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Final Test Report For Vital USA

Results of the SpO_2 and Pulse Rate Accuracy Comparison of VitalDetect™ to Arterial Blood CO-Oximetry and Reference ECG

Study ID# PR 2019-353

Protocol Title:
"Vital USA SpO2 Accuracy Comparison to Arterial Blood CO-Oximetry"

Protocol No.:
PR 2019-353

Investigational Device:
VitalDetect™ pulse oximetry system

Commercial Sponsor:
Vital USA 525 S Flagler Dr. Suite 301, West Palm Beach, FL 33402

Document Ownership:

Function, Title	Name	Signature	Date
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This study was conducted in accordance to CFR for Non-Significant Risk Medical Device Study, following ISO 14155:2011 as appropriate.

Origination Date: 03 Dec 2019 **Revised Date:** 03 Dec 2019

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Summary

Clinical Investigation Plan: "Vital USA SpO2 Accuracy Comparison to Arterial Blood CO-Oximetry"
Clinimark Study ID# PR 2019-353, Version: Rev 1, Date: 15 Oct 2019
Study Dates: November 4-5, 2019

Introduction:

An SpO_2 accuracy comparison was conducted as part of the final validation of the VitalDetect™ pulse oximetry system. 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 80601-2-61:2017 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 validate the SpO_2 accuracy of the VitalDetect™ pulse oximetry system during non-motion conditions over the range of 70-100% SaO_2 as compared to 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 3.0% or less.

A secondary goal was to evaluate the pulse rate performance simultaneously collected over the SpO2 range covered. The Pulse Rate Accuracy Root Mean Square (Arms) performance of the VitalDetect™ pulse oximetry system, were expected to meet a specification of 3 bpm.

Subjects:

Following Institutional Review Board (IRB) approval Title: "Vital USA SpO2 Accuracy Comparison to Arterial Blood CO-Oximetry", Clinimark Study ID# PR 2019-353, eleven healthy adult volunteer subjects were screened and enrolled into the study. One subject was withdrawn from the study due to poor device placement and time sync with the control oximeter. The demographics of subjects included were five males and five females (age: 19-38yrs, weight: 105-228 lbs, height: 63-75", BMI: 18.0-34.7). For race and ethnicity, the subject pool included two Black / African-Americans, one Asian, and seven White. Nine subjects were of Non-Hispanic / Non-Latino and one of Hispanic /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 VitalDetect™ pulse oximetry was placed on the right index finger of all subjects to evaluate the SpO_2 and pulse rate 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 and the real time oxygen saturation status. 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 oximeters. The blood was immediately analyzed by Reference CO-Oximetry providing functional SaO_2 for the basis of the SpO_2 accuracy

comparison. The pulse rate for the VitalDetect™ was compared to Reference ECG Heart Rate collected during the study.

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 3.0% for a range of 70-100%
VitalDetect™ pulse oximetry	3.06 (239 pts)	Fails to meet

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

Table 2: Summary of Pulse Rate Accuracy Results

Comparison to Reference ECG Heart Rate	Pulse Rate A_{RMS} For Heart Rate range 50-118 bpm	A_{RMS} Spec 3 bpm for the range collected during SpO2 of 70-100%
VitalDetect™ pulse oximetry	2.7 (239 pts)	pass

Conclusions:

The results of the study show that the VitalDetect™ pulse oximetry fails to meet an A_{RMS} specification of 3.0% under steady state / non-motion conditions for the range 70-100%. The graphical data shows the VitalDetect™ to in general, under estimate the SaO2 readings below 80% with increased scatter.

Reviewing the pulse rate accuracy, the VitalDetect™ pulse oximetry provides accurate pulse rate values for the range of 50-118 bpm, observed over the oxygen saturation levels between 70-100% meeting a specification of 3 beats per minute.

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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 validate the SpO_2 and pulse rate accuracy of the VitalDetect™ pulse oximetry during non-motion conditions over the range of 70-100% SaO_2 as compared to arterial blood samples assessed by CO-Oximetry and Reference ECG respectively.

The goal, was to provide supporting documentation for the SpO_2 accuracy validation and performance for the VitalDetect™ pulse oximetry. It was expected that the Accuracy Root Mean Square (A_{RMS}) performance would meet the required specification of A_{RMS} 3.0% or lower in non-motion conditions for the range of 70 – 100% SaO_2 thereby demonstrating an acceptable SpO_2 accuracy performance specification. As a secondary goal, the pulse rate accuracy performance was reviewed for the range observed during the non-motion hypoxia study. The pulse rate accuracy was expected to meet an A_{RMS} of 3 bpm as compared to Reference ECG Heart Rate.

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

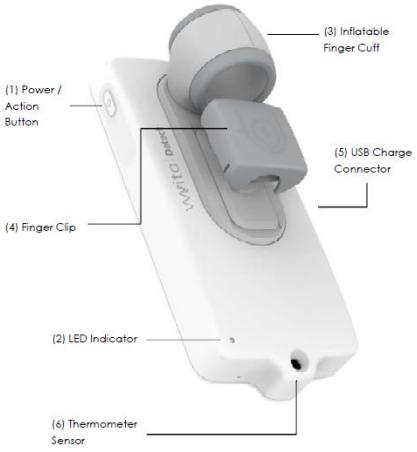
The study was conducted in accordance to the code of federal regulations for non-significant risk medical device studies and applicable ISO 14155 (2nd edition 2011-02-01), applicable sections of ISO 80601-2-61:2017, and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance For Industry and Food and Drug Administration Staff (issued: March 4, 2013).

2. Investigational Device and Methods

2.1 Device Description:

The VitalDetect™ is a non-invasive device designed for spot-checking physiological parameters, such as Non-Invasive Blood Pressure (NIBP), Oxygen Saturation (SpO2), Pulse Rate (PR), Body Temperature (TEMP) and Respiratory Rate (RR). This device is a finger-cuff technology which is applicable for use at-home use or in healthcare facilities in/on individuals 18 years of age and older. It may be used by the individual themselves, or an operator. The VitalDetect™ is not intended for continuous monitoring, or for use with high frequency surgical equipment. It is non transit-operable.

This study focused on the pulse oximetry, SpO_2 parameter. The Vital USA Vital Detect is composed of a sensor head mounted on a base connected to a phone or computer via VitalDetect™ App which is free to download. The pulse oximeter being used in this study collects data from the finger by transmittance of radiation at known wavelength(s) through tissue to measure blood oxygen saturation.



VitalDetect™ Description (see labelled image)		
#	**Name**	**Function**
1	Power / action button 	This user button provides power/reset control and user input independent of the app.
		Press and release to power on the device
		Press and release (tap) during temperature measurement process to take a temperature reading.
		Press and hold for between 3 and 5 seconds to power off the device.
		Press and hold for at least 6 seconds to fully reset the device
2	LED indicator	The LED indicator show the status of the device and indicates any error conditions. Five colors are used: GREEN, RED, BLUE, YELLOW and WHITE. See the subsequent table for more details.
3	Inflatable Finger cuff	The Finger Cuff is the part of the device which is used to measure Blood Pressure. The cuff contains an inflatable membrane (non-latex) which is inflated with air during the measurement process. The cuff should cover the part of the finger between the knuckle and the first joint. The inflatable membrane in the finger cuff is a silicone membrane designed to inflate to a safe pressure during the blood pressure measurement process.
4	Finger clip	The Finger Clip is a flexible silicone clip which allows the fingertip to be inserted fully and contains sensors which collect data to calculate SpO_2, HR and RR. The finger clip slider allows the finger clip position to be adjusted to suit different finger lengths.
5	Charging connector	The USB connector is used to charge the battery of the VitalDetect™. No data is exchanged through the USB port. The device may not be used while the USB cable is plugged in and the device is charging.
6	Thermometer Sensor	The thermometer sensor measures temperature when held close to the forehead. The sensor is sensitive and should be protected from dirt and dust.

The device under test was connected to a mobile and/or PC application that collected data continuously during the hypoxia protocol. Collected data included:

- Measured Heart Rate
- Measured Ratio of Ratios and/or SpO2 value
- Raw data coming from the sensor including PPG signal stored for offline process

The accompanying acquisition software was provided by Vital USA.

Intended Use:
The Vital Detect Pulse Oximeter is indicated for the noninvasive spot checking of:

- Blood Oxygen Saturation, Functional (%SpO2),
- Pulse Rate (PR),
- Respiratory rate (RR),
- Body temperature (TEMP)
- Pulse Rate or Heart rate (PR or HR)
- Non-Invasive Blood Pressure (NIBP)

The VitalDetect™ pulse oximetry is the system that was studied in this investigation.

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 pulse oximetry system 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 Sensor and Oxy-OL3 cable
- Covidien Nellcor N-600x with MaxFast Forehead sensor and DOC-10 cable, for additional stability monitor.

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.

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

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.

