Official Title: Clinical Performance of Masimo Rad-GT

Date of Protocol: February 14, 2023

NCT Number: NCT05779397

Clinical Investigation Title: Clinical Performance of Masimo Rad-GT

Clinical Investigation Number, Version: [redacted]

Other Study Identifier: N/A

Study Device(s): Masimo Rad-GT

Sponsor: Masimo Corporation
52 Discovery
Irvine, California 92618 USA

Investigator Page

Principal Investigator (s): [redacted]

Investigation Site(s): Clinical Laboratory, Masimo Corporation
Address: 52 Discovery
Irvine, CA 92618

IRB: Salus IRB Board 5 – IRB00013544
Address: 2111 W. Braker Lane
Suite 100
Austin, TX 78758

Agreement between Investigator and Sponsor Regarding Responsibilities for Good Clinical Practice

Sponsor and Investigator agree to comply with International Conference of Harmonization (ICH) E6 Good Clinical Practice guidance. ICH E6 GCP 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 participants 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, participant 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:**

1. OVERALL SYNOPSIS OF THE CLINICAL INVESTIGATION

Clinical investigation title:	Clinical Performance of Masimo Rad-GT
Study objective(s):	To validate the performance of Masimo Rad-GT.
Investigational device(s):	Masimo Rad-GT
Number of participants:	Approximately 73 subjects.
Inclusion criteria:	Refer to section 6.3.1
Exclusion criteria:	Refer to section 6.3.2
Duration of the clinical investigation:	The expected duration of study enrollment is 1 to 3 months.
Study endpoint(s):	Accuracy of temperature measurements using the Masimo Rad-GT will be compared to reference temperature measurements

2. IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICE

Masimo Corporation is the developer of noninvasive technologies for the measurement and monitoring of physiological variables, such as arterial oxygen saturation (SpO2), total hemoglobin concentration (SpHb), carboxyhemoglobin concentration (SpCO), methemoglobin concentration (SpMet), and other physiological variables to improve patient outcomes and reduce cost of care.

The Masimo Rad-GT device (see **Figure 1**) is a non-contact infrared thermometry device intended to ascertain body temperature from skin temperature measurements. Non-contact infrared thermometers utilize infrared sensors that detect thermal radiation from the body. The sensor then converts radiant energy to an electrical signal and provides a temperature reading without discomfort for the patient or associated hygiene concerns. Thus, non-contact thermometry is a particularly attractive solution due to its optimization of patient comfort, noninvasiveness, and minimization of cross contamination. The device is a non-invasive, non-contact, handheld pulse oximetry device with a rechargeable battery and LCD display. It uses Masimo Measure-through Motion and Low Perfusion™ SET® pulse oximetry technology to measure SpO2, respiration rate from the Pleth (RRp™), pulse rate (PR), perfusion index (PI), and temperature. The Masimo Rad-GT is not FDA cleared and is considered investigational. Though the Rad-GT may be used to measure the aforementioned parameters, the Rad-GT used in this study will only be used to measure body temperature.

Figure 2 Masimo Rad-GT with integrated infrared temperature sensor at back of the device

[redacted]

3. JUSTIFICATION FOR THE DESIGN OF THE CLINICAL INVESTIGATION

This is a prospective, nonrandomized, single arm study wherein all subjects are enrolled into the experimental arm and will have their temperature taken with Masimo Rad-GT. The study is designed to validate the clinical performance of Masimo Rad-GT in the accuracy of temperature measurements.

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

4.1. Anticipated Benefits

There will be no direct benefits to the enrolled participants; however, this study hopes to learn more about the temperature device to potentially help other patients in the future. Other possible benefits would be to society as a whole.

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

- **Risks Associated with the Device**

  The Rad-GT device does not pose risks to the participant, because the device is non-contact and does not emit any energy. Reference measurements will be obtained using a [redacted] using normal practice.

- **Risks from Inflicted Knowledge**

  The risk of inflicted medical knowledge to subjects is negligible since we de-identify all associated information including those relevant to our clinical and engineering parameter studies. The monitoring and test results are not examined for diagnostic purposes and do not reflect an attempt to ascertain any subject's medical condition. The attending physician's role during this study is to ensure the safety of the subject during the study.

