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Clinical Study Protocol

Study Title:	Maternal Fetal Device Performance Testing During Antepartum Singleton Monitoring
Study Number:	SA-000072
Version Number:	2.0
Version Date:	23SEP2024

Sponsor: GE HealthCare Technologies Inc.
3000 N. Grandview Blvd
Waukesha, WI 53188

Sponsor Contact: See Appendix A – Administrative Structure of Investigation

FOR QUALIFIED INVESTIGATORS, STUDY STAFF, AND THEIR ETHICS COMMITTEE(S) ONLY

CONFIDENTIALITY STATEMENT

Information in this RESEARCH STUDY PROTOCOL is for investigators, site personnel involved with the study, ethics committee(s), and/or their authorized representative(s) except as required to obtain consent from study subjects or as otherwise required by law. Once signed, the terms of the protocol are binding for all parties.

The Sponsor and Investigator have approved this protocol version, and I can confirm hereby to conduct the study according to the protocol and per applicable principles of the World Medical Association Declaration of Helsinki and Good Clinical Practice (GCP) guidelines as per ISO 14155, any conditions of approval imposed by the reviewing ethics committee (EC) or governing regulatory body, and applicable local and federal laws and regulations. The investigator should not deviate from this protocol except for emergency use. I have read and understood and agree to abide by all the conditions and instructions contained in this protocol.

Local Principal Investigator at study site:

Investigator Signature	Date
Print Name	
Site Name, Department, Address	

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Document and Version Control

This section records all changes made to the protocol for a specific study. In the table below, record every relevant change by indicating what changes have been made.

Version	Date	Author	Comments/Changes
1.0	27AUG2024	[redacted] [redacted]	Clinical Writer Research Program Integrator Initial version
2.0	23SEP2024	[redacted]	Updated statistical analysis for clarity. Updated study procedures for clinical workflow. Added range of [redacted] on monitoring time Updated minor grammatical edits throughout

https://gehealthcare.box.com/s/5if8dok2e9j32j388d9aoxdw28vat5j4

LIST OF ABBREVIATIONS AND TERMS

AE	Adverse Event
ADE	Adverse Device Effect
AFAP	As far As Possible
AMA	American Medical Association
ASADE	Anticipated Serious Adverse Device Effects
BMI	Body Mass Index
CA	Competent Authority
CCG	Case Report Form Completion Guidelines
CFR	Code of Federal Regulations
CHF	Clinical History File (synonymous with e-Trial Master File
CIP	Clinical Investigation Plan
CRF	Case Report Forms
CTG	Cardiotocography
CTMS	Clinical Trials Management System
DCF	Data Collection Form
DMP	Data Management Plan
eCRFs	Electronic Case Report Forms
EC	Ethics Committee
EDC	Electronic Data Capture
EHG	Electrohysterography
fECG	fetal Electrocardiography
EMG	Electromyography
FDA	Food and Drug Administration
FHR	Fetal Heart Rate
FMD	Fetal Movement Detection

FSE	Fetal Scalp Electrode
GCP	Good Clinical Practice (see ISO 14155:2020)
GEHC	GE HealthCare Technologies, Inc
HCP	Health Care Provider
IB	Investigator Brochure
ICF	Informed Consent Form
IFU	Instructions for Use
IRB	Investigational Review Board
ISO	International Organization for Standardization
IUPC	Intrauterine Pressure Catheter
MHR	Maternal Heart Rate
MWS	GE HealthCare MyWorkshop Internal Documentation System
PI	Principal Investigator
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
TOCO	Tocodynamometer
UA	Uterine Activity
UC	Uterine Contraction
US	Ultrasound
USADE	Unexpected Serious Adverse Device Event
Veeva	GE HealthCare CTMS Internal Documentation System

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SYNOPSIS	
Sponsor:	GE HealthCare Technologies Inc.
Research Type:	This is a comparative device study to evaluate accuracy and usability.
Regulatory Status:	This is a pre-market research study of the following devices/products: *Pre-market*: [redacted] *Post-market*: Corometrics 259cx

Background and Rationale:	Maternal Fetal Monitoring devices assist the health care professional in acquiring, monitoring, and storing fetal and maternal physiologic data which supports the decision making for pregnant women and the overall fetal health status during pregnancy and delivery. These devices are often used during labor to monitor physiologic parameters including: • Fetal heart rate (FHR) • Maternal parameters such as maternal heart rate (MHR), blood pressure, temperature, and pulse oximetry and • Uterine Activity (UA) Maternal Fetal Monitoring devices are not treatment devices; their performance and indirect benefit is best measured by the accuracy of the physiologic data provided. Their performance is also measured by their ability to provide the relevant physiologic data, especially the FHR, which can be difficult to obtain. Plotting of the FHR and uterine activity on the same graph is referred to as a cardiotocography (CTG). There are three types of FHR and uterine activity devices that are used to comprise the CTG: • An internal fetal scalp electrode (FSE) is used to obtain FHR with an internal intrauterine pressure catheter (IUPC) used to measure contractions during labor. • An external Doppler ultrasound (US) device is used to record the fetal heart rate and is used with an external tocodynamometer (TOCO) used to sense pressure during contractions. • An external device to capture the fetal electrocardiogram (fECG) and uterine electromyography (EMG) Of the three ways to measure FHR, a fetal scalp electrode is generally considered the gold standard for accuracy, but this invasive method requires ruptured membranes and a dilated cervix and is contraindicated with some maternal infections and fetal conditions. Doppler Ultrasound (US) is non-invasive and utilizes an external transducer placed on the maternal abdomen to detect fetal cardiac valve movements utilizing high frequency sound waves. US/TOCO are the most common type of CTG and the term CTG is sometimes used to refer specifically to that method of fetal-maternal monitoring. However, there are challenges with this method due high sensitivity of fetal and maternal movements causing signal void, thus the transducer must often be adjusted to correctly detect the FHR. The accuracy of FSE and US Doppler FHR measurements are not often the subject of publication, likely because the devices are well-established and considered the standard of care.[1,2] This study aims to support a new maternal fetal monitoring device with clinical data to demonstrate the equivalent performance against the currently marketed Corometrics 259cx. FHR and Fetal Movement Detection (FMD) data will be collected during antenatal testing using standard of care Doppler US. The new Maternal/Fetal Monitor is capable of monitoring heart rates (maternal/fetal), maternal uterine contractions, as well as maternal blood pressure and maternal pulse oximetry. This study