- Radiometer ABL 80 Flex OSM (ABL cal) and associated supplies ID#:313093, 317104

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 SpO_2 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. As a secondary goal, the pulse rate accuracy was compared to ECG Heart Rate realized over the range throughout the hypoxia procedure. 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

- 10-15 Adults with a minimum of 3 males and a minimum of 3 females, with the balance made up of either
- 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

Exclusion Criteria

- Subject is considered as being morbidly obese (defined as BMI >39.5)
- Compromised circulation, injury, or physical malformation of fingers, wrist, 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.)
- Female subjects that are actively trying to get pregnant or are pregnant (confirmed by positive urine pregnancy test unless the subject is known to be not of child-bearing potential).
- Smoker Subjects who have refrained will be screened for 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,
    - unresolved respiratory or lung surgery with continued indications of health issues,
    - 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 (reviewed during health screen).
    - have had cardiovascular surgery
    - Chest pain (angina)
    - heart rhythms other than a normal sinus rhythm or with respiratory sinus arrhythmia (reviewed during health screen)
    - 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,
    - uncontrolled 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 symptomatic head injury (within the last 2 months)
    - 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)
- Subjects with severe allergies to iodine (only applicable if iodine is used)
- Subjects with severe allergies to lidocaine (or similar pharmacological agents, e.g. Novocain)
- Failure of the Perfusion Index Ulnar/Ulnar+Radial Ratio test (Ratio < 0.4)
- 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 sensors were placed on the right wrist of each subject to evaluate the SpO_2 accuracy performance. As a secondary goal, the Pulse Rate accuracy was evaluated over the range of oxygen saturation levels elicited during the study.

Subjects were given medical grade mixtures of oxygen and nitrogen to induce stable plateaus across the range of 100% to 70%. 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 any final questions raised by the subject and the subject was released. Follow up was made to subjects post study 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 at least 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 SaO_2. The pulse rate accuracy was also documented over the range realized from the hypoxia changes across the range of 70-100% SaO_2.

Data analysis results provide documentation showing SpO_2 and Pulse Rate accuracy performance of the VitalDetect™ pulse oximetry as compared to arterial blood samples measured by Reference CO-Oximetry and ECG heart rate respectively.

The passing criteria identified in the clinical investigation plan for oxygen saturation was an A_{RMS} specification of 3.0% or less under steady state / non-motion conditions for the range 70-100%. Data analysis results provide documentation showing SpO_2 accuracy performance of the VitalDetect™ pulse oximetry as compared to arterial blood samples measured by Reference CO-Oximetry.

The pulse rate accuracy was compared to ECG Heart Rate as recorded by the S5 Multi-parameter monitor. Passing criteria was an ARMS of 3 bpm or better based measurements observed during the pulse oximetry evaluation.

3. Results

Institutional Review Board (IRB) approval[1] was obtained for validation testing. The study was conducted November 4-5, 2019, 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. Eleven subjects were screen with all being enrolled into the study. Following the study, one subject was identified as having poor sensor placement and as well as an incorrect time sync with the control oximeter. This subject was not included in the data analysis. Each subject was cannulated with an indwelling catheter in the left 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. Testing was conducted under non-motion conditions. The device under test was VitalDetect™ pulse oximetry.

Each subject was presented with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO_2. Arterial blood draws were collected under non-motion conditions. SpO_2 and Pulse Rate values from the pulse oximeters as well as the Reference ECG Heart Rate values 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 ten subjects was included for analysis. There were no serious adverse events or adverse device effects during the study.

3.1 Subject Demographics

Table 3: Summary of Subject Demographics Record

Sex	Male	50%	(5/10)
	Female	50%	(5/10)
Race	Black / African-American	20%	(2/10)
	Asian	10%	(1/10)
	White	70%	(7/10)
Ethnicity	Hispanic or Latino	10%	(1/10)
	Not Hispanic or Latino	90%	(9/10)

[1] IRB approval: Salus Independent Review Board, Board 3 #IRB00009473, Approval 25 Oct 2019
[2] Clinical Investigation Test Plan for: "Vital USA SpO2 Accuracy Comparison to Arterial Blood CO-Oximetry" Clinimark Study ID# PR 2019-353, Version: Rev 1, Date: 15 Oct 2019
[3] Control Oximeter: Datex-Ohmeda 3900 TruTrak® + Pulse Oximeter. TruTrak+ is a registered trademark of Datex-Ohmeda Inc., now GE Healthcare.
[4] Reference CO-Oximeter: ABL80 Flex OSM, Radiometer

Skin Tone	Light	40%	(4/10)
	Medium Light	20%	(2/10)
	Medium	10%	(1/10)
	Dark	30%	(3/10)
Age	Mean +/-SD (N)	25.9 +/- 5.8	10
	Median	26	
	Range (min, max)	(19, 38)	
Weight	Mean +/-SD (N)	161.0 +/- 41.4	10
	Median	155	
	Range (min, max)	(105, 228)	
Height	Mean +/-SD (N)	68.4 +/- 4.2	10
	Median	68.5	
	Range (min, max)	(63, 75)	
BMI	Mean +/-SD (N)	24.0 +/- 5.1	10
	Median	22.3	
	Range (min, max)	(18.0, 34.7)	

3.2 Equipment Record:

Table 4: Equipment Record

Comm.	Unit/Rev.	Unit S/N	Sensor	Sensor S/N	Site
Oxim 1 Desat	3900P TT+ 9.000/11.000	FBZ200195	Oxy-FUN Oxy-OL3 Cable 31601	ABS010804-18 Lot # 36303	Finger
Oxim 2 N395	Nellcor N-600X V 1.6.0.0	G08817962	Nellcor MAX-Fast DOC-10 Cable	ID # Prod Lot # 170410208H	Forehead
Oxim 3 Safety	Datex-Ohmeda S5	Monitor 5014850 MNESTPR 3645308 M-CAiO 3611324	3 lead ECG	ECG 891402-1.0 1997-01-09	Chest
Sponsor	VitalDetect™ App: v1.0.14-34 Main: V10.7.32-48 Tablet: Digiland	E010000012 Built: 2018-12-19 Tablet: 181020101900816	NA		Index Finger

4. Data Analysis

Excel was used as the data analysis tool. Data analysis follows ISO80601-2-61:2017, 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. Simultaneous to oxygen saturation measurements, pulse rate from the test device and the Reference ECG monitor were collected for comparison.

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 through the draw as defined by ISO 80601-2-61:2017.

4.2 Test SpO2 Data handling:

Data recorded as 100% or higher was removed prior to the analysis. Data collected under poor perfusion conditions or invalid / zero readings were also removed prior to the analysis.

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 Line Listing below 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, pulse oximetry system.

For Pulse Rate:
Ref = Reference ECG Heart Rate
DUT = Device Under test Pulse Rate, pulse oximetry system.

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

The 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 the clinical evaluation range 70 – 100% SaO2
SpO2 A_{RMS} ≤ 3.0% in non-motion conditions – Pass result
Pulse Rate A_{RMS} ≤ 3bpm in non-motion conditions – Pass result

4.5 SpO2 Accuracy Results:

Table 5: Comparison to Reference CO-Oximetry

Comparison to Reference CO-Oximetry					
VitalDetect™ pulse oximetry	*70—100	90--100	80--<90	67--<80	A_{RMS} Spec 3.0% for range of 70-100%
# pts	239	75	82	82	**Fails to meet**
Bias	-0.6	-0.4	0.7	-2.0	
A_{RMS}	3.1	1.5	2.1	4.6	

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

Table 6: Comparison to Reference ECG Heart Rate

Comparison to Reference ECG Heart Rate		
VitalDetect™ pulse oximetry	50-119 bpm	A_{RMS} Spec 3 bpm for range of 70-100% SaO_2
# pts	239	**Pass**
Bias	0.6	
A_{RMS}	2.7	

