MOBILE – ECG Study

Evaluation of the mobiCARE™ ECG Monitoring System Electrode Placement Positioning Limits in a Prospective, Non-Randomized, Single-Center U.S. Study

Protocol Number
SEER-CLIN-2024-01
Version 0.0

October 29, 2024

Sponsor
Seers Technology Company, Ltd.
291-13, Dongbu-daero, Jinwe-myeon, Pyeongtaek-si
Gyeonggi-do
Republic of Korea

Clinical Protocol Principal Investigator Acceptance Signature Page

MOBILE-ECG

Evaluation of the mobiCARE™ ECG Monitoring System Electrode Placement Positioning Limits in a Prospective, Non-Randomized, Single-Center U.S. Study

I, the Principal Investigator, will conduct this study in strict accordance with this protocol, applicable regulations: 21 CFR Part 812 – Abbreviated requirements for NSR studies, 21 CFR Part 50, 21 CFR Part 56, the Health Insurance Portability and Accountability Act (HIPAA), local regulatory guidelines, the clinical trial agreement, and conditions of approval imposed by the reviewing IRB. I will make all efforts to complete the study within the time designated. I will ensure that the rights, safety, and welfare of subjects under my care are protected. Only investigators selected and agreed upon by the Sponsor to participate in this study will be trained on the protocol, study requirements, and mobiCARE ECG Monitoring System and listed on the Delegation of Authority Log at the site. I will provide copies of the protocol and all other study-related information supplied by the sponsor to all delegated study personnel. I will discuss this information with them to assure that they are adequately informed regarding the Seers Technology Company, Ltd. mobiCARE™ and conduct of the study. I agree to keep records including case report forms, shipment, and mobiCARE ECG Monitoring System disposition/return, and all other information collected during the study in accordance with applicable regulations. I will not enroll any subjects into this protocol until the Institutional Review Board (IRB) and the sponsor or designee approvals are obtained. I will provide sufficient and accurate financial disclosure information and update this information if any relevant changes occur during the investigation and for one year following the completion of the study.

Protocol #	SEER-CLIN-2024-01
Protocol Version #	0.0
Protocol Date	October 29, 2024

The Principal Investigator's Signature signifies acceptance of the Seers Technology, Ltd. sponsored study and agrees to participate in the study in accordance with the protocol, applicable regulations and informed consent requirements, and Investigator requirements stated in the protocol:

	MCB Clinical Research Centers, LLC.
Principal Investigator's E-Signature / Date	Site Name
Patricia Rand, MD	Colorado Springs, CO
Principal Investigator's Typed Name	City, State

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STUDY SPONSOR

Seers Technology Company, Ltd.
291-13, Dongbu-daero, Jinwe-myeon, Pyeongtaek-si
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1.0 Protocol Synopsis

Study Title	MOBILE – ECG Study: Evaluation of the mobiCARE™ ECG Monitoring System Electrode Placement Positioning Limits in a Prospective, Non-Randomized, Single-Center U.S. Study
Sponsor	Seers Technology Company, Ltd.
Principal Investigator	Patricia Rand, MD
Study Design	Prospective, non-randomized, single-center, non-significant risk study
Investigational Device	mobiCARE™ Cardiac Monitoring System: Model mobiCARE™ MC200ML. The mobiCARE™ system is a single-channel wearable, mobile and reusable ambulatory ECG recorder that can continuously acquire and store ECG signals using disposable electrodes for up to 9 days. The ECG acquisition for model MC200ML is representative of the other three mobiCARE™ devices: MC200M, MC200M7, and MC200ML7, which differ only by the length of the connector cable length and the battery size. The mobiCARE™-MC200M series is not intended for real-time monitoring.
Gold Standard Device	DR Model TBD Holter Monitor NorthEast Monitoring, Inc. 141 Parker Street, Suite 200 Maynard, MA 01754 USA The Holter Monitor (gold standard) will be used to record Lead II ECG simultaneously to the mobiCARE™ Model MC200ML as a Gold Standard for the purpose of having a simultaneous ECG recording. The Lead II Holter tracing will be used to verify that the heart rhythm identified with the mobiCARE™ device correlates with the heart rhythm identified on the Holter monitor tracing.
Indication for Use	The mobiCARE™ Cardiac Monitoring System is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. mobiCARE™ Cardiac Monitoring System is intended for use by patients 18 years or older. The device is not intended for use with critical care patients or for real-time monitoring.
Regulatory Status	This study meets the definition of a non-significant risk (NSR) study. The mobiCARE™ ECG Monitoring Device is a minimal risk device and and no medical care decisions will be made based on the measurements. The Seers Technology Co., Ltd. mobiCARE™ ECG Monitoring System is an investigational device in the U.S.
Primary Objective	The primary objective is to quantify the placement accuracy requirements (i.e., how many cm/in. offset may be tolerated from the nominal placement position) needed to ensure appropriate device performance including heart rhythm interpretability and provide rationale to support that such placement accuracy is adequate.
Secondary Objective	The secondary objectives are to: 1. Demonstrate that the device meets the placement accuracy requirements when in normal use, and 2. Identify if there are factors that may impact the placement accuracy and subsequent heart rhythm identification such as age, sex, educational level, BMI, and dexterity.
Primary Endpoint	Evaluation of the ECG signal at the nominal location and in up to three (3) additional standardized locations in each subject to determine if the signal is interpretable. The term “interpretable” is defined as follows: An independent

