

Official Title: Clinical Performance of Masimo INVSENSOR00048

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Clinical Investigation Title: Clinical Performance of Masimo INVSENSOR00048

Clinical Investigation Number, Version: CIP-1094

Other Study Identifier: DALI0001

Study Device(s): Masimo INVSENSOR00048 - Investigational

Sponsor: Masimo Corporation
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Irvine, California 92618 USA

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1. INVESTIGATOR PAGE

Principal Investigator (s): [redacted]
Investigation Site(s): [redacted]
Address: [redacted]

Site IRB: Office of Research, University of California Davis
Address: 1850 Research Park Drive Suite 300
Davis, California 95618

Agreement between Investigator and Sponsor Regarding Responsibilities for Good Clinical Practice
International Conference of Harmonization (ICH) E6 Good Clinical Practice guidance is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.
It specifies general requirements intended to:

- Protect the rights, safety and well-being of human subjects,
- Ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,
- Assist sponsors, monitors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

The Principal Investigator of the clinical investigation shall:

- Obtain and maintain IRB approval of the study.
- Ensure all subjects are consented prior to enrollment, per FDA Code of Federal Regulations titled 21 CFR 50, unless the investigation is granted a waiver of consent by the IRB of record.
- Ensure only appropriately trained personnel will be involved in clinical investigation.
- Maintain study records mentioned in the Clinical Investigation Plan.
- Maintain logs for study team delegation, site visit/monitoring, equipment disposition, study team training, subject recruitment and enrollment.
- Evaluate all adverse events and adverse device effects and determining whether the study is safe to continue.
- Allow the sponsor to conduct periodic monitoring of study activities to ensure GCP compliance.
- Not promote device prior to clearance by FDA for commercial distribution, except for academic purposes and scientific presentations.

The sponsor shall ensure existence and record of all necessary compliance documents, and will conduct monitoring visits to ensure appropriate conduct of the study.

The principal investigator's signature on this page constitutes the investigator's affirmation that he or she is qualified to conduct the clinical investigation, agreement to adhere to all stipulations of this clinical investigation plan, the conditions of the Institutional Review Board (IRB) or Research Ethics Committee approval, federal and local regulatory requirements, 21 CFR 812, ISO 14155, and International Conference on Harmonization Good Clinical Practice (ICH GCP) guidance.

Principal Investigator: [redacted]	**Title:** [redacted]	**Signature:**	**Date:**
Sponsor Representative: [redacted]	**Title:** [redacted]	**Signature:**	**Date:**

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2. OVERALL SYNOPSIS OF THE CLINICAL INVESTIGATION

Clinical investigation title:	Clinical Performance of Masimo INVSENSOR00048
Study objective(s):	The objective of this clinical study is to validate temperature performance of the noninvasive Masimo INVSENSOR00048.
Investigational device(s):	Masimo INVSENSOR00048
Number of subjects:	Up to 250 subjects

Inclusion criteria:	• Febrile subjects aged 18 years and older who meet the following criteria for screening temperature:
	  ◦ sublingual temperature ≥ 37.5°C (99.5°F),
	  ◦ or axillary temperature ≥ 37.2°C (99.0°F)

Exclusion criteria:	• Subjects with medical conditions such as inflammation at the measuring site or taking medications which might skew clinical accuracy validation results (e.g. barbiturates, thyroid preparations, antipsychotics or immunization within prior 7 days) or per the investigator's judgement • Subjects with conditions at or around site of sensor placement or skin abnormalities affecting the sensor placement area such as psoriasis, eczema, angioma, scar tissue, burn, fungal infection, substantial skin breakdown that would prevent monitoring of physiological parameters during the study • Subjects with known allergies to adhesive material used in medical equipment • Subjects with medical conditions which, in the judgment of the investigator, renders them inappropriate for participation in this study • Excluded at the Principal Investigator's discretion
Duration of the clinical investigation:	Expected duration of study enrollment is approximately 1 year. Subject participation in the study will be approximately 90 minutes.
Study endpoint(s):	Body temperature performance of Masimo INVSENSOR00048 meets its performance specifications.

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3. IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICE

3.1. Study and Technology Background

Masimo Corporation develops non-invasive medical technologies that allow real-time monitoring of patient physiological conditions, such as oxygen saturation, blood pressure, and body temperature. These devices have applications in the operating room, critical care unit, emergency room, emergency transport vehicles, alternative (home) care, as well as physicians' offices.