5. Graphs – List of Graphs

5.1 VitalDetect™ pulse oximetry vs Reference CO-Oximetry

5.2 Bland-Altman Plot: VitalDetect™ pulse oximetry

5.3 Error Plot: VitalDetect™ pulse oximetry

5.4 Individual Subject 1 Error Plots

5.5 Individual Subject 2 Error Plots

5.6 Individual Subject 4 Error Plots

5.7 Individual Subject 5 Error Plots

5.8 Individual Subject 6 Error Plots

5.9 Individual Subject 7 Error Plots

5.10 Individual Subject 8 Error Plots

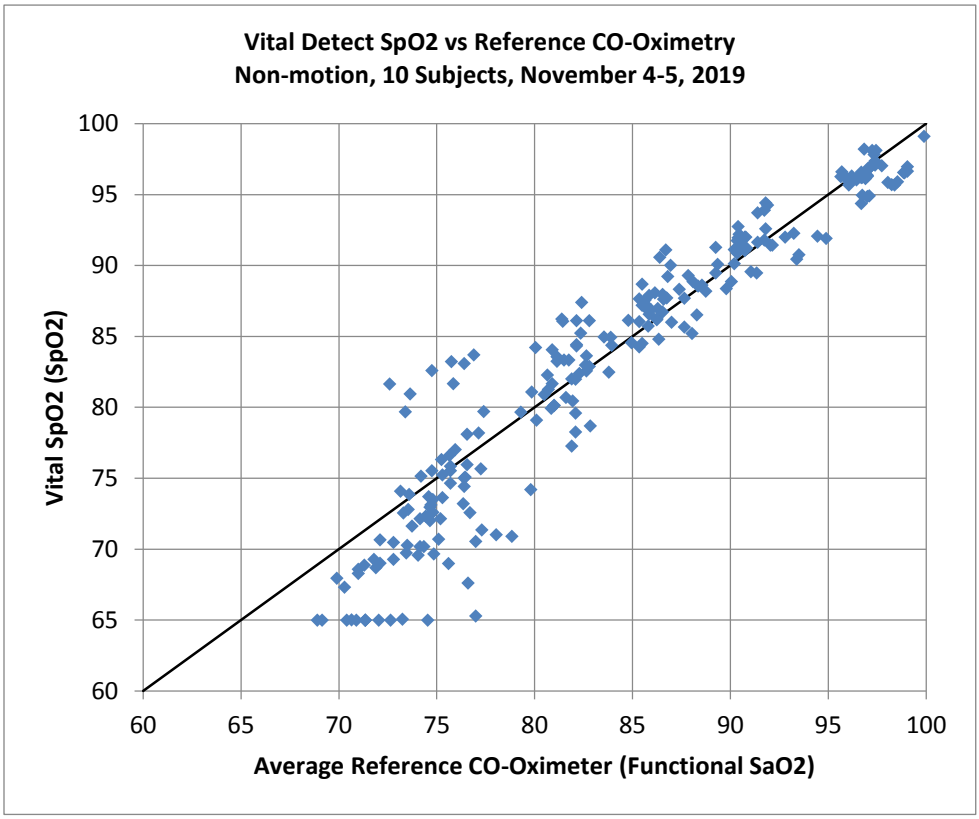
5.11 Individual Subject 9 Error Plots

5.12 Individual Subject 10 Error Plots

5.13 Individual Subject 11 Error Plots

5.14 VitalDetect™ Pulse Rate vs Reference ECG Heart Rate

5.1 VitalDetect™ pulse oximetry vs Reference CO-Oximetry

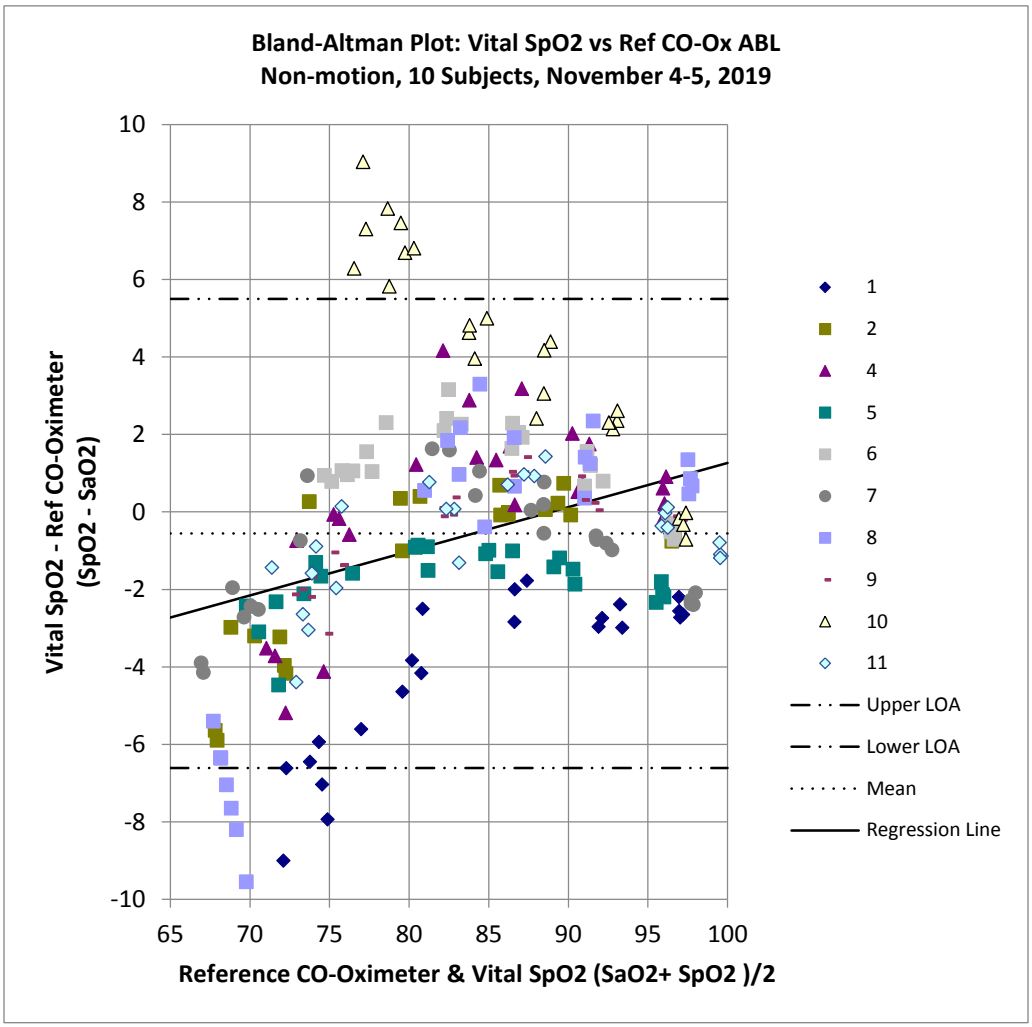


Vital SpO2 vs. CO-Ox ABL

	69--100	70--100	90--100	80--<90	70--<80	60--<70
# pts	239	233	75	82	79	3
Bias	-0.6	-0.5	-0.4	0.7	-1.9	-3.3
ARMS	3.1	3.1	1.5	2.1	4.6	3.5
SDadc	3.0					
Min diff	-11.7	Max diff	9.0			
LR Slope	Y = 1.066 X – 6.130					
SEE	3.0					
CC	0.95					
Upper 95%	0.9					
Lower 95%	-0.2					

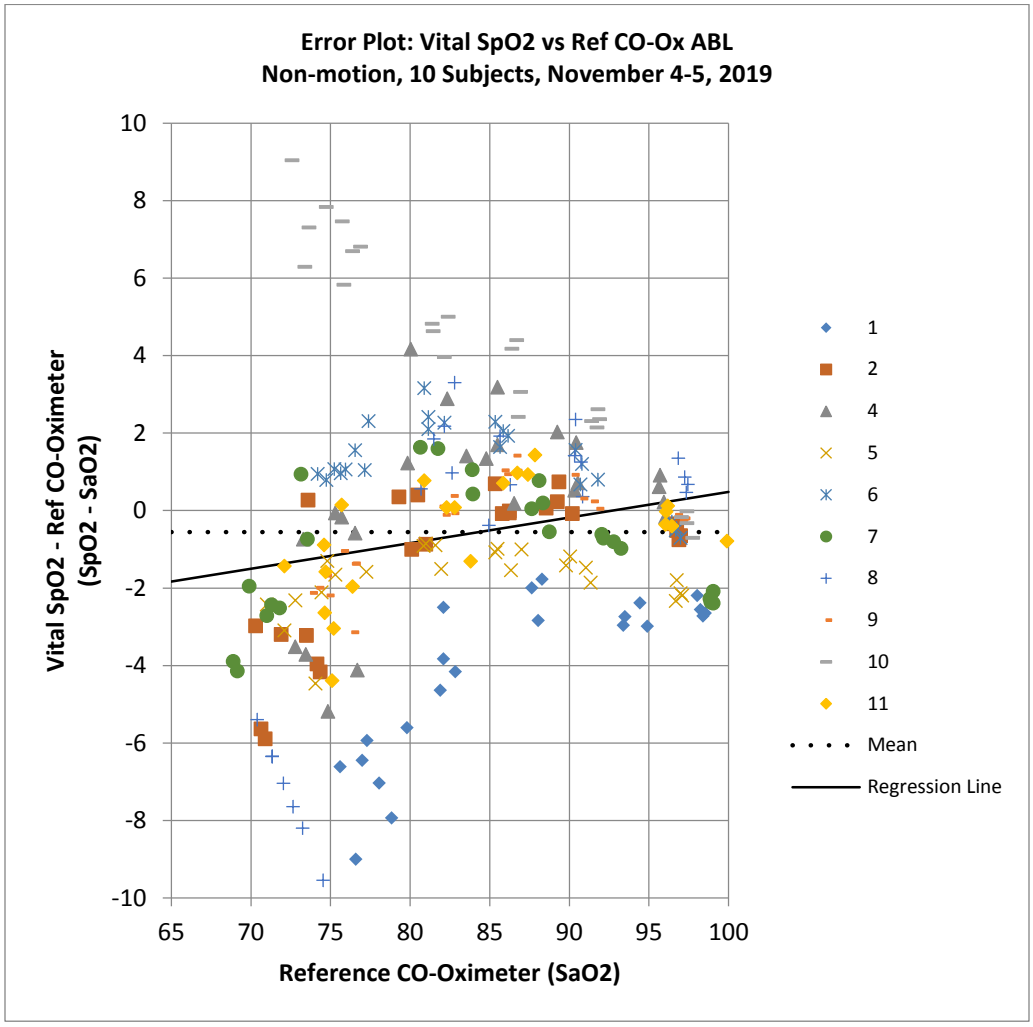
Discussion by subject for noticeable outliers with offsets >5%:
There were twenty-eight points or 12% of the data, that were considered as outliers, reading >5% from the Reference CO-Oximeter reading. Subject #1 (9 pts), Subject #2 (2 pts), Subject #4 (1 pt), Subject #8 (8 pts), Subject #10 (8 pts). All points with a reading >5% from the Reference occurred below 80%. Of the outlying points, only errors for Subject #10 were in the positive direction. Additionally, the data appeared to have a hard lower limit of 65% in the readings. It is expected that greater scatter will occur in the lower oxygen saturation range. The amount of errors observed resulted in a poorer A_{RMS} performance.