	cardiologist is able to identify the ECG rhythm in each location when compared to the ECG rhythm measured in the nominal position of the mobiCARE™ ECG Monitoring System described in the Instructions for Use. ECG rhythm data will be collected for up to two (2) minutes while the patient ambulates. The simultaneous Holter Monitor will be evaluated at the same time points to have a point of reference for the mobiCARE™ system in the case that changes in the rhythm are noted during the study.
Secondary Endpoints (Informational Only)	1. Presence of artifact graded as 1=none, 2=minor (cardiac rhythm is interpretable), or 3=major (cardiac rhythm is not interpretable by the independent cardiologist). 2. ECG Morphology measurements: P wave amplitude, QRS amplitude, QRS duration. 3. Limited Human Factors Evaluation Measures (n=15): A. Initial Healthcare practitioner (HCP) placement according to IFU (correct or incorrect placement when referring to the IFU) B. User demonstrates ability to change electrodes (successful or not successful) C. Observe user to determine sufficient dexterity for user to perform the task D. Observe user electrode placement according to skin markings to determine if electrodes are correctly placed.
Participation Duration	Each subject will participate in this study for one (1) visit, for approximately 30 to 60 minutes.
Sites	One (1) investigational site
Population	The study population will include adults who are asymptomatic or who may suffer from transient symptoms such as arrhythmias, palpitations, chest pain or chest pressure; ranging in age, ethnic group, BMI, educational level and gender.
Sample Size	Up to 50 subjects will be consented and enrolled
Eligibility Criteria	Inclusion Criteria 1. Male and female adults ≥ 18 years of age; 2. Willing and able to provide informed consent; 3. Able to speak and read English fluently; 4. Participant is ambulatory.
	Exclusion Criteria 1. Patients with cardiac pacemaker; 2. Patients with cardioverter defibrillator; 3. Patients with other implantable electrical devices; 4. Currently has a medical history of skin cancer, rash, skin disorder, keloid, and/or any injury in the chest area; 5. Patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient; 6. Patients with known history of life-threatening arrhythmias; 7. Use in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI; 8. Patients with neuro-stimulator, as it may disrupt the quality of ECG data; 9. Critical care patients.
Enrollment Methodology	1. A minimum of 30% of the study subjects will be ≥ 65 years of age to assess the intended use population who may differ in dexterity. 2. All ethnic groups, Caucasian, Asian, African American, Hispanic, Other (Pacific Islanders, Native American) will be enrolled. 3. BMI range from low to high (defined as BMI >35), will be enrolled.

	4. Male and female subjects with a minimum of 40% of the subjects being female. 5. Varied educational levels will be enrolled.
Sponsor Provided Devices	1. Commercially available single use disposable Ag/AgCl ECG electrodes 2. Seers Technology Company Ltd. ECG Monitoring System, Model MC200ML (1 mobiCARE™ ECG Monitoring System per subject) 3. Commercially available DR Model TBD Holter ECG Monitor 4. Samsung Galaxy A10e Smartphone with WiFi capability only Android device with minimum specifications of OS 7.0 or higher and CPU 1.4GHz or higher 5. Skin marking device
Data Management, Biostatistics, Monitoring & EDC	Eminence Clinical Research, Inc. 13521 Northgate Estates Drive Suite 150 Colorado Springs, CO 80921 Main No.: 719-400-7463

2.0 Introduction and Background

For over 20 years, novel devices for ambulatory heart rhythm monitoring have emerged and begun to be integrated with the care of the cardiac patient in the outpatient setting. The evolution of these cardiac monitoring devices will mark a new era in medicine and a transition from population-level health care to individualized medicine in which suitable patients are equipped with advanced biosensors that, in turn, have their data processed through sophisticated algorithms to predict events before they occur.[1]

There are multiple purposes for the various heart rhythm monitoring devices that exist to date. Some monitor ECG rhythms for 30 seconds (Emay), some are used to determine normal sinus rhythm versus atrial fibrillation (Kardio-Mobile), others monitor ECG and blood pressure (Omron), or 12-Lead ECG (Biocare), the Zio Patch(iRhythm), and the S-Patch Ex Wearable ECG Patch (Wellysis Corporation).

Seers Technology Company, Ltd. seeks regulatory clearance to marketing in the U.S. for the mobiCARE™ ECG Monitoring Device. The mobiCARE™ System is an ECG recorder including four models that record ECG for up to 9 days: MC200M, MC200ML, MC200M7, and MC200ML7. The devices will be prescribed by a healthcare professional and will be used by patients both at home and in clinical settings.

The commercial use of the mobiCARE™ ECG Monitoring System in thousands of Korean patients has previously demonstrated the safety of the mobiCARE™ system. Additionally, multiple studies have been completed and published in the Republic of Korea using the Seers Technology Company, Ltd. mobiCARE™ device and its predecessor, MC100.[2-13] This study will be conducted to demonstrate interpretability and usability, as described in the purpose below.

3.0 Purpose

The purpose of the Seers Technology Company Ltd. sponsored study using the mobiCARE™ ECG Monitoring System is to document the variability and interpretability of heart rhythm tracings from the nominal position whereby the mobiCARE™ device is still able to obtain interpretable ECG signals, in a cohort of adults representative of the U.S. population.

Informational data will be collected, such as P-wave amplitude and QRS amplitude and duration to note any morphological ECG signal changes. Human factors (HF) endpoints will be evaluated including: HCP placement according to IFU, subject demonstration of changing electrodes, dexterity for user to perform the task, electrode placement according to skin markings, and the ability of the user to remove and replace the mobiCARE™ device.

4.0 Device Description - Intended Use - Indication for Use

Description: mobiCARE™ MC200M/mobiCARE™ MC200ML (hereinafter mobiCARE™ MC200M series) is single channel, wearable, mobile and reusable ambulatory ECG recorder. It can continuously acquire and store ECG signals through disposable electrodes for more than 6 or 9 days (expected continuous measurement time is different by the model). The mobiCARE™ MC200M series is not intended for real time monitoring.

Indications for Use: The mobiCARE™ Cardiac Monitoring System is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. mobiCARE™ Cardiac Monitoring System is intended for use by patients 18

years or older. The device is not intended for use with critical care patients or for real-time monitoring.

5.0 Study Design

Prospective, non-randomized, single-center non-significant risk study.

5.1 Population

The study population will include adults who are asymptomatic or who may suffer from transient symptoms such as arrhythmias and/or palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety; ranging in age, ethnic group, BMI, educational level and gender.

5.2 Eligibility Criteria

5.1.1 Inclusion Criteria

All answers must be YES to the Inclusion Criteria below:

1. Male and female adults ≥ 18 years of age;
2. Willing and able to provide informed consent;
3. Able to speak and read English fluently;
4. Participant is ambulatory.

5.1.2 Exclusion Criteria

All answers must be NO to the Exclusion Criteria below:

1. Patients with cardiac pacemaker;
2. Patients with cardioverter defibrillator;
3. Patients with other implantable electric devices;
4. Currently or has a medical history of skin cancer, rash, skin disorder, keloid, and/or any injury in the chest area;
5. Patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient;
6. Patients with known history of life-threatening arrhythmias;
7. Use in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI;
8. Patients with neuro-stimulator, as it may disrupt the quality of ECG data;
9. Critical care patients;
10. Chest pain at the time of presentation for the study.