	will compare clinical data between the current and the new monitor on non-laboring singleton gestation women. The results of this study are intended for use in regulatory submissions including FDA 510k and EU CE marking. Results may be used to help commercialize the product in other global regions in the future, at the discretion of the Sponsor. Funding for this study will be provided by GE HealthCare (GEHC). This study does not include patient advisors.
Objectives:	**Primary Objective** The primary objective of this study is to collect clinical data from two devices, [redacted] investigational device and the Corometrics 259cx, a currently approved device. Based on the data collected, a comparative device analysis of the reliability of Fetal heart rate (FHR) from Doppler US will be conducted. **Secondary Objective(s)** The secondary objectives of this study are: • To collect raw parameter data from [redacted] • To collect Automated Fetal Movement Detection (FMD) and Remote Event Marks (REM) of Lotus and Corometrics 259cx. **Safety Objective(s)** The safety objective of this study is to collect safety information, including type and number of AEs, SAEs, and device issues.

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Procedures/ Methods:	After the subject has provided informed consent, the subject is enrolled in the study. The study procedures are outlined below: 1. [redacted] 2. [redacted] 3. [redacted] 4. [redacted] 5. [redacted] 6. [redacted] 7. [redacted] 8. [redacted] 9. [redacted] 10. [redacted] 11. [redacted] 12. [redacted]

<table>
<tr><td>Endpoints:</td><td colspan="2">Primary Endpoints

The primary endpoint of this study is collection of FHR data from 30 subjects undergoing routine monitoring during antenatal period to allow for analysis of the reliability of the two maternal fetal monitors.

Reliability will be measured in terms of success rate which is defined as percentage of time in which the device gives FHR reading during the study monitoring period. Non-inferiority of Lotus with respect to Corometrics 259cx will be tested using a non-inferiority margin of -10%.

Secondary Endpoints

The secondary endpoint of this study is collection of RAW parameter data [redacted]

Safety Endpoints

The safety endpoints of this study are type and number of AEs, SAEs, and device issues.</td></tr>
<tr><td rowspan="2">Eligibility Criteria:</td><td>Inclusion criteria:
Subjects who meet all the following inclusion criteria may be enrolled:
1. Able and willing to provide written informed consent.
2. Singleton pregnancy
3. Aged 18+
4. Greater than or equal to 22 0/7 weeks gestation
5. Patient has none of the exclusion criteria.</td><td>Exclusion criteria:
Subjects who meet any of the following exclusion criteria may not be enrolled:
1. Multiple pregnancy.
2. Involvement in another clinical trial currently or previously in this pregnancy that, in the investigator’s opinion, would affect the conduct of this study.
3. Medical or obstetric problem that in investigator’s opinion would make the patient incapable of taking part in the study.
4. Inability to understand the consent information due to medical illness, diminished intellectual capacity, or insurmountable language barrier.</td></tr>
<tr><td colspan="2">[redacted]</td></tr>
</table>

<table>
<tr><td>Sample Size and Sites:</td><td>This study is intended to be conducted at one United States site. Subjects will be divided into three groups based on gestational age groups.
Table 1: Target Enrollment Groups
<table><tr><th>Subject Gestational Age Groups</th><th>Target Enrollment</th></tr><tr><td>Group 1: 22 0/7 – 24 6/7 Weeks</td><td>10</td></tr><tr><td>Group 2: 25 0/7 – 31 6/7 Weeks</td><td>10</td></tr><tr><td>Group 3: ≧32 0/7 Weeks</td><td>10</td></tr></table>[redacted] andomization schema will be provided by the sponsor within each gestational age group.</td></tr>
<tr><td>Sample Size and Site:</td><td>The sample size has not been derived from a statistically powered endpoint but has been determined based on a review of the literature, bench testing results and publicly available regulatory filings.
[redacted]</td></tr>
<tr><td>Study Duration:</td><td>The study is expected to last 4 months.</td></tr>
<tr><td>Study Completion:</td><td>The study will be deemed completed following completion of data collection of the last enrolled subject.</td></tr>
</table>

1. BACKGROUND AND JUSTIFICATION

Maternal Fetal Monitoring devices assist the health care professional in acquiring, monitoring, and storing fetal and maternal physiologic data which supports the decision making for pregnant women and the overall fetal health status during pregnancy and delivery. These devices are often used during labor to monitor physiologic parameters including:

- Fetal heart rate (FHR)
- Maternal parameters such as maternal heart rate (MHR), blood pressure, temperature, and pulse oximetry and
- Uterine Activity (UA)

Maternal Fetal Monitoring devices are not treatment devices; their performance and indirect benefit is best measured by the accuracy of the physiologic data provided. Their performance is also measured by their ability to provide the relevant physiologic data, especially the FHR, which can be difficult to obtain.

Plotting of the FHR and uterine activity on the same graph is referred to as a cardiotocography (CTG). There are three types of FHR and uterine activity devices that are used to comprise the CTG:

- An internal fetal scalp electrode (FSE) is used to obtain FHR with an internal intrauterine pressure catheter (IUPC) used to measure contractions during labor.
- An external Doppler ultrasound (US) device is used to record the fetal heart rate and is used with an external tocodynamometer (TOCO) used to sense pressure during contractions.
- An external device to capture the fetal electrocardiogram (fECG) and uterine electromyography (EMG)

Of the three ways to measure FHR, a fetal scalp electrode is generally considered the gold standard for accuracy, but this invasive method requires ruptured membranes and a dilated cervix and is contraindicated with some maternal infections and fetal conditions. Doppler Ultrasound (US) is non-invasive and utilizes an external transducer placed on the maternal abdomen to detect fetal cardiac valve movements utilizing high frequency sound waves. US/ Tocodynamometer (TOCO) are the most common type of CTG and the term CTG is sometimes used to refer specifically to that method of fetal-maternal monitoring. However, there are challenges with this method due high sensitivity of fetal and maternal movements causing signal void, thus the transducer must often be adjusted to correctly detect the FHR. The accuracy of FSE and US Doppler FHR measurements are not often the subject of publication, likely because the devices are well-established and considered the standard of care.[1,2]

This study aims to support a new maternal fetal monitoring device with clinical data to demonstrate the equivalent performance against the currently marketed Corometrics 259cx. FHR and Fetal Movement Detection (FMD) data will be collected during antenatal testing using standard of care Doppler US.

