Preliminary Research Evaluation for Ambulatory Leadless Electrocardiogram Recorder Trial (PRE-ALERT)

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1.0 Approvals

Name	Title	Signature	Date (dd-mmm-yyyy)
Andre Bertram	Chief Executive Officer		
Frank Nguyen	Chief Technology Officer		
Derek Exner	Chief Medical Officer		

2.0 Document Revision History

Revision	Date	By	Comments
1	22/OCT/2020	Chief Medical Officer	Revised CIP Release

3.0 Table of Contents

4.0 Signatures

Sponsor Signatures

_____ _____
CEO, HelpWear Inc. Signature Date (dd/mmm/yyyy)

_____ _____
CTO, HelpWear Inc. Signature Date (dd/mmm/yyyy)

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CMO, HelpWear Inc. Signature Date (dd/mmm/yyyy)

Site Principal Investigator Signature

_____ _____
PI Signature Date (dd/mmm/yyyy)

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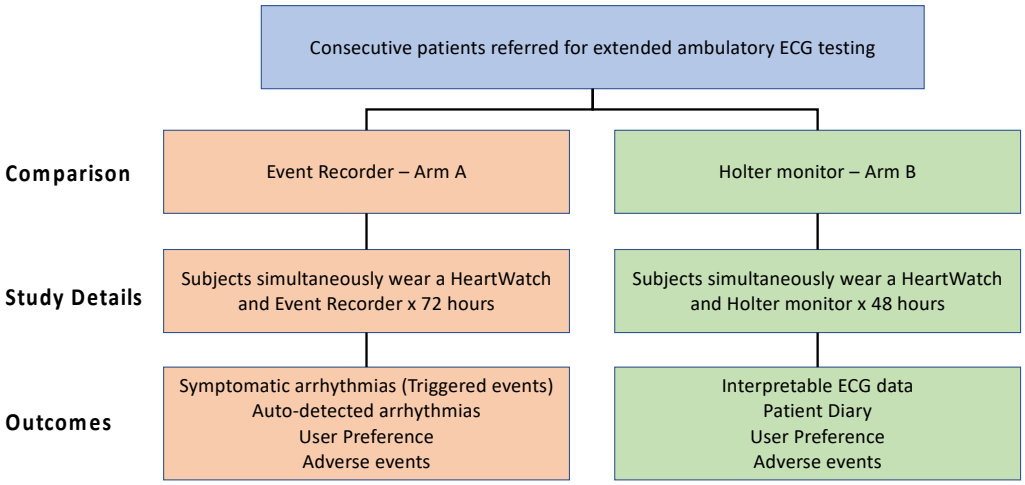
5.0 Study Synopsis

Sponsor	HelpWear Inc.
Product name	HeartWatch
Product Description	The HeartWatch arm band provides continuous, high-quality single lead electrocardiograph (ECG) data in a variety of environments. The ECG data is transmitted via Bluetooth and stored on the user's smartphone. It is then uploaded to the cloud for subsequent analysis using either a commercial ECG software package or a customized software package from HelpWear.
Intended Purpose of Investigational Device	The HeartWatch is indicated for extended diagnostic evaluation of patients with transient symptoms of possible cardiac origin such as syncope and palpitations, as well as patients at risk for arrhythmias, but without significant symptoms. *While the use of the device itself can be managed by both healthcare professionals and patients, interpretation of the collected data for diagnosis is restricted to healthcare professionals, as the data must be loaded and analyzed separately after recording.*
Study Objectives	Collect and pair user-triggered ECG data from the HeartWatch and Event Recorder. Collect and pair auto-triggered ECG data from the HeartWatch and Event Recorder. Collect and pair continuous ECG data from the HeartWatch and Holter. Implement the HelpWear customized ECG software analysis system to import and analyze paired HeartWatch and comparator device ECG data.
Primary Purpose	To implement and test the collection and analysis of paired ECG data from the HeartWatch and two comparator devices, an Event Recorder and Holter.
Primary Question	Can HeartWatch and comparator device ECG data be collected, paired, and analyzed?
Sites	One site in Canada, Toronto Heart Centre, Toronto
Subjects	Consecutive patients referred for extended ambulatory ECG monitoring will be approached for participation. Up to 50 subjects will be enrolled (**Figure 1**).
Study design	Concurrent, prospective, paired and real-world observational study (**Figure 1**). Based on the duration of monitoring requested by the referring physician, subjects will undergo simultaneous comparison of the HeartWatch to an Event Recorder (Arm A) or simultaneous comparison of the HeartWatch to a Holter monitor (Arm B).
Study duration	Up to 6 months, with 3 months of analysis time (9 months total)
Inclusion Criteria (all	• At least 22 years of age at time of consent • Clinically-indicated for an ambulatory Event Recorder or Holter monitor

must be present)	• Able to follow the protocol • Provision of written-informed consent
Exclusion Criteria (none may be present)	• Known allergy to any component of the Event Recorder • Known allergy to any component of the Holter monitor • Known allergy to any component of the HeartWatch • Dextrocardia
Study Intervention	Collect and pair user-triggered and auto-triggered ECG data from the HeartWatch and Event Recorder. Collect and pair continuous ECG data from the HeartWatch and Holter monitor. Analyze ECG data from the HeartWatch, Event Recorder, and Holter using the customized ECG software system.
Description of Procedure / Methods	Patients indicated for extended ambulatory ECG testing will be approached for participation. Subject flow is shown in **Figure 1**. Subjects will wear the HeartWatch and an Event Recorder for up to 72 hours (**Figure 1, left**) or the HeartWatch and Holter monitor for up to 48 hours (**Figure 1, right**). Subjects will be asked to document their activities (standing, sitting, walking, exercise, or laying down). Event recorder subjects (**Arm A**) will collect user-triggered and auto-triggered data, while Holter subjects (**Arm B**) will record diary information on their activities and any relevant symptoms. Adverse events and user preference for one device versus the other being used in that arm will also be collected from all subjects.  **Figure 1. Overview of the PRE-ALERT study** (see descriptions above).
Types of data collected during the study	• Demographics (age, gender, race) • Indication for extended ambulatory ECG monitoring • Limited medical history

	• Symptoms during the extended ambulatory ECG monitoring assessment • ECG data during the extended ambulatory ECG monitoring assessment • Usability of the extended ambulatory ECG monitoring assessment devices • Adverse events related to the extended ambulatory ECG monitoring devices • User preference of the ambulatory ECG monitoring devices being assessed
Criteria for Evaluation:	1. Ability to collect, pair, and analyze at least 20 user-triggered HeartWatch and Event Recorder ECGs. 2. Ability to collect, pair, and analyze at least 20 auto-detected HeartWatch and Event Recorder ECGs. 3. Ability to collect, pair, and analyze at least 200 hours of HeartWatch and Holter data. 4. Assess adverse events with the HeartWatch, Event Recorder, and Holter 5. Assess user preference for the HeartWatch, Event Recorder, and Holter.