5.3 Sample Size

This study will enroll up to 50 subjects who will undergo one (1) study visit that will last approximately one (1) hour. The analysis population will include a minimum of 37 subjects. Up to 50 subjects will be consented and enrolled.

6.0 mobiCARE Placement Methodology

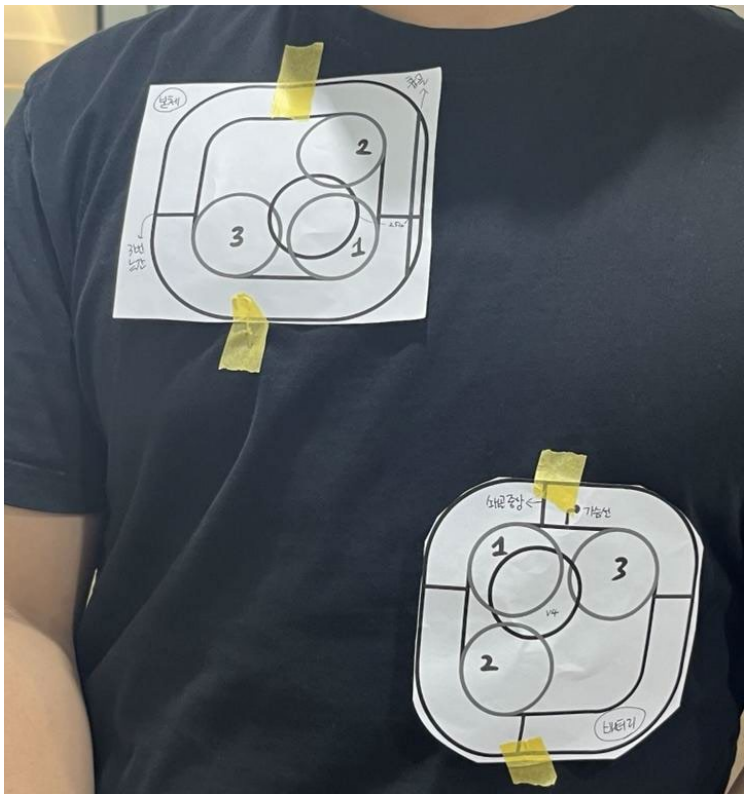
1. The optimal position of the Main Body (top) electrode is horizontally 2.5cm right of the chest's midline, and vertically in the 3rd intercostal space.
2. The optimal position of the Battery Body (bottom electrode) is horizontally equivalent to the middle of the left clavicle, and vertically in the 5th intercostal space (corresponding the the V4 position)
3. The evaluation will include three (3) different alternate locations for the mobiCARE ECG

Monitorng System are as follows. All locations are to monitor the heart rhythm in Lead II.

Table 1. Three Different Placement Locations in Addition to Nominal

Alternate Location	Main Body (Top Electrode)	Battery Body (Bottom Electrode)
1	Horizontally 1 cm left	Horizontally 1 cm right
	Vertically 1 cm inferior	Vertically 1 cm superior
2	Horizontally 1 cm left	Horizontally 1 cm right
	Vertically 3.6 cm superior	Vertically 3.6 cm anterior
3	Horizontally 3.6 cm right	Horizontally 3.6 cm left
	Vertically 1 cm inferior	Vertically 1 cm superior

Figure 1. Three Alternative mobiCARE Electrode Positions As Located on the Torso



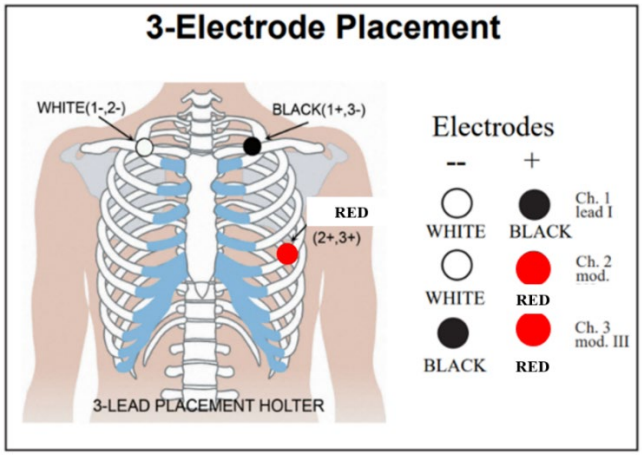
7.0 Holter Monitor Placement Location

The Holter monitor will be placed in one location recommended by the Holter Monitor Company (NorthEast Monitoring, Inc. Maynard, MA. USA) by the HCP for Lead II as indicated below.

Attach the ECG electrode patches for the Holter monitor to the Holter Monitor Leads. Snap the leads from the Holter monitor onto the electrodes. Remove the backing of one electrode and

place the electrode with red, white, or black lead wire in the corresponding location below. Complete these steps for the other two, one at a time. The white lead with electrode should be on the upper right, the black lead with electrode should be on the upper left, and the red lead with electrode should be on the lower left so that Lead II is a diagonal vector from upper right to lower left.

Figure 2. Holter Monitor Electrode and Lead Placement



8.0 Study Recruitment Methods

8.1 Recruitment of Subjects

7.1.1 Pre-screen Failures

All subjects from the investigators participating in the study, and all referral sites will be prospectively documented by the study coordinator. All pre-screening subjects are those who are considered for the study but are not consented. These will be documented weekly as instructed by the CRO.

7.1.2 Screen Failures

Those who are consented and do not meet all eligibility requirements will be documented weekly as instructed by the CRO. Consented screen failures may occur at the time of the run-in period, and at the time of the completion of the run-in period, prior to randomization.

7.1.3 Enrollment

Those who are consented, enrolled, and undergo the ECG readings, and demonstrate the use the application of the elctrodes and the ECG on the study subject.

7.1.4 Enrollment Methodology

The study will include a diverse population to demonstrate the interpretability of ECG heart rhythm tracings obtained by the mobiCARE™ device in various placement locations, as compared to nominal, in a diverse population. Over 30% of the study subjects will be ≥ 65 years of age to assess a range of dexterity, all ethnic groups [Caucasian, Asian, African American, Hispanic, (Other (Pacific Islanders, Native American)] will be enrolled. The BMI range from low to high defined as BMI >35), will be enrolled. Male and female subjects with a minimum of 40% of the subjects being female. Varied educational levels

will be enrolled.