The new Maternal/Fetal Monitor is capable of monitoring heart rates (maternal/fetal), maternal uterine contractions, as well as maternal blood pressure and maternal pulse oximetry. This study will compare clinical data between the current and the new monitor on non-laboring singleton gestation women.

The results of this study are intended for use in regulatory submissions including FDA 510k and EU CE marking. Results may be used to help commercialize the product in other global regions in the future, at the discretion of the Sponsor.

Funding for this study will be provided by GE HealthCare (GEHC). This study does not include patient advisors.

2. DEVICE DESCRIPTION

2.1. Identity, Mechanism, and Function

Name: New Maternal Fetal Monitor (Lotus)

Modality/Type: Patient Care Solutions (PCS) – Maternal Infant Care

Manufacturer: GE HealthCare (GEHC)

Software version:

- Pre-Market device [redacted]
- Post-Market Device (Corometrics 259cx) [redacted]

Regulatory Status: *Pre-market*: [redacted]
Post-market: Corometrics 259cx

NOTE: A record of number of devices issued, along with applicable identification numbers (e.g., serial/lot/batch) and components/accessories used in this study will be retained by the Sponsor as part of the clinical history file (CHF), as required by applicable laws and regulations.

[redacted]

Figure 1: [redacted] Maternal Fetal Monitor

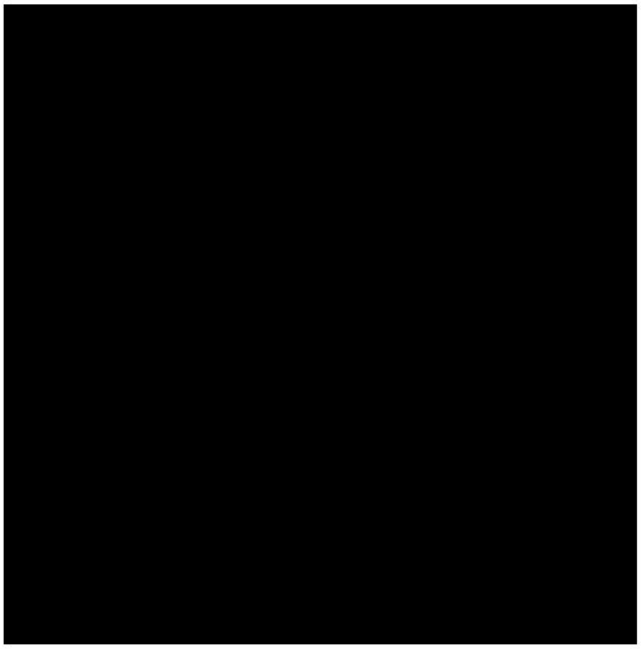


Figure 2: [redacted] Ultrasound Transducer

The investigational device, instructions for use and packaging shall indicate that it is for use in a research investigation, per applicable regulations in the United States, United States FDA 21 CFR, and other applicable laws and regulations.

The investigational device will be exclusively used for research purposes.

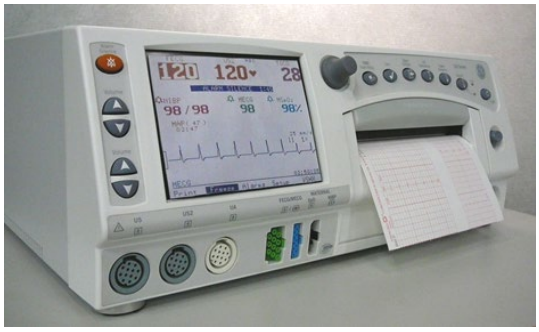
2.2. Intended Use

[redacted]

2.3. Comparators / Reference Standard

The comparator/reference standard is Corometrics 259cx. The Corometrics 259cx Maternal Fetal Monitor System is intended for noninvasive and invasive monitoring of the fetus during the antepartum period as well as throughout labor and delivery (i.e. fetal heart rate and uterine activity monitoring). Fetal movement detection and fetal heart rate alarm options (user selectable high/low and poor signal quality alarms) are available. Corometrics 259cx is used for monitoring maternal vital signs to help assess maternal well-being. Additional information regarding intended use of the device may be found in the IB or IFU.

Figure 3: Corometrics 259cx Maternal Fetal Monitor



Corometrics 259cx is a regulatory cleared, commercially available device (FDA 510k: K072976).

2.4. Concomitant/Ancillary Administrations

2.4.1. Medications and Biologic Products

No medications or biologic products will be administered as part of study procedures.

2.4.2. Laboratory Tests and Sample Processing

No laboratory tests or sample processing is planned as part of the study procedures.

2.5. Accountability

Accurate and adequate records will be maintained for all devices, from time of shipment to the sites until return or disposal of all devices issued by the Sponsor as part of this study, as required by applicable laws and regulations. The Principal Investigator will be responsible for the security and integrity of research devices at the investigational site during the study.

2.5.1. Issuance

The device will be provided by the Sponsor GEHC. Calibration/maintenance of study device is planned to maintain integrity of study data as needed.

2.5.2. Disposition

The devices will be dispositioned after the study by returning to the Sponsor, per applicable safety instruction, laws, and regulations.

2.6. Anticipated Risks and Benefits

The device under study has undergone risk assessment, per International Standards Organization (ISO) 14971, and risks associated with the usage of the device in this study will be mitigated to levels as far as possible (AFAP) prior to study execution.

The risks of study participation are not expected to be greater than those of similar procedures as described in ISO 80601-2-61:2017 Annex EE.3 standard methods routinely conducted in earlier testing. Post-study care or follow-up is not required by this study.

There are no expected risks to subjects, operators, or others in this study beyond those of routine/similar devices in clinical care.

Subjects are not expected to benefit directly from study participation. The results may benefit future patients by helping to better understand the investigational device by introducing an improved flexible mobile platform for patient monitoring before, during and after delivery.

2.6.1. Risk Category and Rationale

The devices, [redacted] and Corometrics 259cx, as used in this study, are not considered a significant risk device per the 21 CFR §812.3(m) definition:

1. it is not intended as an implant;
2. is not purported or represented to be for a use in supporting or sustaining human life;
3. is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health;
4. and it does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

3. OBJECTIVES AND ENDPOINTS

3.1. Purpose of the Study

The purpose of the study is to compare clinical data between the currently approved Corometrics 259cx and the new investigational device, [redacted] maternal fetal monitors to evaluate reliability on non-laboring singleton gestation women. Data will be used for regulatory submission.

