



Official Title: Evaluation of Masimo SET Pulse Oximetry technology and accessories During No Motion and Motion in Normoxic, Hypoxic, and Hyperoxic Conditions

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Desaturation Test Procedure

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Protocol/Test Procedure Title	Desaturation Test Procedure
Lead Investigator	Tala Harake
Other Investigators	
Expected Start Date	
Expected End Date	

Protocol Test Abstract:

This document describes a procedure for the evaluation of Masimo SET and other Pulse Oximeters during no motion and motion in normoxic, hypoxic and hyperoxic conditions.

APPROVALS

Author	Date	Engineering	Date
Tala Harake			
Quality Assurance	Date	Manufacturing	Date

PROTOCOL

Evaluation of Masimo SET Pulse Oximetry technology and accessories During No Motion and Motion in Normoxic, Hypoxic, and Hyperoxic Conditions

1 PURPOSE

This document describes a procedure for evaluating the performance of Masimo SET® and other pulse oximeters against arterial and/ or venous blood samples analyzed by laboratory analysis on a CO Oximeter during normoxic, hypoxic, and hyperoxic conditions.

[REDACTED]

[REDACTED] In addition, volunteer subjects will present with varying tolerance to the desaturation procedure and may not be able to reach the lower saturation levels.

2 BACKGROUND

Pulse oximetry noninvasively determines arterial blood oxygen saturation by comparing the absorbance of two wavelengths of light [REDACTED] during pulsatile blood flow. The use of pulse oximetry has become widespread in the intensive care settings in adult, pediatric, and neonatal applications because of the oximeter's precision and ability to noninvasively monitor oxygen saturation on a continuous basis.

[REDACTED] This protocol describes procedures to evaluate the performance of pulse oximeters under both Motion and No Motion conditions.

3 REFERENCE

FRM-3253:	Consent to Act as a Human Research Subject form
FRM-3254:	Health Assessment Questionnaire
DEO-4871A:	ISO-80601 Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
DEO-1016C:	Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff
FRM-3263:	Desaturation Recruitment Script
FRM-3264:	Advertisement
FRM-3265:	Gender and Ethnicity Form
R-FRM-2449:	Confidentiality
FRM-3255:	Case Report Form (CRF)
FRM-2336:	Clinical Study Request Form (CSRF)
FRM-3267:	Post Care Instructions

4 LOCATION

The study is to be conducted at Masimo Corporation, Irvine CA under an approved IRB Protocol. This study will be titled, "Evaluation of the Masimo SET Radical Pulse Oximeters with Masimo Signal Extraction Technology (Masimo SET®) During No Motion and Motion in Normoxic, Hypoxic, and Hyperoxic Conditions."

5 EQUIPMENT AND MATERIALS

Masimo SET Radical Pulse Oximeter

Masimo Sensors (Cleared, experimental and/ or similar to cleared device)
Masimo Patient Cables (Cleared, experimental and/ or similar to cleared device)

Light shielding bags
Conventional Pulse Oximeters (optional)
Conventional Pulse Oximeter Sensors (optional)
Conventional Pulse Oximeter Patient Cables (optional)
CO Oximeter - Radiometer OSM3 or equivalent

ECG monitor – FDA approved product
ETCO2 monitor - FDA approved product
Respiratory Rate monitor-FDA approved product
20 or 22 gauge radial arterial line - minimum of 20 required
0.5%-2% lidocaine - as required
Urine HCG pregnancy test -female subjects only
Heparin or saline flush solution (as required)- or equivalent
Standard Emergency equipment and medications will be available in the room during the study- Crash cart
A licensed Medical Doctor to be present in the room during study

6 STUDY POPULATION

- 6.1.1 Competent non-smoking adults between the ages of 18 and 45 for each series of tests.
- 6.1.2 Must weigh a minimum of 110 pounds and no more than 250 pounds unless subject is over 6 feet tall.
- 6.1.3 Eligible Subjects
 - 6.1.3.1 Subjects must understand and consent to be in the study.
 - 6.1.3.2 American Society of Anesthesiology Class 1 (Healthy subjects without any systemic disease at all).
 - 6.1.3.3 Subjects with hemoglobin greater than or equal to 11 g/dL.
- 6.1.4 Ineligible Subjects
 - 6.1.4.1 Subjects with polished, gel or acrylic nails.
 - 6.1.4.2 Subjects with damaged and/or finger nail deformities.
 - 6.1.4.3 Subjects who have had caffeine consumption the day of the study.
 - 6.1.4.4 Subjects who have taken pain medication 24 hours before the study.
 - 6.1.4.5 Subjects who have any systemic disease at all.
 - 6.1.4.6 Subjects who do not understand the study and the risks.
 - 6.1.4.7 Subjects who smoke.

