

Official Title: Clinical Performance of Masimo MightySat Rx in Pediatric Populations

Date of Protocol: June 15, 2023

NCT Number: NCT05879081

Clinical Investigation Title:	Clinical Performance of Masimo MightySat Rx in Pediatric Populations
Clinical Investigation Number, Version:	[redacted]
Other Study Identifier:	[redacted]
Study Device(s):	Masimo MightySat Rx – Investigational
Sponsor:	Masimo Corporation 52 Discovery Irvine, California 92618 USA

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1. INVESTIGATOR PAGE

Principal Investigator (s): [redacted]

Investigation Site(s): [redacted]

Address: [redacted]

IRB: WCG IRB

Address: 1019 39th Avenue SE, Suite 120

Puyallup, Washington 98374

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.
- 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 MightySat Rx in Pediatric Populations
Study objective(s):	The primary objective of this study is to validate RRp performance of the noninvasive Masimo MightySat Rx device in pediatric populations.
Investigational device(s):	Masimo MightySat Rx
Number of subjects:	[redacted]
Inclusion criteria:	• Subject is 5 to 18 years of age. • Subject weighs 30 to 50 kg.
Exclusion criteria:	• Subject has a condition at or around the 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. • Subject is unable to sit with minimal movement during data collection. • Subject has any medical condition which, in the judgment of the investigator or study staff, renders them ineligible for participation in this study. • Subject is excluded at the study staff's discretion.
Duration of the clinical investigation:	The expected duration of study enrollment is approximately 1 to 3 months. [redacted]
Study endpoint(s):	RRp performance of MightySat Rx in pediatric populations meets its performance specifications.

3. IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICE

Masimo's FDA-cleared MightySat Rx is a stand-alone fingertip pulse oximeter that combines the functionality of a pulse oximeter monitor and sensor into a single portable device that fits on a user's finger. Through skin contact, the device can measure multiple respiratory parameters including oxygen saturation (SpO_2), pulse rate (PR), perfusion index (PI), and respiratory rate from plethysmography (RRp). The MightySat Rx is indicated for the noninvasive spot checking of RRp for adult patients. The device is considered investigational in this study since RRp is not indicated for use in pediatric patients.



Figure 1: Masimo MightySat Rx device placed on finger.

4. JUSTIFICATION FOR THE CLINICAL INVESTIGATION DESIGN PLAN

Recording respiratory rate is considered standard for patient monitoring. However, manual assessment of respiratory rate can be difficult and time consuming, contributing to infrequent and inaccurate documentation. Poor tracking of respiratory rate occurs even though changes in respiratory rate are some of the best predictors of respiratory deterioration, cardiac arrest, and admission to the intensive care unit (ICU) (1).

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Alternatively, respiratory rate can be determined from the plethysmographic waveform (RRp) because of amplitude changes that correspond to the respiratory cycle. Masimo's MightySat Rx has been FDA-cleared for RRp measurements in adults. The purpose of this investigation is to validate MightySat Rx RRp measurements in the pediatric population.

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

5.1. Anticipated Benefits

There will be no benefit to the subject. 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.

5.2. Risks, Discomforts, and Anticipated Adverse Events Associated with Devices and Sensors

The noninvasive devices used in this study are similar in technology and design to some commercially available pulse oximeters and other non-invasive devices and hence have the same risks. Pulse oximeters and other non-invasive devices are commonly used and are considered to be minimal risk. Devices and sensors in this study are United States Food and Drug Administration (FDA) 510(k) cleared to be used in a manner consistent with their indication for use labeling.

Components of the MightySat Rx, including the battery door, battery or lanyard could pose a potential choking hazard if left unattended. The MightySat Rx should remain with site staff at all times when device is not placed on a subject. During data collection, research personnel should be present with the subject during the entire duration of the study procedures.

There is a risk of skin irritation and drying of mucous membranes [redacted]. The risks are low due to the short study duration. If discomfort occurs, the study can be stopped.