8.2 Advertising

The following advertisements will be IRB approved prior to use:

- Flyers to post in local physician's offices
- Flyers to post in local walk-in clinics
- Contents of flyers can be used for emails

The advertisement will be posters stating the study purpose, location, time required, population, subject demographics, and compensation for study participation.

9.0 Site Compliance

The clinical research staff will ensure compliance in the following areas and will maintain electronic documentation of compliance:

1. The most current version of the protocol, informed consent document, and HIPAA authorization.
2. All required approvals have been obtained at each site.
3. All subject information; such as name code, subject number and subject name list will be secured in the research department with only dedicated research personnel having access to the information.
4. Electronic data will be entered in the 21 CFR 11 compliant EDC database.
5. The research staff will be trained and have an understanding of all protocol requirements to ensure that investigators conduct the study appropriately.
6. Noncompliance with the protocol will be reported to the site PI by the CRO and promptly addressed.

10.0 Study Timelines and Data Collection

10.1 Duration of Subject's Participation

Subjects who consent to this study will participate for the following duration: One (1) day, for an estimated duration of one (1) hour.

10.2 Duration of Enrollment Period

The estimated enrollment phase is up to four (4) weeks.

10.3 Projected Completion Date

The anticipated completion date for the study enrollment, data analysis, report preparation is one (1) to three (3) months after first subject is enrolled.

10.4 Primary and Secondary Objectives

9.4.1 Primary Objective

The primary objective is to quantify the placement accuracy requirements (i.e., cm/in offset may be tolerated from the nominal placement position) needed to ensure appropriate device performance including heart rhythm interpretability and provide rationale to support that such placement accuracy is adequate.

9.4.2 Secondary Objectives

The secondary objectives are to:

1. Demonstrate that the device meets the placement accuracy requirements when in normal use, and
2. Identify if there are any factors that may impact the heart rhythm interpretive accuracy; such as, age, sex, educational level, body size/BMI, and dexterity.

10.5 Primary Endpoints and Secondary Endpoints

10.5.1 Primary Endpoint

Evaluation of the ECG signal at the nominal location and in up to three (3) additional standardized locations in each subject to determine if the signal is interpretable. The term "interpretable" is defined as follows: An independent cardiologist is able to identify the ECG rhythm in each location when compared to the ECG rhythm measured in the nominal position of the mobiCARE™ ECG Monitoring System described in the Instructions for Use. ECG rhythm data will be collected for up to two (2) minutes while the patient ambulates.

The simultaneous Holter Monitor will be evaluated at the same time points to have a point of reference for the mobiCARE™ system in the case that changes in the rhythm are noted during the study.

10.5.2 Secondary Endpoints – Informational Only

1. Presence of artifact graded as 1=none, 2=minor (cardiac rhythm is interpretable), or 3=major (cardiac rhythm is not interpretable by the independent cardiologist).
2. ECG Morphology measurements: P wave amplitude, QRS amplitude, QRS duration.
3. Limited Human Factors Evaluation Measures (n=15):
   A. Initial HCP placement according to IFU (correct or incorrect placement when referring to the IFU)
   B. User demonstrates ability to change electrodes (successful or not successful)
   C. Observe user to determine sufficient dexterity for user to perform the task
   D. Observe user electrode placement according to skin markings to determine if electrodes are correctly placed.

11.0 Study Procedures

Table 2: Schedule of Assessment

Visit / Assessment	Prior to the FSFV	Day of Subject's Study Visit	Study Subject Termination
Train Site on mobiCARE™ device placement and all Study Requirements	X		
Written informed consent		X	
Demographics and medical history		X	
Confirm eligibility criteria		X	X
Place Holter Monitor on Study Subject		X	
Observe HCP placing mobiCARE™ device on subject		X	
Observe subject ambulating, record ECG for ≥ 1 minute		X	
Observe for SAEs / AEs / UADEs			X
Subject is terminated after all data are collected			X
Compensation Provided			X

11.0 Statistical Considerations

11.1 Introduction

Each subject will have the mobiCARE™ ECG measured at the nominal position and at 3 pre-specified alternate locations. For each location, the ECG signal will be read and classified as interpretable or not interpretable. The reading from the mobiCARE™ nominal position will serve as the comparator reading for the alternate mobiCARE™ locations. The primary endpoint analysis is the comparison of each mobiCARE™ alternate location to the nominal position.

The Holter monitor will be used as a method to verify the subjects heart rhythm during simultaneous recordings of mobiCARE™ heart rhythm data at the prespecified measurement locations on the precordium.

11.2 Analysis of Primary Endpoint

The primary endpoint will be analyzed using an asymptotic non-inferiority test for the difference in interpretability of the ECG signal between two correlated proportions. The test is described in the references[15] and discussed in references.[14,16] The null and alternative hypotheses are

$$H_0: P_A - P_N \leq - M_{NI} \text{ and } H_A: P_A - P_N > - M_{NI}$$

where P_N and P_A are the proportions of measurements with interpretable ECG results at the nominal position and each alternative location, respectively, and M_{NI} is the positive non-inferiority margin. This one-sided test will be performed with type I error rate $\alpha = 0.025$ and non-inferiority margin $M_{NI} = 0.20$. The test will be repeated for each alternative location, comparing it to the nominal position. No adjustment will be made for multiple comparisons.[14]

Uninterpretable ECG at onelocation does not consistute a failure for that subject.

11.3 Sample Size Calculation

The required sample size was computed using proc power in SAS v9.4 software for a Farrington-Manning non-inferiority test of the difference of two independent proportions. A sample size of 37 is required based on the following assumptions:

- Type I error rate $\alpha = 0.025$
- Non-inferiority margin $M_{NI} = 0.20$
- 80% power
- Assumed proportions of subjects with interpretable ECG signal:
    - Nominal placement: 95%
    - Alternate placement: 94%

To allow for possible 10% drop-out, a sample size of 44 will be used.

11.4 Justification of non-inferiority (NI) margin

The non-inferiority margin of 20% (for difference in ECG interpretability proportions) is justified based on the low likelihood of incorrect or non-interpretable Nominal electrode placement since electrodes are placed by a HCP with clinical experience according to anatomic landmarks explained in the Instructions for Use. In addition, at the time of Nominal electrode placement the ECG signal is visible to the HCP for confirmation of correct placement. At the time of Nominal electrode placement by the HCP, the skin may be marked if desired, for replacement of electrodes by the patient when in use at home, ensuring proper future electrode placement. The skin marking is also included in the Instructions for Use for the mobiCARE™ ECG Monitoring System.