- 6.1.4.8 Subjects who use recreational drugs.
- 6.1.4.9 Subjects who are pregnant or nursing.
- 6.1.4.10 Subjects having either signs or history of peripheral ischemia.
- 6.1.4.11 Subjects with open wounds, lacerations, inflamed tattoos or piercings, visible healing wounds.
- 6.1.4.12 Subjects with psychiatric conditions or are on psychiatric medications.
- 6.1.4.13 Subjects who have had invasive surgery within the past year- including but not limited to major dental surgery, gallbladder, heart, appendix, major fracture repairs (involving plates/ screws), jaw surgery, Urinary tract surgery, plastic surgery, major ENT surgery, joint replacement or gynecological surgeries.
- 6.1.4.14 Subjects who have had minor surgery or conditions in the past two months including but not limited to minor foot surgery (bunion), arthroscopic procedure, blood donation, plasma donation, skin biopsy/ procedures, root canal, fractures, eye surgery, and other minor procedures.
- 6.1.4.15 Subjects that have been on antibiotics had congestion, head colds, flu, ear infection, chest congestion will have a 2 week waiting period from the time of finishing medications or must have no more symptoms.
- 6.1.4.16 Subjects with claustrophobia, or anxiety.
- 6.1.4.17 Subjects who have been in severe car accidents or a similar type of accidents will have a 12 month waiting period, from the time of the accident.
- 6.1.4.18 Subjects who have had a concussion will have a 12 month waiting period, from the time of the concussion.
- 6.1.4.19 Subjects with chronic unresolved asthma, lung disease and respiratory disease.
- 6.1.4.20 Allergies to lidocaine, latex, adhesives, or plastic.
- 6.1.4.21 Subjects with finger deformities or injuries (specific finger will not be used).
- 6.1.4.22 Subjects with heart conditions, diabetes or hypertension.
- 6.1.4.23 Subjects with resting heart rates greater than 85BPM or below 45BPM
- 6.1.4.24 Subjects who have given birth naturally will have 6 month waiting period. Subjects who had a pregnancy terminated, a miscarriage or had a c-section will have a 12 month waiting period.
- 6.1.4.25 Others deemed ineligible by the clinical staff.

7 PROCEDURE

- 7.1.1 Calibrate the CO-Oximeter
- 7.1.2 Upon passing the screening tests, each subject will read and sign a Consent to Act As A Human Research Subject prior to being enrolled in the study. All subjects will have their medical history done at the time of the screening period. Female subjects will have a pregnancy test prior to being admitted to the study.
- 7.1.3 Subjects will be designated an alpha numeric code to identify their data. All health information and identifiable information will be stored in locked fire proof cabinets in a secured limited access room.
- 7.1.4 Standard noninvasive monitors will be placed on the subjects, including ECG, and ETCO2.
- 7.1.5 After a positive Allen's Test, radial arterial line and/ or a venous will be placed on one arm using aseptic technique and 0.5 - 2% lidocaine for local anesthesia.
- 7.1.6 Sensor Location
 - 7.1.6.1 There may be [REDACTED] pulse oximeters or other Masimo devices used during any one test. In general the sensors will be placed on fingers, but may also be placed on the face, nose, head, ears, neck, chest, toes, arms, hands, fingers, forehead, stomach, back, legs and feet.
 - 7.1.6.2 The appropriate sensor being tested will be applied to the volunteer's finger or other appropriate location. [REDACTED]

7.1.6.3 Where necessary each of the sensors will be covered with a light shielding bag to prevent optical cross-talk between the sensors.