3.1.1. Primary Objective

The primary objective of this study is to collect clinical data from two devices, [redacted] Based on the data collected, a comparative device analysis of the reliability of Fetal heart rate (FHR) from Doppler US will be conducted.

3.1.2. Secondary Objective(s)

The secondary objectives of this study are:

- To collect raw parameter data from [redacted]
- To collect [redacted]

3.1.3. Safety Objective(s)

The safety objective of this study is to collect safety information, including type and number of AEs, SAEs, and device issues.

3.2. Study Endpoints

3.2.1. Primary Endpoints

The primary endpoint of this study is collection of FHR data from 30 subjects undergoing routine monitoring during antenatal period to allow for analysis of the reliability of the two maternal fetal monitors.

Reliability will be measured in terms of success rate which is defined as percentage of time in which the device gives FHR reading during the study monitoring period. Non-inferiority of [redacted] with respect to Corometrics 259cx will be tested using a non-inferiority margin of -10%.

3.2.2. Secondary Endpoints

The secondary endpoint of this study is to collection of RAW parameter data on [redacted] and Corometrics 259cx to support further algorithm development in pregnant women.

3.2.3. Safety Endpoints

The safety endpoints of this study are type and number of AEs, SAEs, and device issues.

4. STUDY DESIGN

4.1. Summary of Study Design

This is a pre-market, open label, prospective, randomized research study conducted at one site.

The study will be considered complete when subject enrollment and data collection requirements are met.

4.2. Study Population

Subjects meeting all inclusion criteria will be consented for enrollment in the study. Subjects enrolled are expected to be representative of the general population prescribed to receive electronic fetal monitoring.

- Singleton pregnancy
- Greater than or equal to 22 0/7 weeks gestation
- Aged 18+

Participation is expected to last approximately 90 minutes.

4.3. Number of Subjects/Cases

The study includes a minimum of 30 subjects (with a maximum of 60 subjects), divided equally (10 subjects) in each gestational age group. Based on the vulnerability of subjects at the time of study eligibility, subjects may be consented prior to meeting all inclusion/exclusion criteria. Subjects must go on to meet all inclusion/exclusion criteria prior to conducting study procedures, any subject who does not go on to meet all inclusion/exclusion criteria will be considered a screen failure and will be withdrawn from the study. Subjects will be enrolled until the target numbers of 10 completed subjects in each gestational age groups are met: Group 1, 22 0/7 – 24 6/7 weeks, Group 2, 25 0/7 – 31 6/7 weeks and Group 3, ≥ 32 0/7 weeks is achieved.

4.4. Protection of Vulnerable Subjects

Vulnerable subjects are individuals whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate.

The Sponsor shall avoid improper influence on, or inducement of, the subject, monitor, any investigator(s), or other parties participating in, or contributing to, the clinical investigation.

All investigators shall avoid improper influence on, or inducement of, the subject, Sponsor, monitor, other investigator(s), or other parties participating in, or contributing to, the clinical investigation.

The study activities cannot otherwise be performed without the use of vulnerable populations.

Pregnant women/fetuses/neonates: Pregnant women and fetuses, will be subjects in this study. The purpose of this study involves meeting the health needs of these populations. The mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, and risk to the fetus will be minimal.

4.5. Eligibility Criteria

4.5.1. Inclusion Criteria

Subjects who meet all the following inclusion criteria may be enrolled:

1. Able and willing to provide written informed consent.
2. Singleton pregnancy.
3. Aged 18+.
4. Greater than or equal to 22 0/7 weeks gestation.
5. Patient has none of the exclusion criteria.

4.5.2. Exclusion Criteria

Subjects who meet any of the following exclusion criteria may not be enrolled:

1. Multiple pregnancy.
2. Involvement in another clinical trial currently or previously in this pregnancy that, in the investigator's opinion, would affect the conduct of this study.
3. Medical or obstetric problem that in investigator's opinion would make the patient incapable of taking part in the study.
4. Inability to understand the consent information due to medical illness, diminished intellectual capacity, or insurmountable language barrier.

Note: Subjects may participate in more than one gestational age group during the duration of study enrollment but may only participate in each gestational age group once.

4.6. Recruiting and Screening

Subjects will be recruited for potential enrollment in this study according to the standard procedures of the investigational site, unless otherwise specified by the Sponsor in this study protocol. All participation will be voluntary.

Following recruitment and screening, a subject will be considered enrolled (the point of enrollment) once the ICF is signed and dated. Once enrolled, the subject is assigned a unique subject number which will not contain information that could identify the subject (such as subject date of birth). Unique subject number will be used to label electronic Case report form (eCRF (MediData) data for the subject throughout her participation in the study.

Based on the vulnerability of subjects at the time of study eligibility, subjects may be consented prior to meeting all inclusion/exclusion criteria. Subjects must go on to meet all inclusion/exclusion criteria prior to conducting study procedures, any subject who does not go on to meet all inclusion/exclusion criteria will be considered a screen failure and withdrawn from the study. The number of screen failures will be included in the screening and enrollment log.

4.7. Assignment to Study Groups and Enrollment Quotas

This study is intended to be conducted at one United States site. Subjects will be divided into three groups based on gestational age groups.

Table 1: Target Enrollment Groups

Subject Gestational Age Groups	Target Enrollment
Group 1: 22 0/7 – 24 6/7 Weeks	10
Group 2: 25 0/7 – 31 6/7 Weeks	10
Group 3: ≥32 0/7 Weeks	10

[redacted]

4.8. Criteria for Withdrawal/Discontinuation

A subject may withdraw from study participation at any time, for any reason. The Investigator may withdraw a subject at any time, for any reason. The reasons for withdrawal and discontinuation for any subject shall be recorded on an electronic Case Report Form (eCRF). These will be reported to the Sponsor. The EC should be notified per their notification of subject withdrawal policy.

Subjects who are enrolled but do not receive/undergo the study intervention may be replaced. Withdrawn or discontinued subjects who are enrolled, and who do not complete at 30 minutes of monitoring on each device, will not be considered complete and will be replaced. Subjects who withdraw or are withdrawn by a member of the study team prior to completion of all study procedures may have their completed data used as part of the study.

5. STUDY PROCEDURES

5.1. Subject Preparation

Study staff will confirm that the subject is eligible and complies with applicable site requirements prior to starting study procedures.