5.2 Bland-Altman Plot: VitalDetect™ pulse oximetry



Reference: Bland-Altman Range	70-100%
Linear Regression (Bland Altman)	y = -10.1356 + 0.11400 x
Mean Bias	-0.56
# pts	239
Bland-Altman Results for Multiple Observations Per Individual	
Between-Subject Variance (σ_μ^2)	4.64
Within-Subject Variance (σ^2)	4.90
Upper 95% Limits of Agreement	5.50
Lower 95% Limits of Agreement	-6.61

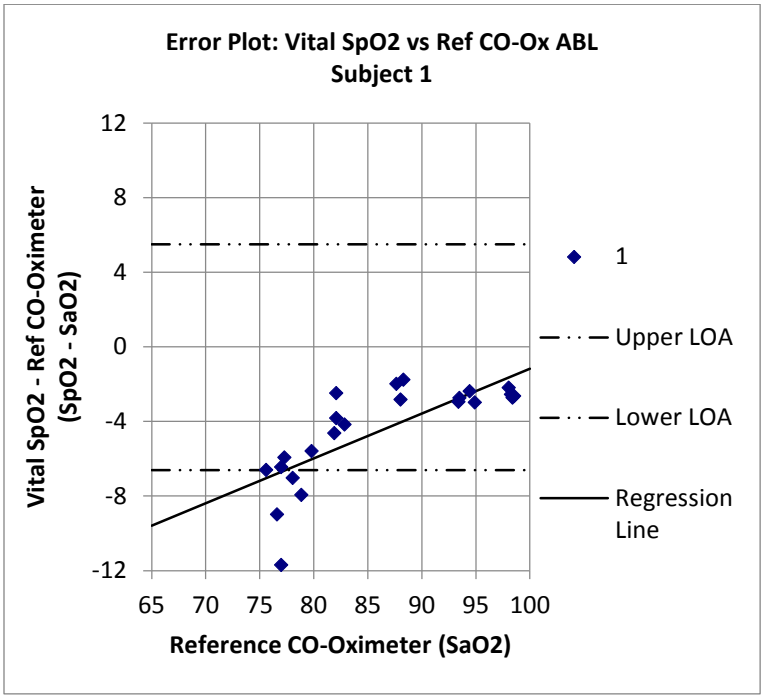
5.3 Error Plot: VitalDetect™ pulse oximetry



Reference: Reference CO-Oximetry	70-100%
Linear Regression (Error Plot)	y = -6.1295 + 0.06611 x
Mean Bias (μ_o)	-0.56
# pts	239

5.4 Individual Subject 1 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
1	F	20	125	66	20.2	Med Light	White	Non-Hispanic

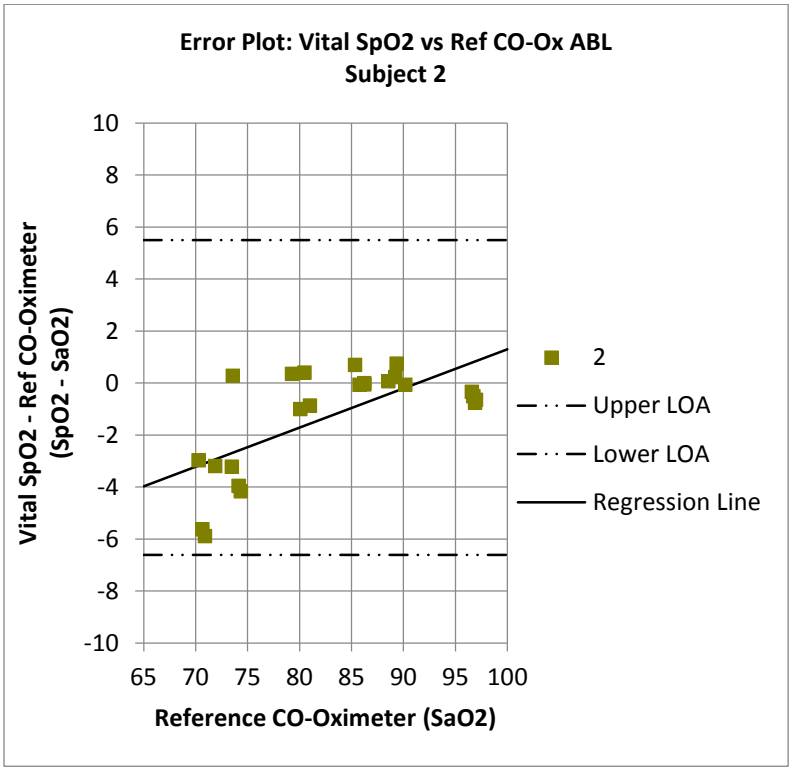


Mean Bias	-4.5
# pts	23
Linear Regression	y = -25.2186 + 0.24046 x
Data points with abs(error) > 3	11

82.1	-3.8
82.9	-4.2
81.9	-4.6
79.8	-5.6
77.3	-5.9
78.1	-7.0
78.9	-7.9
77.0	-6.5
76.6	-9.0
77.0	-11.7
75.6	-6.6

5.5 Individual Subject 2 Error Plots

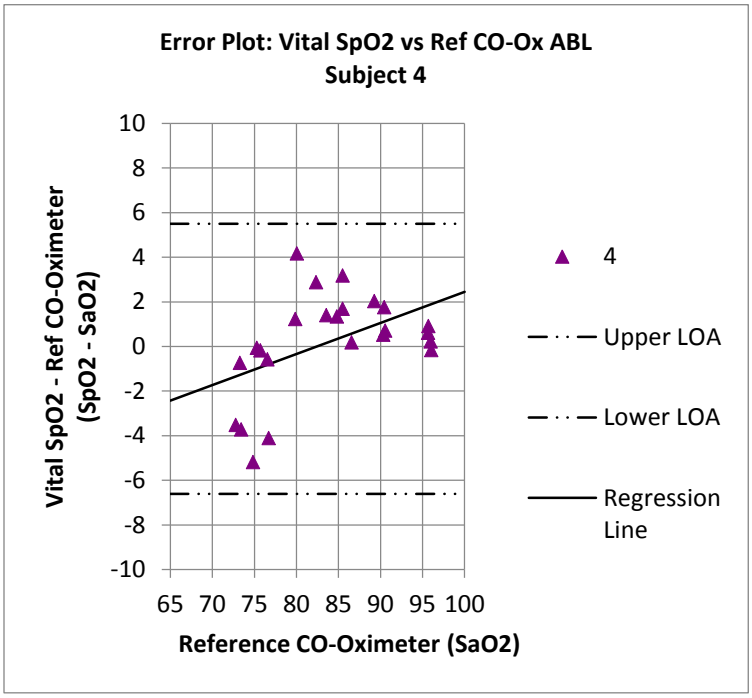
Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
2	M	27	207	70	29.7	Dark	Asian	Non-Hispanic



Mean Bias	-1.3
# pts	24
Linear Regression	y = -13.7607 + 0.15060 x
Data points with abs(error) > 3	6
74.2	-4.0
74.4	-4.2
73.5	-3.2
71.9	-3.2
70.7	-5.6
70.9	-5.9

5.6 Individual Subject 4 Error Plots

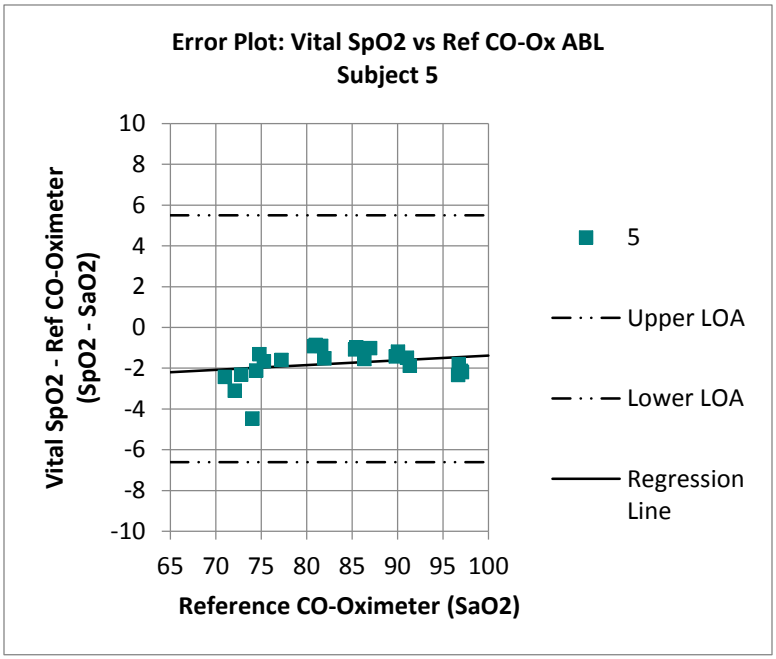
Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
4	F	25	105	64	18.0	Light	White	Non-Hispanic



Mean Bias	0.19
# pts	24
Linear Regression	y = -11.4844 + 0.13933 x
Data points with abs(error) > 3	6
85.5	3.2
80.1	4.2
73.5	-3.7
72.8	-3.5
74.9	-5.2
76.7	-4.1

