Official Title: INVSENSOR00011 Clinical Performance Study

Date of Protocol: December 5, 2017

NCT Number: NCT03641937

Protocol/Test Procedure Title	INVSENSOR00011 Clinical Performance Study
[redacted]	[redacted]
Other Investigators	
Expected Start Date	
Expected End Date	
IRB	E&I West Coast Board – IRB00007807

Protocol Test Abstract:

This study assesses the investigational sensor's (INVSENSOR00011) performance for detection of subjects' position and posture in bed, along with [redacted] respiratory rate.

APPROVALS

Author	Date	Engineering	Date
[redacted]	11/14/2017		
Quality Assurance	**Date**	**Manufacturing**	**Date**

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, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 812, ISO-14155, and International Conference on Harmonisation E6 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.

1. PURPOSE

The objective of this study is to assess INVSENSOR00011's clinical performance for detection of a subject's position and posture in bed, subject's activity (sitting, standing, etc.) [redacted] and respiratory rate. Only noninvasive sensors and corresponding devices will be employed to collect data from healthy volunteers in this study.

This is a nonrandomized single arm study where all of the subjects are enrolled into the experimental arm and will receive the INVSENSOR00011 device on their chest or back, along with a RAM (Rainbow Acoustic Monitoring) sensor on their neck, a pulse oximeter on their finger, and a nasal cannula which will be attached to the capnography device.

Outcome Measure: Assess the clinical performance of the detection of position, posture and activity through comparing INVSENSOR00011 measurements to observer's notes. Assess INVSENSOR00011's [redacted] respiratory rate measurements through comparison with those from [redacted] RAM.

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.

2.1. Background and Rationale

People with the most risk of developing bedsores are those with a medical condition that limits their ability to change positions, requires them to use a wheelchair or confines them to a bed for a long time.

Bedsores can develop quickly and are often difficult to treat. Automated detection of patients' position can help medical staff monitor position to time and optimize interventions. Masimo has developed a new noninvasive sensor named INVSENSOR00011 as a device to aid in preventing hospital-acquired pressure injury or worsening of existing pressure injury by monitoring patient movement, position, and orientation. The sensor is also able to detect falls through the same monitoring features. This type of monitoring may be effective in reducing the debilitating conditions for patients and their duration of stay in hospitals, especially in the patient population vulnerable to pressure and/or fall related injuries.

Each year over 2.5 million individuals in the U.S. develop a pressure injury [1]. Pressure injuries are painful, debilitating and are usually avoidable. Routine repositioning relieves and redistributes pressure over bony prominences; it is a recommended procedure to help mitigate the risks for developing a pressure injury [2]. The INVSENSOR00011 device, through detection of patient position, is a modality to ensure repositioning occurs routinely.

As many as 1 million Americans fall in the hospital every year. Falls result in fractures, lacerations, bleeding and even death. Current practices to prevent falls include assessment of patient risk, scheduled rounding practices and patient specific interventions to prevent falls [3]. The INVSENSOR00011 device is proposed to supplement current practices with a unique modality to assess risk for fall based on patient position.

The INVSENSOR00011 system consists of a wearable, battery-operated, adhesive sensor and a back-end user interface and display at the patient bedside as well as a central location (e.g., nursing station). The sensor contains sensing elements (accelerometers, gyroscopes), processor, and a blue-tooth communication chip (BTLE 2.4 GHz). An algorithm processes three-dimensional acceleration and rotation information and calculates the patient's relative position and fall [redacted] and respiration rate as its key parameters. Position related parameters are then combined over a given time period to compute trend and potential risk for pressure injury. The system can generate alarms configured for adverse events related to patient posture, stress level for pressure injury and detected fall events.

Literature Review:

1. Berlowitz, et al. (2014). Preventing pressure ulcers in hospitals: A toolkit for improving quality of care. Retrieved http://www.ahrq.gov/sites/default/files/publications/files/putoolkit.pdf
2. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Ulcer Injury Alliance. Prevention and treatment of pressure ulcers: Quick reference guide. Emily Haesler (Ed.). Cambridge Media: Perth, Australia; 2014
3. Ganz, DA, Huang, C, Saliba D, et al. Preventing falls in hospitals: A toolkit for improving quality of care. (Prepared by RAND corporation, Boston University School of Public Health, and ECRI Institute under Contract No. HHSA2902010000171 TO#1). Rockville, MD: Agency for Healthcare Research and Quality; January 2013. AHRQ Publication No. 13-0015-EF.