6. Background

Heart rhythm disorders are common and significantly impact the lives of those affected and their families. The four main problems are: a) atrial fibrillation or AF, b) supra-ventricular tachycardia or SVT, c) excessively slow heart beats (i.e., bradycardia or pauses) and d) ventricular arrhythmias.

6.1 Atrial Fibrillation (AF)

AF is the most common heart rhythm disorder. In this condition the upper heart chambers beat rapidly and erratically. This results in the sensation of an abnormally fast heartbeat (i.e., palpitations) and can lead to other serious health problems including stroke, weakened heart muscle (i.e., cardiomyopathy) or death. Nearly 1% of Canadians, 350,000 persons, are affected with AF. Further, the number of persons with AF is growing. It is one of seven causes of death that are increasing worldwide. Deaths from AF relate primarily to much higher risk of stroke (six-fold) and heart failure (four-fold).

The problem with AF determination is two-fold. First, many patients with AF do not know they have this arrhythmia, so treatments are either delayed or not provided. Although there are many proven therapies that both control AF and reduce the risk of stroke, they require that the AF first be diagnosed. Second, among those with AF and symptoms, *reduced exercise capacity,* anxiety, depression and a loss of control are common complaints. Methods to identify the frequency and severity of AF will allow for improved management.

Continuous ECG monitoring allows doctors to detect and to better treat patients with AF and provides patients with control over the management of their disease. Both result in better health outcomes.

6.2 Supra-Ventricular Tachycardia (SVT)

SVT are another common group of disorders. In these conditions the upper and lower heart chambers beat rapidly, resulting in palpitations and a feeling of dread. If this condition is not treated quickly, chest pain, a heart attack, fainting or another serious problem can result.

SVT episodes often come and go, making a diagnosis difficult, since an ECG during the SVT episode is necessary to confirm the diagnosis and determine the best therapy. Moreover, having ECG data just prior (onset of SVT) and at the end of the episode (offset of the SVT) is vital in determining what the most likely electrical mechanism(s) of the SVT are, as this helps to guide the best treatment. This is extremely important information in deciding upon the person's suitability for and guiding delivery of, a curative procedure called a cardiac ablation.

6.3 Bradyarrhythmias and Pauses

Bradyarrhythmias can present as slow or missed heart beats are relatively common and typically treated with a permanent pacemaker, but other therapeutic options may be preferable in some patients. Symptoms that herald significant bradycardia or pauses include tiredness, fatigue, near-fainting and fainting.

Identifying persons who do and those who do not, need a pacemaker can be difficult as these slow heart rhythm problems, as well as the patients' symptoms, frequently come and go. This delays diagnosis, treatment and puts the patient at risk of serious problems. As with SVT, an ECG is necessary to confirm the diagnosis. Like SVT, having ECG data just prior (onset) and immediately after an episode (offset) is key to determining what the most

likely electrical mechanism(s) of the bradyarrhythmia or pause are very important, as this information in extremely useful deciding whether a permanent pacemaker is necessary or if other treatments are required.

6.4 Ventricular Arrhythmias

Ventricular arrhythmias occur when the bottom heart chambers beat in a dangerous, irregular manner. This can lead to cardiac arrest, where the heart is not pumping sufficiently to allow for blood flow to the brain, vital organs and death. It is estimated by the Heart and Stroke Foundation that 40,000 Canadians will die prematurely this year from cardiac arrest, a persistent, dangerous and irregular beating of the lower heart chambers. These events occur over a vast array of ages, across genders and are difficult to reliably predict. However, certain groups are known to have a higher risk of cardiac arrest, including patients with diabetes, heart failure, a family history of certain inherited conditions, or those who have had a prior heart attack.

6.5 Monitoring Technologies

Two general types of consumer products are used to monitor patients with or at risk of heart rhythm disorders. Most estimate heart rhythm using blood flow (photoplethysmography) alone or in combination with activity sensors (accelerometer). Other methods record an ECG when the patient has symptoms. These devices are useful, but require the wearer to recognize their symptoms, attach the device and rest quietly in order to obtain an ECG recording of reasonable quality. The user then needs to send that information to a healthcare provider in order for verification. Hence, existing technologies are far from ideal.

7.0 Investigational Device

7.1 Device Description

The HeartWatch is a low cost, continuous, and non-invasive ECG monitor worn on a patient's bicep. The device leverages 4 novel dry sensors to extract the voltage difference in the subject's heart to determine lead 1 ECG. Collected ECG data is sent via Bluetooth wireless transmission to the patient's smartphone. The HeartWatch allows the user to note (tag) any symptoms they experience (e.g., palpitations, light-headedness, fainting, etc.) using the device itself or the paired smartphone to allow for symptom-rhythm correlation and subsequent review by a physician. The HeartWatch displays all the elements of an ECG signal (i.e., PQRST) to facilitate diagnoses by physicians. The form factor of the device is comprised of medical grade plastics (e.g. Makrolon 2858, 2859), metal electrodes, and elastane fabric.

For this study, participants will be provided a smartphone with the HeartWatch which they will return upon completing their monitoring session. Additionally, the HeartWatch system itself will only record patient's ECG data categorized using the research patient ID from the study's master linking log.

For the study the data will be collected using the HelpWear app and stored on the phone. The app does not require any identifying information to be entered. As such, only de-identified ECG, user symptom, and user activity data is collected and stored.