The sensors have been subjected to performance, mechanical, and electrical testing, skin surface temperature and results demonstrate that the sensors meet the requirements for safety and effectiveness for intended use of the product, refer to investigational brochure for further details.

6. OBJECTIVES OF THE CLINICAL INVESTIGATION

The objective of this study is to validate the RRp performance of the noninvasive Masimo MightySat Rx device in pediatric populations.

7. DESIGN OF THE CLINICAL INVESTIGATION

7.1. General

This is a single-center, nonrandomized single arm study wherein all subjects are enrolled into the experimental arm and receive the MightySat Rx [redacted]

[redacted]

[redacted]

7.2. Investigation Site(s)

[redacted]

7.3. Definition of Completion of the Clinical Investigation

The study will be considered complete once data has been collected from [redacted] eligible subjects and a clinical study report is finalized.

7.4. Study device(s) and comparator(s)

Investigational device: Masimo MightySat Rx

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[redacted]

7.5. Subjects

7.5.1. Inclusion Criteria

- Subject is 5 to 18 years of age.
- Subject weighs 30 to 50 kg.

7.5.2. Exclusion Criteria

- Subject has a condition at or around the 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.
- Subject is unable to sit with minimal movement during data collection.
- Subject has any medical condition which, in the judgment of the investigator or study staff, renders them ineligible for participation in this study.
- Subject is excluded at the study staff's discretion.

7.5.3. Subject Withdrawal and Follow-up

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. The study team may terminate the subject from the study prior to expected completion 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 to the Sponsor.

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

7.5.4. Point of Enrollment

The point of enrollment is defined as the time at which a subject and parent or Legal Guardian complete the informed assent (if applicable) and consent processes.

7.5.5. Expected Duration of Subject Participation

[redacted] Total duration of study participation from time of consent will be approximately 60 min.

7.5.6. Expected Duration of Study Enrollment

Study enrollment will continue until the sample size (see 8.2) is achieved. This will be approximately 1 to 3 months.

7.5.7. Subject Classification

Subjects will be classified according to the criteria below:

- **Screened** – Subjects who are assessed for study eligibility, after the child's parent(s), guardian(s), or legally authorized representative have signed the informed consent form (ICF).
- **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:
  - The child's parent(s), guardian(s), or legally authorized representative voluntarily withdrew their consent.
  - Subject was discontinued from study at the discretion of the principal investigator (PI).
- **Completed** – [redacted]

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7.6. Procedures

7.6.1. Patient demographic information including, but not only limited to, age, gender, weight, height, skin pigmentation (for example using Massey scale), finger circumference, race or ethnicity will be recorded on the case report form (CRF), as well as current medical conditions and recent medical history (up to 90 days prior).

7.6.2. A MightySat Rx pulse oximeter will be placed on the subject's [redacted] finger.

[redacted]

7.6.4. After the MightySat Rx pulse oximeter [redacted] are placed, the subject will be observed [redacted] while sitting at rest.

[redacted] After approximately 5 minutes, about 3 to 5 spot check measurements using the MightySat Rx device will be taken [redacted]

[redacted]

7.6.7. The MightySatRx study sensor placement location, study sensor ID/lot number, and other relevant information will be recorded in eCRF.

7.6.8. At the conclusion of the study, devices and data recording will be stopped. All sensors will be removed.

7.6.9. Data collected by the study devices is not intended to be used for clinical decisions.

7.7. Monitoring plan

Oversight for this clinical trial is provided by the sponsor, investigators, and local IRBs.

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 Standard Operating Procedures (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, and every 2-4 weeks thereafter
- A final close out visit after the last subject had finished the study.

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. The Investigator will provide the monitor access to all necessary records to ensure the integrity of the data (21 CFR 812).

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 the CRF against source documentation.

After each visit, the monitor will provide a monitoring report to the Investigator within 4 weeks of visit completion. The monitoring report will detail findings and open action items observed during the visit. It is the responsibility of the PI 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 report. Any open action items not completed within the time allowed may be

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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.