Temperature is one of the vital sign parameters routinely used to assess patient health. Masimo has been developing non-invasive technologies, such as the FDA cleared Radius T Thermometer, (510(k) Number K203215), to allow for continuous temperature monitoring via wireless communication to a smart device application or compatible patient monitor. This technology promotes better monitoring of temperature trends, enables sooner intervention if a patient's condition is worsening, decreases user burden on providers and patients compared to standard (non)contact thermometers, and allows for remote monitoring of temperature (which can help with infectious disease control and earlier patient discharge from hospital settings).

3.2. Investigational Device(s)

Masimo INVSENSOR00048:

The Masimo INVSENSOR00048 device is a non-invasive, [redacted] temperature sensor [redacted] that captures continuous body temperature data [redacted]

[redacted]

Figure 1. Masimo INVSENSOR00048 device



Figure 2. Masimo INVSENSOR00048 device placement

Refer to the Investigator's Brochure for more details on the investigational device.

4. JUSTIFICATION FOR THE DESIGN OF THE CLINICAL INVESTIGATION

This study is designed as a data collection protocol to validate that the Masimo INVSENSOR00048 meets its performance specifications for body temperature. The noninvasive body temperature measurements from the investigational device will be compared to reference temperature measurements using temperature probes.

5. BENEFITS AND RISKS OF THE INVESTIGATIONAL DEVICE, CLINICAL PROCEDURE, AND CLINICAL INVESTIGATION

5.1. Anticipated Benefits

There will be no benefit to the subjects. Other possible benefits would be to society as a whole. Evaluation of the accuracy of this device could enable users to more appropriately monitor and identify potentially life-threatening conditions.

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5.2. Risks/Discomforts Associated with Participation in the Clinical Investigation

Refer to the Investigator Brochure for full instructions and description of warnings and cautions.

The Masimo INVSENSOR00048 will be attached to the subject's skin with a medical-grade, biocompatible adhesive. There is potential for the adhesive to cause redness or irritation to the skin. The sensor will be placed on the subject's skin for a limited amount of time [redacted]

The sensor, when removed from the disposable adhesive base, presents a possible choking hazard. The sensor and components, including the disposable adhesive base, should be removed after use and properly disposed of in an area away from subjects. Study staff will be trained to safely dispose of these plastic items.

The Masimo INVSENSOR00048 should be removed in the event that a defibrillator needs to be used, or prior to MRI or CT scan procedures. The study personnel will be trained and made aware of these possible risks.

All subject-contacting materials, including the adhesive used in the design of the device have been subjected to biocompatibility tests per ISO 10993-1 to demonstrate that the materials are non-toxic, non-irritating, and non-sensitizing. The Masimo INVSENSOR00048 has been subjected to performance, mechanical, and electrical testing to ensure that it has met the requirements for safety and effectiveness for the intended use of the product.

There is a risk associated with the study of a potential breach of confidentiality which will be minimized by limiting the collection of protected health information (PHI) and through secure data storage practices.

None of our measures are intended to be diagnostic in nature.

See the Adverse Events section below for a list of anticipated adverse events.

6. OBJECTIVES OF THE CLINICAL INVESTIGATION

The objective of this study is to validate temperature performance of the noninvasive Masimo INVSENSOR00048.

7. DESIGN OF THE CLINICAL INVESTIGATION

7.1. General

This is a prospective, nonrandomized, multi-center study of the Masimo INVSENSOR00048. All subjects will wear the investigational sensor for body temperature measurements. Reference body temperature measurements will be obtained through sublingual, or axillary as tolerated.

The outcome measure is the determination of the Masimo INVSENSOR00048 performance by comparing the Clinical Bias and Limits of Agreement (LOA) between the device under test (DUT) and reference thermometer.

[redacted]

[redacted]

7.3. Definition of Completion of the Clinical Investigation

7.3.1. The study will be considered complete once data has either 1) been accepted from at least 32 eligible febrile subjects and a clinical study report is finalized or 2) the eligible febrile subjects when combined with data from other studies equate to at least 105 eligible subjects, with 30-50% being classified as febrile, per ISO standard 80601-2-56:2017 (E) and a clinical study report is finalized.

7.3.2 Study device(s) and comparator(s)

Equipment and materials are to be used as required. All study personnel will be trained on the use of relevant equipment.

