3% for range of 70-100%
# pts	240	79	81	80	**Pass**
Bias	-0.6	-1.1	-0.9	0.1	
A_{RMS}	1.9	1.7	2.0	2.1	

Note: The range of 70% to 100% includes reference data down to 67%.

5. Graphs – List of Graphs

5.1 Oxitone 1000 Pulse Oximeter vs Reference CO-Oximetry

5.2 Bland-Altman Plot: Oxitone 1000 Pulse Oximeter

5.3 Error Plot: Oxitone 1000 Pulse Oximeter

Individual Subject Error Plots includes discussion of Individual Errors >3%
Data points where abs(error) was > 3% were reviewed for subject demographics, perfusion levels, proximity to unstable control points.

5.4 Individual Subject 1 Error Plots

5.5 Individual Subject 2 Error Plots

5.6 Individual Subject 3 Error Plots

5.7 Individual Subject 4 Error Plots

5.8 Individual Subject 5 Error Plots

5.9 Individual Subject 6 Error Plots

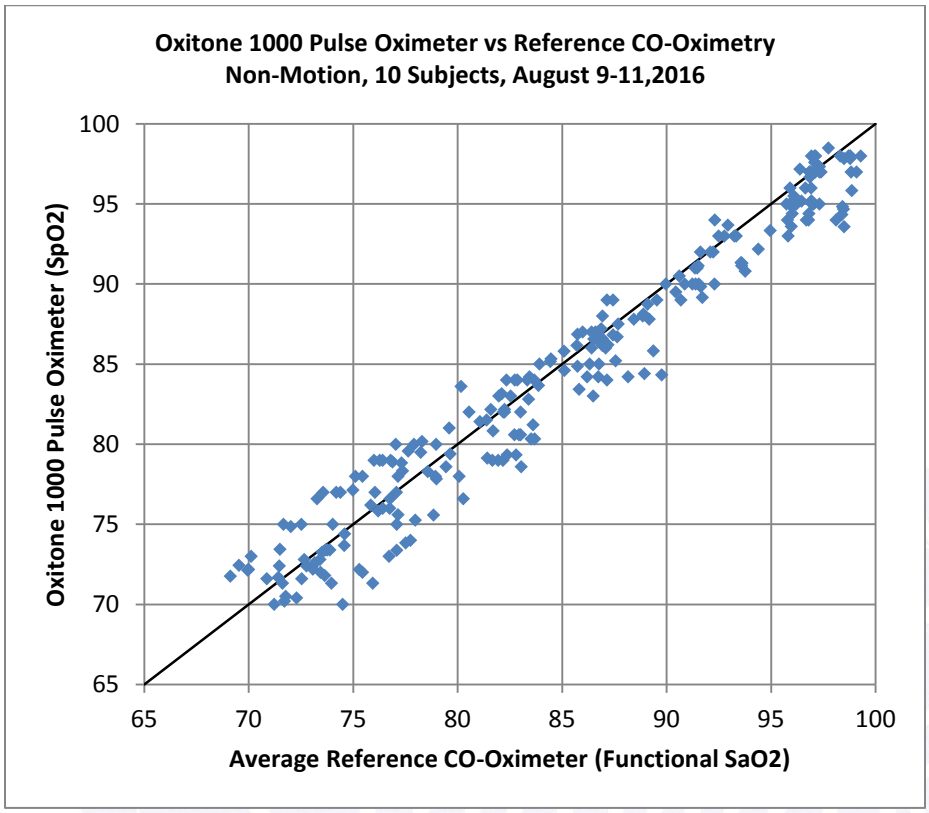
5.10 Individual Subject 7 Error Plots

5.11 Individual Subject 8 Error Plots

5.12 Individual Subject 10 Error Plots

5.13 Individual Subject 12 Error Plots

5.1 Oxitone 1000 Pulse Oximeter vs Reference CO-Oximetry



Oxitone vs. Ref CO-Ox

	69--100	70--100	90--100	80--<90	70--<80	60--<70
# pts	240	237	79	81	77	3
Bias	-0.6	-0.6	-1.1	-0.9	0.0	2.6
ARMS	1.9	1.9	1.7	2.0	2.1	2.6
SDadc	1.8					