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.

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

8. STATISTICAL DESIGN AND ANALYSIS

8.1. Acceptance Criteria

The MightySat Rx device will be determined to have comparable performance and should meet the acceptable limit of ≤ 3.0 RPM A_{RMS} and ≤±1.0 RPM Mean Error.

8.2. Sample Size

Sample size for this study has been determined [redacted] based on previous experience with similar devices and Masimo internal procedures for sample size calculation.

[redacted]

8.3. Statistical Analysis

[redacted]

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

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

[redacted]

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

[1] Sample Size Calculations, Practical Methods for Engineer and Scientists, Paul Mathews ISBN 978-0-615-32461-6

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8.4. Expected Dropout Rates

Data collection will continue until a sufficient number of cases have been obtained with quality data (e.g., no data drop-outs).

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. 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, whether subject consent was obtained before start of study, 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 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.

Only authorized sponsor personnel will have access to study data, and will move it to a secure and backed-up drive at Masimo.

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.

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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 a given 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 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

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 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

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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, 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.

14. INFORMED CONSENT PROCESS

- The investigator shall not enroll any subject to participate in the study or consent any subject prior to receiving IRB approval of the informed consent form.
- No study-related activities will be conducted until the assent/consent is signed and dated from the subject (if age-applicable), and the parental consent form is signed and dated by the subject's parent or legal guardian.
- Following identification of a potential eligible subject as defined by the inclusion and exclusion criteria, the subject will be approached by the study staff. Study staff will explain the purpose and procedures of the study with respect to potentials risks and benefits, and clarification of the subject's rights and privacy information. The research team will emphasize that participation is voluntary and declining participation in the study will not result in any penalty or loss of benefits that the subject is otherwise entitled.
- Individuals will be given ample time to review the assent, consent and/or parental consent form and the opportunity to ask the person obtaining consent any questions.
- Once the subject or parent(s)/Legal Guardian questions have been answered and the informed consent is signed and dated, the Principal Investigator or delegate will also sign the informed consent document, approving that the subject will be enrolled in the study. The investigator shall retain the original copy of the signed informed consent document in each subject's records and provide a copy to the subject.
- The point of enrollment is defined as the time at which the assent is signed and dated from the subject (if applicable), and the parental consent form is signed and dated by the subject's parent or legal guardian. The subject may withdraw from the study at any time.

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

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- 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.

- 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. List of Anticipated Adverse Events

15.2.1. Anticipated Device-Related Adverse Events

The noninvasive device used in this study is similar to commercially available pulse oximeters and hence has minimal risks. Pulse oximeters and other non-invasive devices are commonly used and are considered to be minimal risk.

There is an extremely small risk of damage to the subject's skin where sensors are placed, from the device, including temporary skin irritation or discomfort associated with exposure to the sensor, as well as potential temporary mechanical irritation or discomfort. There is a remote, yet possible, risk of a burn from the sensor. In the case of a sensor burn, there is the potential for permanent skin damage (scar/discoloration).

15.2.2. List of Non-Reportable Adverse Events

All adverse events will be reported to the Sponsor.

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.

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- 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.

16. VULNERABLE POPULATION

16.1. Definition

Vulnerable population are research participants, such as children, 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. Children, economically or educationally disadvantaged persons may be enrolled in this study.

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.
- For children, the Investigator will ensure that the parent/legal guardian does not unduly influence subjects to participate (21 CFR Part 50). Parents/legal guardian of the participant will have ample time to ask questions and understand the information being presented.

16.3. Responsible Parties

- The EC/IRB will review research with vulnerable populations and evaluate consent, 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 determine 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.

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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.