After providing consent, the subject will be enrolled in the study.

Pregnant women of ≥22 weeks gestation will undergo two 30 (+5 minute range) -minute monitoring sessions (60 minutes total). [redacted]

[redacted]

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[redacted]

5.2. Description of Study Procedures

After the subject has provided informed consent, the subject is enrolled in the study. The study procedures are outlined below:

1. [redacted]

as

Figure 4: Study Set-up Illustrations

5.3. Follow-up

This study does not require follow-ups. The Sponsor is responsible for assuring that the study device fulfills the biomedical safety and standards requirements of the investigational site.

No follow-up will be conducted after the subject's participation has ended. The subject will be followed for AEs from the time the research device is connected to the subject. In addition, all AEs, including those involving delayed reactions, will be followed through to resolution.

6. STUDY DATA COLLECTION AND ASSESSMENTS

Only data relevant to the conduct of the study shall be collected by the Sponsor.

6.1. Primary Assessment

During the study period, the following subject information shall be collected if available:

1. Demographics to include age, race, and ethnicity.
2. Vitals to include height (cm), current weight (kg/g), calculated BMI.
3. Gestational Age (weeks, days).

During the study procedures, electronic and manual data collection shall take place. Subject data collected from the investigational system and Corometrics 259cx devices shall include:

1. Clinical outputs (digital output):
    a. Fetal heart rate
    b. Maternal Pulse rate
2. Plotting of the FHR and MHR on the same CTG
3. Doppler US raw data
4. FMD output
5. REM output

6.2. Secondary Assessments

During the study procedures, electronic and manual data collection shall take place. Subject data collected from [redacted] and Corometrics 259cx shall include:

1) Corometrics 259cx device parameter data
2) [redacted] device raw parameter data

6.3. Safety Assessments

The description, severity, and device relatedness of any AE or SAE during the study will be recorded. Subjects will, if necessary, be provided with emergency care. In the event of any device issues, the event will be recorded. Safety reporting will be conducted as described in this protocol.

7. QUALIFICATION AND TRAINING PLAN

7.1. Staff Qualifications

All members of the study staff participating in the conduct of the investigation shall be qualified by education, training and/or experience to perform their tasks, and this shall be documented appropriately, per ISO 14155:2020 for clinical studies. Study staff and the PI's qualification for the study will be verified by collecting their CV's and GCP certifications. If study staff or PI qualification lapses, the Sponsor will work with the site to requalify the respective role or ensure the duties are reassigned appropriately by the site. The Sponsor reserves the right to disqualify PI with appropriate justification, such as repeated issues that impact subject safety and data integrity.

7.2. Training Plan for the Protocol and Research Device

Before starting the study, the study staff will be trained on the clinical investigation requirements set forth in this study protocol according to Training Plan defined by the Sponsor. This includes any individual that will operate any equipment involved in the study, collect any data that is a part of the study, analyze any data associated with the study, or is in any other way involved with the study. Training to the site personnel will be conducted prior to the first subject enrolled.

The following training information will be collected in the training log prior to study enrollment:

- Title of Training
- Training objectives
- Training logistics (who conducts training and training method)
- Target audience (who will be trained)
- Training content (including device operation, protocol review and understanding)

Study staff directly operating or maintaining the research device will be trained based on the training plan and qualified based on experience, and the hospital/clinical site policy.

The Principal Investigator will be ultimately responsible for execution of this study per the protocol and for device use in this study by members of the study staff.

8. SAFETY

8.1. Anticipated Adverse Events

Being in this study involves some foreseeable risks, which include:

The risks in this study are not expected to be beyond those of routine/similar use of comparable devices in clinical care.

Doppler Ultrasound Transducer:

The Doppler Ultrasound placement involves positioning the transducer on the volunteer subject in the same manner that is used on pregnant women in clinic or hospital settings. Possible risks associated with Doppler Ultrasound include, but are not limited to, potential skin irritation or reaction (i.e. contact dermatitis) from the transducer and/or gel. The transducer under normal operating conditions, (no fault conditions) is not expected to cause discomfort or pain, or pressure sores. Proper placement and handling or repositioning can help minimize these risks. The subject may experience positioning discomfort, and every effort will be made to ensure the subject's comfort and repositioning support. System may fail to pick up valid fetal heart rate or miss reporting of non-reactive, tachycardia or bradycardia fetal heart rate. The devices under test are not intended for clinical decision making. Subject's will be closely monitored by study staff, and testing will be discontinued if more than minor discomfort or any signs or symptoms that could indicate medically important adverse effects related to testing are observed. The risk to use of ultrasound Doppler transducers is believed to be minimal.

Abdominal Transducer Belt

The abdominal transducer belt involves positioning a belt attached to the Doppler Ultrasound Transducer around the subject's abdomen in the same manner that is used on pregnant women in clinic or hospital settings. Possible risks

associated with the abdominal transducer belt include, but are not limited to, potential skin irritation or reaction (i.e., contact dermatitis), abrasions discomfort or pain, or pressure sores. The subject may experience positioning discomfort, and every effort will be made to ensure the subject's comfort and repositioning support. Subjects will be closely monitored by study staff, and testing will be discontinued if more than minor discomfort or any signs or symptoms that could indicate medically important adverse effects related to testing are observed. The risk to use of abdominal transducer belt is believed to be minimal.

Ultrasound Gel:

The Ultrasound gel is a water soluble aqueous ultrasonic gel with a pH of 6.5 to 6.95 and is used as a coupling medium to the ultrasound transducer to replace air between the patient's skin and the transducer. The Ultrasound gel is used in the same manner that is used on pregnant women in clinic or hospital settings. Possible risks associated with the ultrasound gel include, but are not limited to, potential skin irritation or reaction (i.e., contact dermatitis). Subjects will be closely monitored by study staff, and testing will be discontinued if more than minor discomfort or any signs or symptoms that could indicate medically important adverse effects related to testing are observed. The risk to use of Ultrasound gel is believed to be minimal.

Pulse Oximetry Sensor

Pulse Oximetry Sensor placement involves positioning pulse oximetry sensors on the volunteer subject in the same manner that is used on clinic or hospitalized patients. The sensors may be warm to the touch. Under normal operating conditions, (no fault conditions), the sensors are not expected to overheat. If the sensors are too warm, they will be removed immediately. If the sensors are too uncomfortable, they will be removed immediately. The risk in the use of pulse oximetry sensors is believed to be minimal.