The patient population is not a high risk population. The intended use population for the mobiCARE™ device is a low risk non-emergent ambulatory population who may be asymptomatic or who may have transient symptoms; the mobiCARE™ device is placed for more than 6 days without clinical surveillance, and patients will receive follow-up assessments and will have more clinic visits. The intended patient population may not include those who require real-time ECG monitoring and they are not critical care patients.

11.5 Analysis of Secondary Endpoints

11.5.1 MobiCARE™ vs. Holter

The Holter data will be used as the gold standard to verify the subjects heart rhythm during simultaneous recording of the mobiCARE™ device at the prespecified placement locations on the chest precordium. Correlation of the heart rhythm between the Holter and mobiCARE™ tracings will be designated as yes or no for each mobiCARE™ placement location. This will aid in the interpretation of findings should there be a change in the ECG rhythm between the mobiCARE placement location measurements.

11.5.2 Descriptive Statistics for secondary mobiCARE™ ECG Readings

Descriptive statistics for the following will be tabulated for the MobiCARE™ nominal placement and each alternative location reading; no formal hypothesis tests will be run:

1. Presence of artifact:
   - no artifacts = 0
   - minor artifact = 1 defined as the ECG is interpretable
   - major artifact = 2 defined as the ECG is not interpretable
2. ECG morphology: P wave amplitude, QRS amplitude, QRS duration
3. Limited Human factors data (physician and patient) relating to correct placement of electrodes (n=15):

   A. HCP placement according to IFU (correct or incorrect placement when referring to the IFU)
   B. User demonstrates ability to change electrodes (successful or not successful)
   C. Observe user to determine sufficient dexterity for user to perform the task
   D. Observe user electrode placement according to skin markings
   E. Assess if ECG still interpretable after user removes and replaces electrodes, and replaces the mobiCARE™ device

4. Patient demographic characteristics: age, sex, race, ethnicity, BMI, education level.

A summary of frequencies and percentages will be calculated for categorical variables (e.g., presence of artifacts, sex, race, ethnicity, education level), and mean ± SD and range will be calculated for continuous variables (e.g., ECG morphology, age, BMI).

12.0 Procedures to Minimize Risks

12.1 Source Data and Source Worksheets

Source data and source worksheets provided to the monitors will be de-identified. Site number and subject numbers will be the only identifier on the documents. A list of subject names and corresponding subject numbers will be confidentially maintained at the site.

12.2 Securing the Demographic and Human factors Data

The data will be collected by a research coordinator with ECG experience. All protected health information in the database will be de-identified. Subjects will be assigned a study number at time of randomization. A master list of the patient's name, name code, and subject number, at a minimum, will be kept securely in the research office for reference, if needed, for the research staff or the PI to match the subject data to the subject.

12.3 Securing the ECG Data

12.3.1 mobiCARE ECG Data

The ECG data will be downloaded from the Seers mobiCARE ECG Monitoring System device to the Seers Technology Company, Ltd. laptop provided. The data from the laptop will then be uploaded to the secure cloud storage (Citrix Cloud Software Group, Inc., Santa Clara, CA, USA) where the independent qualified cardiologist M.D. who will serve as the clinical reader and ECG Data Interpreter will have access to the anonymized and randomized ECGs.

12.3.2 NorthEast Monitoring Holter Monitor Data

The NorthEast Monitoring, Inc. (Maynard, MA, USA) Holter Monitor Data will be recorded on the Holter Monitor. A dongle key, provided by NorthEast Monitoring, Inc. will be used to upload the data to a secure network for review. Each person who will have access to the data will be required to use the dongle key to access the data. The secure network will be accessed only through a virtual private network and only the folders with the ECGs be available for analysis to the four (4) personnel who will have ECG data access. The four (4) personnel who will have data access will be the the following:

1. Independent qualified cardiologist M.D. who will serve as the clinical reader and ECG Data Interpreter
2. One (1) Sponsor Representative
3. Two (2) CRO Representatives

13.0 Adverse Events

13.1 Anticipated Adverse Events Related to ECG Electrodes

- Skin irritation
- Skin allergic reaction evident by swelling, itching, and/or inflammation
- Erythema evident by skin redness with or without inflammation

13.2 Anticipated Adverse Events Related to the mobiCARE™ ECG Monitoring System

- User damage (infection, minor electric shock, burn)
- Inconvenience
- Delay in treatment
- Confusion due to incorrect diagnosis
- Measurement error

13.3 Serious Adverse Event Definition

Serious adverse events will be reported to the IRB according to local or central IRB requirements.

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and will be collected when the patient outcome is:

1. Death
2. Life-threatening – Report if suspected that the patient was at substantial risk of dying at the time of the adverse event or use or continued use of the device or other medical product might have resulted in the death of the patient.
3. Hospitalization (initial or prolonged) – Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event. Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).
4. Disability or Permanent Damage – Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.
5. Congenital Anomaly/Birth Defect – Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
6. Required Intervention to Prevent Permanent Impairment or Damage (Devices) – Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.
7. Other Serious (Important Medical Events) – Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (wound management) to prevent one of the other outcomes. Examples include allergic bronchospasm (a serious problem with breathing) requiring wound management in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

Table 3: Causality Categories for Procedure and Device Related AEs and SAEs

Definitely Procedure- Related	AE that has a strong temporal relationship to the procedure and an alternative etiology is unlikely
Probably Procedure-Related	AE that has a strong temporal relationship to the procedure and an alternative etiology is less likely than the potential relationship to the procedure
Probably Not Procedure- Related	AE that has minimal or no temporal relationship to the procedure and /or a more than likely alternative etiology
Not Procedure-Related	AE is due to the underlying disease state or concomitant medication or therapy and not caused by the procedure
Definitely Device- Related	AE that has a strong temporal relationship to the device and an alternative etiology is unlikely
Probably Device-Related	AE that has a strong temporal relationship to the device and an alternative etiology is less likely than the potential relationship to the procedure
Probably Not Device-Related	AE that has minimal or no temporal relationship to the device and /or a more than likely alternative etiology
Not Device-Related	AE is due to the underlying disease state or concomitant medication or therapy and not caused by the procedure

13.4 Reporting of Adverse Events

13.4.1 Adverse Events

Procedure and product related adverse events will be documented in the EDC and source data for each event will be provided to the study monitor during the monitoring visits. Adverse events that are not serious will be reviewed at the monitoring visits.