19. BIBLIOGRAPHY

1. Cretikos MA, Bellomo R, Hillman K, Chen J, Finfer S, Flabouris A. Respiratory rate: the neglected vital sign. Med J Aust [Internet]. 2008 Jun 2 [cited 2022 Dec 2];188(11). Available from: https://www.mja.com.au/journal/2008/188/11/respiratory-rate-neglected-vital-sign

20. Revision history

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

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Clinical Investigation Title:	Clinical Performance of Masimo MightySat Rx in Pediatric Populations
Clinical Investigation Number, Version:	[redacted]
Other Study Identifier:	[redacted]
Study Device(s):	Masimo MightySat Rx – Investigational
Sponsor:	Masimo Corporation 52 Discovery Irvine, California 92618 USA

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1. INVESTIGATOR PAGE

Principal Investigator (s): [redacted]

Investigation Site(s): [redacted]

Address: [redacted]

IRB: WCG IRB

Address: 1019 39th Avenue SE, Suite 120

Puyallup, Washington 98374

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.
- 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 MightySat Rx in Pediatric Populations
Study objective(s):	The primary objective of this study is to validate RRp performance of the noninvasive Masimo MightySat Rx device in pediatric populations.
Investigational device(s):	Masimo MightySat Rx
Number of subjects:	[redacted]
Inclusion criteria:	• Subject is 5 to 18 years of age. • Subject weighs 30 to 50 kg.
Exclusion criteria:	• Subject has a condition at or around the 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. • Subject is unable to sit with minimal movement during data collection. • Subject has any medical condition which, in the judgment of the investigator or study staff, renders them ineligible for participation in this study. • Subject is excluded at the study staff's discretion.
Duration of the clinical investigation:	The expected duration of study enrollment is approximately 1 to 3 months. [redacted]
Study endpoint(s):	RRp performance of MightySat Rx in pediatric populations meets its performance specifications.

3. IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICE

Masimo's FDA-cleared MightySat Rx is a stand-alone fingertip pulse oximeter that combines the functionality of a pulse oximeter monitor and sensor into a single portable device that fits on a user's finger. Through skin contact, the device can measure multiple respiratory parameters including oxygen saturation (SpO_2), pulse rate (PR), perfusion index (PI), and respiratory rate from plethysmography (RRp). The MightySat Rx is indicated for the noninvasive spot checking of RRp for adult patients. The device is considered investigational in this study since RRp is not indicated for use in pediatric patients.



Figure 1: Masimo MightySat Rx device placed on finger.

4. JUSTIFICATION FOR THE CLINICAL INVESTIGATION DESIGN PLAN

Recording respiratory rate is considered standard for patient monitoring. However, manual assessment of respiratory rate can be difficult and time consuming, contributing to infrequent and inaccurate documentation. Poor tracking of respiratory rate occurs even though changes in respiratory rate are some of the best predictors of respiratory deterioration, cardiac arrest, and admission to the intensive care unit (ICU) (1).

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Alternatively, respiratory rate can be determined from the plethysmographic waveform (RRp) because of amplitude changes that correspond to the respiratory cycle. Masimo's MightySat Rx has been FDA-cleared for RRp measurements in adults. The purpose of this investigation is to validate MightySat Rx RRp measurements in the pediatric population.

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

5.1. Anticipated Benefits

There will be no benefit to the subject. 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.

5.2. Risks, Discomforts, and Anticipated Adverse Events Associated with Devices and Sensors

The noninvasive devices used in this study are similar in technology and design to some commercially available pulse oximeters and other non-invasive devices and hence have the same risks. Pulse oximeters and other non-invasive devices are commonly used and are considered to be minimal risk. Devices and sensors in this study are United States Food and Drug Administration (FDA) 510(k) cleared to be used in a manner consistent with their indication for use labeling.

Components of the MightySat Rx, including the battery door, battery or lanyard could pose a potential choking hazard if left unattended. The MightySat Rx should remain with site staff at all times when device is not placed on a subject. During data collection, research personnel should be present with the subject during the entire duration of the study procedures.

There is a risk of skin irritation and drying of mucous membranes [redacted]. The risks are low due to the short study duration. If discomfort occurs, the study can be stopped.