5.7 Individual Subject 5 Error Plots

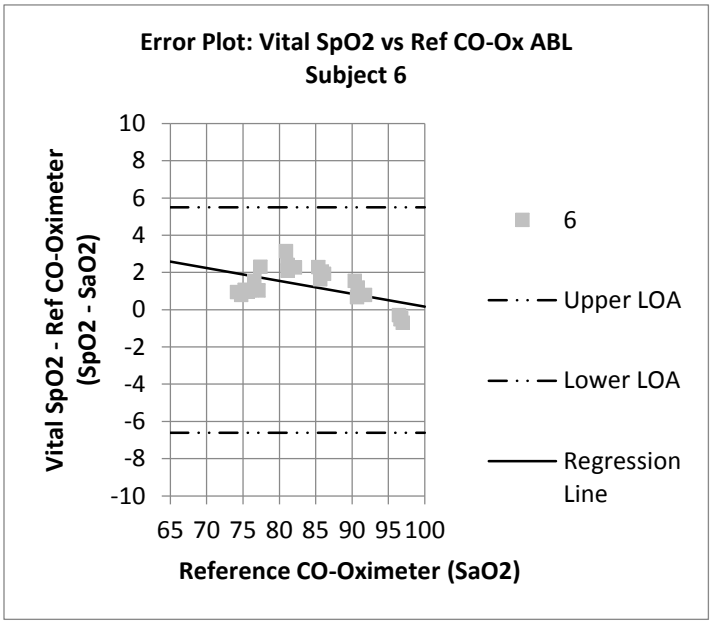
Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
5	M	32	150	69	22.1	Light	White	Non-Hispanic



Mean Bias	-1.76
# pts	24
Linear Regression	y = -3.7164 + 0.02334 x
Data points with abs(error) > 3	2
74.1 -4.5	
72.1 -3.1	

5.8 Individual Subject 6 Error Plots

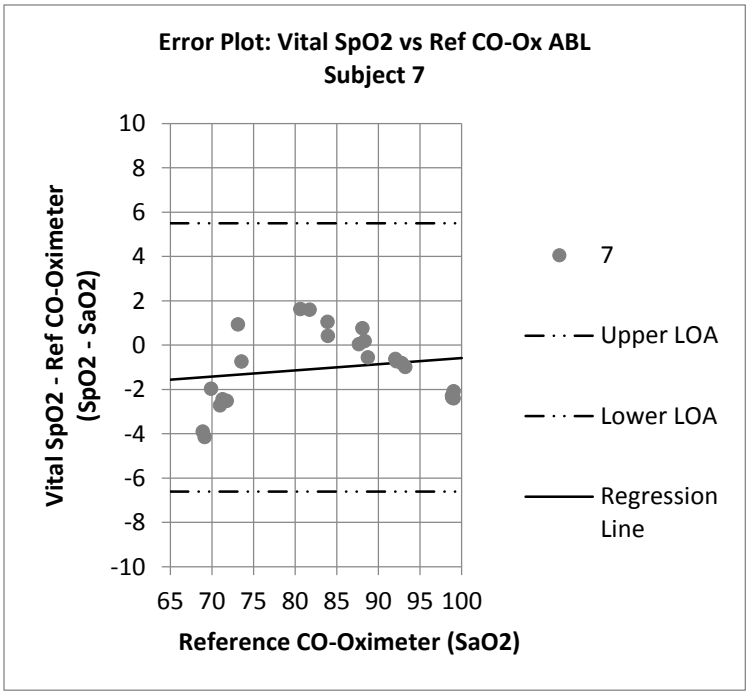
Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
6	F	27	228	68	34.7	Dark	Black / African-American	Non-Hispanic



Mean Bias	1.24
# pts	24
Linear Regression	y = 7.0782 + -0.06914 x
Data points with abs(error) > 3	1
80.9 3.2	

5.9 Individual Subject 7 Error Plots

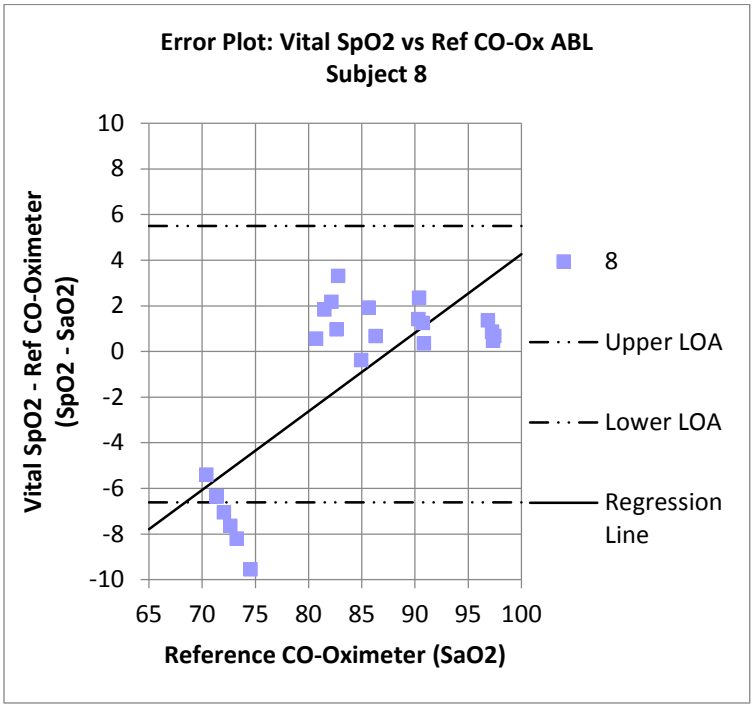
Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
7	M	27	200	75	25.0	Light	White	Non-Hispanic



Mean Bias	-1.03
# pts	24
Linear Regression	y = -3.3709 + 0.02789 x
Data points with abs(error) > 3	2
69.2 -4.2	
68.9 -3.9	

5.10 Individual Subject 8 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
8	F	38	120	63	21.3	Medium	White	Hispanic

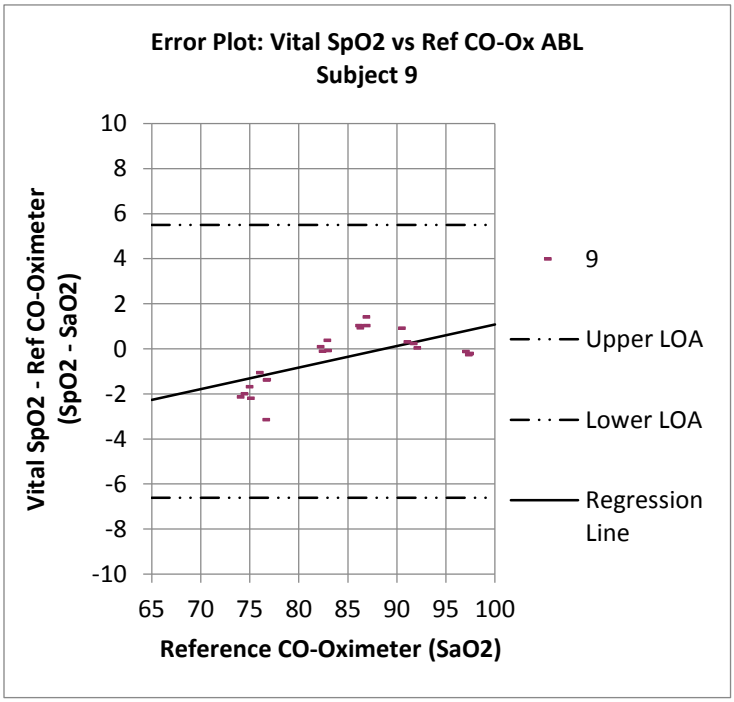


Mean Bias	-1.55
# pts	24
Linear Regression	y = -30.1614 + 0.34422 x
Data points with abs(error) > 3	9

82.8	3.3
72.7	-7.7
71.4	-6.3
72.1	-7.1
70.4	-5.4
71.4	-6.3
71.4	-6.3
74.6	-9.6
73.3	-8.2

5.11 Individual Subject 9 Error Plots

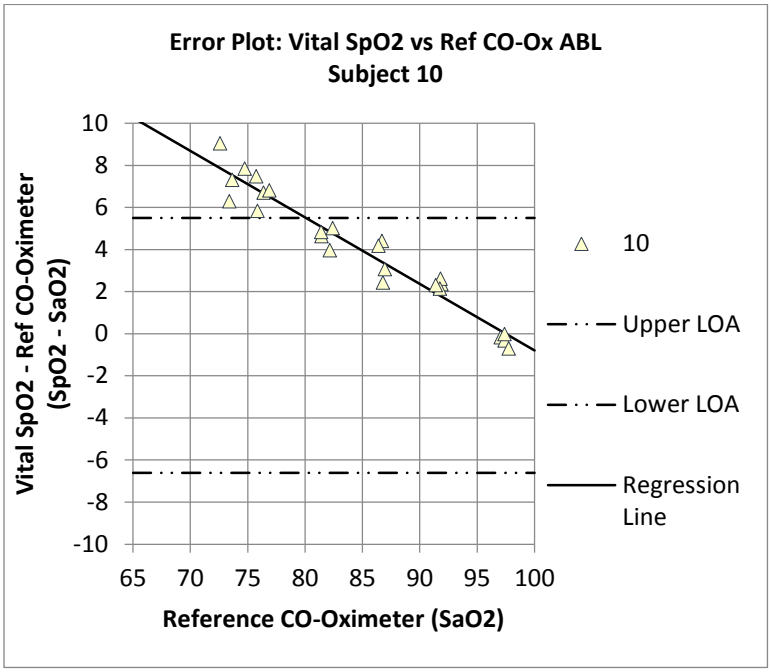
Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
9	F	21	135	65	22.5	Med Light	White	Non-Hispanic