13.4.2 Serious Adverse Events

Serious adverse events shall be reported to the CRO within 24 hours of knowledge of the event. The SAE form will be completed in the EDC, and source data shall be provided to the CRO upon request for review. Source data for each SAE shall be provided to the study monitor during the monitoring visits, as requested.

14.0 Withdrawal of Subjects

14.1 Circumstances for Subjects to Be Withdrawn Without Their Consent

All study subjects have the right to withdraw their consent at any time during the study. However, withdrawal of a subject from the study can occur at the direction of the PI or the sponsor. Reasons for physician directed withdrawal could include but are not limited to the subject's not adhering to the study follow-up protocol, the subject enrolls in another study, or if the physician determines it is in the subject's best interest for safety or welfare of the subject to withdraw.

14.2 Procedures for Study Termination

The coordinator should obtain written documentation from the subject that wishes to withdraw his/her consent for future follow-up and contacts. If written documentation is unable to be obtained, all information regarding the subject's withdrawal must be recorded in the subject's medical record or in a source document. In addition, the appropriate CRF's must be completed in the EDC and clear documentation of the subject's withdrawal shall be documented in the EDC.

15.0 Potential Risks and Benefits to Subjects

15.1 Potential Risks to Subjects

Subjects in this study will not be exposed to additional risk beyond that experienced during routine ECG monitoring. Standard intervals for follow-up will be employed and will pose no additional risk for subjects in either arm of the study. Each study site will be experienced in research and understand and adhere to all HIPAA and confidentiality requirements.

15.2 Potential Benefits to Subjects

There are no potential benefits to the study subject from the use of the Seers Technology Company, Ltd. mobiCARE™ ECG Monitoring System in this study, but the results of this study may help patients in the future.

16.0 Qualification, Resources, and Training

16.1 Qualifications of Research Investigators and Staff

The investigator will be qualified and have extensive experience in the surgeries performed on the population in this study. The investigator and research staff will have extensive research experience as documented in the CVs of the investigators and staff.

16.2 Site and Investigator Training

The sponsor or a representative of the sponsor will conduct a training session with the Principal Investigator and his/her research staff to review the protocol, instructions for use of the Seers Technology Company, Ltd. mobiCARE™ ECG Device, case report forms (CRFs)/EDC, responsibilities, reporting requirements, and general guidelines for good clinical practice (GCP).

16.3 Clinical ECG Reader

An independent qualified cardiologist will serve as the clinical reader and ECG Data Interpreter. This person will have the appropriate training to perform an assessment of the anonymized ECGs for interpretability and will evaluate primary and secondary endpoints for study subjects.

17.0 Required Documentation Prior to Site Activation

Prior to enrolling subjects at the investigational site, the following documents will be provided to the CRO for the study files:

1. IRB approval letter for the study site principal investigator to conduct this study
2. IRB approved Informed Consent Form for the study for each study site
3. Investigator's Curriculum Vitae (CV) and Medical License (ML)
4. Financial Disclosures of the principal investigators and sub-investigators
5. Signed Investigator agreement and if applicable, sub-investigators agreements
6. Training Record documenting each participating physician has been trained on the Seers Technology Company, Ltd. mobiCARE™ ECG Device for ECG recording and all protocol requirements
7. Training Record documenting each research coordinator has been trained on all mobiCARE™ ECG Monitorng System study protocol requirements
8. Completed Delegation of Authority (DOA) Log

18.0 Confidentiality

The data will be collected by a research coordinator with ECG experience, who has received training on the study requirements. Only study personnel will have access to the data which will be restricted to an as needed basis. Subjects will be informed of efforts to maintain confidentiality of protected health information. Only subjects who are agreeable to these terms will be enrolled. The research team, sponsor, sponsor representatives, and CRO will be permitted to access any source of information on a subject (i.e. medical record, hospital financial record, physician office record, laboratory results) on an as needed basis.

19.0 Research Related Injury

This research poses only minimal risk to patients for the monitonig of ECGs.

20.0 Costs to Study Subjects and Subject Compensation

Subjects will not incur any expense as a result of participation in the study. Each study subject will be provided a 100.00 (USD) gift card for the time and effort for participting in this study.

21.0 Consent Process

Informed consent will be obtained from all subjects prior to enrollment by one of the following study personnel: coordinator, Sub-investigator, or PI. The site will follow the standard operating procedure for the Informed Consent Process. Consent will be obtained after the subject has been provided with information concerning the study and has answered all questions satisfactorily.

22.0 Storage and Handling of the mobiCARE™ ECG Monitoring System

22.1 Storage

The ECG Device will be stored in a secure area in the research storage area where only research personnel will have access to the devices for study purposes only. The device can be stored at temperatures between -13ºF (-25ºC) and 158ºF (70ºC).

22.2 Handling

The mobiCARE™ ECG Monitorng System is a non-sterile device that is for individual use only. The site's standard policies for patient contact with non-sterile medical devices will be followed.

23.0 Return Goods Policy for and Disposal of the mobiCARE™ ECG System

The following DHL Number will be used for courier trackability: 960550085

23.1 Device Return for Device Issues

For devices whereby an issue has been identified, the devices will be returned to: An RMA # request will be sent by the site to Seers Technology Company Ltd. and the RMA # will be issued by email to the requester.

The device will be returned to: Seers Technology Company Ltd., 291-13, Dongbu-daero, Jinwe-myeon, Pyeongtaek-si, Gyeonggi-do, 17707, Republic of Korea.

23.2 Device Return for Return of Unused Devices

For devices whereby an issue has been identified, the devices will be returned to Seers Technology Company Ltd. (address above). An RMA # request will be sent by the site and an RMA # will be issued by email to the requester.

The unused devices will be returned to: Seers Technology Company Ltd., 291-13, Dongbu-daero, Jinwe-myeon, Pyeongtaek-si, Gyeonggi-do, 17707, Republic of Korea.