7.2 Indication for Use

The HeartWatch device is indicated for extended diagnostic evaluation of patients with symptomatic and transient symptoms such as light-headedness, syncope and palpitations, as well as patients at risk for arrhythmias, but without significant symptoms. *While the use of the device itself can be managed by both healthcare professionals and patients, interpretation of the collected data for diagnosis is restricted to healthcare professionals, as the data must be downloaded and analyzed separately using dedicated software analysis systems.*

7.3 Prior Investigations

HelpWear conducted an exploratory study of the HeartWatch to determine whether the device was capable of collecting a continuous single lead ECG. Other biometrics (e.g. temperature, pulse oximetry) were collected to obtain data on their relationship to the ECG data and to temporally synchronize the ECG data. The main purpose of the feasibility study was to demonstrate the ability to collect continuous ECG from the bicep.

7.4 Manufacturing Information

The design and manufacture of the HeartWatch device is managed by HelpWear Inc. at the following location: 209 Victoria Street, Room 774, Toronto, Ontario M5B1T8.

Individual components are purchased by HelpWear. Manufacturing is done at No.3 Zhen An Middle Road, Wu Sha Community, Changan Town, Dongguan City, Guangdong, China 523857. Devices are tested at HelpWear's office (previously listed address).

The design and developing activities are outlined in the project design history file managed by HelpWear Inc. The HeartWatch is manufactured in a clean and controlled environment according to approved manufacturing specifications. Manufacturing records are created and maintained for each lot of HeartWatch devices providing traceability to raw materials and components. Each device is carefully inspected and must meet all quality control acceptance criteria prior to release. The safety of the device was designed to meet following standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;
- IEC 60601-2-47 Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems;
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process;

While formal audit for these compliances is pending, HelpWear will attain an Investigation Testing Authorization (ITA) to use the device for the PRE-ALERT study. Any additional requirements imposed by the EC or regulatory authority shall be followed, if appropriate.

7.5 Release and Distribution for Study

Product is released and distributed to clinical sites by HelpWear Inc. only following and executed investigator agreement.

7.6 Storage Requirements

The HeartWatch device and any associated components are shipped to the clinical site by HelpWear Inc. The device has no special storage or handling requirements. Product can be stored at ambient room conditions.

7.7 Labeling

The HeartWatch device has labels for identification and to communicate essential information related to the product. See attached label and Instructions for Use in Section 16.

7.8 Modification of Investigational Product for Study

All investigational products will be stored and used in accordance with the protocol. No modifications to the study product will be permitted. If a device malfunctions or produces an unexpected result, as deemed by the technician, physician, participant, etc., the site coordinator will notify the sponsor immediately to troubleshoot the device and, if need be, replace the malfunctioning device.

7.9 Accountability Procedures

HelpWear Inc. will ship the investigational device only to qualified sites.

The Principal Investigator at each site is responsible for proper storage of received devices and for maintaining a current Clinical Inventory Form for the duration of the study. The study monitor will review device storage conditions and the completion of the site's Clinical Inventory. Reconciliation of device disposition will be documented. The names of all persons who received and/or used the device at the site will be recorded. At the end of the study, all investigational products remaining at the sites will be returned to the Sponsor.

8.0 Study Overview

This proof of concept study will enroll consecutive patients referred for extended ambulatory ECG testing. All clinical decisions will be based on data from the clinical comparator devices (i.e., Event Recorder or Holter) and the approved software analysis systems for those devices. Neither the HeartWatch data nor the paired ECG signal analyses will be used for clinical decision-making.

Subject flow is shown in **Figure 1**. Subjects will wear the HeartWatch and an Event Recorder for up to 72 hours (**Figure 1, arm A**) or the HeartWatch and Holter monitor for up to 48 hours (**Figure 1, arm B**). Subjects will be asked to document their activities (standing, sitting, walking, exercise, or laying down). Event Recorder subjects (**arm A**) will collect user-triggered and auto-triggered data, while Holter subjects (**arm B**) will record diary information on their activities and any relevant symptoms. Adverse events and user preference for one device versus the other being used in that arm will also be collected from all subjects.

In Arm A, the HeartWatch triggered and auto-detected data will be compared to single or two-lead triggered and auto-detected data Event Recorder data. Subjects will be required to wear both the HeartWatch and ambulatory Event Recorder for a 72-hour period. In Arm B the HeartWatch continuous ECG data compared to continuous ECG Holter data. Subjects will be required to wear both the HeartWatch and Holter for a 48-hour period.

All participants will be required to provide written, informed consent.

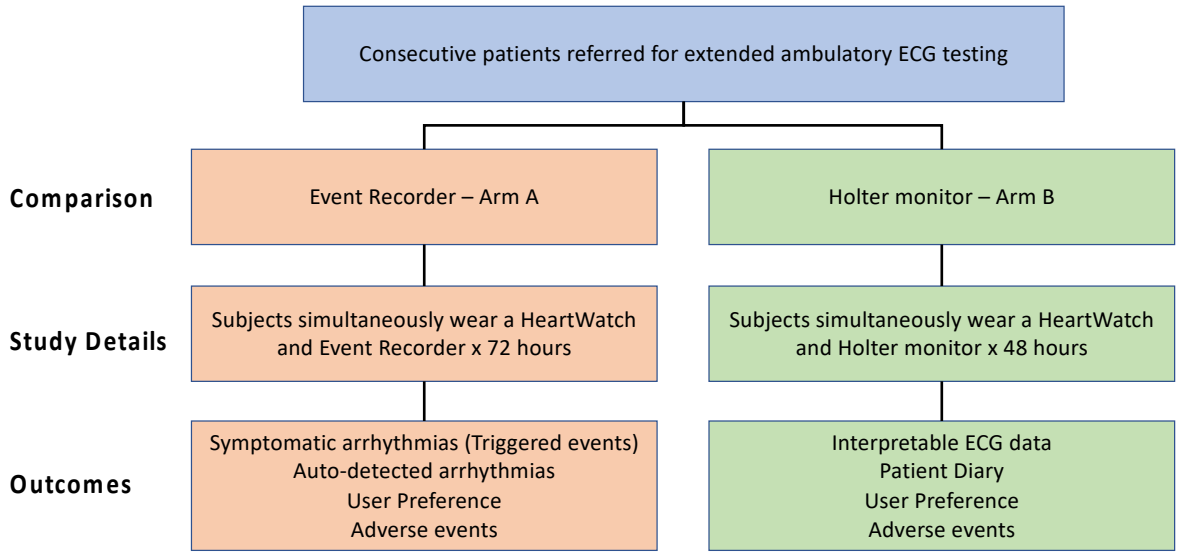


Figure 1. Study overview

8.1 Primary purposes

A. To demonstrate the capacity to collect and pair user-triggered (tagged) and auto-triggered ECG data from the HeartWatch and Event Recorder in preparation for a larger, multi-centre study.
B. To demonstrate the capacity to collect and pair continuous ECG data from the HeartWatch and Holter monitor in preparation for a larger, multi-centre study.