Max diff = 3.4 Min diff = -5.4

Linear Regression Y = 0.934 x + 5.016

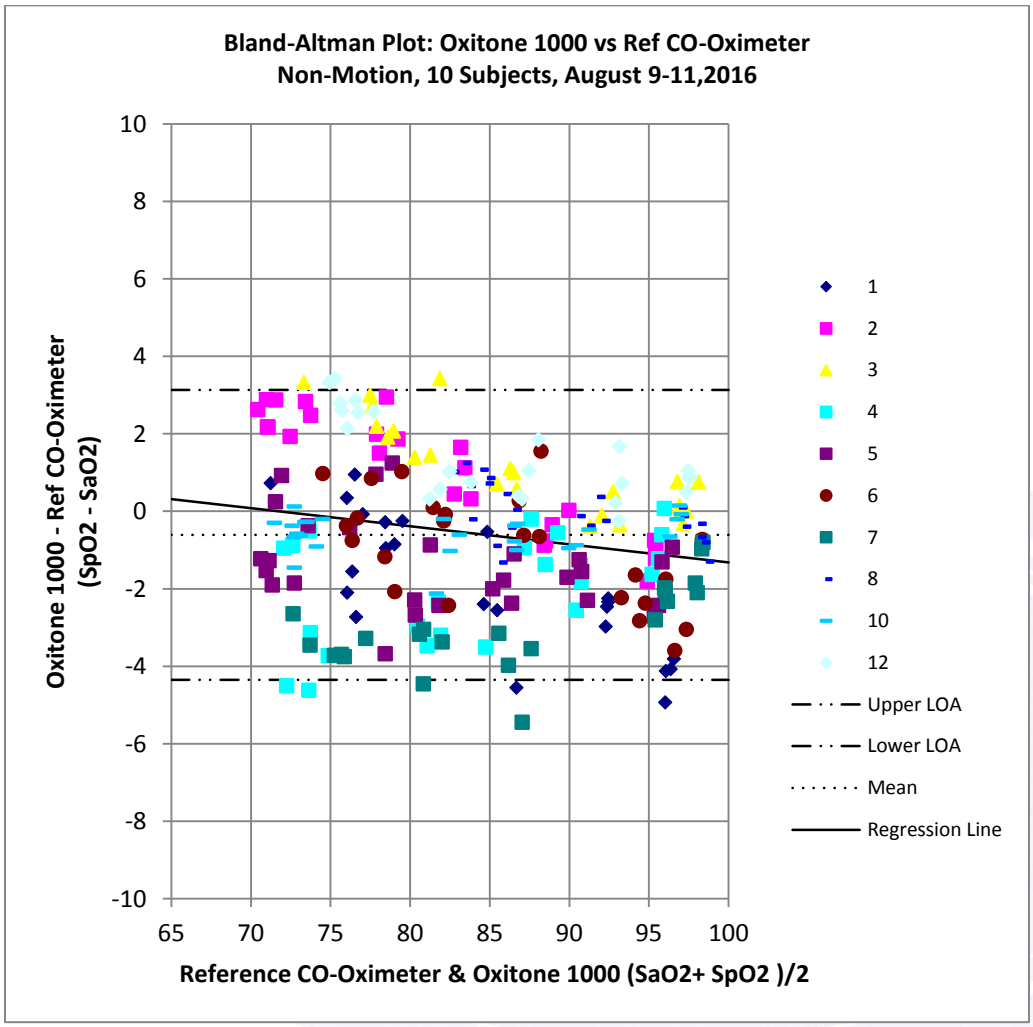
SEE = 1.8 CC = 0.98

Discussion by subject for noticeable outliers with offsets >5%:

There was 1 noticeable outlier in this data set that yielded an offset value with an absolute value > 5% offset from the Reference CO-Oximeter.
This was seen in subject #7 in the upper 80% SaO2 range. The test system generally tracked with a slightly lower bias for this subject but in a clinically safe manner with 1 obvious outlying point.

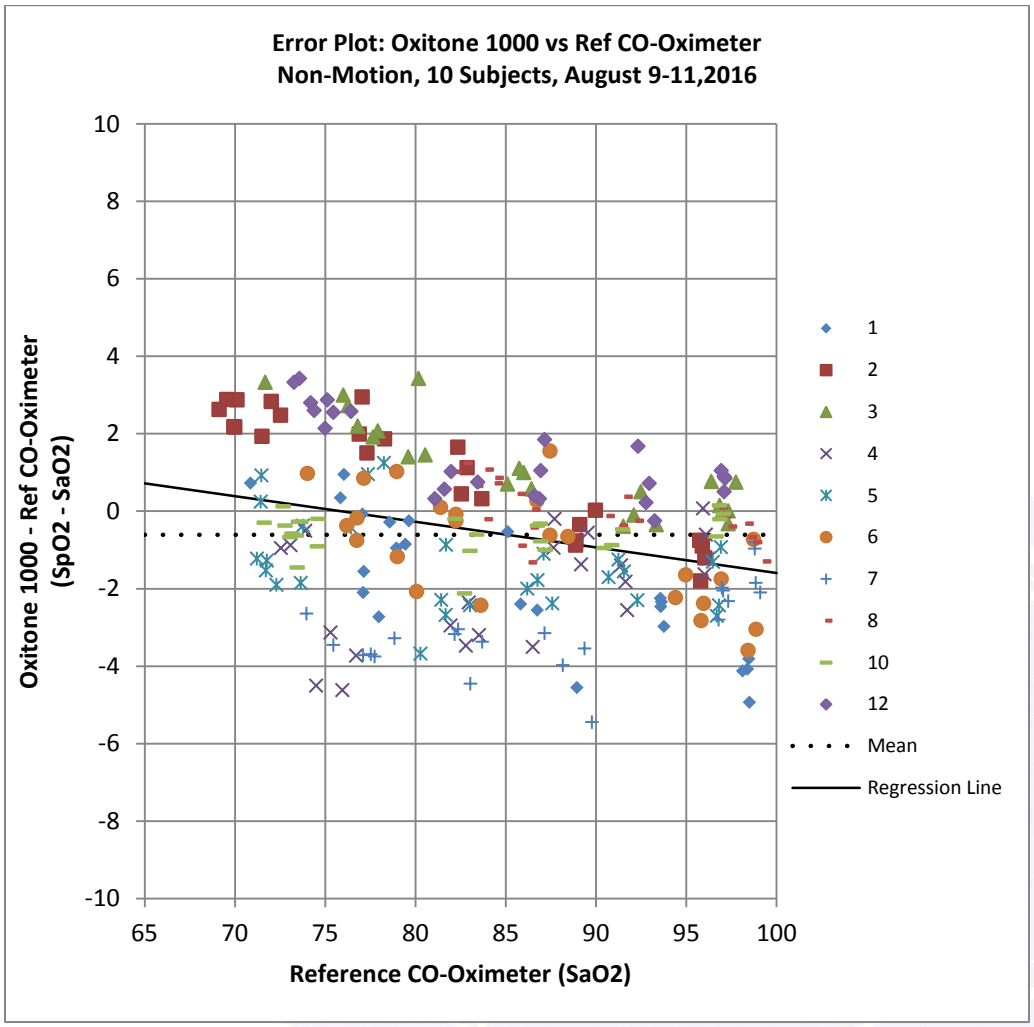
Subject	Ref.	Test
7	89.775	84.33

5.2 Bland-Altman Plot: Oxitone 1000 Pulse Oximeter



Reference: Bland-Altman Range	70-100%
Linear Regression (Bland Altman)	y = 3.3482 + -0.04667 x
Mean Bias	-0.61
# pts	240
Bland-Altman Results for Multiple Observations Per Individual	
Between-Subject Variance (σ_μ^2)	2.13
Within-Subject Variance (σ^2)	1.52
Upper 95% Limits of Agreement	3.13
Lower 95% Limits of Agreement	-4.35

