Official Title: MightySat - Clinical Performance Comparison Study

Date of Protocol: June 20, 2017

NCT Number: NCT03239574

Protocol/Test Procedure Title	MightySat – Clinical Performance Comparison Study
Lead Investigator	[redacted]
Other Investigators	
Expected Start Date	
Expected End Date	

Protocol Test Abstract:

This study compares the performance of Respiratory rate from pleth (RRp) measured prospectively with MightySat device against capnography, Rainbow Acoustic Monitoring (RAM) Respiratory rate (RR) and manual annotation in healthy adult subjects.

APPROVALS

Author	Date	Engineering	Date
[redacted]	[redacted]		
Quality Assurance	**Date**	**Manufacturing**	**Date**

1 PURPOSE

The objective of this study is to compare the noninvasive RRp performance of the Masimo MightySat device against the RR measured by capnography, Masimo's RAM technology and the manual annotation. All of the devices are noninvasive and data will be collected from healthy volunteers.

This is a nonrandomized single arm study where all of the subjects are enrolled into the experimental arm and receive the MightySat device on their index finger along with a RAM sensor on their neck, a pulse oximeter on their other index finger, and a nasal cannula which will be attached to the capnography device.

Outcome Measure: Comparison of MightySat, capnography, rainbow acoustic monitoring and manual annotation of RR by ARMS calculation.

2 BACKGROUND

Masimo Corporation develops non-invasive medical technologies. These devices have applications in the operating room, critical care unit, emergency room, emergency transport vehicles, as well as physician's offices.

Recording respiratory rate is considered standard for monitoring patients. However, measurement frequency and documentation of respiratory rate is often poor and inaccurate. Respiratory rate is difficult to assess and often is not even recorded in the patient record. This is in spite of the fact that elevated respiratory rate is one of the best predictors of respiratory deterioration, cardiac arrest, and admission to the intensive care unit (ICU). Our Masimo MightySat and RAM technologies allows for real-time, non-invasive monitoring of respiratory rate in patients and has the potential to improve clinical outcomes while reducing the cost of care and risks to patients.

Respiratory rate can be determined by the plethysmographic waveform. This method measures respiration per minute (rpm) based on plethysmgraphic amplitude changes that correspond to the respiratory cycle.

Literature Review:

Accuracy of a Novel Bioacoustic Sensor in Adult Postoperative Patients. Macknet MR, Kimball-Jones PL, Applegate RL, Martin RD, Allard MW. Anesthesiology. 2007;107:A 83.

Accuracy of a Novel Bioacoustic Sensor in Pediatric Postoperative Patients. Macknet M, Kimball-Jones P, Applegate R, Martin R, Allard M. Presented at the 17th Annual Meeting for Society for Technology in Anesthesia, January 17-20, 2007.

Recording system and data fusion algorithm for enhancing the estimation of the respiratory rate from photoplethysmogram. Cernat RA, Ciorecan SI, Ungureanu C, Arends J, Strungaru R, Ungureanu GM. Conf Proc IEEE Eng Med Biol Soc. 2015;2015:5977-80. doi: 10.1109/EMBC.2015.7319753. PubMed PMID: 26737653.

3 REFERENCE

[redacted]

Consent 18 years and greater
Recruitment Script
Web Ad
Health Questionnaire
Confidentiality Agreement
Case Report Form
Gender and Ethnicity Questionnaire

[redacted] Device Accountability Log
Protocol Deviation Report
Adverse Event Form
[redacted]
Investigator's Brochure for MightySat

4 LOCATION

Masimo Corporation
52 Discovery
Irvine, CA 92618

5 EQUIPMENT, MATERIALS AND SAMPLE SIZE JUSTIFICATION

5.1 EQUIPMENT AND MATERIALS

[redacted]	Radical7 2012 or equivalent
[redacted]	RAM Dual Cable LNC-10 or equivalent
[redacted]	Acoustic Respiration Monitoring (RAM) Sensor or equivalent
[redacted]	Pulse oximeter or equivalent
[redacted]	Investigational MightySat (modified per [redacted])
NA	Data Collection Laptop, Software and other equipment as necessary to record the data
NA	Capnography device, [redacted] or equivalent
NA	Nasal cannula (capnography accessory)

5.2 STUDY DEVICES

Investigational Device:

- MightySat pulse oximeter– [redacted] The device has undergone risk assessment prior to use in human subjects to safeguard subject safety and well-being [redacted]

Control Devices:

- Masimo FDA-cleared RAM cloth sensor
- Masimo FDA-cleared Radical-7 pulse oximeter or equivalent
- FDA-cleared [redacted] Capnography device

5.3 Inclusion/Exclusion Criteria

Inclusion Criteria

- 18 to 45 years old
- Physical status of ASA I or II
- Must be able to read and communicate in English
- Has signed all necessary related documents, e.g. written informed consent, confidentiality agreement.
- Passed health assessment screening

- Negative pregnancy test for female subjects of child bearing potential.