8.2 Primary Research Questions

A. Can paired user-triggered (tagged) and auto-triggered ECG data from the HeartWatch and Event Recorder be successfully collected?
B. Can paired continuous ECG data from the HeartWatch and Holter monitor be successfully collected?

8.3 Secondary Research Questions

Does body position and activity affect the quality of the HeartWatch, Event Recorder, and Holter data?

8.4 Ancillary Research Questions

Collect initial data to estimate the following:
a) Incidence of adverse events among the HeartWatch and comparator devices,
b) The types of adverse events that may occur, and
c) User preferences of subjects with the HeartWatch versus the comparator devices.

8.5 Hypothesis

Paired ECG data from the HeartWatch and comparator devices will be similar in terms of the events documented and the proportion of data that is clinically interpretable.

8.6 Objectives

1. To demonstrate the capacity to collect and pair user-triggered (tagged) and auto-triggered, clinically interpretable ECG data from the HeartWatch and Event Recorder in preparation for a larger, multi-centre study.
2. To demonstrate the capacity to collect and pair clinically interpretable, continuous ECG data from the HeartWatch and Holter monitor in preparation for a larger, multi-centre study.

8.7 Endpoints

A. Primary endpoints:

1. User-triggered (tagged) and auto-triggered ECG data from the HeartWatch and Event Recorder.
2. Continuous ECG data from the HeartWatch and Holter monitor.

B. Secondary endpoints

1. Incidence of adverse events.

   The HeartWatch is anticipated to have a similar rate of adverse events as compared to the Event Recorder and Holter monitor.

2. User preference for the extended ECG monitoring test.

   The HeartWatch is anticipated to be similarly preferred to the Event Recorder and Holter monitor.

8.8 Study Duration

It is anticipated that the enrolment period will last up to 6 months, with a total study duration of 9 months total.

8.9 Subjects

8.9.1 Study Population

Consecutive patients referred to participating clinics for extended ambulatory ECG testing.

8.9.2 Inclusion Criteria

- At least 22 years of age at time of consent
- Clinically-indicated for an ambulatory Event Recorder or Holter monitor test
- Able to follow the protocol
- Provision of written-informed consent

8.9.3 Exclusion Criteria

- Known allergy to any component of the Event Recorder
- Known allergy to any component of the Holter monitor
- Known allergy to any component of the HeartWatch
- Dextrocardia

8.9.4 Recruitment

Subjects referred for extended ambulatory ECG testing will be recruited from the Toronto Heart Centre.

Referring physicians will be asked to indicate if longer-term (i.e., Event Recorder) or shorter-term monitoring (i.e., Holter monitor) is desired for a given patient. If no preference is provided by the referring physician, the Heart Rhythm Society guidance document[a] will be used to select the appropriate extended ECG monitoring tool, as outlined in **Table 1**.

Table 1. Summary of Guidance from the 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring / telemetry.[a]

Medical history and indication(s) for extended ECG testing	Shorter-term, (Holter)	Longer-term, (Event Recorder)
Symptomatic event frequency	Frequent, daily	Less than daily or uncertain
Correlation of symptoms and underling rhythm	+	+
Qualitative analysis of QRS morphology	+	-
Quantification and trending of arrhythmia burden / pattern	+	-
Detection of asymptomatic arrhythmias (e.g., atrial fibrillation among patients with a cryptogenic stroke)	-	+
Assessment of the efficacy of arrhythmia suppression	+	-
Detection of non-sustained arrhythmias	+	+
Assessment of heart rate dynamics	+	-
Detection of pro-arrhythmic adverse drug responses	+	-
Detection of pacemaker / defibrillator device malfunction	+	-

Legend: '+' preferred / acceptable, '-' not preferred / not acceptable

Patients referred for a clinically-indicated ambulatory ECG testing will be provided with information about the two studies and a screening appointment will be scheduled.

Potential subjects will be evaluated by a study coordinator against the inclusion and exclusion criteria prior to enrollment.

8.9.5 Screening Procedures

All subjects screened for participation in this study will be documented using the study screening log. A screening log will be used to provide insight into the reasons for study exclusion. No information will be recorded in that log apart from the number of potential subjects exclude and the reason(s) for refusal. Consent will not be obtained for patients that are screened, but not enrolled since no identifying or personal data will be collected. Patients meeting the study criteria will be asked to participate in this study and sign informed consent.

Patients who are screened but not eligible to participate or who are eligible but do not want to participate in this study, with reason, will be documented on the screening log.

Patients who fulfill eligibility criteria will be asked to sign the study-specific informed consent.

8.9.6 Enrollment

A subject is considered enrolled when they meet all eligibility criteria, including having signed the study-specific informed consent. All study-specific procedures will be collected after subjects provide written informed consent.

Upon signing the consent form, the following procedures will be completed to ensure eligibility:

- Information received from the referring physician
- History obtained from the patient
- Review of medical records

Both male and female subjects will be uniquely and consecutively enrolled.

8.10 Study Schedule of Assessments

The study's schedule of events is shown in **Table 2.** Details of assessments are provided. Information captured in assessments will be documented in study- case report forms.

Table 2. Schedule of Assessments

Study Requirement	Screening	Study	Adverse events
Informed consent	X		
Medical history and medications	X		
Eligibility criteria assessment	X		
Reason(s) for extended ECG testing	X		
Symptoms during extended ECG testing		X	
Activities during extended ECG testing		X	

Adverse events related to ECG testing			X
Usability of ECG monitoring tests		X	
User preference of ECG monitoring tests		X	

8.11 Clinical Benefits/Risks

The HeartWatch is a non-invasive, accurate solution to ambulatory ECG monitoring.

8.11.1 HeartWatch Usage Benefit

The HeartWatch is painless and non-invasive. It is a small, light-weight, self-contained arm band that continuously records the electrical activity of the heart. It does not require electrodes (skin patches) or other bulky equipment and can be worn discreetly under everyday clothing.