The sensors have been subjected to performance, mechanical, and electrical testing, skin surface temperature and results demonstrate that the sensors meet the requirements for safety and effectiveness for intended use of the product, refer to investigational brochure for further details.

6. OBJECTIVES OF THE CLINICAL INVESTIGATION

The objective of this study is to validate the RRp performance of the noninvasive Masimo MightySat Rx device in pediatric populations.

7. DESIGN OF THE CLINICAL INVESTIGATION

7.1. General

This is a single-center, nonrandomized single arm study wherein all subjects are enrolled into the experimental arm and receive the MightySat Rx [redacted]

7.2. Investigation Site(s)

[redacted]

7.3. Definition of Completion of the Clinical Investigation

The study will be considered complete once data has been collected from [redacted] eligible subjects and a clinical study report is finalized.

7.4. Study device(s) and comparator(s)

Investigational device: Masimo MightySat Rx

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[redacted]

7.5. Subjects

7.5.1. Inclusion Criteria

- Subject is 5 to 18 years of age.
- Subject weighs 30 to 50 kg.

7.5.2. Exclusion Criteria

- Subject has a condition at or around the 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.
- Subject is unable to sit with minimal movement during data collection.
- Subject has any medical condition which, in the judgment of the investigator or study staff, renders them ineligible for participation in this study.
- Subject is excluded at the study staff's discretion.

7.5.3. Subject Withdrawal and Follow-up

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. The study team may terminate the subject from the study prior to expected completion 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 to the Sponsor.

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

7.5.4. Point of Enrollment

The point of enrollment is defined as the time at which a subject and parent or Legal Guardian complete the informed assent (if applicable) and consent processes.

7.5.5. Expected Duration of Subject Participation

[redacted]. Total duration of study participation from time of consent will be approximately 60 min.

7.5.6. Expected Duration of Study Enrollment

Study enrollment will continue until the sample size (see 8.2) is achieved. This will be approximately 1 to 3 months.

7.5.7. Subject Classification

Subjects will be classified according to the criteria below:

- **Screened** – Subjects who are assessed for study eligibility, after the child's parent(s), guardian(s), or legally authorized representative have signed the informed consent form (ICF).
- **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:
  - The child's parent(s), guardian(s), or legally authorized representative voluntarily withdrew their consent.
  - Subject was discontinued from study at the discretion of the principal investigator (PI).
- **Completed** – [redacted]

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7.6. Procedures

7.6.1. Patient demographic information including, but not only limited to, age, gender, weight, height, skin pigmentation (for example using Massey scale), finger circumference, race or ethnicity will be recorded on the case report form (CRF), as well as current medical conditions and recent medical history (up to 90 days prior).

7.6.2. A MightySat Rx pulse oximeter will be placed on the subject's [redacted] finger.

[redacted]

7.6.4. After the MightySat Rx pulse oximeter [redacted] are placed, the subject will be observed [redacted] while sitting at rest.

7.6.5. After approximately 5 minutes, about 3 to 5 spot check measurements using the MightySat Rx device will be taken, [redacted]

[redacted]

7.6.7. The MightySatRx study sensor placement location, study sensor ID/lot number, and other relevant information will be recorded in eCRF.

7.6.8. At the conclusion of the study, devices and data recording will be stopped. All sensors will be removed.

7.6.9. Data collected by the study devices is not intended to be used for clinical decisions.

7.7. Monitoring plan

Oversight for this clinical trial is provided by the sponsor, investigators, and local IRBs.

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 Standard Operating Procedures (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, and every 2-4 weeks thereafter
- A final close out visit after the last subject had finished the study.

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. The Investigator will provide the monitor access to all necessary records to ensure the integrity of the data (21 CFR 812).

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 the CRF against source documentation.

After each visit, the monitor will provide a monitoring report to the Investigator within 4 weeks of visit completion. The monitoring report will detail findings and open action items observed during the visit. It is the responsibility of the PI 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 report. Any open action items not completed within the time allowed may be

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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.

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.