24.0 Investigator Responsibilities

The following responsibilities are required for investigators participating in this study:

An investigator is responsible for ensuring that the investigation is conducted according to the signed agreement, the protocol, and local, state, and federal regulations, for protecting the rights, safety and welfare of subjects under the investigator's care and for the control of the mobiCARE ECG Monitoring System in this study. Specific responsibilities include:

1. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the protocol and applicable regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of the mobiCARE™ ECG System in this study.
2. An investigator is responsible for ensuring that informed consent is obtained in accordance with 21 CFR part 50 prior to treating the patient.
3. Awaiting approval: an investigator may determine whether potential subjects would be interested in participating in an investigation but shall not request the written informed consent of any subject to participate and shall not allow any subject to participate before obtaining IRB approval.
4. Compliance: an investigator shall conduct the mobiCARE™ Study in accordance with the signed agreement with the sponsor, the investigational plan, any applicable regulations and any conditions of approval imposed by an IRB.

5. Financial Disclosure: an investigator shall disclose to the sponsor sufficient accurate financial information to allow the applicant to comply with 21 CFR 54 and shall promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.
6. The PI Signature Page t is required to be reviewed and signed by the principal investigator prior to commencement of enrollment.
7. Investigator Records and Reports: participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:
    a. All correspondence with the IRB, the sponsor, a monitor, including required reports.
    b. Records of study subject ECG:
        i. Model Number for the product(s) used for each subject.
8. Each subject's demographics, history, as required in the CRF and exposure to the device.
9. The Principal Investigator is required to prepare and submit to the Sponsor the following complete, accurate, and timely reports on this investigation, when necessary:
    a. Withdrawal of IRB approval (within 5 working days)
    b. Deviations from the protocol (Not permitted unless to protect health, safety, welfare)
    c. Informed consent deviations (within 5 working days)

25.0 Sponsor Responsibilities

25.1 General Duties

a. Selecting qualified investigators
b. Ensuring proper monitoring
c. Ensuring sites adhere to informed consent being documented and obtained

25.2 Selection of Investigators

a. Assure selection of investigators qualified by training and experience
b. Shipping the investigational product only to participating investigators
c. Obtaining a signed investigator's agreement containing:
    i. Investigator's curriculum vitae including investigator's relevant experience, location, extent, and type of experience
    ii. If an investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to the termination
    iii. Statement of the investigator's commitment to:
        - Conduct the investigation in accordance with the investigator agreement, the protocol, 21 CFR Parts 50 and 56, the clinical trial agreement, and any conditions of approval imposed by the IRB.
        - Supervise all testing of the device involving human subjects.

25.3 Providing Investigators with the Required Supplies and Information

25.3.1 The following Supplies Will be Provided by the Sponsor:

a. Commercially available single use disposable ECG electrodes
b. Seers Technology Company Ltd. ECG Monitoring System, Model MC200ML (1 mobiCARE™ ECG Monitoring System per subject)
c. Commercially available DR Model TBD Holter ECG Monitor
d. Samsung Galaxy A10e Smartphone with WiFi capability only Android device with minimum specifications of OS 7.0 or higher and CPU 1.4GHz or higher
e. Skin marking device

25.3.2 Information provided

a. Seers Protocol (this document)
b. mobiCARE™ ECG Monitoring System Instructions for Use
c. Worksheets in hard copy for study data collection
d. Electronic Case Report Form
e. Informed Consent
f. EDC Access

25.4 Monitoring and Close-out

a. Ensure site coordinators are available for monitoring visits. Monitoring will be conducted on-site.
b. Ensure sites are closed out at the end of study.

26.0 Non-significant Risk Justification

The regulatory approval required for this non-significant risk (NSR) study is Institutional Review Board (IRB) approval. Sponsors are responsible for making the initial risk determination and presenting it to the IRB. NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b). These abbreviated requirements address labeling, IRB approval, informed consent, monitoring, records, reports, and prohibition against promotion.

The sponsor is responsible for making the initial risk determination, SR or NSR, and presenting it to the IRB. If the sponsor has determined that a device study is NSR, the IRB must review the sponsor's determination.
The Seers Technology Company Ltd. mobiCARE™ ECG Monitoring System does not meet the definition of significant risk (SR) device. Per 21 CFR 812.3(m) an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a patient; ***mobiCARE™ ECG Monitoring System is NOT an implant;***
- Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a patient; ***mobiCARE™ ECG Monitoring System is NOT for use in supporting or sustaining human life;***
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a patient; ***mobiCARE™ ECG Monitoring System is NOT for use in diagnosing, curing, mitigating, or treating disease;***

  or

- Otherwise presents a potential for serious risk to the health, safety, or welfare of a patient. ***mobiCARE™ ECG Monitoring System is NOT a potential for serious risk to the health, safety, or welfare of a patient.***

27.0 FDA Approval

The mobiCARE™ ECG Monitoring System is not FDA cleared. This study will support a 510(k) premarket notification for the potential FDA 510(k) clearance of the mobiCARE™ ECG Monitoring System.

27.0 Abbreviations and Definitions

Abbreviation or Term	Definition
Adverse Event	Any undesirable medical occurrences in a subject whether or not it is related to the study device, procedure or study requirements that is identified or worsens during the clinical study
Allergic Reaction	A reaction which could result in nausea, rash, wheezing, edema induced thrombotic events, urticaria, or shock.
Artifact Grades	0=No artifact 1=Minor artifact present, ECG is interpretable 2=Major artifact present, ECG is NOT interpretable
BMI	Body Mass Index - A tool that Healthcare practitioners use to estimate the amount of body fat by using your height and weight measurements.
CFR	Code of Federal regulations
Conmeds	Concomitant Medication used at screening and during the study
CRC	Clinical Research Coordinator
CRO	Contract research organization responsible for study oversight
Device Malfunction	Defined as a malfunction in the device that did not allow it to perform its intended function when used in accordance with the *Package Insert*
ECG	Electocardiogram
EDC	Electronic data capture (database)
Enrollment	The subject is enrolled after he/she has signed the informed consent and has been determined to meet all the inclusion criteria and no exclusion criteria
FDA	Food and Drug Administration
Fever	An increase in body temperature to levels above normal: (37° C or 98.6° F)
HCP	Healthcare practitioner: A person who is licensed to provide healthcare services within the scope of their state's laws. In this case the HCP of interest is an ECG technician or other medical professional trained to perform an ECG.
Subject Withdrawal	Withdrawal of the subject from the study can occur due to multiple reasons: 1. At the direction of the principle investigator. Reasons for physician directed subject withdrawal include but are not limited to the subject not adhering to the study protocol requirements, the subject enrolls in another study, or if the PI deems it is in the best interest for safety and welfare of the subject to withdraw. 2. Subject refuses to continue participation
PI	Principal investigator (PI), the professional medical care provider responsible for the oversight of the study at his/her institution. The PI assumes responsibility and accountability for the clinical team and for data obtained from each subject participating in the study, assures compliance with the protocol, applicable laws and applicable regulations, ensures informed consent is obtained and documented, and reviews an signs case report forms indicating that documents are accurate and complete
Protocol Deviation	Any divergence from the study protocol
S/W	Software

28.0 Table of Changes

Protocol Version	Approval Date MM/DD/YYYY	Rationale for Change
0.0	10/29/2024	N/A – Initial Version

Add each revision to the table above.