Exclusion Criteria

- Age < 18 years old or > 45 years old
- ASA physical status of III, IV, and V
- Subject has any medical condition which in the judgment of the investigator, renders them inappropriate for participation in this study
- Inability to tolerate sitting still or minimal movement for at least 30 minutes
- Positive pregnancy test for female subjects
- Refusal to take pregnancy test for women of child bearing potential
- Nursing female subjects
- Refusal of male subjects to agree to shave hair off areas where sensors will be applied (neck) when deemed necessary
- Excluded at the Principal Investigator's discretion

Withdrawal and Replacement of Subjects

Subjects must be withdrawn under the following circumstances:

- The subject withdraws consent or assent
- Serious adverse event
- Discretion of investigator
- Malfunction of the device for greater than 10 minutes

In the case a subject is withdrawn from the study, another may be recruited.

5.4 Sample Size Justification

[redacted]

6 PROCEDURES

6.1 Advertisement and Recruitment

[redacted]

6.1.1 Subjects will be recruited using IRB-approved advertisements. Our Web Ad [redacted] will be posted publically on [redacted] websites. Subjects may also be referred to the study by previous volunteers.

6.2 Phone Screening

6.2.1 Once the potential subject sees the recruitment material (i.e. Web Ad), they contact our clinical schedulers to inquire more about details about the screening. The recruitment process is taken care of by the designated clinical staff who are trained for screening/scheduling.

6.2.2 Appointments are made once the phone screening process is completed and the person screening the subject determines if they qualify or not for the screening based on the Recruitment Script [redacted]

6.2.3 If the person does not qualify at this time their information will not be kept.

6.3 Consent Process

6.3.1 Have each subject read and sign the correct forms set below. The consent form must be stamped with current IRB approval. No study related activities will be conducted until the correct document is signed.

6.3.2 Have each subject complete [redacted]- Confidentiality Agreement

6.4 Screening

6.4.1 Have each subject complete [redacted] – Health Assessment Questionnaire.

6.4.2 Female volunteers of child bearing potential will be required to take a pregnancy test as part of screening. A positive pregnancy test will disqualify them from the study. A negative pregnancy test qualifies them for the study.

6.5 Study Procedure

6.5.1 Have each subject complete [redacted] – Gender and Ethnicity Questionnaire

6.5.2 Have subject at rest, sitting in a dental chair.

6.5.3 Apply the MightySat device onto the subject's index finger. Apply the RAM sensor onto the subject's neck and a pulse oximeter onto the subject's other index finger. A flexible tube called a nasal cannula will be put in their nose. In some cases, it may be required for subjects to shave their neck hair for the purpose of applying an adhesive sensor with their consent. The study starts once the first sensor is placed.

6.5.4 Photos may be taken of sensor placement. Photos may only be taken with the subject's consent. All photos will be de-identified and will not show the subject's face.

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

6.5.6 Subjects may stop the study at any time.

6.5.7 Non-disposable devices will be sanitized after each subject completes the study.

6.5.8 Data collected in this study may be used in the future for product development and/or applications to the FDA or other regulatory agencies.

6.6 Discontinuation

In the event that a study is discontinued prior to completion, whether it is due to the investigator's discretion or the subject's request, the subject will be paid for their time according to the Financial Compensation chart below in the Appendix H – Financial Compensation.

6.7 Protocol Deviation

If there is a protocol deviation it shall be recorded on the Case Report Form [redacted] The Protocol Deviation Report [redacted] shall also be completed.

7 ACCEPTANCE CRITERIA (IF APPLICABLE)

The MightySat device will be determined to have comparable performance and should meet the acceptable limit of ≤ 2.0 RPM A_{RMS}.

8 DATA ANALYSIS PROCEDURE TO BE USED

Statistical Analysis:

Accuracy will be reported as the A_{RMS} using the following equation:

$$Bias = \frac{1}{n}\sum_{i=1}^{n}(RRp - RR)$$

$$\text{Precision} = \sqrt{\frac{\sum_{i=1}^{n}(\,(RRp - RR) - Bias)^2}{n}}$$

$$A_{RMS} = \sqrt{\frac{\sum_{i=1}^{n}(RRp - RR)^2}{n}}$$

*RR is the manual annotation

APPENDICES

A. DEVICE ACCOUNTABILITY

Device accountability will be logged on the Device Accountability Log [redacted] Devices shall also be recorded on the Case Report Form [redacted] for each subject.