Investigational device(s):

Masimo INVSENSOR00048

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Reference device(s):

Masimo Root with Noninvasive Blood Pressure and Temperature Monitoring:

The Masimo Root Monitoring System is FDA-cleared and equipped with noninvasive blood pressure and temperature monitoring (Figure 3) for monitoring of multiple physiological parameters in healthcare environments. In this study, the Root temperature module will be used to collect the reference temperature measurements.



Figure 3. Masimo Root with Noninvasive Blood Pressure and Temperature Monitoring

Other Research Equipment:

Laptop with Data Collection Software

Smart Phone with Data Collection Application

Ambient temperature thermometer

7.4. Subjects

7.4.1. Inclusion Criteria (Eligible Subjects)

- Febrile subjects aged 18 years and older who meet the following criteria for screening temperature:
  - sublingual temperature ≥ 37.5°C (99.5°F),
  - or axillary temperature ≥ 37.2°C (99.0°F)

7.4.2. Exclusion Criteria (Ineligible Subjects)

- Subjects with medical conditions such as inflammation at the measurement site or taking medications e.g. barbiturates, thyroid preparations, antipsychotics, or immunization within prior 7 days, which might skew clinical accuracy validation results, per the investigator's judgement
- Subjects with conditions at or around site of sensor placement or skin abnormalities affecting the sensor placement area such as psoriasis, eczema, angioma, scar tissue, burn, fungal infection, substantial skin breakdown that would prevent monitoring of physiological parameters during the study.
- Subjects with known allergies to adhesive material used in medical equipment
- Subjects with any medical conditions which, in the judgment of the investigator, renders them inappropriate for participation in this study.
- Excluded at the Principal Investigator's discretion.

7.4.3. Subject Withdrawal, Follow-up, and Replacement of Subjects

Subjects can leave the study at any time with or without reason without any consequences or loss of benefits to which they are otherwise entitled. Principal Investigator may terminate the subject from the study prior to expected completion at their discretion for reasons such as safety concerns, failure to adhere to protocol requirements, etc. Any data collected until the time of subject withdrawal may be included in the final data analysis. Information on the subject's withdrawal should be documented in the case report forms and should include clear documentation of the reason for withdrawal if available.

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There are no long-term effects anticipated from participating in this study therefore no follow-up is required for participants who withdraw from the study.

Additional subjects may be enrolled to replace withdrawn subjects, including subjects withdrawn from data analysis.

7.4.4. Point of Enrollment

The point of enrollment is defined as the time at which a subject has met eligibility criteria and has been assigned a subject identification number.

7.4.5. Expected Duration of Subject Participation

Data collection will occur for approximately 90 minutes.

7.4.6. Expected Duration of Study Enrollment

Study enrollment will continue until the sample size (see Sample Size Section below) is achieved. The expected duration of the study is expected to be approximately 1 year.

7.4.7. Relationship of investigation population to target population.

The population being enrolled in this study is the same as the target population.

7.4.8. Subject Classification

Subjects will be classified according to the criteria below:

- **Screened** – Subjects who are assessed for study eligibility.
- **Enrolled** – Subjects who have met all the inclusion criteria, do not meet any exclusion criteria, and have been assigned a subject identification number.
- **Screen Failure** – Subjects who do not meet all the eligibility criteria (Reason for the subject's ineligibility will be documented on a Screening and Enrollment Log).
- **Withdrawn** – Subjects who do not complete the study due to reasons listed below:
    - Subject voluntarily opts not to participate.
    - Subject discontinued from study at the discretion of the principal investigator (PI).
- **Completed** – Subjects with a minimum of three (3) reference measurement groups.

7.5. Procedures

7.5.1. Recruitment, Consenting and Screening

This clinical study will operate under a waiver of informed consent as it poses minimal risk to subjects. The principal investigator or delegated study personnel will review EMR current vital signs records for febrile subjects in the OR, ICU, or hospital wards to screen for potential subjects. Subjects who meet inclusion and exclusion criteria will be enrolled in the study. The investigator shall not recruit subjects to participate in the study prior to receiving IRB approval of the study.

Per FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects" issued on January 2017, waiver of informed consent for certain FDA-regulated minimal risk clinical investigations will facilitate investigators' ability to conduct studies that may contribute substantially to the development of products to diagnose or treat diseases or conditions or address unmet medical needs. The IRB can waive the requirements to obtain informed consent when the IRB finds that:

- The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The clinical investigation could not practicably be carried out without the waiver or alteration;
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation

This study meets all the criteria listed by the FDA above. As approved by the IRB, this study will be conducted utilizing a waiver of informed consent. Enrolled subjects will have a note entered in their hospital record documenting their enrollment in this study.