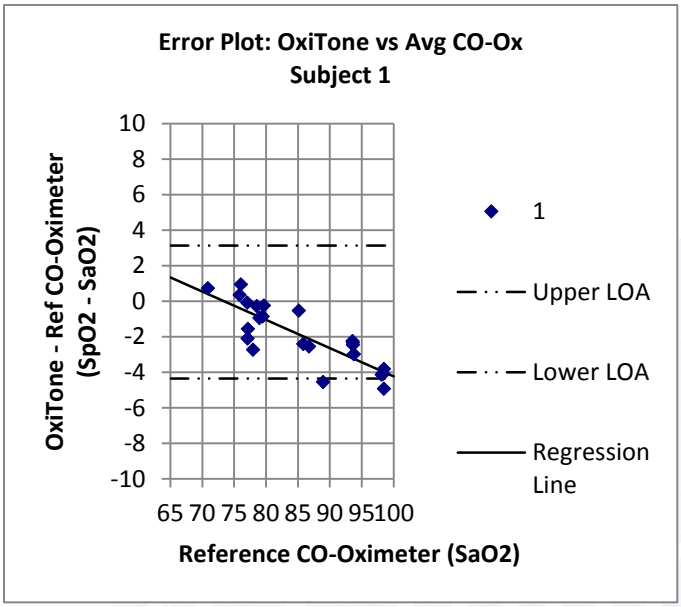
5.3 Error Plot: Oxitone 1000 Pulse Oximeter



Reference: Reference CO-Oximetry	70-100%
Linear Regression (Error Plot)	y = 5.0157 + -0.06610 x
Mean Bias (μ_o)	-0.61
# pts	240

5.4 Individual Subject 1 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
1	F	24	100	60	19.5	Medium	Asian	Non-Hispanic

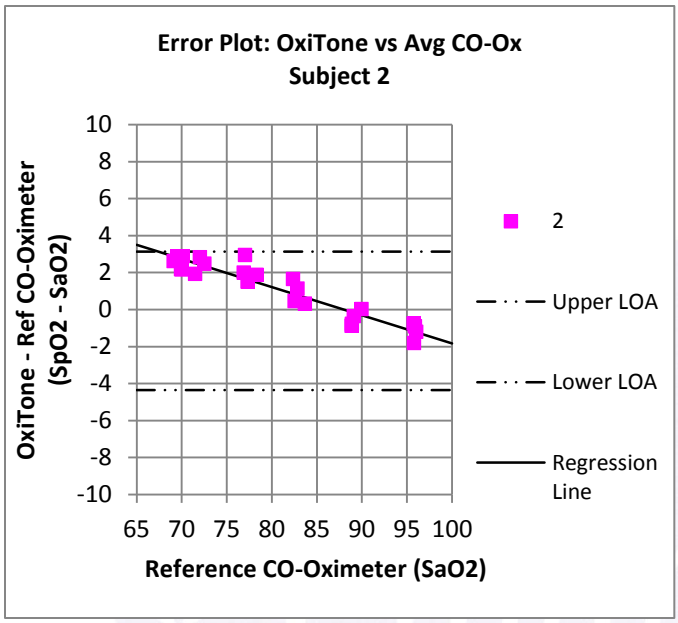


Mean Bias	1.9
# pts	23
Linear Regression	y = 11.6905 + -0.15921 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	5 pts
98.4	-4.1
98.5	-4.9
98.1	-4.1
98.5	-3.8
89.0	-4.5

Abs(error) was > 3% 5 pts (23 pts total)
There were 5 pts with an Abs(error) >3% in the upper oxygen saturation range. This subject has a negative slope in the data recorded. The magnitude of error was within expected deviations for oximetry and is clinically safe.

5.5 Individual Subject 2 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
2	M	29	155	66	25.0	Med Light	White	Non-Hispanic

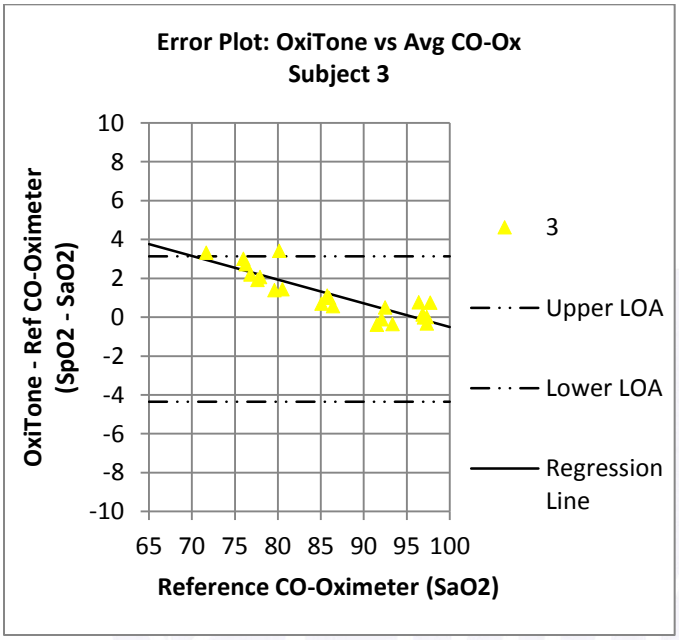


Mean Bias	1.1
# pts	24
Linear Regression	y = 13.3988 + -0.15228 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	0 pts

There were no points with an Abs(error) > 3% 0 pts (24 pts total)

5.6 Individual Subject 3 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
3	F	20	150	65	25.0	Med Dark	Asian	Non-Hispanic

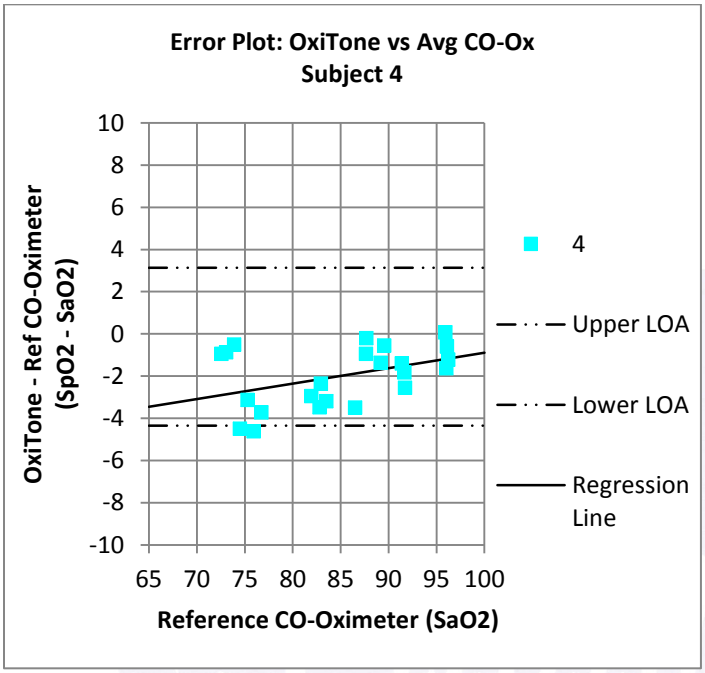


Mean Bias	1.1
# pts	23
Linear Regression	y = 11.6847 + -0.12190 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	2 pts
80.2	3.4
71.7	3.3

Abs(error) was > 3% 2 pts (23pts total)
There were 2 points with an absolute value >3 in the lower SaO2 range. The magnitude of error was within expected deviations for oximetry and is clinically safe.