  We will reduce the risk of inflicted knowledge by assuring the subjects that device readings are for research use only. In the case that a subject becomes aware of a condition (hypertension, arrhythmia, etc.) they have during the course of our study, our study staff will recommend that they contact their primary care physician and we will document this recommendation. As part of that process, we will follow up with these individuals prior to enrollment if their condition meets exclusion criteria for a study.

- **Risks from Loss of Confidentiality**

  Masimo upholds the highest standards to protect hard and electronic data, however, a complete promise for confidentiality cannot be guaranteed due to unforeseeable events.

4.3. Importance of Knowledge Gained

Development of new temperature technologies could enable users to monitor temperature vital signs remotely and lessen the need for hospital visits.

4.4. Emergency Response Plan for Medical Emergencies

A crash cart equipped with medications to provide immediate care during emergencies is on site and full emergency services are within 3 miles.

Study staff will dial 911 for medical emergencies that require emergency medical services (EMS) to be contacted.

4.5. Alternatives

The alternative is to not participate in the study.

5. OBJECTIVES OF THE CLINICAL INVESTIGATION

The objective of this study is to validate Masimo Rad-GT to evaluate the performance of the device in obtaining temperature measurements. Measurements from the Masimo Rad-GT will be compared to [redacted].

6. DESIGN OF THE CLINICAL INVESTIGATION

6.1. General

This is a prospective, nonrandomized, single arm study. Temperature data will be obtained using the Masimo Rad-GT while obtaining [redacted] as a reference.

Accuracy of temperature measurements using the Masimo Rad-GT will be compared to the [redacted].

The validation of the accuracy of the temperature measurement in the investigational device may be determined using data collected from this study, in addition to data from other Masimo sponsored studies.

6.2. Equipment and Materials

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

Investigational Device

- Masimo Rad-GT

Reference Equipment

- Hospital standard of care [redacted]

Research Equipment

- Laptop with data collection software

6.3. Investigational device(s) and comparator(s)

The study will collect data to calibrate and validate the performance of the Masimo Rad-GT as compared to [redacted].

6.3.1. Inclusion Criteria (Eligible Subjects)

- Subject is 18 to 80 years of age.
- Subjects are able to read and communicate in English as well as understand the study and the risks involved.

6.3.2. Exclusion Criteria (Ineligible Subjects) (* = Per study staff discretion)

- Subject is pregnant or nursing.
- Subject has a known neurological and/or psychiatric disorder (e.g., schizophrenia, bipolar disorder, Multiple Sclerosis, Huntington's disease) that interferes with the subject's level of consciousness. *
- Subject has any medical condition which in the judgment of the investigator and/or study staff, renders them ineligible for participation in this study or subject is deemed ineligible by the discretion of the investigator/study staff.

6.4. Procedures

6.4.1. Recruitment and Pre-Screening

6.4.1.1. Advertisement and Recruitment

[redacted]

6.4.1.2. Phone Screening

[redacted]

6.4.2. Consenting and Screening

[redacted]

The subject must read and sign the consent document, using our informed consent process.

The paper consent must be stamped with a current IRB approval. Due to the limitations of the electronic consent, the consent form may not be stamped with a current IRB approval; however, the IRB will review and approve the electronic document prior to implementation. The electronic consent will contain indicators that show the version of the form. No study-related activities will be conducted until consent is obtained from the subject.

After informed consent is obtained, subjects will be asked a brief series of health questions to ensure their eligibility for this study. Subjects who do not meet the inclusion criteria and/or meet exclusion criteria will not be eligible to participate in the study.

[redacted]

Body mass index (BMI) may also be calculated to assess for eligibility for the study.

Female subjects will be required to take a pregnancy test. Results will be noted. If the pregnancy test is positive, the subject will be removed from the study and notified of their pregnancy test results.

In addition, a medical history will be recorded after the initial screening questionnaire. [redacted]

Subjects may be offered a snack (e.g., granola bar) and/or beverage (e.g., water, juice) due to the amount of time their involvement in this study may take.

6.4.3. Data Collection Procedure

Data collected by the Rad-GT is not intended to be used for clinical decisions, and research personnel should continue to use standard of care procedures for monitoring participants.

Record subject demographic information such as, but not only limited to, age, gender, weight, height, Massey scale, race or ethnicity on the case report form (CRF), as well as current medical conditions and recent medical history.

[redacted].