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HIPAA Waiver for Subject Screening

The screening of subjects will require the investigators to access personal health information to identify prospective subjects without HIPAA authorization. The participants' rights and welfare will not be adversely affected by waiving HIPAA authorization. This protected health information will not be inappropriately reused or disclosed to any other person or entity. To further safeguard all protected health information, the data will not be labeled with any personal identifying information. Also, the data will not be stored with any protected health information identifiers.

The point of enrollment is defined as the time at which a subject has met eligibility criteria and has been assigned a subject identification number.

The subject may exit the study at any time.

Subjects will be screened to determine eligibility for study enrollment. Subjects must meet all inclusion criteria and none of the exclusion criteria to participate in the study. All subjects screened will be documented on the Screening and Enrollment Log. Subjects who do not meet the eligibility criteria will be considered screen failures and the reason for the status of screen failure will be documented on the Screening and Enrollment Log.

Febrile subjects aged 18 years and older will be recruited and enrolled in the study if interested in participating. To ensure uniform distribution of subjects in all age categories, and to meet the ISO standard 80601-2-56:2017(E) requirements for febrile temperature categories, when applicable only febrile subjects and specific age groups will be enrolled.

7.5.2. General Procedures

Subjects may continue to be monitored using standard of care devices while enrolled in this study. At any time during study procedures, the physician or bedside nurse, at their discretion, can discontinue study procedures and exercise clinical judgment to safeguard the subject's health, safety, and welfare.

Masimo study device data will not be used to guide clinical care or decisions. No treatment decisions will be made based on any data from study devices.

7.5.3. Data Collection (General)

7.5.3.1. Captured study data on the case report form (CRF) may include but are not limited to:

- Demographics including age, gender, weight, height, [redacted] race or ethnicity
- Screening Temperature
- Current medical conditions and recent medical history
- Current medications, dosage, and timing
- Recent immunizations
- Medical records, clinical and office charts, laboratory notes, memoranda, recorded data from automated instruments, and copies or transcriptions certified after verification as being accurate and complete may be accessed to obtain above defined data.

[redacted]

7.5.3.2. Data from the Masimo INVSENSOR00048 will be collected using a data acquisition software application installed on a smart phone or a data collection laptop.

7.5.3.3. At the conclusion of the study, devices and data recording will be stopped and the sensor will be removed.

7.5.3.4. De-identified subject data will be stored by the data collection system software on the study smart phone and laptop system and will be exported to Masimo by the study staff.

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7.5.4. Temperature Collection with Masimo INVSENSOR00048 and Reference Temperature Measurements

7.5.4.1. The Masimo INVSENSOR00048 sensor will be used according to the study's procedure manual's step-by-step instructions.

7.5.4.2. Data from the Masimo INVSENSOR00048 sensor may be collected using a smartphone application on a mobile device. Specific instructions on the use of the mobile application will be provided by the sponsor.

7.5.4.3. After powering on, the Masimo INVSENSOR00048 sensor will be paired via Bluetooth to the smartphone app as appropriate.

7.5.4.4. The Masimo INVSENSOR00048 sensor will be applied to the subject's chest. The subject's skin may need to be prepared (e.g., skin cleaned with alcohol wipe) to ensure that the sensor can make adequate contact with the skin. Study staff should inspect for skin integrity prior to sensor placement [redacted]

7.5.4.5. Data collection with the INVSENSOR00048 will begin after placement on the subject. Refer to the Study Procedure Manual for details.

7.5.4.6. Reference temperature measurements will begin after the Masimo INVSENSOR00048 sensor has been on the subject's chest [redacted] and will be obtained after data collection with the INVSENSOR00048 is started.

7.5.4.7. Reference measurements may be obtained [redacted], depending on the subject's status and tolerance. [redacted]

7.5.4.8. The Root monitor has the capability to obtain temperature measurements using two different modes: Monitor mode and Predictive mode.

- Monitor mode, also referred to as Continuous mode, provides continuous temperature [redacted]
- Predictive mode, also referred to as Spot Check mode provides a one-time measurement [redacted]

7.5.4.9. The mode used for each subject will depend on their status and tolerance. Refer to the Study Procedure Manual and Root Operator's Manual for details on the use of the different modes.