7.1.7 Arterial and/ or venous blood samples will be drawn as baselines and during the procedure at different saturation levels [REDACTED]

7.1.8 At any point in the study, if the subject feels uncomfortable, the subject will be given 100% oxygen and the study stopped.

7.1.10 Continuous pulse oximeter readings, using on-line computer data collection, will be done for all parts of the study. The sampling points of the ABG's will be noted into the on-line computer.

7.1.11 Emergency equipment and medications will be available in the room during the study. Clinical personnel will monitor Subject safety using FDA approved instruments not involved in the study.

7.1.12 No Motion Study

In the case of a non-motion study the subject will be taken to different saturation levels while [REDACTED] blood draws are collected. [REDACTED]

[REDACTED]

[REDACTED]

7.1.13 Motion Study

In the case of a motion study, [REDACTED] will simulate [REDACTED] motion during the saturation levels of the procedure. [REDACTED]. The subject will be taken to different saturation levels while [REDACTED] blood draws are collected.

[REDACTED]

7.1.14

[REDACTED].

[REDACTED]

7.1.14.2 At least one minute after the motion begins, [REDACTED] blood gas samples will be taken [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- 7.1.15 The study will continue similar to a No Motion study with a series of lower levels of saturation
- 7.1.16 At the end of the study, the volunteer will be given a FiO₂ greater than that of room air
- 7.1.17 The sensors and the arterial line will be removed and the volunteer will be allowed to leave after medical personnel determine it is safe to do so.

8 DATA ANALYSIS PROCEDURE TO BE USED

- 8.1.1 The saturation measurements are to be analyzed for Bias, Precision and RMS accuracy as defined by ISO-80601 with respect to the Co-Oximeter readings. Bland Altman plots and analysis by SaO₂ range and By Subject will be calculated.

9 ACCEPTANCE CRITERIA

- 9.1.1 As defined by the Product Design Requirements document for the device under test.

10 POSSIBLE RISKS OR DISCOMFORTS

- 10.1.1 Low oxygen concentration
 - 10.1.1.1 It is expected that some people will hyperventilate, become dizzy, nauseous, throw-up or become short of breath. If or when this occurs, the study can be stopped. There is also a risk of drowsiness and headache.
 - 10.1.1.2 In the very unlikely worst case, lack of oxygen could cause a person to black out or to die. The study shall be stopped by you or us long before this could occur.
 - 10.1.1.3 The listed discomforts and risks associated with low oxygen concentrations can be expected and are not related to the sensors or devices used in the study.
- 10.1.2 Sensor Burn
 - 10.1.2.1 There is a remote, yet possible, risk of a burn from the sensor.
- 10.1.3 Venous Line Placement & Venous Puncture
 - 10.1.3.1 The most common complications associated with venous puncture and venous line placement (IV) are hematomas or bruising, which occur in approximately 50% of people who have a venous blood draw or an IV line placed.
 - 10.1.3.2 Insertion of the IV may be discomforting and can hurt like drawing blood sample. Although local anesthetics will be used, it may not ease the discomfort of the IV. The discomfort may last for up to 48 hours.
 - 10.1.3.3 The listed discomforts and complications associated with the venous line (IV) placement can be expected and are not an act of neglect, failure to follow standards or related to the sensors or devices used in the study.
- 10.1.4 Arterial Line Placement & Arterial Puncture
 - 10.1.4.1 The most common complications associated with arterial line placement are hematomas or bruising, which occur in approximately 50% of people who have an arterial line placed.
 - 10.1.4.2 Other potential risks include thrombosis (blood clot), limb ischemia (decreased blood supply), infection, nerve injury, and embolization (blocking of an artery by a blood clot or air). However, these risks are rare (less than 0.1%) in subjects with an arterial catheter in place for two hours or less.
 - 10.1.4.3 Insertion of the arterial line may be more discomforting than the IV. It can hurt like drawing a blood sample. Although local anesthetics will be used, it may not ease the discomfort of the arterial line. The discomfort may last for up to 48 hours.

The listed discomforts and complications associated with the arterial line placement can be expected and are not an act of neglect, failure to follow standards or related to the sensors or devices used in the study.