The HeartWatch automatically detects and records abnormal heart rhythms and allows users to indicate when they are having symptoms, so that their physician can determine whether these symptoms are related to changes in the user's heart rhythm.

8.11.2 HeartWatch Usage Risks

While the HeartWatch is painless and non-invasive, participants may experience minor skin irritation from where it is in contact with their skin.

8.11.3 Ambulatory ECG Recording Risks

Ambulatory ECGs, Holter and Event Recorder devices are painless and non-invasive. They require the user to keep a log of activities and symptoms, remove and replace skin patches when they are worn for extended periods and carry a monitor (receiver) on their belt or other clothing. Users may experience skin irritation and discomfort from the gel patches (adhesive electrodes) on their skin are required to record the electrical activity of the heart.

8.12 Discontinuation of Study

During study conduct, if the Sponsor or site Principal Investigator discover a condition that indicates that the study should be discontinued, this action will be taken. If the study is terminated, the investigator will inform the ethics board or Institutional Review Board (IRB) of the study termination and the reason(s) for its' termination. If a terminated study is planned to be resumed, the Sponsor may not re-engage without first obtaining ethics approval.

If the study was terminated related to an unanticipated adverse device effect (UADE) the study may not be resumed without IRB and Food and Drug Administration (FDA) approval. If the study was terminated related to withdrawal of IRB approval, the Sponsor shall notify the FDA. The investigator(s) will return all study materials, documentation, and Case Report Forms to the Sponsor. The IRB will be informed of study termination and the reason(s) for the termination by the Sponsor or investigator, as specified by the applicable regulatory requirements.

Conditions that may warrant termination of the study include, but are not limited to, the following:

- Discovery of an unexpected, serious, or unacceptable risk to subjects.

- Recommendation by an Institutional Review Board or Regulatory authority
- The Sponsor decides to discontinue testing of the study device.

Conditions that may warrant study termination at site include, but are not limited to:

- Failure to comply with pertinent regulations and ethical guidelines
- Deliberate submission of false information
- Inadequate adherence to protocol requirements
- Inadequate enrollment

All subjects have the right to withdraw at any point during the study without prejudice. A subject may be withdrawn from study at any time for any of the following reasons:

- Voluntary withdrawal of consent
- Termination of the study by the Sponsor

The withdrawal of the subject is documented with the case report forms for this study. If a subject withdraws prematurely from the study all documentation must be completed as best as possible up until the withdrawal, such as documenting the patient as "lost". The patient also retains the right to request that any and all data collected up to the point of withdrawal be omitted from the final analysis.

All study-related documents will be stored for 25 years as required for all regulated studies.

A privacy breech is considered unlikely due to the fact that only de-identified data are being collected and provided to the Sponsor. Nonetheless, the Research Ethics Board and the Privacy Office will be notified in the event of a privacy breach.

9.0 ECG Data Collection and Transfer

9.1 Event Recorder

For participants in Arm A, the Event Recorder and HeartWatch will be worn for a period of 72 consecutive hours. The comparator Event Recorder for arm A is the Sirona Event / Holter Recorder (Intricon Datrix Corporation, FDA 510(k) number K112601). Like the HeartWatch, the Sirona records ECG data on demand when the patient has symptoms (manual activation) and has automatic arrhythmia detection for bradycardia, tachycardia, AF, and pauses. It can store up to 2,000 events. Electrodes are placed on the chest and connected, via leads, to the recorder. The Sirona Event Recorder has an input impedance of 5 MΩ, a bandwidth: 0.05 Hz to 40 Hz, samples at 256 samples per second, and has a resolution of 10 bits.

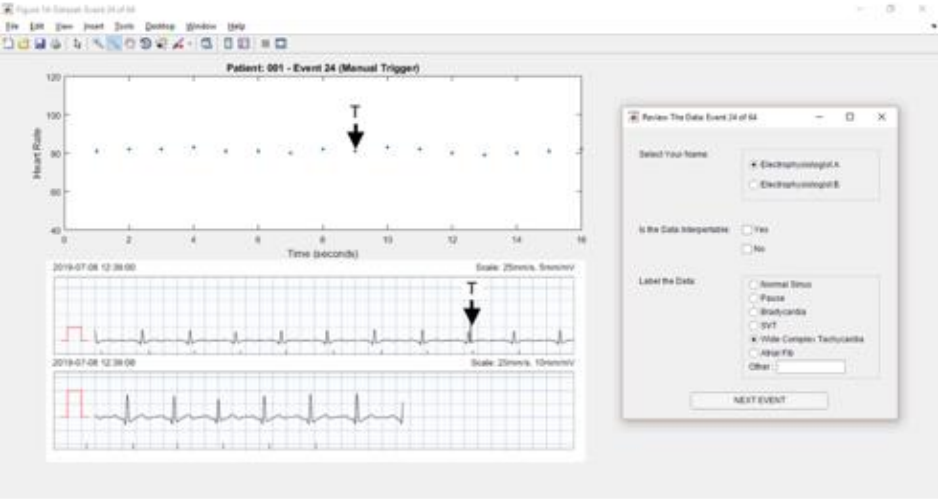
Sirona data will be downloaded for analysis with Global ECG Management System (GEMS, CardioComm Inc.) software after the 72 hours, as per usual clinical practice at the participating sites. The GEMS data is stored on the clinic network. As per the usual clinical care pathway, ECG technicians will analyze the Sirona data and the results will be over-read by a cardiologist.

Only the data collected using the Sirona recorders and interpreted using the GEMS software will be used for clinical decision making.

9.2 Event Recorder Event Adjudication

For the purposes of this study in Arm A, at least two cardiac electrophysiologists will adjudicate all clinical events (subject activated episodes, as well as auto-detected abnormal rhythms). Additionally, they will classify these as clinically-interpretable (i.e., adequate quality ECG to make a clinical arrhythmia diagnosis; such as tachycardia, bradycardia, AF event or to exclude a clinical arrhythmia diagnosis). In cases of disagreement between the categorization of initial two cardiac electrophysiologists a third cardiac electrophysiologist will evaluate the data. The final categorization will be based on majority consensus. The categorization of events by the cardiac electrophysiologists will be used as the gold standard by which the HeartWatch is compared.

Event categorizations will be done through a customized research software interface (**Figure 2**). The interface allowing the HeartWatch and Event Recorder data to be masked (i.e., the data form the devices will appear similar), as will the interpretation of the other cardiac electrophysiologist.