Record start and end time of data collection procedures on the CRF.

Reference Measurements:

* Measurements may be taken several times throughout the study.

[redacted] (see **Figure 3**) [redacted] the hospital's standard of care [redacted]. Multiple reference measurements may be obtained.

[redacted]

Data from [redacted] at the end of data collection for each subject.

Rad-GT Device Measurements:

* Measurements may be taken several times throughout the study.

To obtain measurements using the Rad-GT device, start by locating the temperature button (**Figure 4a**) and sensor lens (**Figure 4b**). Make sure there are no obstructions to the sensor's field of view (i.e., hair, glasses, fingers, clothing).

[redacted]

6.4.4. Ending Procedure

At the conclusion of the procedure, the sensor(s)/device(s) will be removed (if applicable).

The approximate subject participation is 1 hour.

All subjects will be encouraged to remain in the study area until they feel fit to leave. Subjects should feel safe and able before returning to work directly after participation in the study. [redacted]

Subjects will be paid according to the compensation breakdown on the consent form.

6.5. Monitoring plan

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

and GCP compliance.

7. STATISTICAL DESIGN AND ANALYSIS

7.1. Acceptance Criteria

Parameter	Acceptance Criteria[1]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

7.2. Sample Size

The sample size of up to 73 participants per ISO 80601-2-56:2017, section 201.102.

7.3. Statistical Analysis

The statistical analysis will follow the procedure outlined in ISO 80601-2-56:2017 section 201.102.

7.3.1. Exclusion

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

- Any subject administered antipyretic medications during study participation
- Any subject who does not complete at least one full round of measurements.
- Any subject whose data suggests a defective device or sensor.
- Any subject whose data suggests existence of external conditions that interfere with Rad-GT or reference measurements.

7.4. Expected Dropout Rates

Participants may not complete the study for various reasons, at the investigator's or study staff's discretion, or because the participant does not want to continue the study. Due to the short duration and simple, noninvasive procedures of this study, there are limited expected dropouts.

8. DATA MANAGEMENT

8.1. 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.

8.2. 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

[redacted].

after verification as being accurate and complete.

8.3. Case Report Forms

The site shall capture study data in case report forms (CRFs) for each participant 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 participants who fail to complete the study. If a participant 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 participant 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 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.

8.4. 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.

8.5. 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.

9. 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.

10. 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 participants, 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.

11. DEVICE ACCOUNTABILITY

11.1. 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.

11.2. Use of Study Device

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

11.3. 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.

12. 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 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.

13. INFORMED CONSENT PROCESS

A waiver of formal, written informed consent is requested because this study involves minimal risks and does not adversely affect participant rights and welfare. An information sheet will be provided at the start of the study to inform the patient/LAR about the study and what data will be collected. Verbal consent will be collected prior to study procedures. Reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality is no greater than minimal.

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

14.1. 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 participants, 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 participant, 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) fetal distress, fetal 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 participants, users or other persons, and that requires prompt remedial action for other participants, 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.

14.2. List of non-reportable adverse events

All adverse events will be reported and documented as described below. However, there are no anticipated adverse events as the Rad-GT device does not pose risks to the participant, because the device is non-contact and does not emit any energy.

14.3. 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.

14.4. 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.

15. VULNERABLE POPULATION

15.1. Definition

Vulnerable populations 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. This study is targeting to enroll vulnerable populations such as children.

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

15.2. Protection of vulnerable participants

- For children, the Investigator will ensure that the parent/legal guardian does not unduly influence participants to participate. Parents/legal guardian of the participant will have ample time to ask questions about study devices and procedures.
- Educationally disadvantaged participants will be provided ample time to ask questions and comprehend information.
- Medical care will be provided to these participants 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.

15.3. Responsible Parties

- The IRB will review research with vulnerable populations and evaluate consent, level of risk, coercion, and the reason for choosing this particular participant population. The 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 participants by ensuring that all regulations and proper documentation of consent is handled in a compliant and timely manner.

16. SUSPENSION OR PREMATURE TERMINATION OF THE CLINICAL INVESTIGATION

16.1. 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 participants.

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 participant 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.

16.2. 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 participants. 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.

17. 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 validation phase of the clinical investigation will be made publicly available.

18. BIBLIOGRAPHY

N/A

19. REVISION HISTORY

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