There is always a chance of unexpected risks. Throughout the study, the Sponsor will evaluate and update safety information in study documents.

8.2. Adverse Event Definitions

Adverse Event (AE): any 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. This includes events related to the investigational device or the comparator and to the procedures involved. For users or other persons, this is restricted to events related to the use of investigational medical devices or comparators.

Serious Adverse Event (SAE): an adverse event that led to death; led to a serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following: a life-threatening illness or injury, a permanent impairment of a body structure or a body function including chronic disease, or in-patient or prolonged hospitalization, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to body structure or a body function; or led to fetal distress, fetal death or a congenital abnormality or birth defect including physical or mental impairment. Planned hospitalization for a pre-existing condition, or a procedure required by the protocol without serious deterioration in health, is not considered a SAE.

Adverse Device Effect (ADE): an adverse event related to the use of an investigational or comparator medical device. This includes any adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This includes any event that is a result of a user error or intentional misuse of the investigational device.

Serious Adverse Device Effect (SADE): an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Unanticipated serious adverse device effect (USADE): a serious adverse device effect, which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment.

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

8.3. Documentation of Adverse Events

All adverse events (AE), including all serious adverse events (SAE), are required to be collected, investigated, and documented. AEs will be collected from subject enrollment period, and during scanning period for each visit. All AEs will be followed through to their resolution. Documentation will include:

- Description of Event
- Date of onset
- Date of resolution unless resolution does not occur during study reporting period. In the instance that resolution does not occur, the status of the AE will be documented (not resolved/recovered or resolving/recovering)
- Severity (mild, moderate, or severe)
    - *Mild*: Symptom(s) barely noticeable to the subject or does not make the subject uncomfortable. The AE does not influence performance or functioning. Prescription drugs are not ordinarily needed for relief of symptom(s).
    - *Moderate*: Symptom(s) of a sufficient severity to make the subject uncomfortable. Performance of daily activities is influenced. Treatment of symptom(s) may be needed.
    - *Severe*: Symptom(s) of a sufficient severity to cause the subject severe discomfort. Treatment for symptom(s) may be given.
- Serious (yes/no)
- Causal relationship to investigational or comparator medical device? (not related, possible, probable, or causal relationship)
    - *Not related*: Relationship to the device, comparator or procedures can be excluded when:
        - the event has no temporal relationship with the use of the investigational device, or the procedures related to application of the investigational device;
        - the serious adverse event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible;
        - the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious adverse event;
        - the event involves a body-site or an organ that cannot be affected by the device or procedure;
        - the serious adverse event can be attributed to another cause (e.g., an underlying or concurrent illness/clinical condition, an effect of another device, drug, treatment or other risk factors);
        - the event does not depend on a false result given by the investigational device used for diagnosis, when applicable;

In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.

- *Possible*: The relationship with the use of the investigational device or comparator, or the relationship with procedures, is weak but cannot be ruled out completely. Alternative causes are also possible (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.
- *Probable*: The relationship with the use of the investigational device or comparator, or the relationship with procedures, seems relevant and/or the event cannot be reasonably explained by another cause.
- *Causal relationship*: the serious adverse event is associated with the investigational device, comparator or with procedures beyond reasonable doubt when:
    - the event is a known side effect of the product category the device belongs to or of similar devices and procedures;
    - the event has a temporal relationship with investigational device use/application or procedures;
    - the event involves a body-site or organ that:
        - the investigational device or procedures are applied to;
        - the investigational device or procedures have an effect on;
    - the serious adverse event follows a known response pattern to the medical device (if the response pattern is previously known);
    - the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious adverse event (when clinically feasible);
    - other possible causes (e.g., an underlying or concurrent illness/clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out;
    - harm to the subject is due to error in use;
    - the event depends on a false result given by the investigational device used for diagnosis, when applicable;

In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.

- Causal relationship to investigational procedure (not related, possibly related, probably related, or causal relationship)
- Treatment given and/or action taken (procedure stopped, withdrawn from study, or no action)
- Anticipated (yes/no)
- Signals from AE that might indicate a serious health threat.

8.4. Reporting of Safety Events

The following events are to be reported to the Sponsor within 72 hours of the event occurrence and to the EC per their policy:

- All SAEs and USADEs

- All device issues that could possibly lead to an SAE
- Any signal from an AE that might indicate a serious health threat
- Unanticipated AE and unanticipated ADEs

Additional follow-up information may be requested by the Sponsor. In addition, safety information may be shared with regulatory agencies and other participating sites, as required by applicable law and regulation.

The Sponsor contact for reporting safety events:

[redacted]

8.5. Reporting of Device Deficiencies/Complaints

Device deficiency: an inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety, or performance, such as malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling.

Device deficiencies/complaints should be reported to the study Sponsor contact identified on the cover page of this protocol. All device deficiencies/complaints will to be collected, fully investigated, and documented in the source document during the study reporting period. The Principal Investigator is responsible for notifying the Sponsor in the event that there is any device issue that could potentially lead to a SAE.

9. ETHICAL CONDUCT OF THE STUDY

The study will be carried out per the protocol and with principles enunciated in the current version of the Declaration of Helsinki; the guidelines of Good Clinical Practice (GCP) for medical devices, as set forth by ISO 14155 and ISO 14971; applicable sections of United States FDA 21 Code of Federal Regulations (CFR); and applicable regulatory authority's requirements of the site.

The study will be conducted and reported per applicable policies of the Ethics Committee (EC) and governing regulatory authorities.

If national or regional EC requirements are less strict than the requirements of GCP, such as ISO 14155 for medical devices, the Sponsor shall apply the requirements of this International Standard to the greatest extent possible, irrespective of any lesser requirements, and shall record such efforts.

9.1. Ethics Committee

The responsible Principal Investigator at each site will ensure that approval from an appropriately constituted EC is attained for the clinical study prior to enrolling subjects, and the Principal Investigator will ensure that documentation of approval is maintained for the duration of the study.

The Principal Investigator will ensure that the Sponsor is notified of any withdrawal of EC approval within 5 working days of such occurrence. If approval is terminated or suspended, the Principal Investigator will notify the Sponsor and provide written explanation.

9.2. Regulatory Agencies and Competent Authority(ies)

The Sponsor will obtain approval from the local regulatory agency or competent authority before the start of the clinical study, if necessary, per applicable local laws and regulations. Any additional requirements imposed by the EC or regulatory authority shall be followed, if applicable.