B. DEVICE DEFICIENCY

If there is a device deficiency during the study, it will be documented on the Case Report Form

C. AMENDMENTS TO THE PROTOCOL

[redacted]The amended protocol shall be submitted through Masimo's documentation process. IRB approval is necessary prior to implementation of the amended protocol.

D. ADVERSE EVENTS

Definitions:

Adverse event: Any untoward medical occurrence in a subjects, users or other persons, whether or not related to the medical device under study.

Device-related adverse event: Adverse event related to, associated with, or caused by, the use of a medical device under study, including but not limited to events that may have been attributed to the device because of device failure or malfunction, improper or inadequate design, manufacture or user error.

Device deficiency: Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors and inadequate labeling.

Serious adverse event: Adverse event that: a) led to death, b) led to serious deterioration in the health of the subject, that resulted in: (i) a life-threatening illness or injury, (ii) a persistent or significant impairment of a body structure or a body function, (iii) in-patient or prolonged hospitalization, or (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, or c) led to fetal distress, fetal death or a congenital abnormality or birth defect. NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without serious deterioration in health, is not considered a serious adverse event.

D.1 Adverse Events

All devices used in the study are non-significant risk devices. All study procedures are noninvasive. In the unlikely event that an adverse event should occur, it will be reported and documented as described below.

All adverse events that occur during the study shall be recorded on the Case Report Form. The Adverse Event Form [redacted] shall also be completed.

Skin irritation/redness from the adhesive is an anticipated adverse event.

D.2 Serious and Unanticipated Adverse Events

The investigator shall promptly report to the IRB within 24 hours any serious and unanticipated adverse event involving subjects.

At the time of discharge from the study, an unresolved serious and unanticipated adverse event(s) will be followed up by the investigator until the event(s) are resolved, stabilized, or the patient is unable to follow-up or the adverse event is otherwise explained. The investigator will also instruct the subject to report any subsequent events occurring in the next 30 days, which the subject or the

subject's physician believes might reasonably be regarded as caused by or have a reasonable possibility of being caused by the test device or procedures involved in the study.

E. MEASURES TAKEN TO PROTECT THE RIGHTS AND WELFARE OF SUBJECTS

E.1 All subjects will be monitored closely throughout the study.

E.2 The following measures will be taken to insure the privacy of the subjects:

E.2.1 An identification number (code) for each subject will be kept on file.

E.2.2 Only their corresponding number will identify subjects.

E.2.3 Access to identifying documents and data will only be made to the investigators in the study.

E.2.4 The confidentiality and retention of these documents will be protected to the extent provided and required by the law.

E.3 Documents and Database:

E.3.1 Documents will be kept a minimum of 5 years after the specific product/tested for is no longer being made. If destroyed, these documents will be shredded and done by a certified company used for destroying medical and clinical data.

[redacted]

E.4 Vulnerable Population

E.4.1 Employees are considered to be a vulnerable population.

E.4.1.1 Participation is not a condition of employment. There will be no repercussions in the workplace in the case that the employee refuses to participate in the study or withdraws at any point during the study

E.4.1.2 Neither supervisors nor superiors will be involved in the recruitment of employees for participation in the study.

E.4.2 Economically disadvantaged or unemployed and educationally disadvantaged.

E.4.2.1 Reasonable compensation will be provided for economically disadvantaged subjects to eliminate the possibility of undue influence due to financial incentive.

E.4.2.2 Educationally disadvantaged subjects will be provided ample time to ask questions and comprehend information.

F. RISKS/DISCOMFORT

F.1 Risks can be categorized into the following categories:

- Risks associated with the devices and sensors
- Risks associated with disclosure of confidential information

F.2 Device Risks: "Devices and Sensors"

- *See* [redacted], *Radical-7 Operator's Manual*
- *See* [redacted], *MightySat Fingertip Pulse Oximeter Operator's Manual*
- [redacted]
- [redacted] *MightySat Investigator's Brochure*
- Risks of skin irritation from the adhesives. Additionally any adhesive may leave a temporary mark on the subject's skin.

F.3 Risk of disclosure of Confidential Information:

- There is minimal risk to the privacy of the subject because access to study data will be kept in a secure location and limited to study personnel and to others legally authorized to view it.

G. BENEFITS

There would be no other benefit to the subject. Other possible benefits would be to society as a whole.

H. FINANCIAL COMPENSATION

Subjects will be compensated for the time and discomfort involved in study participation according to the chart below.

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

I. STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study sponsored by Masimo Corporation. The study will be conducted in compliance with all stipulations of this protocol, the conditions of IRB approval, 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 812, ISO-14155, and International Conference on Harmonization Good Clinical Practice (ICH GCP).

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.