5.7 Individual Subject 4 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
4	M	34	170	74	21.8	Med Light	White	Non-Hispanic

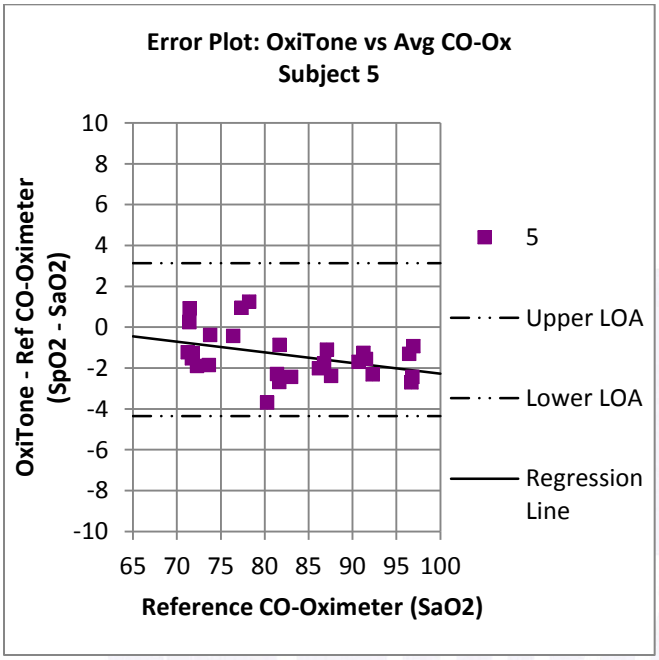


Mean Bias	-2.0
# pts	23
Linear Regression	y = -8.2138 + 0.07319 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	7 pts
83.5	-3.2
82.8	-3.5
76.7	-3.7
76.0	-4.6
75.3	-3.1
74.5	-4.5
86.5	-3.5

Abs(error) was > 3% 7 pts (23pts total)
There were 7 points with an absolute value >3 in the lower SaO2 range. With an overall bias of -2 for this subject, the magnitude of error was within expected deviations for oximetry and is clinically safe.

5.8 Individual Subject 5 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
5	M	40	168	71	23.4	Med Light	White	Non-Hispanic

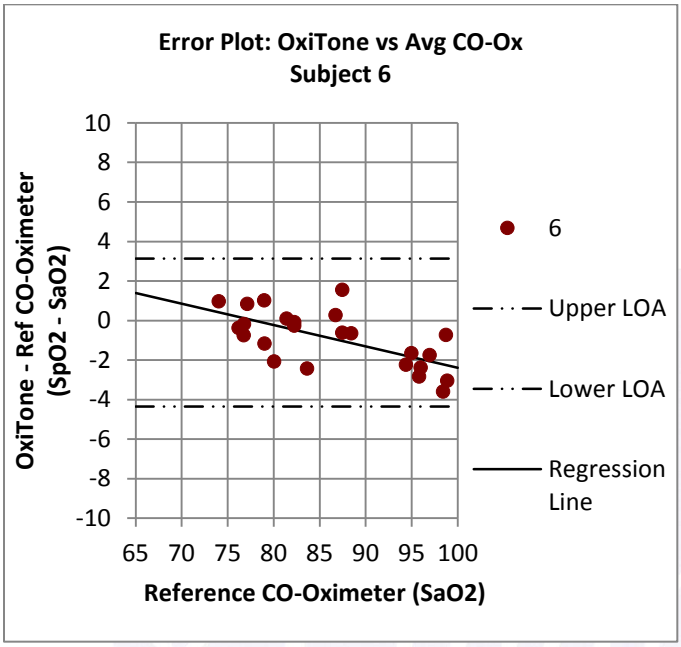


Mean Bias	-1.4
# pts	28
Linear Regression	y = 2.9458 + -0.05221 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	1 pt
80.3	-3.7

There was 1 incidental point with the abs value >3% at 80% SaO2. The magnitude of error was within expected deviations for oximetry and is clinically safe.

5.9 Individual Subject 6 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
6	F	36	195	65	32.4	Med Light	White	Non-Hispanic

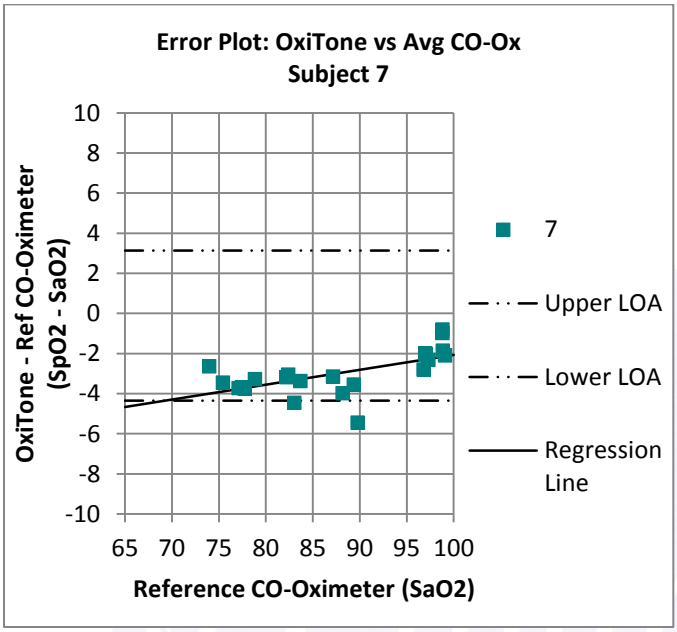


Mean Bias	-0.9
# pts	24
Linear Regression	y = 8.4145 + -0.10804 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	2 pt
98.4	-3.6
98.9	-3.0

There were 2 points with an absolute value >3 at 98% SaO2. This is expected with a negative mean bias of -0.9 and typical for oximetry and is safe.