7.5.4.10. When using the Monitor mode, each temperature measurement will be obtained [redacted]

7.5.4.11. In Predictive mode when using the [redacted] thermometer, [redacted] The temperature probe needs to be replaced in the probe well after each measurement, and the Root monitor display should indicate "Ready to obtain measurement" prior to taking the next measurement.

[redacted]

7.5.4.13. Research personnel is to remain with the subject during all measurements to monitor for potential skin irritation in the area of the Masimo INVSENSOR00048 placement. If any skin irritation is noted, the sensor should be removed with care and the subject's participation should be discontinued. Development of redness or irritation on the sensor site should be reported as an adverse event.

7.5.4.14. Subjects participating in the study should be instructed not to touch the sensor while it's on their chest and not to remove it. If any issues arise, the research staff should be notified immediately.

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[redacted]

7.5.4.17. [redacted] All sensors will be removed from the subject when data collection is completed.

[redacted]

7.5.4.19. When data collection is complete, reference data from the Root and Masimo INVSENSOR00048 data from the smart phone will be downloaded to a data collection laptop and transferred to the Sponsor for review. Detailed instructions on downloading and transferring data will be provided in the Study Procedure Manual

7.6. Monitoring plan

As the sponsor of this clinical investigation, Masimo Corporation is required by 21 CFR, Part 812 of the Food and Drug Administration regulations to monitor and oversee the progress of the investigation. The monitor(s) assigned by Masimo Corporation to this task will be trained on departmental SOPs on conduct and monitoring of sponsored studies.

In accordance with good clinical practices guidelines, there will be at least three scheduled monitoring visits to ensure overall regulatory compliance of the study:

- An initiation visit, prior to any subject enrollment to confirm site readiness, and to document training on the study protocol and procedures, and use of equipment.
- At least one monitoring visit during initial enrollment (approximately 20-30 subjects), and/or every 1-2 months thereafter based up on rate of enrollment until completion of the study.
- A final close out visit after the last subject had finished the study.

Depending on the quality of the data and/or changes to factors affecting subject safety, additional monitoring visits may be necessary according at the sponsor's discretion.

The monitor will contact and visit the investigator and will be allowed, on request, to have access to all source documents needed to verify the entries in the CRFs and other GCP-related documents (IRB approvals, IRB correspondences, and ICFs) provided that subject confidentiality is maintained in agreement with HIPAA regulations.

It will be the monitor's responsibility to inspect the CRFs at regular intervals throughout the study, to verify the adherence to the CIP and the completeness, consistency and accuracy of the data being entered on them.

During each visit, the monitor will also verify adherence to the inclusion/exclusion criteria, and documentation of SAEs/SADEs and protocol deviations/violations, and check CRF against source documentation.

After each visit, the monitor will provide a monitoring follow-up letter to the investigator approximately within 4 weeks of visit completion. The monitoring follow-up letter will detail findings and open action items observed during the visit. It is the responsibility of the Principal Investigator and Study Coordinator(s) to respond to the findings of the monitoring report and complete any open action items as soon as possible but no later than 60 days of receiving the monitoring follow-up letter. Any open action items not completed within the time allowed may be sufficient grounds for study site suspension or termination; it will be up to the sponsor to determine whether any incomplete action items are sufficient grounds for suspension or termination. See Section 16 for details on suspension and termination.

8. STATISTICAL DESIGN AND ANALYSIS

8.1. Acceptance Criteria

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[redacted]

[redacted]

8.2. Sample Size

Per the ISO standard 80601-2-56:2017(E), the minimum sample size shall be 105 subjects, with 30-50% being classified as febrile (see below for definitions of "febrile"). For validation of an adjusted mode continuous clinical thermometer, no separation of age groups is required. However, the ages of the subjects should be uniformly distributed within the tested population.

Per the ISO standard 80601-2-56:2017(E), febrile temperature is defined as:

- Elevated core or rectal temperature ≥ 38.0°C (100.4°F)
- Elevated sublingual temperature ≥ 37.5°C (99.5°F)
- Elevated axillary temperature ≥ 37.2°C (99.0°F)

8.3. Statistical Analysis

The Clinical Bias and Limits of Agreement (LOA) will be compared between the device under test (DUT) and reference thermometer.

Clinical bias is computed as shown below:

$$\Delta_{cb} = \frac{\sum_{i=1}^{n}(T_{DUT,i} - T_{b,i})}{n}$$

where:

- i = index for paired data points.
- n = total number of paired data points
- $T_{DUT,i}$ = i[th] temperature estimated by the DUT.
- $T_{b,i}$ = i[th] reference temperature.