29.0 References

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30.0 Appendices

30.1 APPENDIX 1 - Informed Consent Form

Provided separately in Word® Format for site customization

30.2 APPENDIX 2 – Instructions for Use (IFU)

A Copy of the IFU will be provided separately

30.3 APPENDIX 3 – Use Steps and Limited Human Factors Assessment

30.3.1 Administrative and Healthcare Professional Use Steps for Mobile – ECG Clinical Study

30.3.2 Healthcare Professional and Subject Human Factors Assessment (n=15 Subjects)

Appendix 30.3.1 Administrative and Healthcare Professional Use Steps for Mobile – ECG Study

Attached separately in PDF Format

Appendix 30.3.2 Healthcare Professional and Subject Human Factors Assessment (n=15)

Healthcare Professional and Subject Human Factors Assessment (n=15)

Subject Number	
Healthcare Professional Initials	
Date of Study	

HEALTHCARE PROFESSIONAL USAGE EVALUATION

The healthcare professional will be provided with the Instructions for Use and asked to connect the electodes and initiate measurement of the ECG using the mobiCARE device in the nominal position.

1. The electrodes and mobiCARE device are placed on the study subject in the **Nominal Position**.
2. The following HF observations will be made by the CRC.

Healthcare Professional Usability Performance Evaluation as Observed by the CRC

OBSERVER RATING (1-5): *1=Very Difficult, 2=Difficult, 3= Neutral, 4= Easy, 5= Very Easy*

OBSERVED TASKS	TASK	OBSERVER RATING (1 difficult to 5 easy)
→ Observed Task 1	How easy or difficult was it for the healthcare professional to place the mobiCARE device and electrodes in the Nominal Location using only the Instructions for Use?	
→ Observed Task 2	Could the healthcare professional read the ECG signal on the mobile phone app to confirm both Lead II and a clear signal after the device was placed?	

Acceptance Criteria: The average Likert score must be ≥3.

STUDY SUBJECT USAGE EVALUATION

1. After completion of the ECG measurements at the Nominal position and three (3) alternate locations, the Subject will be asked to replace the mobiCARE electrodes in the **Nominal Position**.
2. The CRC will observe the subject placing the mobiCARE electrodes in the **Nominal Position.**
3. The following HF observations will be made by the CRC.

Subject Usability Performance Evaluation as Observed by the CRC

OBSERVER RATING: (1-5) *1=Very Difficult, 2=Difficult, 3= Neutral, 4= Easy, 5= Very Easy*

OBSERVED TASKS	TASK	OBSERVER RATING (1 difficult to 5 easy)
→ Observed Task 1	How easy or difficult was it for the subject to remove the mobiCARE device and electrodes from their location in Alternate location 3?	
→ Observed Task 2	How easy or difficult was it for the subject to remove the used electrodes from the mobiCARE?	
→ Observed Task 3	How easy or difficult was it for the subject to replace the electrodes with new electrodes on the mobiCARE device??	
→ Observed Task 4	How easy or difficult was it for the subject to locate the markings for the Nominal position?	
→ Observed Task 5	How easy or difficult was it for the subject to replace the new mobiCARE device (electrodes) in the Nominal position	

Acceptance Criteria: The average Likert score must be ≥3.

30.4 APPENDIX 4 – Script for Subject Recruitment Flyers and Emails

Script for Subject Recruitment Flyers and Emails

We are recruiting for volunteers who are interested in participating in a clinical research study. The study includes monitoring your heart rhythm. No medical decisions will be made for participating in this study. This study is no cost to you.

What Will Be Required of Study Volunteers?

- You will be required to wear 2 small ECG electrodes that are placed using the adhesive, like what are standard for any ECG heart rhythm monitoring for a portable ECG. A healthcare professional will place the electodes on the skin of your chest and torso, and you may need to have the area shaved if you have a lot of hair in the location.
- You will also be required to wear 3 other electrodes for another ECG that are also standard for any ECG monitor. This second ECG with 3 electrodes is for a Holter monitor used to record your heart rhythm at the same time the small device with two electrodes records your hear rhythm.
- You will walk a short distance while monitoring your heart rhythm, for 1-2 minutes.
- The 2-electrode portable ECG will then be moved to a 2nd position and on the front of your torso and recorded for 1 to 2 minutes while you walk a short distance; and then a 3rd position and recorded for 1 to 2 minutes while you walk a short distance.
- You will be asked to remove and replace the 2 electrode ECG on the front of your torso at the end of the study and remove them. Then your participation is complete.

We are looking for volunteers who are male or female adults 18 years old and older and:

1. Speak and read English fluently
2. Will read and sign the consent form prior to participation
3. Are able to walk

The volunteers for this study must NOT have:

1. A cardiac pacemaker
2. A cardioverter defibrillator
3. Any other implantable electric devices
4. Current or medical history of skin cancer, rash, skin disorder, keloid, and/or any injury in the chest area
5. Symptoms of heart difficulty where changes in heart performance could result in your immediate danger
6. A known history of life-threatening arrhythmias
7. A neuro-stimulator
8. Be under a doctor's critical care.

Study Location
MCB Research Centers, LLC.
110 South Parkside Drive
Colorado Springs, CO 80910

Your participation will be ONCE and take approximately 30 minutes to 1 hour after you sign the consent form.

If you are interested in participating, please call:
MCB Research Centers, LLC.
(719) 634-6576
Call us TUE – FRI 7:00am – 6:00pm

You will be given a $100.00 gift card to compensate you for your time.