5.10 Individual Subject 7 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
7	F	23	133	65	22.1	Med Light	Asian	Non-Hispanic



Mean Bias	-3.0
# pts	22
Linear Regression	y = -9.4910 + 0.07421 x

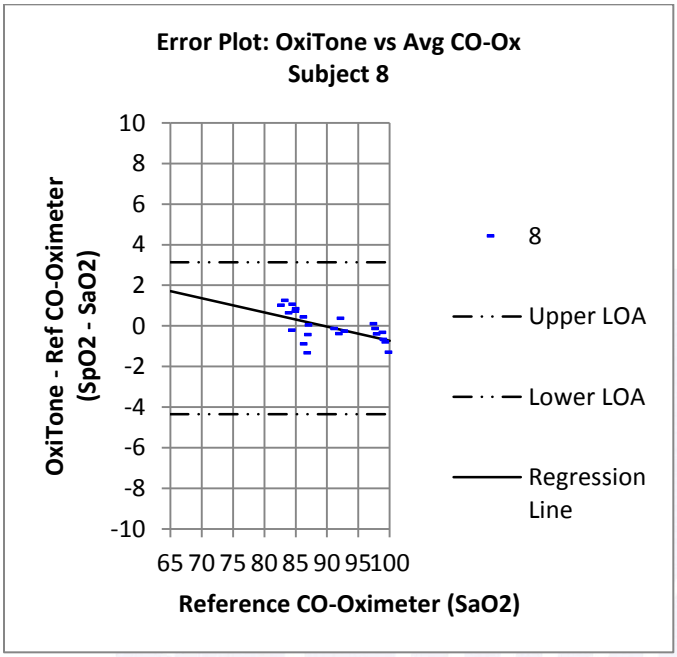
Data points with abs(error) > 3

Ref CO-Ox	Offset
	13 pt
89.4	-3.5
89.8	-5.4
88.2	-4.0
87.2	-3.2
83.7	-3.4
83.1	-4.5
82.4	-3.0
82.2	-3.2
78.9	-3.3
77.5	-3.7
77.8	-3.8
77.1	-3.7
75.5	-3.4

There were 13 points >3% with 1 outlier point >5%. Given the overall mean bias for this subject was -3.0 it is understandable that several readings were hovering around 3% low. The device tracked the oxygen saturation appropriately but read with a lower bias throughout.

5.11 Individual Subject 8 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
8	M	26	175	71	24.4	Med Light	White	Non-Hispanic

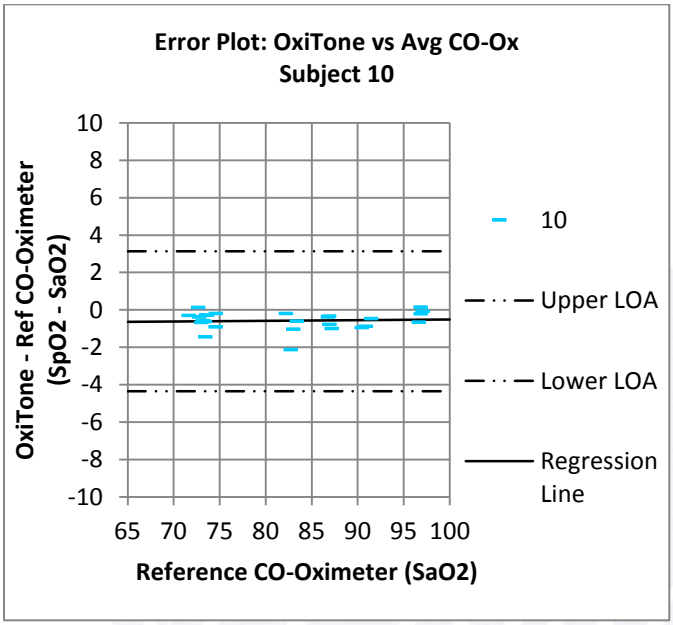


Mean Bias	-0.03
# pts	23
Linear Regression	y = 6.2557 + -0.06991 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	0 pt

There were no points with an Abs(error) > 3% 0 pts (23 pts total)

5.12 Individual Subject 10 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
10	F	24	120	64	20.6	Med Light	White	Non-Hispanic

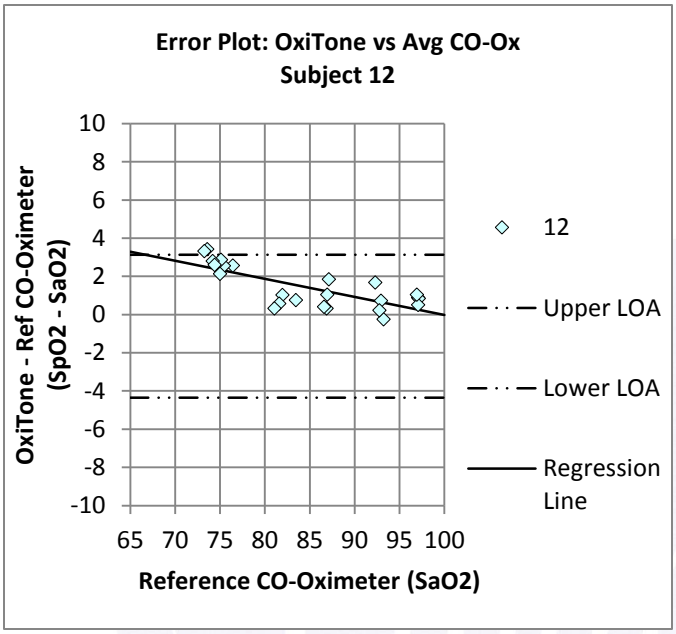


Mean Bias	-0.6
# pts	26
Linear Regression	y = -0.8756 + 0.00360 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	0 pt

There were no points with an Abs(error) > 3% 0 pts (26 pts total)

5.13 Individual Subject 12 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
12	F	27	124	66	20.0	Medium	White	Hispanic



Mean Bias	1.4
# pts	24
Linear Regression	y = 9.4388 + -0.09459 x
Data points with abs(error) > 3	
Ref CO-Ox	Offset
	2 pt
73.6	3.4
73.3	3.3

Abs(error) was > 3% 2 pts (24pts total)
There were 2 points with an absolute value >3 in the lower SaO2 range. The magnitude of error was within expected deviations for oximetry and is clinically safe.