2.2. Study Devices

2.2.1. Investigational Devices and Sensors:

2.2.1.1. INVSENSOR00011 sensor is an investigational, non-invasive sensor that measures signals regarding patient's movement and posture [redacted] and respiratory rate. This sensor has undergone a risk assessment prior to use in human subjects to safeguard their safety and well-being. [redacted]

2.2.1.2. Root® is a noninvasive monitoring platform. [redacted]

2.2.2. FDA cleared Sensors and Devices:

- Masimo FDA-cleared Radical-7
- Masimo FDA-cleared RAM cloth sensor
- Masimo FDA-cleared pulse oximeter sensor
- Masimo FDA-cleared RAM dual cable

[redacted]

3. REFERENCE

3.1.1.	[redacted]	Rev. A	Consent 18 years and greater
3.1.2.	[redacted]	Rev. A	Recruitment Script
3.1.3.	[redacted]	Rev. A	Web Ad
3.1.4.	[redacted]	Rev. A	Health Questionnaire
3.1.5.	[redacted]	Rev. A	Gender and Ethnicity Questionnaire
3.1.6.	[redacted]	Rev. A	Confidentiality Agreement
3.1.7.	[redacted]	Rev. A	Case Report Form
3.1.8.	[redacted]		Device Accountability Log
3.1.9.	[redacted]		Protocol Deviation Report
3.1.10.	[redacted]		Adverse Event Form
3.1.11.	[redacted]		Clinical Study Request Form

4. LOCATION

Masimo Corporation
Clinical Laboratory
52 Discovery
Irvine, CA 92618

The Masimo Clinical Laboratory facility is designed as a Phase 1 clinical study research center. All personnel undergo routine required training on GCP and human subject research protections. The laboratory is equipped with standard FDA-approved medical monitoring equipment. Hospitals and urgent care facilities are within three miles of Masimo Clinical Laboratory.

5. STUDY POPULATION

5.1. Inclusion Criteria

- 18 to 80 years old
- Physical status of ASA I or II
- Subjects must be able to read and communicate in English
- Has signed all necessary related documents, e.g. written informed consent, health assessment questionnaire, gender and ethnicity form, confidentiality agreement
- Passed Health Assessment Screening

5.2. Exclusion Criteria

- 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
- Nursing female volunteers
- Excluded at the Principal Investigator's discretion
- Refusal to take the pregnancy test (for female subjects)
- Positive pregnancy test for female subjects of child bearing potential. This is done for the safety of this population.
- Refusal to shave hair (neck, chest) off areas where sensors will be applied (male subjects)

5.3. Withdrawal of Subjects

Subjects must be withdrawn under the following circumstances:

- The subject withdraws consent
- Non-verbal consent withdrawal
- Serious adverse event
- Discretion of investigator
- Malfunction of the device for greater than 10 minutes

6. EQUIPMENTAND MATERIALS

Equipment and Materials: All lab equipment will be maintained per manufacturer specifications and all study personnel will be trained on the use of relevant equipment.

Test Devices:

- INVSENSOR00011
- Root [redacted]

Control Devices:

- Masimo Radical-7
- Masimo pulse oximeter sensor
- Masimo RAM sensor

[redacted]

Research Equipment:

- Data Collection Laptop, software and other equipment as necessary to record the data

7. PROCEDURES

7.1. Advertisement and Recruitment

7.1.1. Our Web Ad [redacted] will be posted publically on craigslist or similar websites.

7.2. Phone Screening

[redacted]

7.2.1. Once the potential subject sees the recruitment material (i.e. Web Ad), they contact our clinical schedulers to elicit more details about the screening. The phone screening is handled by designated clinical staff that is trained for screening/scheduling.

7.2.2. Appointments are made once the phone screening process is completed and the person screening the subject determines they qualify for screening based on the Recruitment Script [redacted]

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

7.3. Consent Process.

7.3.1. Have each volunteer read and sign the correct forms which include the consent form [redacted] Gender and Ethnicity Questionnaire [redacted] and Confidentiality Agreement [redacted] The consent form must be stamped with current IRB approval. No study related activities will be conducted until consent is signed.

7.3.2. Subject demographic information including age, gender, height, weight, and ethnicity may be collected. In addition, a brief medical history and vital signs may be recorded.

7.4. Screening:

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

7.4.2. 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.

7.4.3. If the subject does not pass screening, he/she will be compensated [redacted] for travel.

7.5. Study Procedure

7.5.1. Apply sensors. [redacted]

7.5.2. [redacted]

7.5.3. [redacted]

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

7.5.4. All enrolled subjects will be paid after the completion of the study with no additional compensation for travel. Subjects who do not complete the study will be paid with no additional compensation for travel.

7.5.5. In case of an error in following the instruction set, subject can repeat the missed steps.

7.5.6. Subjects may stop the study at any time.

7.5.7. Data collected in this study may be used in the future for product development, publications, and/or submissions to the FDA or other regulatory agencies.

7.6. Discontinuation

7.6.1. 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, refer to Section 7.5.4.