9.3. Management of Protocol Modifications and Amendments

Substantial amendments will only be implemented after approval of the EC. Non-substantial modifications may be made during the normal course of device optimization, maintenance, and feasibility testing. Non-substantial modifications will be communicated to the competent authority (CA) as soon as possible, if applicable, and to the EC per their policy.

9.4. Management of Protocol Deviations

A deviation is any instance(s) of failure to follow, intentionally or unintentionally, the requirements of the protocol. Under emergency circumstances, deviations from the protocol to protect the rights, safety, and wellbeing of human subjects may proceed without prior approval of the Sponsor and the EC/CA. Such deviations shall be documented and reported to the Sponsor and the EC/CA as soon as possible. Deviations will be reported as:

- **Critical Deviations:** Deviations that significantly affect the safety, efficacy, integrity, or conduct of the study. These deviations must be reported to the Sponsor no later than 5 working days from awareness of occurrence and reported to the EC per the deviation reporting policy.
- **Non-Critical Deviations:** Protocol deviations that do not significantly affect the safety, efficacy, integrity, or conduct of the study. These deviations must be documented on the CRF Protocol Deviation page and will be reviewed by the study monitor.

The Sponsor will assess and implement any corrective or preventative actions necessary, such as retraining the study staff and PI.

9.5. Subject Information and Informed Consent

The investigators will explain to each subject the nature of the study, its purpose, the procedures involved, the expected duration of exposure to the investigational device (if applicable), the potential risks and benefits, and any potential discomforts. Each subject will be informed that participation in the study is voluntary, that she may withdraw from the study at any time, and that withdrawal of consent will not affect her subsequent medical assistance and treatment. The subject must be informed that her medical records may be examined by authorized individuals other than their treating physician.

All subjects for the study will be provided an informed consent form (ICF), describing the study and providing sufficient information to allow the subject (i) to make an informed decision about her participation in the study, and (ii) to be fully aware of her rights under the applicable law. Informed consent documents will be subject to approval by the EC prior to enrolling subjects in the study.

The subject should read and consider the statement before signing and dating the ICF and shall be given a copy of the signed document. The ICF must also be signed and dated by the investigator (or his/her designee), and it shall be retained as part of the study records.

9.6. Suspension/Early Termination of the Study

The Sponsor, PI, EC, or regulatory authority may suspend or terminate the study prematurely for various significant and documented reasons. Reasons for suspension or termination may include but are not limited to insufficient subject recruitment, updated risk profile impacting subject safety, alterations in accepted clinical practice impacting study procedures, early evidence of benefit or harm of the research product, or serious or repeated deviations by the investigator.

Suspension or termination can occur at individual sites or across the study, as applicable. The decision to suspend or terminate the study should be shared in writing with all parties described above.

If the reason for study suspension is resolved, the deciding party shall inform all appropriate parties of the decision and actions to resume study procedures.

10. STATISTICAL METHODS

10.1. Statistical Hypothesis

Non-inferiority of [redacted] with respect to Corometrics 259cx will be tested using the following primary hypothesis:

Reliability as measured by Success rate (SR) for FHR data:

H_0 = Mean SR[redacted] - Mean SR (Corometrics 259cx US) ≤ -10%

H_A = Mean SR[redacted] - Mean SR (Corometrics 259cx US) > -10%

The test will be performed using two-sided 95% CI of the difference in Mean SR. If lower 95% CI of the difference is greater than -10%, non-inferiority will be concluded.

10.2. Sample Size Determination

Minimum sample sizes are described in Section 4.7.

The sample size has not been derived from a statistically powered endpoint but has been determined based on a review of the literature, bench testing results and publicly available regulatory filings.

Based on those factors it has been concluded that 30 Corometrics and Lotus data sets would sufficiently confirm the intended use of the investigational maternal fetal monitor.

10.3. Statistical Analysis

Data collected will be analyzed by the GEHC Statistician and Engineering Team.

10.3.1. General Statistical Methods

The study data will be presented in tables, listings, and figures. Data will be summarized using descriptive statistics. The descriptive statistics for continuous variables will include mean, standard deviation, median, Q1 and Q3, minimum, maximum, and sample size. Categorical variables will be described with counts, percentages, and sample size. A 95% confidence interval may be presented, when necessary. For comparison (between arms or against null values), categorical variables will be tested using appropriate contingency table analyses (exact or chi-square

approximations), and continuous variables will be tested using Student's t-test or non-parametric methods, depending on variable distribution. P-values will be presented to three decimal places and p-values less than 0.001 will be presented as '<0.001'.

To determine whether the FHR data [redacted] Doppler US is non-inferior to Doppler US from the Corometrics 259cx in terms of reliability, the data collected from the two devices will be compared. Data is generated at a rate of 4 samples per second.

All the processing and statistical analysis will be done by the CSV assessed software application (CoroCare Process Software) or SAS v9.4. Using the CoroCare process software, the collected data will be stored in a CSV file which has a specific column allotted to each parameter.

10.3.2. Analysis of Primary Endpoint(s)

Fetal Heart Rate (FHR)

For each subject, the whole length of time when both Corometrics 259cx and [redacted] independently record data will be considered for statistical analysis. The reliability of the FHR data will be analyzed based on the following primary endpoint.

Success rate (SR) for FHR data:

To ensure that most of the epochs are available and evaluable, the individual SR, which measures the percentage of time that [redacted] or Corometrics Ultrasound (independently) generates a value for FHR, will be computed per subject (irrespective of the other device generating a value or not)). Overall SR across subjects will be summarized along with its 95% CI for each device.

$$SR(FHR)_i(\%) = \frac{a_i}{a_i + b_i} * 100$$

Where,

SR_i is the ith individual SR;

a_i is represents the number of sample points when the FHR is present (i.e. has a value other than 0) for the ith subject;

b_i is the number of sample points when the FHR is not present (i.e. the device is turned on but has a value of 0) for the ith subject;

From the start of the FHR trace, only a segment of 30 minutes duration will be considered for calculating the SR value. If the data length is greater than 30 minutes, the first 30 minutes of data will be considered for analysis. If either Corometrics or [redacted] has less than 30 minutes of recording, the data from both devices will be eliminated from the primary endpoint analysis but could be used for engineering development. Any gaps in the data due to pausing study procedures will be excluded from the 30-minute monitoring data that will be used for analysis. The difference in mean SR (Lotus – Corometrics 259cx) will be computed along with its two-sided 95% CI to test non-inferiority. If the lower 95% CI is greater than -10%, non-inferiority will be concluded.