Mean Bias	-0.40
# pts	24
Linear Regression	y = -8.4837 + 0.09565 x
Data points with abs(error) > 3	1
76.4 -3.1	

5.12 Individual Subject 10 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
10	M	19	160	75	20.0	Dark	Black / African-American	Non-Hispanic

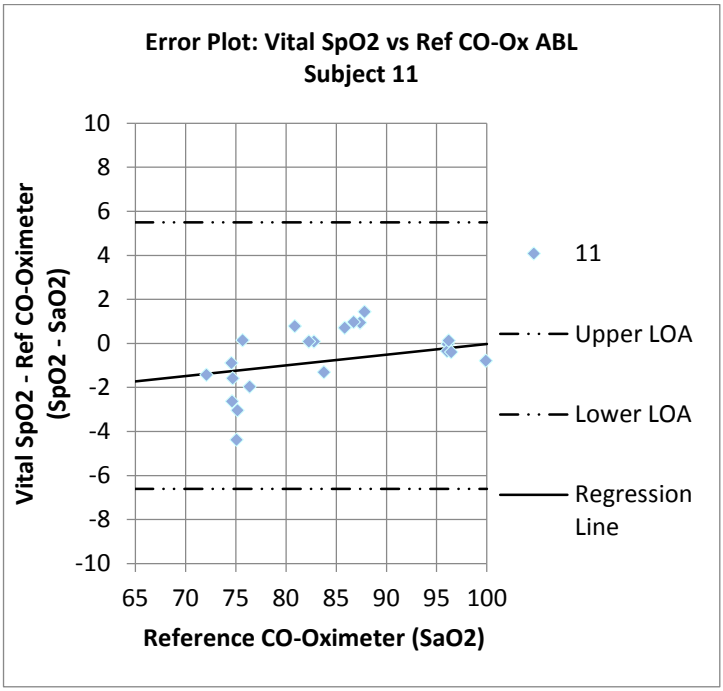


Mean Bias	4.076466
# pts	24
Linear Regression	y = 30.8014 + -0.31596 x
Data points with abs(error) > 3	15

86.7	4.4
87.0	3.1
86.4	4.2
81.5	4.6
81.4	4.8
82.4	5.0
82.2	4.0
76.4	6.7
76.9	6.8
75.9	5.8
75.8	7.5
74.8	7.8
73.7	7.3
73.4	6.3
72.6	9.0

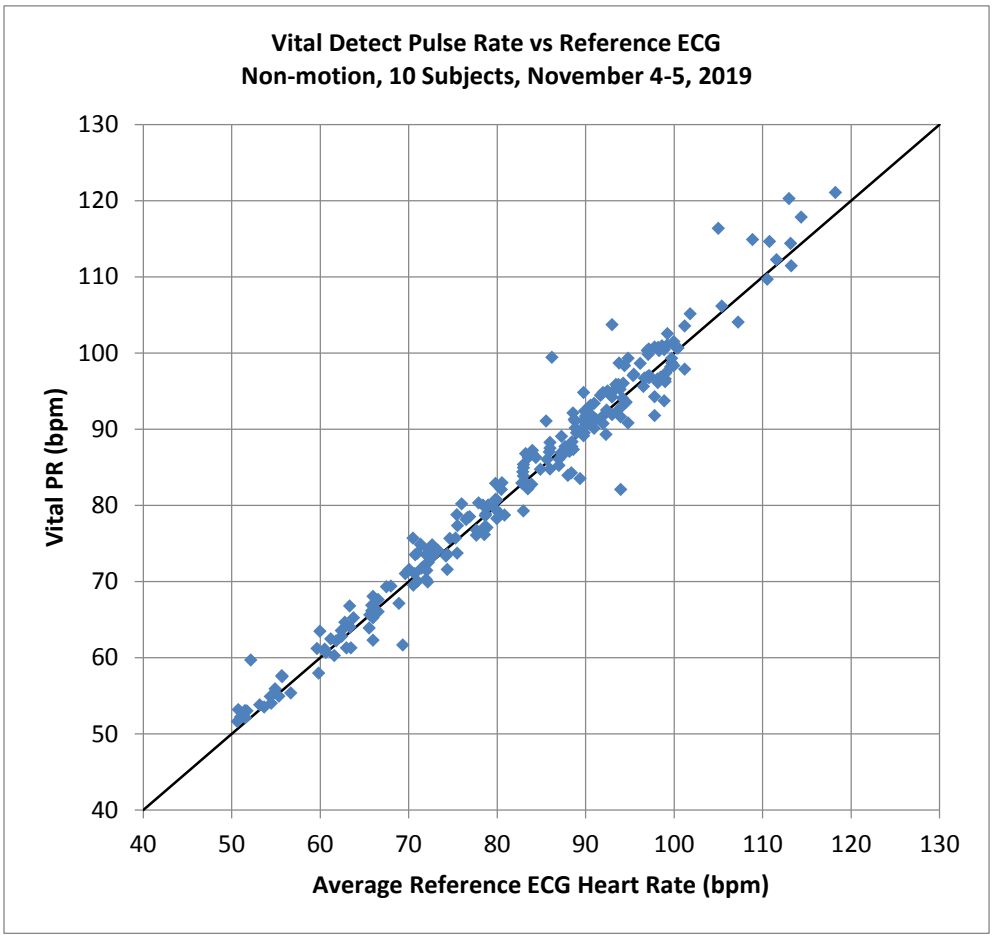
5.13 Individual Subject 11 Error Plots

Subject ID#	Gender	Age (yrs)	Weight (lbs)	Height (in)	BMI	Skin Tone	Race	Ethnicity
11	M	23	180	69	26.6	Light	White	Non-Hispanic



Mean Bias	-0.71
# pts	24
Linear Regression	y = -4.8837 + 0.04856 x
Data points with abs(error) > 3	2
75.1 -4.4	
75.2 -3.1	

5.14 VitalDetect™ Pulse Rate vs Reference ECG Heart Rate



Vital PR vs. ECG

	50-119
# pts	239
Bias	0.6
ARMS	2.7
SDadc	2.6
Range of diff	-13.2 to 11.9
LR Slope	Y = 1.006x + 0.165
SEE	2.7
CC	0.98
Upper 95%	0.98
Lower 95%	-0.3

6. Conclusions

The Accuracy root mean square (A_{RMS}) between measured SpO_2 and reference SaO_2 did not meet a 3.0% specification for the VitalDetect pulse oximetry. The results for SpO_2 accuracy as indicated below is an A_{RMS} of 3.1. A_{RMS} is based on statistically distributed measurements, therefore, a sensor/oximeter with an A_{RMS} specification of 3, 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 of the reference SaO_2.

The SpO_2 and Pulse Rate accuracy performance results showed the following A_{RMS} values for the SaO_2 range of 70-100%.

Table 7: Summary of SpO_2 Accuracy Results

Comparison to Reference CO-Oximetry (functional SaO_2)	A_{RMS} SpO_2 70-100%	A_{RMS} Spec 3.0% for a range of 70-100%
VitalDetect™ pulse oximetry	3.1 (239 pts)	Fails to meet

Table 8: Summary of Pulse Rate Accuracy Results

Comparison to Reference ECG Heart Rate	Pulse Rate A_{RMS} For Heart Rate range 50-118 bpm	A_{RMS} Spec 3 bpm for the range collected during SpO2 of 70-100%
VitalDetect™ Pulse Rate	2.7 (239 pts)	Pass

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

The results of the study provide evidence that the VitalDetect™ pulse oximetry fails to meet an A_{RMS} specification of 3.0% under steady state / non-motion conditions for the range 70-100%. It is recommended that the sponsor review and determine a means to improve accuracy performance especially for SpO2 levels <80%.

Reviewing the pulse rate accuracy, VitalDetect™ pulse oximetry provides accurate pulse rate values for the range of 50-119 bpm, observed during simultaneous data collection of oxygen saturation levels between 70-100%.

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 or deoxyhemoglobin

HR – Heart Rate as measured by electrical activity from and electrocardiogram.

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

PR – Pulse Rate as measured by photoplethysmography from a pulse oximeter

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 100 Austin, TX 78758
Alexander Kenaston, RN, MS, PhD, CIP : Chairman Board 3

IRB approval: Salus Independent Review Board, Approval 25 October 2019,

IRB Protocol Title:
"Vital USA SpO2 Accuracy Comparison to Arterial Blood CO-Oximetry"

IRB Protocol #: PR 2019-353, Version: Rev 1, Date: 15 Oct 2019

9. Investigators and Administrative Structure of Investigation

Clinimark was retained by Vital USA to conduct an impartial SpO_2 accuracy investigation of the VitalDetect™ pulse oximetry, during stationary (non-motion) conditions over the range of 70-100% SpO_2 compared to a Reference CO-Oximetry and pulse rate to Reference ECG heart rate. Financial support to the study was provided by Vital USA.