T – Manual Trigger

Figure 2. Customized research software interface.

9.3 Holter Monitor

For participants in Arm B, the Holter and HeartWatch will be worn for a period of 48 consecutive hours. The comparator in Arm B is the SEER Holter recorder (GE Medical Systems Information Technologies, Inc., FDA 510(k) number K130626). The Holter monitor is considered the gold standard for ambulatory ECG recordings. Electrodes are placed on the chest and connected, via leads, to the recorder. Unlike an Event Recorder, the Holter continuously records ECG data. Patients are provided with a diary to record their symptoms and activities. All ECG data, including arrhythmia events, are recorded. The SEER Holter has an input impedance of 10 MΩ, a bandwidth: 0.05 Hz to 40 Hz, samples at 125 samples per second, with a resolution of 10 bits.

SEER data will be downloaded for analysis with MARS software for analysis after the 48 hours, as per usual clinical practice at the participating sites. The MARS Database is stored on the local clinic network. As per the usual clinical care pathway, ECG technicians will analyze the SEER data and the results will be over-read by a cardiologist.

Only the data collected using the SEER recorders and interpreted using the MARS software will be used for clinical decision making.

9.4 Holter Data Evaluation

For the purposes of this study in Arm AB, the percent of data that is interpretable will be based on hour-by-hour analysis by experienced Holter technicians and confirmed by at least two cardiac electrophysiologists. The over-read adjudications by the cardiac electrophysiologists will be used as the gold standard by which the HeartWatch is compared. Data will be segmented into blocks of one hour. The percentage of data will be calculated as the number of blocks where the overall ECG data is clinically-interpretable (the heart rate is measurable, all bradyarrhythmias and tachyarrhythmias are identified, and abnormal beats are identified) over the total number of blocks recorded (e.g., data interpretable in 17 of 21 blocks = 81%).

9.5 HeartWatch

For participants completing either study, the HeartWatch will be worn for the same length of time as the comparator device. The HeartWatch arm band is designed to provide non-invasive, continuous ECG data. It continuously records ECG data for subsequent, offline analysis using a custom-designed research software product (**Figure 2**). The HeartWatch allows the user to note (flag) symptoms they experience (e.g., palpitations, chest pain, fainting, etc.) to allow for symptom-rhythm correlation and subsequent review by a physician. The HeartWatch displays the elements of an ECG signal to facilitate diagnoses by the physician.

When secured to the left upper arm, the device collects continuous ECG signals from four (4) built-in electrodes and transmits the data to the user's personal communication device (e.g., smartphone) and the cloud using the Android Operating System (OS) and Bluetooth. The HeartWatch is powered by a rechargeable lithium ion battery. The HeartWatch collects a single channel ECG, has bandwidth from 0.67 Hz to 45 Hz (and impedance 10 MΩ), sampling rate of 300 samples per second, and 12-bit resolution.

The data obtained using he HeartWatch and any data analyzed using the customized research software interface will be not used for clinical decision making.

9.6 HeartWatch Data Adjudication

For the purposes of this study in Arm A, at least two cardiac electrophysiologists will adjudicate all clinical events (subject activated episodes, as well as auto-detected abnormal rhythms). Additionally, they will classify these as clinically-interpretable (i.e., adequate quality ECG to make a clinical arrhythmia diagnosis [e.g., tachycardia, bradycardia, or AF event or to exclude a clinical arrhythmia diagnosis]). In cases of disagreement between the categorization of initial two cardiac electrophysiologists a third cardiac electrophysiologist will evaluate the data. The final categorization will be based on majority consensus. The categorization of events by the cardiac electrophysiologists will be used as the gold standard by which the HeartWatch is compared.

Event categorizations will be done through a customized software interface (**Figure 2**). The interface allowing the HeartWatch and Event Recorder data to be masked (i.e., the data form the devices will appear similar), as will the interpretation of the other cardiac electrophysiologist.

For Arm B, the over-read adjudications of the cardiac electrophysiologists will be used as the gold standard by which the HeartWatch is compared.

10.0 Methods

10.1 Baseline Visit

Unless otherwise specified, the study coordinators will conduct the following study activities.

Prior to collecting ECG data, an assessment of the participant will be conducted to confirm eligibility. Subjects will be provided with the HeartWatch and instructed on proper placement, use, and troubleshooting at the same clinical appointment in which they receive the comparator device. The recorders will be placed and turned on within the same time frame (within 2 hours).

The baseline visit will also include a collection of relevant medical data, including: age, gender, height, weight, blood pressure, medications used, medical history, the indication for the extended ECG test and relevant symptoms.

10.2 Study Visits

Participants will be seen at a baseline visit when they will receive the devices and a subsequent visit where the Event Recorder or Holter monitor data are downloaded and assessment of adverse events conducted. Both of these visits follow the usual clinical work flow and procedures for extended ambulatory ECG testing. Hence, no additional in person study visits, outside of these usual visits will be required. A phone follow-up 1 to 3 days after the ECG monitoring devices are returned will be performed to assess for any adverse events that were not apparent at the time the devices were returned.

10.3 Follow Up

None beyond the stated study periods (72 hours for Arm A and 48 hours for Arm B).

10.4 Unscheduled Visits

There is potential for unscheduled clinic visit occurring in the event of a clinical or study device malfunction, inadequate recording from either device, or the development of an adverse event.

Should clinical or study device malfunction or inadequate recording from either device occur the subject will be offered the opportunity to repeat the recordings. If they chose not to repeat the testing their data will be considered incomplete or they will be excluded from the analyses (see Section 10.2). The details surrounding subject data that is excluded from the analyses (i.e., frequency, device type, device and subject reason(s), and relevant demographic features) will be tabulated and reported.

10. 5 Site Selection, Participation, and Management

This study will be undertaken at one site, with enrollment of up to 50 subjects. The Sponsor has determined that the Principal Investigator and their staff have the facilities and expertise required. The selected site has a sufficient volume of patients who meet the inclusion and

no exclusion criteria, is able and willing to follow this clinical study protocol (including the collection of data, and has a staff member who can serve as a research coordinator).