10.3.3. Safety Analysis

a. Analysis of Adverse Events

When applicable, AE will be listed per subject, summarized with counts and percentages of events, and summarized with counts and percentages of subjects with events.

When applicable, the incidence of AE will be computed by the number of AEs divided by the total enrolled subjects. The AEs will be categorized into different groups and reported using summary tables and listings.

b. Analysis of Device Deficiencies/Complaints

If applicable, the device deficiencies will be reported using summary tables and listings. The incidence of device deficiencies will be computed by the number of device deficiencies divided by their corresponding totals.

10.3.4. Subgroup analysis

Analysis may also be performed for subgroups based on gestational age as an exploratory analysis.

10.3.5. Interim Analysis

No interim analyses are intended to be conducted as part of this study.

10.4. Handling of Missing Data

Analysis will be based on collected data, and no imputation will be done for missing data.

10.5. Deviation(s) from the Original Statistical Plan

Any changes or deviations from the original statistical plan specified in this protocol will be described and justified in the study final report per 14155:2020.

11. QUALITY ASSURANCE AND CONTROL

11.1. Data Management

Data management processes for handling study data will be maintained by the Sponsor.

11.1.1. Completion of Case Report Forms (CRFs)

The data reported on the eCRFs shall be derived from source documents and be consistent with these source documents. Electronic CRFs (eCRFs) will be used to collect data. The Sponsor will provide eCRFs and train study staff on completion of eCRFs using Good Documentation Practices (GDP). eCRF Completion Guidelines (CCG) may be provided by the Sponsor to help facilitate training.

eCRFs are to be completed as information becomes available at the site. CRFs should be signed by indicated parties, in indicated area(s), to certify the contents of the form. The Principal Investigator is ultimately responsible for ensuring completion of eCRFs.

If discrepancies are discovered on paper CRFs during monitoring, the Sponsor's representative will ensure that the study staff makes necessary corrections directly to the CRF(s) prior to collection.

Following CRF collection, the Sponsor will review the data. A Data Clarification Form (DCF) may be provided to the site to correct or clarify discrepancies.

If the Sponsor discovers discrepancies on eCRFs, a query will be raised, and necessary corrections will be made by the site. The reason for any changes will be noted. All queries will be resolved prior to study completion.

11.1.2. Data Handling and Record Keeping

All documents and data shall be produced and maintained in a manner that assures control and traceability.

11.1.3. Source Data and Documents

Source data includes information in original records, certified copies of original records of clinical findings, observations, or other activities for the study. Source documents for each subject must be retained throughout the investigation, including printed or electronic documents containing source data. Elements should include:

- **Source data and documentation** relevant to data recorded for subject screening and eCRF corroboration.
- **Subject records** containing the completed ICFs and (e)CRFs
- **Regulatory binder** containing the protocol and any subsequent amendments, EC submissions and approvals, blank ICF(s), and site logs
- **Reference manuals** containing investigator responsibilities, Sponsor, AE/SAE and informed consent guidelines, applicable study aids and training materials.

The Principal Investigator or institution shall provide direct access to source data during and after the clinical investigation for monitoring, audits, EC review, and regulatory authority inspections.

11.1.4. Archiving

All study data must be archived for a minimum of 10 years after study termination or premature termination of the clinical study.

12. MONITORING PLAN

In collaboration with the site, the Sponsor will ensure proper monitoring of the study to confirm that all the research requirements are met. Monitoring visits will oversee the progress of a clinical investigation and ensure that it is conducted, recorded, and reported per the protocol, written procedures, Good Clinical Practice (GCP) ISO 14155:2020, and the applicable regulatory requirements.

12.1. Confidentiality and Data Protection

The investigator affirms and upholds the principle of the subject's right to privacy, and the investigator shall comply with applicable privacy laws. Especially, data privacy will be ensured when presenting the data at scientific meetings or publishing data in scientific journals.

Individual subject medical information obtained as a result of this study will be considered confidential, and disclosure to third parties will be prohibited. Subject confidentiality will be further ensured by utilizing subject identification code numbers. For data verification purposes, authorized representatives of the Sponsor, a competent authority (CA), or an ethics committee (EC) may require direct access to parts of the medical records relevant to the study, including subject medical history.

12.2. Storage of Images and Associated Health Data

Image data and associated data will be collected and disclosed to the Sponsor as part of this study.

Fully de-identified data, which has had all personal identifying information removed, may be stored and used by the Sponsor. The Sponsor and/or its authorized representatives may use any de-identified data collected in this study for future technology and engineering development, marketing purposes, education, regulatory submissions, publications, or other possible uses.

13. RESEARCH AGREEMENTS

GE HealthCare will fund this clinical investigation, which will be conducted under contractual agreements between the investigational sites and the Sponsor, GE HealthCare. Agreement details for each participating site will be stored by the Sponsor.

13.1. Clinical Study Report and Publication Policy

Prior to recruitment, a description of this clinical investigation will be registered in a publicly accessible database. This database will be updated per regional or national requirements throughout the conduct of the clinical investigation and results will be entered upon completion.

A clinical study report will be generated upon completion of the study and associated analyses.

The results of this study may be used in future publications. The conditions of publication are described in a separate contractual agreement.

APPENDIX A – ADMINISTRATIVE STRUCTURE OF INVESTIGATION

See Study Contact List

APPENDIX B – STUDY SITE AND INVESTIGATOR LIST

The following investigators at each study site will be responsible for the conduct of this study:

Investigator(s):[1]	[redacted]	[redacted]

[1] The role of the ***Principal Investigator*** is to implement and manage the conduct of the investigation as well as ensure data integrity and the rights, safety, and well-being of humans involved in the study [ISO 14155 9.1]. ***Co-Investigators*** share all responsibilities of the ***Principal Investigator***, and ***Sub-Investigators*** share only those responsibilities designated by the ***Principal Investigator***.

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3. Watson K, Mills TA, Lavender T. Experiences and outcomes on the use of telemetry to monitor the fetal heart during labour: findings from a mixed methods study. *Women Birth*. May 2022;35(3):e243-e252. doi:10.1016/j.wombi.2021.06.004

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