7.7. Protocol Deviation

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

8. ACCEPTANCE CRITERIA (IF APPLICABLE)

There are no acceptance criteria.

9. SAMPLE SIZE JUSTIFICATION AND DATA ANALYSIS PROCEDURE TO BE USED

9.1. Sample Size Determination

In each subject, the protocol induces at least five position changes during the study. To assess INVSENSOR00011's detection capability, the device output will be compared against observer's notes for each change. Assuming a sample size N = 30, there will be at least 150 independent data points collected, which will be used for validation. This data will be enough for calculating sensitivity and specificity of the position detection algorithm.

9.2. For heart rate and respiration rate comparison, the study does not have an accuracy requirement to meet. However, INVSENSOR00011's heart rate and respiration rate measurements will be compared against reference measurements for an assessment. N=30 is deemed sufficient for a qualitative assessment of performance.

9.3. Statistical Analysis

9.3.1. For each subject's position detection, INVSENSOR00011 output will be compared against observer's notes at each turn of the subject.

9.3.2. Correctly detected position changes will be marked as True Positive.

9.3.3. Missed detections (if any) will be counted.

9.3.4. Combining the two, sensitivity of INVSENSOR00011's posture change detection will be computed as Sensitivity = True Positive/(True Positive + Missed Detection)

9.3.5. From the INVSENSOR00011's output, all false positives will be counted, i.e., when a turn is indicated by INVSENSOR00011 but the observer's notes do not agree with that. These will present a measure of specificity of the device.

9.3.6. Heart rate readings from INVSENSOR00011 will be compared against reference pulse-rates to compute mean and standard deviation of the differences.

9.3.7. Respiration rate readings from INVSENSOR00011 will be compared against reference respiration rate to compute mean and standard deviation of the differences.

9.4. Expected Dropout Rates

Subjects may not complete the study for various reasons, such as a clinical screening test failure, at the Principal Investigator's discretion, or because the subject does not want to continue the study. Expected dropout rate for this study is approximately 0% of the total number of subjects enrolled.

10. 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.

If there is a device deficiency during the study, it will be documented on the Case Report Form, [redacted] and it will be reported according to department procedures.

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.

10.1 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 or redness from the adhesive are anticipated adverse events.

10.2 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.

10.3 Unanticipated Problems

Any unanticipated problems involving subjects will be reported to the IRB, such as protocol violations or deviations as required by the IRB reporting procedures.

11. SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

11.1. Measures Taken to Protect the Rights and Welfare of Subjects

11.1.1 All subjects will be monitored closely throughout the study.

11.1.2 The following measures will be taken to insure the privacy of the subjects:

11.1.2.1 Information about the patients will be kept confidential.

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

11.1.2.3 The study documents will only contain the subject's corresponding identification number except in the Informed Consent Document.

11.1.2.4 Access to identifying documents and data will only be granted to the investigators in the study.

11.1.2.5 Study data that will be released to Masimo and other regulatory authorities will be de-identified and will only pertain to study data collection, demographics, sensor placement locations and recordings from devices.

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

11.2 Vulnerable Populations

11.2.1 Employees are considered to be a vulnerable population.

11.2.1.1 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.

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

11.2.2 Economically disadvantaged or unemployed and educationally disadvantaged.

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

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

11.3 Documents and Database

11.3.1 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.

11.3.2 [redacted]

12. DEVICE ACCOUNTABILITY

12.1. Receipt of Study Device

Upon receipt of the study device supplies, an inventory must be performed and the Device Accountability Log [redacted] filled out and signed by the person accepting the shipment. It is important that the designated study staff counts and verifies that the shipment contains all the items noted in the shipment inventory. Any damaged or unusable study devices in a given shipment will be documented in the study files.

12.2. Use of Study Device

Use of devices and sensors will be documented on Case Report Forms for each subject.

13. RISKS AND BENEFITS

13.1. Benefits

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

13.2. Device Risks

[redacted]

Risks of skin irritation or redness to adhesives. Additionally any adhesive may leave a temporary mark on the subject's skin.

13.3. Risks associated with 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.

13.4. Risks associated with study procedures

[redacted]

There is minimal risk. The study procedures involve the subject changing their position in and getting out of bed.

14. EMERGENCY RESPONSE PLAN FOR MEDICAL EMERGENCIES

A crash cart is on site and emergency services are available within a 3 mile radius of the facility.

15. MONITORING PLAN

A separate document for the study monitoring plan will be developed and followed to ensure subject safety and GCP compliance.

16. PROTOCOL DEVIATIONS AND AMENDMENTS

Deviations from the protocol will be documented on the Case Report Form or a separate document. Protocol deviations will be reported to the sponsor and IRB per IRB reporting guidelines.

Modifications to the protocol, informed consent materials, recruitment materials, or any other materials provided to subjects must be reviewed and approved by the IRB.