Limits of agreement (LOA) are computed as shown below:

$$L_A = 2 * \sigma_{\Delta_{cb}},$$

and

$$\sigma_{\Delta_{cb}} = \sqrt{\frac{\sum_{i=1}^{n}\left[(T_{DUT,i} - T_{b,i}) - \Delta_{cb}\right]^2}{n-1}}$$

where:

- $\sigma_{\Delta_{cb}}$ = standard deviation of the error between the DUT and reference temperature.
- Δ_{cb} = clinical bias, as calculated above.
- i = index for paired data points.
- n = total number of paired data points.
- $T_{DUT,i}$ = i^{th} clinical temperature measurement collected from the DUT.
- $T_{b,i}$ = i^{th} reference temperature.

[1] Based on internal requirement.

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[redacted]

[redacted]

8.4. Data Exclusion

Data from the following subjects will be excluded from data analysis:

[redacted]

Brief pauses in study enrollment may occur per sponsor discretion to allow for data analysis.

9. DATA MANAGEMENT

9.1. Data Management and Confidentiality

All documents associated with this protocol will be securely stored in a physical location or on password-protected computers. The confidentiality and retention of these documents will be protected to the extent provided and required by the law. All data will be de-identified before any statistical analysis. Only de-identified data will be shared with Masimo for research purposes stated in this protocol. Data collected by data capture software and data entered in case report form will be shared with Masimo via a secure, password-protected server that only study staff, and Masimo study team members will have access to. Data will be retained for a minimum to 2 years following completion of the final analysis.

9.2. Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, recorded data from automated instruments, and copies or transcriptions certified after verification as being accurate and complete.

9.3. Case Report Forms

The site shall capture study data in case report forms (CRFs) for each subject enrolled, to be provided to the sponsor. CRFs may be in paper or electronic format through electronic data capture (EDC) software. Masimo shall ensure that systems used for electronic CRFs are compliant with the requirements of 21 CFR Part 11 and ISO / IEC 27001 Certification. The CRFs will be completed and signed by the principal investigator or delegate. This also applies to those subjects who fail to complete the study. If a subject withdraws from the study, the reason must be noted on the CRF. Case report forms are to be completed on an ongoing basis. CRF entries and corrections will only be performed by study site staff, authorized by the investigator. For paper CRFs, entries and corrections to the CRF will be made following Good Documentation Practices.

The CRF may include the following information, including but not limited to: inclusion / exclusion criteria, demographic information, device readings, and if occurrence of any adverse event, protocol deviation, and device deficiencies, etc. The CRFs will be signed by the PI or delegate to attest that the data are complete and accurate.

CRF entries will be checked by the study monitor and any errors or inconsistencies will be queried to the site on an ongoing basis. Any changes made within an electronic CRF will be tracked by audit trail. Any changes on a paper CRF will be made directly on the CRF and will be initialed and dated by the person making the change. Query resolution will be assessed and confirmed by study monitor during site visit.

9.4. Data Transfer and Storage

Original paper CRFs will be stored in a secure location at the site. Copy of the original paper CRFs may be scanned and sent to sponsor. If using electronic CRFs, the site staff will be assigned unique usernames and passwords for data security. Final copies of the electronic CRFs in EDC are stored on a secure server.

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[redacted]

Only authorized sponsor personnel will have access to study data and will move it to a secure and backed-up drive at Masimo. Authorized sponsor personnel will review each set of data to ensure that the enrolled subjects have met eligibility criteria for the study. The data will be reviewed by sponsor personnel to confirm that the data is valid prior to being used in submission or a test report.

CRFs will be checked for completeness and if there are inconsistent or missing data points, queries will be generated. If delegated study staff are to correct the paper CRF, they shall follow GDP practices to strike through old entry, add in new entry, and initial and date it, and provide the corrected information to sponsor. Corrections made to electronic CRFs will be tracked by audit trail and require PI or delegate sign-off.

9.5. Record Retention

Study data will be retained for the necessary period of time as required by the institution's regulations. Study records shall be retained for a minimum of two years after study closure. The Institution's own retention policies and regulations may apply in addition to the minimal requirement.

10. AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN

Any changes made to the clinical investigational plan/study protocol will be documented by way of an amendment. Before submitting a protocol amendment to the IRB, the protocol amendment must be agreed upon and signed by both the principal investigator and the sponsor. The protocol amendment will be submitted to the IRB for approval. At a minimum, a redline version and a clean version of the new protocol amendment will be kept on file by the PI and the sponsor. Protocol amendments will need to be version controlled. Both PI and sponsor will retain the IRB approval letter as confirmation that the protocol amendment was approved.

11. DEVIATIONS FROM CLINICAL INVESTIGATION PLAN

Deviations from the protocol must receive both sponsor and the investigator's IRB/ethics committee approval before they are initiated, with the exception that under emergency circumstances, deviations from the Clinical Investigation Plan to protect the rights, safety and well-being of human subjects may proceed without prior approval of the sponsor or the IRB/ethics committee. Any protocol deviations initiated without sponsor and the investigator's IRB/ethics committee approval that may affect the scientific soundness of the study, or affect the rights, safety, or welfare of study subjects, must be documented and reported to the sponsor and to the investigator's IRB/ethics committee as soon as a possible, but no later than 5 working days after the occurrence of the protocol deviation. In addition to documenting deviations on the CRF, the Protocol Deviation Form may also be used. If protocol deviations continue to occur frequently at a study site, a corrective and preventive action (CAPA) may be opened by the sponsor.

Withdrawal of IRB approval: An investigator shall report to the sponsor a withdrawal of approval by the investigator's reviewing IRB as soon as possible, but no later than 5 working days of the IRB notification of withdrawal of approval.

12. DEVICE ACCOUNTABILITY

12.1. Receipt of Study Device

Upon receipt of the of the study device supplies, an inventory must be performed, and the device accountability log 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 each shipment will be documented in the study files. The investigator must notify the study sponsor of any damaged or unusable study devices that were supplied to the investigator's site.

12.2. Use of Study Device

Use of the device will be documented on case report forms for each subject. Any unused devices must be returned to the sponsor at the end of the study or before product expiration date.

12.3. Return or Destruction of Study Device

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At the completion of the study, there will be a final reconciliation of study devices shipped, devices used, and devices remaining. This reconciliation will be logged on to the device accountability log. Any discrepancies noted will be investigated, resolved, and documented prior to return or destruction of unused study devices. Devices destroyed on site will only be upon written instruction from the sponsor and will be documented in the study files. When a Masimo device deficiency is observed, every effort should be made to return the device and its packaging to the sponsor in a timely manner.

13. STATEMENTS OF COMPLIANCE

This document is a clinical investigational plan for a human research study sponsored by Masimo Corporation. The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. By participating in the study, the Investigator agrees to adhere to all stipulations of this protocol, the conditions of the Institutional Review Board (IRB) or Research Ethics Committee approval, federal and local regulatory requirements, 21 CFR 812, ISO-14155, International Conference on Harmonization Good Clinical Practice (ICH GCP) guidance.

The protocol, recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of the protocol 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.

14. INFORMED CONSENT PROCESS

This clinical study will operate under waiver of informed consent as its design poses minimal risk. See *Subject Recruitment* section under *Study Procedures*.

15. ADVERSE EVENTS, ADVERSE DEVICE EFFECTS, AND DEVICE DEFICIENCIES

15.1. Definitions

The definitions for adverse event, adverse device effect, serious adverse event, serious health threat, serious adverse device effect, and unanticipated adverse device effect, device deficiencies are provided below (ISO 14155, 21 CFR 812.3(s)).

- adverse event: untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users, or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated (ISO 14155)
- adverse device effect: adverse event related to the use of an investigational medical device
- serious adverse event: adverse event that led to any of the following:

  a) death

  b) serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:

  1) a life-threatening illness or injury, or

  2) a permanent impairment of a body structure or a body function including chronic diseases, or

  3) in-patient or prolonged hospitalization, or

  4) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function,

  c) foetal distress, foetal death, a congenital abnormality, or birth defect including physical or mental impairment

  Note: Planned hospitalization for a pre-existing condition, or a procedure required by the Clinical Investigation Plan, without serious deterioration in health, is not considered a serious adverse event.

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- serious health threat: signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects, users, or other persons, and that requires prompt remedial action for other subjects, users or other persons.

  Note: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.

- serious adverse device effect: adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event

- unanticipated serious adverse device effect: serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment

  Note: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity, or outcome has been identified in the risk assessment.

- device deficiency: inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety, or performance

  Note 1: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling.