Commercial Sponsor:
Vital USA, 525 S Flagler Dr. Suite 301, West Palm Beach, FL 33402

Principal Investigator:
Arthur Ruiz Cabrera, MD.,
Avista Adventist Hospital, Staff Anesthesiologist
100 Health Park Drive, Louisville, CO

Sub-Investigators:
Paul Batchelder, LRCP, RRT
Clinimark, Chief Clinical Officer
Clinimark, LLC, 1923 Pinal Road, Golden, CO

Dena Raley, BS Bio-Engineer
Clinimark, Chief Technical Officer

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	03 Dec 2019	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.
- Removal of Test SpO2 data highlighted in pink. See column "Reason for Removal"
- Test values >3% from the Ref CO-Ox are highlighted in yellow.
- Test values >5% form the Ref CO-Ox are highlighted in orange.

Subject ID#	CO-Ox ABL	ECG	Syringe #	Control 3900	Vital SpO2	Vital PR	Score	>= 3	Reason for Removal
1	98.05	83.25	1	97.43	95.85	86.80	1	0.5	
1	98.25	89.00	2	97.60	95.69	89.50	1	0.2	
1	98.55	88.40	3	97.76	95.90	84.27	1	0.4	
1	98.4	98.91	4	97.46	95.67	93.71	1	0.4	
1	94.9	89.40	5	93.57	91.91	83.51	1	1.1	
1	94.45	86.20	6	93.61	92.06	99.45	1	1	
1	93.5	97.82	7	92.97	90.76	100.77	1	0.6	
1	93.4	97.80	8	92.11	90.44	91.76	1	0.6	
1	87.65	101.20	9	87.51	85.65	103.55	1	1.4	
1	88.05	94.80	10	87.55	85.21	90.82	1	1	
1	88.3	93.00	11	88.93	86.53	103.73	1	1.7	
1	89.6	110.50	12	88.30	86.86	102.39	1	**3.1**	Control Unstable
1	82.1	108.90	13	82.97	79.60	114.89	1	2.5	
1	82.1	110.56	14	82.76	78.27	109.68	1	1.1	
1	82.85	105.42	15	82.26	78.68	106.16	1	1.7	
1	81.9	105.00	16	83.12	77.26	116.38	1	1.5	
1	79.8	110.80	17	79.83	74.19	114.62	1	0.4	
1	77.3	113.20	18	78.09	71.36	114.40	1	2	
1	78.05	111.60	19	78.14	71.01	112.24	1	1.1	
1	78.85	107.25	20	77.68	70.91	104.07	1	1	
1	77	114.40	21	77.45	70.55	117.85	1	2.2	
1	76.6	118.25	22	76.33	67.60	121.06	1	1.3	
1	77	113.25	23	75.12	65.29	111.45	2	2.1	
1	75.6	113.00	24	76.50	68.99	120.29	1	1.8	
2	96.6	71.50	1	95.93	96.26	71.74	1	0.8	
2	96.9	68.00	2	96.32	96.14	69.38	1	0.6	
2	97	73.33	3	96.29	96.35	74.08	1	0.3	
2	96.75	78.67	4	96.10	96.23	76.91	1	0.4	
2	90.2	83.00	5	89.94	90.12	79.26	1	0.5	
2	89.35	84.40	6	89.80	90.08	86.26	1	0.8	
2	89.25	80.00	7	88.86	89.47	78.26	1	1.2	
2	88.55	80.50	8	89.11	88.61	82.08	1	0.6	
2	86.25	87.25	9	87.13	86.24	86.91	1	0.8	

2	86.25	85.67	10	86.43	86.19	86.02	1	0.7
2	85.8	86.00	11	86.60	85.72	84.75	1	0.3
2	85.35	84.00	12	87.05	86.04	87.21	1	0.8
2	80.5	88.60	13	83.21	80.89	92.12	1	0.8
2	81	91.00	14	81.78	80.12	93.39	1	1.2
2	79.3	90.00	15	82.10	79.65	91.72	1	1
2	80.1	90.00	16	81.32	79.09	90.82	1	1
2	73.6	89.80	17	78.09	73.86	94.81	2	2.9
2	74.15	94.60	18	75.66	70.19	93.56	1	2.5
2	74.35	97.80	19	76.26	70.18	94.25	1	1.6
2	73.5	96.20	20	76.52	70.27	98.63	1	1.1
2	71.9	97.18	21	75.26	68.70	100.51	1	0.9
2	70.3	98.18	22	74.12	67.31	96.10	1	1.7
2	70.65	99.00	23	73.18	65.01	96.22	1	0.5
2	70.9	96.67	24	73.07	65.00	96.72	1	0.6
4	95.7	79.00	1	95.29	96.61	79.98	1	1.3
4	95.65	82.80	2	94.81	96.26	82.93	1	1
4	96.05	83.00	3	94.64	95.88	85.35	1	0.5
4	95.95	83.00	4	95.45	96.17	83.86	1	0.6
4	90.45	87.00	5	90.57	92.21	86.08	1	2
4	90.55	88.80	6	90.06	91.26	91.06	1	0.6
4	90.35	94.00	7	89.88	90.87	91.63	1	0.9
4	89.25	92.50	8	90.15	91.28	94.97	1	0.6
4	85.5	93.00	9	87.97	88.68	94.20	1	0.6
4	86.55	90.17	10	86.91	86.73	90.72	1	0.9
4	85.5	88.45	11	86.67	87.19	87.71	1	1.1
4	84.8	90.80	12	85.87	86.14	91.71	1	0.6
4	82.35	90.60	13	84.79	85.23	93.14	1	2
4	83.55	91.20	14	85.13	84.95	91.28	1	1.5
4	80.05	88.73	15	83.57	84.21	91.29	1	**3**
4	79.85	93.45	16	82.44	81.07	95.87	1	1.2
4	76.55	94.82	17	78.80	75.97	99.29	1	2
4	75.7	93.60	18	78.39	75.53	95.74	1	1.1
4	73.3	94.27	19	76.04	72.56	96.02	1	2.1
4	73.45	97.00	20	75.11	69.73	96.86	1	0.7
4	72.8	99.73	21	75.45	69.28	99.31	1	0.9
4	74.85	94.40	22	75.21	69.66	98.34	1	2
4	76.7	95.40	23	77.34	72.58	97.04	1	1.2
4	75.3	97.20	24	78.22	75.24	97.02	1	1.2
5	96.7	66.57	1	94.91	94.36	66.03	1	0.5
5	96.75	62.82	2	95.36	94.95	64.65	1	0.5

5	97	65.83	3	95.33	94.86	66.14	1	0.3
5	97.1	63.38	4	95.52	94.90	64.01	1	0.3
5	91.35	72.17	5	90.32	89.48	69.91	1	1
5	91.05	67.50	6	89.87	89.57	69.29	1	0.4
5	90.05	70.69	7	89.39	88.86	71.02	1	1
5	89.8	72.08	8	88.60	88.38	71.45	1	0.4
5	87	72.00	9	86.31	85.99	72.27	1	1
5	86.35	72.67	10	85.54	84.80	74.79	1	0.9
5	85.5	75.50	11	85.12	84.51	73.71	1	1
5	85.35	74.25	12	84.87	84.27	73.33	1	0.3
5	81.95	76.67	13	81.63	80.44	78.39	1	1.7
5	81.6	74.67	14	81.08	80.70	75.65	1	0.5
5	80.85	79.85	15	80.37	79.93	80.76	1	0.8
5	81	76.50	16	80.41	80.14	78.14	1	0.2
5	77.25	78.67	17	76.99	75.66	78.61	1	0.9
5	75.3	78.57	18	76.21	73.64	76.14	2	1.8
5	74.8	77.67	19	75.18	73.49	76.72	1	0.4
5	74.45	79.00	20	74.56	72.33	80.03	1	0.7
5	74.05	94.00	21	73.05	69.58	82.07	1	1.7
5	72.8	76.93	22	72.64	70.48	78.49	1	0.4
5	72.1	78.42	23	72.44	69.00	80.03	1	1.4
5	71	80.85	24	71.62	68.57	78.72	1	0.4
6	96.45	90.50	1	96.06	96.16	90.63	1	0.8
6	96.7	89.80	2	95.90	96.19	89.15	1	0.6
6	97	90.00	3	96.39	96.29	90.51	1	0.5
6	96.75	90.00	4	96.35	96.29	91.42	1	0.5
6	91.8	94.45	5	91.40	92.60	93.37	1	1.7
6	90.8	90.09	6	91.54	92.00	91.19	1	1.2
6	90.7	89.90	7	91.06	91.37	92.37	1	0.7
6	90.4	94.20	8	90.34	91.96	94.04	1	0.5
6	86.15	93.73	9	86.82	88.08	95.88	1	2.1
6	85.85	98.33	10	86.03	87.90	100.32	1	0.5
6	85.35	93.82	11	85.76	87.64	98.65	1	0.5
6	85.65	99.00	12	85.53	87.28	96.59	1	0.7
6	82.15	98.91	13	82.49	84.42	100.44	1	0.7
6	80.9	97.20	14	82.23	84.06	96.72	1	0.7
6	81.15	98.20	15	80.66	83.25	100.74	1	1.3
6	81.15	101.20	16	81.56	83.56	97.87	1	1
6	77.4	98.64	17	77.95	79.71	100.94	1	1.7
6	77.15	97.10	18	76.96	78.19	99.80	1	1
6	76.55	99.78	19	76.52	78.11	98.67	1	1
6	75.95	100.00	20	76.25	77.01	98.35	1	0.6