6. Conclusions

The Accuracy root mean square (A_{RMS}) between measured SpO_2 and reference SaO_2 met the 3.0 specification for the Oxitone 1000 Pulse Oximeter. A_{RMS} is based on statistically distributed measurements, therefore, a sensor/oximeter with an A_{RMS} specification of 3.0, is expected to have approximately 68% of the data points fall within that range. This in turn means that approximately one-third of the measurements fall outside the range of ± 3.0 of the reference SaO_2.

SpO2 accuracy performance for the systems evaluated over the SaO2 range of 70-100% under non-motion conditions were shown to have:

Oxitone 1000 Pulse Oximeter vs. Reference CO-Oximetry
SpO2 Accuracy Results =A_{RMS} value of 1.9%

This provides supporting evidence that the SpO_2 accuracy performance meets an acceptable specification for the Oxitone 1000 Pulse Oximeter passing an A_{RMS} specification of 3 under steady state / non-motion conditions for the range 70-100%. Additionally, the SpO2 performance meets an A_{RMS} specification of 2 or 2.5 and could be labeled as such.

7. Abbreviated Terms And Definitions

A_{RMS} - Accuracy Root Mean Square

$$Arms = \sqrt{\frac{\sum_{i=1}^{n}(DUT_i - \mathrm{Re}\, f_i)^2}{n}}$$

Where:
A_{RMS} is the accuracy root mean square.
DUT is the test pulse oximetry readings during sample i.
Ref is the Reference CO-Oximetry functional oxygen saturation SO2 reading during sample i.
n is the number of points.

Bias – The mean difference between the Device Under Test and the Reference CO-Oximetry oxygen saturation readings.

$$Bias = \frac{\sum_{i=1}^{n}(DUT_i - \mathrm{Re}\, f_i)}{n}$$

BMI – Body Mass Index

COHb – Carboxyhemoglobin

CIP - Clinical Investigative Plan

ECG – Electrocardiogram. Electrical rhythm of the heart

EtCO2 – End tidal CO2 – as measured by respiration on exhalation

FDA – Food and Drug Administration

HHb – reduced hemoglobin

IRB - Institutional Review Board

ISO – the International Organization for Standardization

MetHb – Methhemoglobin

NSR – Non-Significant Risk

OEM – Original Equipment Manufacturer

O2Hb – oxygenated hemoglobin

PI – Perfusion Index – strength of signal

SaO_2 – arterial oxygen saturation

SO2 – arterial oxygen function saturation as measured by a CO-Oximeter

SpO_2 – oxygen saturation as measured by a pulse oximeter

8. Ethics

Ethics committee review of the Protocol / Clinical Investigation Plan was provided:

ETHICS COMMITTEE REVIEW:

Salus Independent Review Board
2111 West Braker Lane, Suite 400 Austin, TX 78758

Emory S. Martin, III, PharmD, BCPS: Chairman Board 2
Frederick N. Kopec, JD: Vice-Chair Board 2

IRB approval: Salus Independent Review Board, Approval 01 Aug 2016,

IRB Protocol Title:
"Accuracy Validation of the Oxitone SpO2 System", Version 1, Dated 07/26/2016

IRB Protocol #: PR 2016-192

9. Investigators and Administrative Structure of Investigation

Clinimark was retained by Oxitone Medical, Ltd. conduct an impartial SpO_2 accuracy investigation of the Oxitone 1000 Pulse Oximeter during stationary (non-motion) conditions over the range of 70-100% SpO_2 compared to a Reference CO-Oximetry. Financial support to the study was provided by Oxitone Medical.

Commercial Sponsor:

Oxitone Medical, Ltd. Kfar Saba, Israel

Principal Investigator:

David M. Ransom, MD.,
Avista Adventist Hospital, Staff Anesthesiologist
100 Health Park Drive, Louisville, CO

Sub-Investigators:

Paul Batchelder, LRCP, RRT — Clinimark, Chief Clinical Officer
Dena Raley, BS Bio-Engineer — Clinimark, Chief Technical Officer
Clinimark, LLC, 1923 Pinal Road, Golden, CO

Study Site:

Clinimark Desaturation Laboratory, 303 717-4820
80 Health Park Drive Suite 20 Louisville, CO Site #001

10. Revision History

Revision	Date	Description
1	08/18/2016	Initial Release

11. Annexes to the Report

11.1 Line Listing / Data Removal Record

11.2 Clinical Investigation Plan – (Separate Attachment)

11.1 Line Listing / Data Removal Record

- Pink highlighted cells indicate data that has been removed. See column “Reason for Removal”
- Column “>3” indicates stability of the Control Oximeter. Pink highlighted is unstable / removed.
- No removal of Test SpO2 data observed. See 4.2 Test SpO2 Data handling

Subject ID	Avg CO-Ox	Control 3900	Syringe #	OxiTone	Score	> 3	Reason for Removal
1	98.40	97.29	1	94.3	1	0.4	
1	98.50	97.82	2	93.6	1	0.7	
1	98.13	97.39	3	94.0	1	0.8	
1	98.48	97.66	4	94.7	1	0.6	
1	93.60	92.66	5	91.1	1	1.5	
1	93.78	93.36	6	90.8	1	0.8	
1	93.58	92.76	7	91.3	1	0.7	
1	93.63	92.78	8	91.3	1	0.5	
1	88.95	86.95	9	84.4	1	2.2	
1	86.75	87.98	10	84.2	1	1.7	
1	85.83	86.40	11	83.4	1	1.6	
1	85.13	85.71	12	84.6	1	1.9	
1	76.05	74.98	13	77.0	1	1.9	
1	77.15	73.93	14	75.6	1	1.2	
1	77.10	74.76	15	75.0	1	1.1	
1	77.98	74.74	16	75.3	1	1	
1	78.95	75.46	17	78.0	1	1.8	
1	79.45	77.52	18	78.6	1	1	
1	79.65	78.19	19	79.4	1	1.2	
1	78.58	75.97	20	78.3	2	2.2	
1	77.08	74.69	21	77.0	1	1.5	
1	75.85	74.49	22	76.2	1	0.7	
1	72.40	72.67	23	74.2	1	**3.1**	Control Unstable
1	70.88	68.71	24	71.6	2	3	
2	95.90	94.40	1	95.0	1	0.5	
2	95.80	94.30	2	94.0	1	0.2	
2	96.03	93.76	3	94.8	1	0.5	
2	95.75	93.89	4	95.0	1	0.4	
2	89.98	89.42	5	90.0	1	1.6	
2	89.10	89.04	6	88.8	1	0.7	
2	88.90	88.91	7	88.1	1	1.6	
2	88.88	88.96	8	88.0	1	1.2	
2	82.35	83.25	9	84.0	2	2.9	
2	83.68	84.56	10	84.0	1	1.4	