10.5.1 Clinical Monitoring Procedures

Site Monitors may be used and will be managed by the Sponsor. They will have relevant experience in clinical trials involving cardiac conditions. Monitors will be chosen, based on monitoring experience in medical devices, preferably with IDE/ITA trial experience. These individuals have experience in GCP/ICH guidelines for conducting clinical studies. At a minimum, these individuals hold the credentials equivalent to that of a Clinical Research Associate (CRA).

10.5.2 Site Monitoring Procedures

Prior to study initiation, the Sponsor will develop a site monitoring plan. Monitoring the study will consist primarily of site qualification and initiation, remote monitoring of the case report forms (CRFs) and ongoing on-site monitoring and source verification.

10.5.3 On-site Monitoring

A representative of the Sponsor will visit the Investigator periodically for the purpose of monitoring the progress of this study and data collection within the chosen electronic data capture (EDC) system, in accordance with current Good Clinical Practice regulations. These include but are not limited to assuring subjects are protected, study data integrity, and compliance with applicable regulations. Any additional requirement imposed by the monitor or other regulatory authorities shall also be followed.

It is the responsibility of the Investigator to be present or available for consultation during such scheduled monitoring visits. During these routine visits, all medical source data pertaining to a patient's participation in this clinical investigation must be made available to the monitor. Medical source data are any medical records associated with the subject's health prior to study initiation and change in health during the study period.

On-site review of eCRFs focuses primarily on source verification, a comparison of data entered into the eCRF vs. source records. eCRF data points will undergo source verification using a risk-based approach that will be outlined a study-specific clinical monitoring plan. The Sponsor, or Sponsor's authorized representatives, will also review study files, including the administrative and regulatory files, subject binders and all source documentation for review in order to verify the accuracy and completeness of the records, as well as appropriate subject consent procedures.

The Investigator and appropriate personnel may be invited to attend meetings/workshops organized by the Sponsor to assure acceptable protocol execution. The study may be subject to audit by the Sponsor, Sponsor's representatives, or by regulatory authorities. If such an audit is announced or occurs, the Investigator must agree to allow access to required patient records. By signing this protocol, the Investigator grants permission to qualified personnel from the Sponsor, its authorized representatives, and appropriate regulatory authorities for on-site monitoring of all appropriate study documentation, as well as on-site review of the procedures employed in CRF generation, where clinically appropriate.

At study termination, a monitor will conduct an on-site study closeout visit, the purpose of which is to review all study documents and CRFs and prepare this information for proper storage.

Monitoring visits will occur as appropriate and commiserate with subject enrollment. The frequency of monitoring visits will be determined by ongoing evaluation of site performance and level of enrollment.

10.5.4 Training

All physicians and support staff who will participate in this study will undergo orientation by the Sponsor prior to study initiation at the site. Training consists of:

- Review of the study protocol
- Review of the HeartWatch device Instructions for Use
- Product Training log for study staff

10.6 Data Collection

10.6.1 Event Recorder and Holter Data

A standard 1 or 2-lead Sirona Event Recorder will be used to collect high-resolution data. Subjects will be asked to wear the clinical monitor for at least 48 hours and no longer than 84 hours. ECG signals will be continuously collected as long as the skin patches are attached to the skin and the recorder is properly connected to the wires.

A standard 5-lead SEER Holter will be used to collect 3-channels of high-resolution data. Subjects will be asked to wear the clinical, conventional monitor for at least 36 hours and no longer than 60 hours. During this time ECG signals will be continuously collected.

Specific variables of interest within both ambulatory recordings are:

- Symptoms during the extended ambulatory ECG monitoring assessment
- ECG data during the extended ambulatory ECG monitoring assessment
- Usability of the extended ambulatory ECG monitoring assessment tests
- Adverse events related to the extended ambulatory ECG monitoring tests
- User preference of the ambulatory ECG monitoring tests assessed

10.6.2 Clinical Data

Basic data related to each subject's medical history and their medications will be collected:

- Demographic (age, sex, race)
- Indication for extended ambulatory ECG testing
- Medical history

All data will be managed as per the outlined procedures in Section 8, Data Management.

11.0 Statistical Analysis Plan

11.1 Statistical Considerations

This is a preliminary study to assess the feasibility of conducting a larger multi-centre study. The objectives of this study are largely logistical (see 8.6, demonstrate the capacity to collect and pair user-triggered and auto-triggered ECG data from the HeartWatch and Event

Recorder and the capacity to collect and pair continuous ECG data from the HeartWatch and Holter monitor). As such, only a limited number of subjects need to be enrolled. The sample size and statistical plan are based on the comparison of the paired data.

11.2 Primary Measure of Study Success

The capacity to collect clinically-interpretable paired data. The criteria for evaluation include:

1. Ability to collect, pair, and analyze at least 20 user-triggered HeartWatch and Event Recorder ECGs.
2. Ability to collect, pair, and analyze at least 20 auto-detected HeartWatch and Event Recorder ECGs.
3. Ability to collect, pair, and analyze at least 200 hours of HeartWatch and Holter data.
4. Assess adverse events with the HeartWatch, Event Recorder, and Holter
5. Assess user preference for the HeartWatch, Event Recorder, and Holter.

11.3 Sample Size

A total of 50 patients will be enrolled to collect the required number of events in Arm A (20 triggered and 20 auto-detected) and 200 hours of continuous ECG data. This sample size takes into account that up to 20% of the data may be uninterpretable. Although we expect that less than 10% of the data will be missing or uninterpretable, a more conservative estimate is being used given the uncertainties involved in this preliminary study.

Up to 40 patients will be enrolled in Arm A, providing a sufficient number of triggered and auto-triggered events. While patients undergoing extended ECG monitoring have an unpredictable number of events, clinical observations indicate that ~25% of patients will have events, with an average of 3 triggered and 3 auto-detected events per recording. Thus, the 40 patients will provide up to 30 triggered and up to 30 auto-detected events. Assuming 20% of the data may be missing or uninterpretable, ~24 triggered and ~24 auto-detected events will be available for analysis.

Up to 10 patients will be enrolled in Arm B, providing over 250 hours of continuous ECG data. This will provide over 200 hours of usable data, assuming 20% of the data may be missing or uninterpretable.

11.4 Statistical Analysis

The purpose of this study is to collect data to allow for paired data evaluation. As such, descriptive statistics will be employed. Standard statistical methods will be used. It is anticipated that the following techniques may be used: descriptive summary statistics, Student's t-test, Chi-square, Fisher's exact test, analysis of variance, analysis of covariance, and graphical displays.