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

8. STATISTICAL DESIGN AND ANALYSIS

8.1. Acceptance Criteria

The MightySat Rx device will be determined to have comparable performance and should meet the acceptable limit of ≤ 3.0 RPM A_{RMS} and ≤±1.0 RPM Mean Error.

8.2. Sample Size

Sample size for this study has been determined [redacted], based on previous experience with similar devices and Masimo internal procedures for sample size calculation.

[redacted]

8.3. Statistical Analysis

[redacted]

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

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

[redacted]

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

[1] Sample Size Calculations, Practical Methods for Engineer and Scientists, Paul Mathews ISBN 978-0-615-32461-6

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8.4. Expected Dropout Rates

Data collection will continue until a sufficient number of cases have been obtained with quality data (e.g., no data drop-outs).

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. 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, whether subject consent was obtained before start of study, 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 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.

Only authorized sponsor personnel will have access to study data, and will move it to a secure and backed-up drive at Masimo.

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.

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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 a given 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 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

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 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

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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, 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.

14. INFORMED CONSENT PROCESS

- The investigator shall not enroll any subject to participate in the study or consent any subject prior to receiving IRB approval of the informed consent form.
- No study-related activities will be conducted until the assent/consent is signed and dated from the subject (if age-applicable), and the parental consent form is signed and dated by the subject's parent or legal guardian.
- Following identification of a potential eligible subject as defined by the inclusion and exclusion criteria, the subject will be approached by the study staff. Study staff will explain the purpose and procedures of the study with respect to potentials risks and benefits, and clarification of the subject's rights and privacy information. The research team will emphasize that participation is voluntary and declining participation in the study will not result in any penalty or loss of benefits that the subject is otherwise entitled.
- Individuals will be given ample time to review the assent, consent and/or parental consent form and the opportunity to ask the person obtaining consent any questions.
- Once the subject or parent(s)/Legal Guardian questions have been answered and the informed consent is signed and dated, the Principal Investigator or delegate will also sign the informed consent document, approving that the subject will be enrolled in the study. The investigator shall retain the original copy of the signed informed consent document in each subject's records and provide a copy to the subject.
- The point of enrollment is defined as the time at which the assent is signed and dated from the subject (if applicable), and the parental consent form is signed and dated by the subject's parent or legal guardian. The subject may withdraw from the study at any time.

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

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- 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.

- 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. List of Anticipated Adverse Events

15.2.1. Anticipated Device-Related Adverse Events

The noninvasive device used in this study is similar to commercially available pulse oximeters and hence has minimal risks. Pulse oximeters and other non-invasive devices are commonly used and are considered to be minimal risk.

There is an extremely small risk of damage to the subject's skin where sensors are placed, from the device, including temporary skin irritation or discomfort associated with exposure to the sensor, as well as potential temporary mechanical irritation or discomfort. There is a remote, yet possible, risk of a burn from the sensor. In the case of a sensor burn, there is the potential for permanent skin damage (scar/discoloration).

15.2.2. List of Non-Reportable Adverse Events

All adverse events will be reported to the Sponsor.

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.

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- 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.

16. VULNERABLE POPULATION

16.1. Definition

Vulnerable population are research participants, such as children, 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. Children, economically or educationally disadvantaged persons may be enrolled in this study.

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.
- For children, the Investigator will ensure that the parent/legal guardian does not unduly influence subjects to participate (21 CFR Part 50). Parents/legal guardian of the participant will have ample time to ask questions and understand the information being presented.

16.3. Responsible Parties

- The EC/IRB will review research with vulnerable populations and evaluate consent, 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 determine 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.

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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.

19. BIBLIOGRAPHY

1. Cretikos MA, Bellomo R, Hillman K, Chen J, Finfer S, Flabouris A. Respiratory rate: the neglected vital sign. Med J Aust [Internet]. 2008 Jun 2 [cited 2022 Dec 2];188(11). Available from: https://www.mja.com.au/journal/2008/188/11/respiratory-rate-neglected-vital-sign

20. Revision history

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