  Note 2: This definition includes device deficiencies related to the investigational medical device or the comparator.

15.2. Anticipated Adverse Events

Below is a list of adverse events that may potentially occur. Any AE that occurs while the subject is enrolled in the study must be reported to the sponsor and IRB as applicable.

- Mild allergic reaction to sensor material and adhesives.
- Discomfort, redness or skin irritation at site of sensor placement.
- Choking hazard form small components.

15.3. Adverse Event Reporting

- All Adverse Events, both Anticipated and Unanticipated, must be recorded in the within the CRF and in the Adverse Event Report Form.
- All Adverse Events must be promptly reported to the sponsor.
- All Unanticipated Adverse Device Effects will be also reported to both the sponsor and the IRB.
- Both Serious Adverse Events and Unanticipated Adverse Device Effects must be reported to the sponsor within 48 hours. All other Adverse Events should be reported to the sponsor within 5 business days.
- All Serious Adverse Events will be also reported to the IRB per IRB reporting requirements. These reports may include but will not be limited to: date of onset; brief description of the events; their treatment; whether they resulted in death, inpatient hospitalization, severe or permanent disability or were life threatening; their relationship to the study device; and resolution.

15.4. Device Deficiencies Reporting

All Masimo device related deficiencies should be reported to the sponsor and must be recorded in the CRF in a timely manner. When a Masimo device deficiency is observed, every effort should be made to return the device and its packaging to the sponsor in a timely manner.

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16. VULNERABLE POPULATION

16.1. Definition

Vulnerable population are research participants, such as prisoners, pregnant women, handicapped, or mentally disable persons, or economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion and undue influence.

The federal regulations that govern the protection of human subjects require additional protection for the vulnerable population.

16.2. Protection of vulnerable subjects

- Reasonable compensation will be provided for economically disadvantaged subjects to eliminate possibility of undue influence due to financial incentive.
- Educationally disadvantaged subjects will be provided ample time to ask questions and comprehend information.
- Medical care will be provided to these subjects after the clinical investigation has been completed if they are injured as a direct result of participating in this research study. The cost of treatment for any research related injury will be covered by Masimo.

16.3. Responsible Parties

- The EC/IRB will review research with vulnerable populations and evaluate level of risk, coercion, and the reason for choosing this particular subject population. The EC/IRB will be responsible for determining what practices will include continuing review for compliance while monitoring these studies.
- The Investigator holds the ultimate responsibility for protecting the rights, safety, and welfare of research subjects by ensuring that all regulations and proper documentation of consent is handled in a compliant and timely manner.

17. SUSPENSION OR PREMATURE TERMINATION OF THE CLINICAL INVESTIGATION

17.1. Suspension or Termination of Study Site

The sponsor can suspend or prematurely terminate the PI's and study site's participation in the study, particularly if sponsor finds serious non-compliance by the PI or site, and if such non-compliance was not resolved in a timely manner. The sponsor will document the decision to suspend or terminate the investigation in writing. A suspended study site cannot enroll new subjects.

If the sponsor determines that the study site's compliance to be inadequate at any point during the study, and sponsor move to suspend or terminate the study site, the sponsor will provide notification in writing to the principal investigator and IRB as necessary. The study site is eligible for reinstatement upon correction of any findings and any open action items prior to the suspension and provides a written guarantee that the same non-compliance will not reoccur in the future. Site can only resume subject enrollment upon receiving written notification of reinstatement from the sponsor.

If for any GCP and Regulatory non-compliance reasons the study site is prematurely terminated by the sponsor, then the study site is not eligible for reinstatement under the same Clinical Investigational Plan/Study Protocol.

17.2. Termination of Clinical Investigation/Study due to UADE

The clinical investigation may be terminated if sponsor determines that an unanticipated adverse device effect presents an unreasonable risk to the subjects. Termination shall occur not later than 5 working days after the sponsor makes this determination, and not later than 15 working days after the sponsor first received notice of the effect.

The sponsor may resume the terminated clinical investigation with prior IRB approval if the device is non-significant risk.

18. PUBLICATION POLICY

In compliance with 42 CFR Part 11, a study that meets the definition of an Applicable Clinical Trial (ACT) and that is initiated after September 27, 2007 must be registered on ClinicalTrials.gov. Results of the clinical investigation will be made publicly available.

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19. REVISION HISTORY

Version	Version Date	Summary of Revisions Made
[redacted]	[redacted]	[redacted]

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