2	82.88	83.16	11	84.0	1	1.1	
2	82.55	83.68	12	83.0	1	0.5	
2	78.30	79.10	13	80.2	1	1.5	
2	77.05	78.88	14	80.0	1	0.5	
2	77.33	78.45	15	78.8	1	0.9	
2	76.90	79.38	16	78.9	1	1.9	
2	72.53	76.16	17	75.0	1	1.1	
2	72.03	74.88	18	74.9	1	1.4	
2	71.50	73.89	19	73.4	1	1.1	
2	70.13	73.47	20	73.0	1	1	
2	70.00	73.39	21	72.2	1	0.7	
2	69.55	72.42	22	72.4	1	1.5	
2	69.95	73.52	23	72.1	1	0.7	
2	69.13	72.02	24	71.8	1	1.6	
3	97.00	97.56	1	97.0	1	0.4	
3	96.85	97.40	2	97.0	1	0.5	
3	97.33	97.20	3	97.0	1	0.4	
3	97.33	97.90	4	97.3	1	0.6	
3	93.35	93.53	5	93.0	1	1.1	
3	92.50	93.62	6	93.0	1	0.4	
3	92.10	92.91	7	92.0	1	0.7	
3	91.53	92.18	8	91.1	1	0.8	
3	86.00	87.23	9	87.0	1	1.3	
3	86.43	86.72	10	87.0	1	0.8	
3	85.75	87.06	11	86.9	1	0.5	
3	85.10	85.96	12	85.8	1	2	
3	80.55	81.80	13	82.0	1	1.5	
3	79.60	79.71	14	81.0	1	1.7	
3	77.93	77.87	15	80.0	1	2	
3	80.18	77.30	16	83.6	2	2.9	
3	77.65	77.26	17	79.6	1	2	
3	76.80	76.33	18	79.0	1	1.8	
3	76.28	75.23	19	79.0	1	1.1	
3	76.00	75.49	20	79.0	1	0.6	
3	71.73	71.11	21	76.0	2	**4.1**	Control Unstable
3	71.68	70.39	22	75.0	1	1.2	
3	97.75	98.80	23	98.5	1	0.8	
3	96.40	98.13	24	97.2	1	1	
4	96.23	96.06	1	95.0	1	0.3	

4	95.93	96.22	2	96.0	1	0.6	
4	96.10	95.67	3	95.5	1	0.7	
4	96.03	95.84	4	94.4	1	0.6	
4	89.55	91.47	5	89.0	1	0.8	
4	89.18	89.38	6	87.8	1	1.9	
4	87.65	89.28	7	86.7	1	0.5	
4	87.70	88.37	8	87.5	1	1.3	
4	83.53	83.45	9	80.3	1	2.1	
4	82.95	83.49	10	80.6	1	1.1	
4	81.95	83.66	11	79.0	1	1.6	
4	82.80	82.72	12	79.3	1	1.3	
4	76.73	77.88	13	73.0	1	1.3	
4	75.95	77.51	14	71.3	1	0.9	
4	75.30	76.70	15	72.2	1	1.2	
4	74.50	75.98	16	70.0	1	1.5	
4	73.90	74.80	17	73.4	1	1.2	
4	73.55	71.81	18	72.3	2	**3.5**	Control Unstable
4	73.08	72.15	19	72.2	1	1.5	
4	72.55	73.14	20	71.6	1	1.2	
4	86.50	89.65	21	83.0	2	2.9	
4	91.65	91.89	22	89.8	1	1.5	
4	91.73	92.07	23	89.2	1	1	
4	91.40	91.32	24	90.0	1	0.3	
5	96.70	95.32	1	94.0	1	0.2	
5	96.48	95.14	2	95.2	1	0.4	
5	96.83	95.30	3	94.4	1	0.3	
5	96.93	95.68	4	96.0	1	0.5	
5	92.30	91.24	5	90.0	1	1.1	
5	91.55	91.08	6	90.0	1	0.9	
5	91.25	90.56	7	90.0	1	0.5	
5	90.70	89.90	8	89.0	1	1.2	
5	87.58	87.00	9	85.2	1	1.4	
5	87.10	86.33	10	86.0	1	0.7	
5	86.78	86.04	11	85.0	1	0.8	
5	86.20	85.77	12	84.2	1	0.3	
5	83.03	82.40	13	80.6	1	0.4	
5	81.70	80.86	14	80.8	1	1.7	
5	81.43	80.96	15	79.1	1	0.5	
5	81.68	80.50	16	79.0	1	0.8	
5	80.28	78.18	17	76.6	1	1.2	

5	78.25	78.15	18	79.5	1	1.5	
5	77.38	77.69	19	78.3	1	0.9	
5	76.43	75.43	20	76.0	1	1.8	
5	73.78	71.70	21	73.4	1	1.7	
5	73.65	71.33	22	71.8	1	1	
5	72.30	71.94	23	70.4	1	1.1	
5	71.48	71.28	24	72.4	1	0.4	
5	71.43	69.38	25	71.7	1	1.8	
5	71.73	69.91	26	70.2	1	0.6	
5	71.78	70.30	27	70.5	1	1.2	
5	71.23	68.38	28	70.0	1	2	
6	94.40	93.83	1	92.2	1	0.7	
6	95.83	93.57	2	93.0	1	1.2	
6	95.98	94.98	3	93.6	1	1.6	
6	94.98	94.47	4	93.3	1	1	
6	88.45	88.80	5	87.8	1	0.6	
6	87.45	86.97	6	89.0	1	2	
6	86.73	86.23	7	87.0	1	1.7	
6	87.45	86.45	8	86.8	1	0.6	
6	82.25	82.30	9	82.2	1	1	
6	81.40	81.06	10	81.5	1	1.6	
6	83.63	80.88	11	81.2	2	2.2	
6	82.25	83.32	12	82.0	1	1.4	
6	78.98	79.63	13	80.0	1	0.9	
6	80.08	78.21	14	78.0	1	1.5	
6	79.00	79.76	15	77.8	1	1.5	
6	77.15	78.67	16	78.0	1	0.9	
6	76.78	76.82	17	76.6	2	2.6	
6	76.75	75.86	18	76.0	1	2.1	
6	76.20	76.20	19	75.8	1	1.2	
6	74.03	74.68	20	75.0	1	2.5	
6	96.95	97.03	21	95.2	1	0.9	
6	98.43	96.42	22	94.8	1	0.8	
6	98.73	98.42	23	98.0	1	0.5	
6	98.88	98.26	24	95.8	1	0.4	
7	96.98	96.44	1	95.0	1	0.3	
7	97.05	96.60	2	95.0	1	0.3	
7	96.80	96.52	3	94.0	1	0.3	
7	97.33	96.32	4	95.0	1	0.5	