6	75.65	100.00	21	75.47	76.61	101.18	1	1
6	75.25	100.44	22	75.03	76.31	100.63	1	0.5
6	74.75	100.30	23	74.70	75.54	100.66	1	1.1
6	74.2	100.00	24	74.08	75.14	101.51	1	1.2
7	99.05	51.57	1	97.30	96.96	52.11	1	0.2
7	98.85	51.54	2	97.02	96.57	53.05	1	0.4
7	99.05	50.67	3	96.83	96.66	51.60	1	0.1
7	98.9	51.00	4	96.92	96.53	52.19	1	0.5
7	93.25	50.77	5	92.20	92.27	53.18	1	1.1
7	92.8	54.50	6	91.88	91.99	54.00	1	0.9
7	92.15	53.18	7	90.76	91.43	53.81	1	1
7	92.05	51.73	8	90.91	91.43	53.01	1	0.4
7	88.1	55.36	9	88.32	88.87	54.94	1	1.1
7	88.35	54.36	10	88.08	88.54	54.91	1	0.8
7	87.65	52.18	11	87.47	87.69	59.69	1	1.6
7	88.75	53.69	12	88.01	88.20	53.50	1	2.2
7	83.95	55.73	13	84.49	84.37	57.49	1	2.2
7	83.9	56.69	14	84.68	84.95	55.36	1	0.8
7	81.75	55.67	15	83.42	83.34	57.60	1	2.4
7	80.65	54.92	16	81.95	82.28	55.88	1	0.6
7	73.55	62.42	17	76.66	72.81	63.53	1	1.4
7	73.15	59.67	18	76.49	74.09	61.18	2	**3**
7	71	61.85	19	72.75	68.28	62.20	2	**3**
7	71.8	63.33	20	73.97	69.28	66.77	1	1.7
7	71.3	62.46	21	72.95	68.86	62.81	1	1.1
7	69.15	63.00	22	72.65	65.00	61.26	1	1.4
7	69.9	61.20	23	71.72	67.94	62.46	1	1.3
7	68.9	69.36	24	71.11	65.00	61.64	1	2.7
8	97.25	66.00	1	98.27	98.11	65.24	1	0.5
8	96.85	66.57	2	98.13	98.20	67.62	1	0.6
8	97.35	66.00	3	97.42	97.81	68.02	1	0.3
8	97.45	68.92	4	97.70	98.12	67.13	1	0.5
8	90.75	70.09	5	90.75	91.99	71.56	1	1.5
8	90.35	72.79	6	90.99	91.76	73.34	1	0.9
8	90.4	70.55	7	92.12	92.75	69.53	1	1.7
8	90.85	72.00	8	90.20	91.20	70.25	1	1.4
8	82.8	75.46	9	85.92	86.10	78.76	1	2.5
8	84.95	75.33	10	85.86	84.56	75.68	1	2.5
8	86.3	74.36	11	87.72	86.96	71.59	1	2
8	85.65	77.67	12	87.55	87.56	76.08	1	1.1
8	82.15	71.40	13	84.67	84.32	74.75	1	1.5

8	82.65	70.78	14	84.04	83.62	73.50	1	1
8	81.5	72.40	15	83.47	83.34	74.26	1	0.9
8	80.7	71.33	16	81.78	81.25	74.89	2	2.6
8	72.65	76.00	17	71.63	65.00	80.17	1	1.7
8	71.35	80.58	18	71.13	65.00	82.97	2	2.7
8	72.05	83.50	19	69.12	65.00	82.18	1	1.8
8	70.4	84.91	20	69.57	65.00	84.71	1	2.1
8	71.35	83.93	21	69.46	65.00	82.75	1	0.7
8	71.35	83.40	22	70.24	65.00	82.83	1	1.1
8	74.55	78.86	23	69.91	65.00	77.05	1	1
8	73.25	79.86	24	72.02	65.05	82.89	1	1
9	96.7	65.85	1	95.62	96.58	66.86	1	0.6
9	97.1	63.77	2	95.88	96.88	65.21	1	0.4
9	97	65.62	3	96.03	96.73	65.62	1	0.4
9	97.15	66.08	4	95.90	96.95	66.12	1	0.3
9	91.75	71.00	5	90.43	91.79	70.02	1	0.8
9	91.4	72.33	6	89.58	91.63	74.08	1	1.1
9	90.75	72.00	7	89.80	91.06	73.49	1	0.9
9	90.2	71.00	8	89.38	91.12	73.72	1	0.6
9	86.55	80.00	9	86.13	87.97	80.69	1	1.4
9	86.6	77.92	10	85.63	87.62	80.31	1	0.8
9	85.8	87.00	11	85.23	86.83	85.22	1	1.4
9	85.95	79.82	12	84.69	86.88	79.50	1	0.5
9	82.1	87.31	13	80.44	81.99	86.46	1	2.2
9	82.65	83.00	14	81.23	82.58	82.90	1	0.9
9	82.6	84.00	15	81.62	82.97	86.75	1	1
9	81.9	88.00	16	80.91	82.00	83.93	1	0.8
9	76.35	91.00	17	74.01	73.20	90.10	2	**3**
9	76.4	93.00	18	74.39	75.02	91.93	1	1.2
9	76.45	87.29	19	74.26	75.08	89.03	1	0.8
9	75.7	92.00	20	73.78	74.65	90.72	1	1.3
9	74.65	93.73	21	72.72	72.96	92.55	1	1.2
9	74.8	92.08	22	73.24	72.61	91.84	1	1.4
9	74.15	93.92	23	71.60	72.15	95.24	1	1
9	73.75	92.00	24	71.48	71.62	94.79	1	0.8
10	97.05	85.93	1	96.43	96.87	87.01	1	0.6
10	97.4	88.62	2	96.83	97.07	87.34	1	0.8
10	97.75	88.08	3	97.33	97.04	87.31	1	0.4
10	97.4	88.50	4	97.60	97.38	88.35	1	0.4
10	91.9	85.57	5	92.56	94.25	91.05	1	1.1
10	91.8	92.33	6	92.40	94.41	89.30	1	0.4

10	91.75	92.38	7	92.41	93.89	92.49	1	0.4
10	91.4	89.85	8	91.98	93.71	89.50	1	1
10	86.7	90.42	9	88.75	91.09	92.88	1	0.8
10	86.8	92.50	10	87.90	89.21	94.98	1	0.7
10	86.95	91.69	11	88.38	90.01	94.44	1	0.4
10	86.4	88.85	12	88.47	90.57	90.13	1	0.5
10	81.45	93.36	13	83.79	86.08	95.27	1	0.8
10	81.4	92.77	14	83.54	86.22	94.57	1	1.1
10	82.4	98.15	15	83.42	87.40	96.58	1	0.8
10	82.15	99.09	16	84.26	86.11	97.36	1	0.6
10	76.4	97.00	17	79.48	83.09	100.33	1	0.9
10	76.9	95.46	18	79.21	83.70	97.22	1	1
10	75.85	96.55	19	79.39	81.68	95.62	1	0.8
10	75.75	99.25	20	79.22	83.21	102.52	1	0.7
10	74.75	98.50	21	79.05	82.58	96.81	1	1.1
10	73.65	99.27	22	78.18	80.95	101.06	1	0.8
10	73.4	99.62	23	77.45	79.68	98.18	1	1.4
10	72.6	101.83	24	76.48	81.64	105.16	1	0.8
11	96.1	66.00	1	95.76	96.07	62.30	1	0.3
11	96.05	59.83	2	95.67	95.69	57.96	1	0.4
11	96.2	63.50	3	96.08	96.32	61.26	1	0.3
11	96.45	65.55	4	95.90	96.05	63.89	1	0.5
11	87.85	74.36	5	88.63	89.28	73.61	1	1.4
11	87.4	70.50	6	87.74	88.33	75.70	1	1.1
11	86.75	69.64	7	86.72	87.72	71.01	1	0.6
11	85.85	72.25	8	85.55	86.55	72.51	1	1.1
11	83.8	78.55	9	81.91	82.49	77.06	1	2
11	82.8	75.55	10	82.67	82.87	77.32	1	1.6
11	82.3	78.73	11	81.58	82.38	78.84	1	1
11	80.9	80.31	12	81.31	81.67	78.94	1	0.9
11	75.7	87.70	13	75.75	75.84	87.69	1	0.9
11	76.4	82.91	14	74.88	74.43	84.40	1	1.3
11	74.6	86.00	15	74.04	73.71	87.48	1	0.3
11	74.7	88.18	16	73.08	73.11	87.09	1	1.6
11	74.65	86.00	17	71.67	72.00	88.24	1	1.3
11	75.1	89.60	18	71.50	70.71	89.50	1	0.9
11	75.2	83.55	19	72.99	72.15	86.26	1	1.6
11	72.1	83.00	20	71.80	70.66	84.95	1	1.3
11	100.2	60.00	21	99.18	99.06	63.45	1	0.5
11	100.1	61.60	22	99.06	99.00	60.28	1	0.3
11	100.15	60.54	23	99.15	98.96	61.12	1	0.3
11	99.9	60.67	24	99.40	99.11	60.67	1	0.5

11.2 Clinical Investigation Plan - (Separate Attachment)

IRB Protocol Title:
"Vital USA SpO2 Accuracy Comparison to Arterial Blood CO-Oximetry"

IRB Protocol #: PR 2019-353, Version: Rev 1, Date: 15 Oct 2019

Salus Independent Review Board
2111 West Braker Lane, Suite 100 Austin, TX 78758
IRB Approved Study: Salus Independent Review Board, Board 3 Review & Approval 25 Oct 2019