Official Title: INVSENSOR00027 Fall Detection Clinical Performance Study

Date of Protocol: Dec. 3, 2019

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Protocol/Test Procedure Title	INVSENSOR00027 Fall Detection Clinical Performance Study
[redacted]	[redacted]
Other Investigators	N/A
Expected Start Date	N/A
Expected End Date	N/A
IRB	E&I West Coast Board – IRB00007807

Protocol Test Abstract:

This study assesses the investigational sensor's (INVSENSOR00027) fall detection performance.

APPROVALS

Author	Date	Engineering	Date
[redacted]			
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 INVSENSOR00027's fall detection clinical performance in healthy volunteers.

This is a nonrandomized single arm study where all of the subjects are enrolled into the experimental arm and will receive the INVSENSOR00027 device on their chest.

Outcome Measure: Assess the fall detection clinical performance.

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

Masimo has developed a new noninvasive sensor named INVSENSOR00027 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 fall related injuries.

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 [1]. The INVSENSOR00027 device is proposed to supplement current practices with a unique modality to assess risk for fall based on patient position.

The INVSENSOR00027 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 [redacted] processor, and a blue-tooth communication chip (BTLE 2.4 GHz). An algorithm [redacted] and calculates the patient's relative position and fall, heart rate and respiration rate as its key parameters. [redacted]

Literature Review:

1. 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. INVSENSOR00027 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]

3. REFERENCE

3.1.1.	[redacted]	Consent To Be A Research Subject
3.1.2.	[redacted]	Recruitment Script
3.1.3.	[redacted]	Web Ad
3.1.4.	[redacted]	Health Questionnaire
3.1.5.	[redacted]	Confidentiality Agreement
3.1.6.	[redacted]	Case Report Form
3.1.7.	[redacted]	Volunteer Payment 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. EQUIPMENT, MATERIALS AND SAMPLE SIZE JUSTIFICATION

5.1. Equipment and 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:

- INVSENSOR00027
- Root [redacted]
- Data Collection Laptop, software and other equipment as necessary to record the data

5.2. Sample Size Justification

5.2.1. STUDY POPULATION

Inclusion Criteria

- 18 to 45 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, volunteer payment form, confidentiality agreement
- Has completed Health Assessment Questionnaire and passed health assessment screening

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 physical activities including jumping and fall simulation
- 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 (chest) off areas where sensors will be applied (male subjects)

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

We apply the following model to determine minimum data points needed for sensitivity calculation.

[redacted]

6. PROCEDURES

6.1. Advertisement and Recruitment

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

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 elicit more details about the screening. The phone screening is handled by designated clinical staff that is trained for screening/scheduling.

6.2.2. 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]).

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 volunteer read and sign the correct forms which include the Consent form ([redacted]), Confidentiality Agreement ([redacted]), and Volunteer Payment Form ([redacted]). The consent form must be stamped with current IRB approval. No study related activities will be conducted until consent is signed.

6.4. Screening:

6.4.1. Have each subject complete [redacted] – Health Assessment Questionnaire. Subject demographic information including age, gender, height, weight, Massey scale, and ethnicity may be collected.

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.

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

6.5. Study procedure

6.5.1. Apply sensors. INVSENSOR00027 sensors will be placed [redacted] The study starts once the sensor is placed.

[redacted]

6.5.4. In the event the subject fails screening, he/she will be compensated [redacted] for travel.

6.5.5. If the subject passes screening and participates in the study, they will not receive travel compensation and will be paid [redacted] for completing the study. Subjects may stop the study at any time. If the subject withdraws from the study any time after the placement of the sensors, he/she will be paid [redacted]

6.5.6. 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.

6.6. Discontinuation

6.6.1. 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 [redacted]

6.7. Protocol Deviation

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

7. ACCEPTANCE CRITERIA (JUSTIFY IF NOT APPLICABLE)

[redacted]

8. DATA ANALYSIS PROCEDURE TO BE USED

8.1. For each subject's [redacted], INVSENSOR00027 output will be computed

8.2. 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.

9. 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.

9.1. 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 Report Form [redacted] shall also be completed.

Skin irritation or redness from the adhesive are anticipated adverse events.

9.2. 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.

9.3. 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.

10. SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

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

10.1.1. All subjects will be monitored closely throughout the study.

10.1.2. The following measures will be taken to ensure the privacy of the subjects:

10.1.2.1 Information about the patients will be kept confidential.

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

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

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

10.1.2.5 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.

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

10.2. Vulnerable Population

10.2.1. Employees are considered to be a vulnerable population.

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

10.2.2. Economically disadvantaged or unemployed and educationally disadvantaged.

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

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

10.4. Documents and Database

10.4.1. 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.

10.4.2. Documents and information stored electronically will be protected using a multi-faceted procedures included, but not limited to, the following steps:

[redacted]

10.5. Device Accountability

10.5.1. **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.

10.5.2. **Use of Study Device**

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

11. RISKS AND BENEFITS

11.1.1. Benefits

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

11.1.2. Device Risks

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

11.1.3. 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.

11.1.4. Risks associated with study procedures

[redacted]

11.1.5. 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.

11.1.6. MONITORING PLAN

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

11.1.7. 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.

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