7	89.38	89.30	5	85.8	1	1.6	
7	89.78	88.50	6	84.3	1	0.4	
7	88.18	87.32	7	84.2	1	1.6	
7	87.15	87.10	8	84.0	1	0.9	
7	83.70	83.53	9	80.3	1	1.7	
7	83.05	81.61	10	78.6	1	2.4	
7	82.38	81.92	11	79.3	1	1.4	
7	82.18	81.08	12	79.0	1	1.2	
7	78.85	76.76	13	75.6	1	2.3	
7	77.53	76.30	14	73.8	1	1.5	
7	79.05	78.11	15	75.0	2	**4.2**	Control Unstable
7	77.75	77.85	16	74.0	1	0.5	
7	77.10	76.82	17	73.4	1	1.5	
7	76.98	74.34	18	73.6	2	**3.1**	Control Unstable
7	75.45	74.12	19	72.0	1	1.8	
7	73.98	72.85	20	71.3	1	2.1	
7	99.10	98.90	21	97.0	1	0.2	
7	98.85	98.58	22	97.0	1	0.7	
7	98.80	98.88	23	97.8	1	0.7	
7	98.80	98.98	24	98.0	1	0.4	
8	96.90	96.03	2	97.0	1	0.5	
8	97.40	96.01	3	97.0	1	0.5	
8	97.13	96.06	4	97.0	1	0.5	
8	92.25	91.44	5	92.0	1	0.7	
8	91.63	90.58	6	92.0	1	1.1	
8	91.38	89.80	7	91.0	1	1.5	
8	90.63	89.76	8	90.5	1	0.7	
8	85.73	86.80	9	86.2	1	1.5	
8	86.43	85.43	10	86.0	1	1.3	
8	86.53	85.67	11	86.6	1	0.3	
8	86.33	86.04	12	85.0	1	0.7	
8	85.75	86.00	13	84.9	1	0.3	
8	84.45	84.70	14	85.2	1	1.6	
8	84.48	84.37	15	85.3	1	0.5	
8	83.93	84.19	16	85.0	1	0.5	
8	83.88	83.36	17	83.7	1	0.5	
8	82.75	84.18	18	84.0	1	0.5	
8	83.35	83.64	19	84.0	1	0.7	
8	82.13	83.37	20	83.1	1	0.3	
8	99.30	98.38	21	98.0	1	0.5	

8	98.80	97.74	22	98.0	1	0.5	
8	98.50	96.84	23	97.8	1	0.7	
8	98.33	96.69	24	98.0	1	0.7	
10	96.85	95.52	1	97.0	1	0.7	
10	97.08	95.63	2	97.0	1	0.1	
10	96.88	95.90	3	96.7	1	0.3	
10	96.65	95.40	4	96.0	1	0.6	
10	91.48	90.66	6	91.0	1	0.8	
10	90.88	89.98	7	90.0	1	0.3	
10	90.45	89.78	8	89.5	1	0.4	
10	86.78	86.64	9	86.4	1	0.4	
10	86.93	86.96	10	86.6	1	0.7	
10	87.20	86.70	11	86.2	1	0.6	
10	86.95	86.79	12	86.2	1	0.5	
10	83.40	84.03	13	82.8	1	0.5	
10	82.73	83.25	14	80.6	1	1.2	
10	83.03	83.63	15	82.0	1	0.9	
10	82.20	83.29	16	82.0	1	1.2	
10	74.40	76.29	17	73.4	2	**3.4**	Control Unstable
10	74.60	76.58	18	74.4	1	0.8	
10	74.58	76.49	19	73.7	1	0.5	
10	73.68	75.77	20	73.4	1	0.7	
10	73.18	74.68	21	72.6	1	1.5	
10	71.63	73.48	22	71.3	1	1.1	
10	72.68	74.81	23	72.8	1	1.6	
10	72.78	74.34	24	72.4	1	0.8	
10	73.43	74.93	25	72.8	1	0.5	
10	73.53	75.30	26	73.3	1	0.9	
10	73.05	74.96	27	72.4	1	0.8	
10	73.45	75.18	28	72.0	1	1.5	
12	97.10	98.13	1	98.0	1	0.4	
12	97.15	97.99	2	98.0	1	0.3	
12	97.10	97.69	3	97.6	1	0.4	
12	96.95	97.68	4	98.0	1	0.3	
12	92.95	93.12	5	93.7	1	0.5	
12	93.25	92.76	6	93.0	1	0.5	
12	92.33	92.93	7	94.0	1	0.3	
12	92.78	92.41	8	93.0	1	0.4	
12	87.15	87.64	9	89.0	1	1.8	

12	86.95	86.80	10	88.0	1	0.8	
12	86.88	86.44	11	87.2	1	0.6	
12	86.60	86.15	12	87.0	1	1	
12	83.45	82.80	13	84.2	1	0.7	
12	81.98	81.74	14	83.0	1	1.3	
12	81.60	80.59	15	82.2	1	0.9	
12	81.08	79.58	16	81.4	1	1.4	
12	76.43	74.79	17	79.0	2	2.8	
12	75.45	72.69	18	78.0	1	1.9	
12	75.13	72.59	19	78.0	1	1	
12	75.00	71.91	20	77.1	1	0.5	
12	74.20	72.23	21	77.0	1	0.9	
12	74.40	71.48	22	77.0	1	0.7	
12	73.58	71.72	23	77.0	1	2.2	
12	73.28	70.44	24	76.6	1	0.9	

11.2 Clinical Investigation Plan - (Separate Attachment)

Study Title:
"Accuracy Validation of the Oxitone SpO2 System", Version 1, Dated 07/26/2016
Study ID# PR 2016-192

Salus Independent Review Board
2111 West Braker Lane, Suite 400 Austin, TX 78758

IRB Approved Study: Salus Independent Review Board, Board 2 Review & Approval 01 Aug 2016