11.5 Safety Evaluation

All adverse events reported in the study will be tabulated for all subjects enrolled. Events will be tabulated by severity and relationship. Latent events will be tabulated separately. Adverse events will be evaluated and described as outlined in Section 13.

11.6 Usability Endpoint Analyses

Behavioral qualitative data from the product usability testing sessions will be assessed separately. In addition, all subjects participating in Study A and Study B will be asked to complete a brief questionnaire on device preference (**Figure 3)**.

Please check off the box above the statement that best described your experience?				
□	□	□	□	□
Strongly prefer chest monitor	**Slightly prefer chest monitor**	**No preference** of monitor	**Slightly prefer arm monitor**	**Strongly prefer arm monitor**
Numeric values assigned to the subjects' response.				
-2	**-1**	**0**	**1**	**2**

Figure 3: Extended ECG Monitoring Test Preference.

User preference will be summarized and values ranging from -2 to +2 (**Figure 3**, lower panel) assigned to the subject's selection.

12.0 Risk Management

12.1 Adverse Events

Information on all adverse events (non-serious, serious and unanticipated events, device deficiencies) will be collected for the entire duration of the Study

12.2 Recording Adverse Events, Device Deficiencies and Protocol Deviations

All adverse and serious adverse events will be recorded on the adverse event case report form. Information to be collected and recorded will include event description, onset and resolution dates, severity, interventions performed (including the administration of pharmaceuticals) and the Investigator's assessment of relatedness to the investigational procedure and treatment.

The Sponsor or Sponsor's designee may also identify reportable events during audits or monitoring visits. Each event will be followed until resolved or stabilized at a level acceptable to the Investigator and the Sponsor's medical monitor, if utilized.

All deficiencies, anticipated or not, will be recorded on the device deficiency event case report form. Information to be collected and recorded will include the date of device deficiency, a detailed description of the deficiency and actions taken due to deficiency, model and serial number.

12.3 Reporting Requirements

Any serious adverse events (SAEs) or UADEs that may occur must be reported by the Principal Investigator to their Institutional Review Boards, and per 21 CFR 812.150(b)(1). The Investigator will obtain, in writing, the requirements for reporting such events and file requisite documentation along with the Study documents. Serious Adverse Events should be reported to the local Institutional Review Board (IRB) per local policy. In addition, all

SAEs and UADEs must be reported to the Sponsor within 24 hours of the Investigator's (or other Study staff) knowledge of the event. The reporting individual shall telephone the Sponsor to report all known details at that time; if no live telephone conversation is possible, the reporting individual shall leave a telephone message followed by an electronic mail (email) transmission of all known details to the Sponsor.

Within three (3) days of the Investigator's knowledge of the SAE or adverse device effect, the appropriate adverse event case report form should be entered in the EDC system and accompanying source documentation shall be sent to the Sponsor (or the authorized representative). The Sponsor will be responsible for reporting as applicable per the statutory reporting requirements.

13.0 Clinical Site and Informed Consent

13.1 Participating Sites

One Canadian site will participate in this preliminary study.

13.2 Institutional Review Boards

This protocol and related documents will be approved by local or regional IRBs as per local policies before the study is initiated at the site. A copy of the study-specific IRB approval letter and the IRB-approved Informed Consent Form must be sent to the Sponsor prior to initiating the study at the site. Subsequently, the Investigator is responsible for keeping the IRB advised of the progress of the study as deemed appropriate but, in any case, at least once a year during the course of the study. Also, the Investigator must keep the IRB and Sponsor informed of any significant adverse events. After the completion or termination of the study, the Investigator will submit a report of its experience in the study to the IRB and to the Sponsor.

13.3 Informed Consent Process

Informed consent is required of all subjects participating in this study. An informed consent form should be signed before performing any test or intervention that goes beyond standard medical care. The consenting process must be compliant with the U.S. Code of Federal Regulations 21 CFR 50, 21 CFR 812 and all other applicable national, local and institutional requirements.

The consenting process, oral and written, must take place in the patient's native language. Patients must be informed of their right to withdraw from the study at any time, and for any reason, without sanction, penalty or loss of benefits to which the subject is otherwise entitled, and that withdrawal does not jeopardize their future medical care. The patient will then be given sufficient opportunity to discuss the study with family members, to carefully read the written consent form, and have any questions answered. To participate, the patient must sign and date the written consent form. The investigator and/or designee must also sign and date the form. A copy should be provided to the patient and the original should be placed in the patient's study binder.

In the event of a consent form or consent process revision, subjects who were already enrolled at the time of the revision may be required to re-consent, as determined by the IRB. New subjects entering the study after a consent revision should be consented with the currently in-force consent form and consenting process.

13.4 Informed Consent for Minors

This study excludes subjects who are below the age of minority, therefore there is no consent process for minors.

13.5 Special Populations

The study will not focus on any particular subset of patients based on ethnicity or race. Further, no subject will be excluded from the study on the basis of racial or ethnic origin. The racial and ethnic composition of the study is expected represent the demographics of the typical population seeking evaluation of symptoms related to cardiac disease.

In situations where informed consent cannot be provided to the coordinator (perceived lack of understanding of the consent form or protocol, language barrier, emergency circumstances or otherwise), the subject will not be enrolled.

13.6 Confidentiality

The clinical investigation shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. All documents in the study files must identify the subject by subject ID number and initials only. All subject information will be handled in strict compliance with the professional standards of confidentiality, institutional and national requirements. Compliance with the guidelines of ICH E6 regarding subject confidentiality are also recommended. All subject study records and files must be kept in a secure location with limited access. Access will be granted only to those individuals who are recorded as authorized study staff members, the Sponsor and their authorized representatives, regulatory agencies and when required by law.

Data collected during the clinical trial will be stored within a password-protected electronic database, which is managed by the Clinical Research Unit at the University of Calgary and protected behind institutional firewalls. Master study files and any paper-based source documents with identifying information (i.e. consent forms) will be stored securely within the locked and secure Clinical Research Unit laboratory. All staff in contact with data must complete standardized ethics training, and privacy and security training at their respective institutions. Paper-based data and all study files will be stored confidentially and securely in Iron Mountain once the study is complete.

14.0 Data Management

14.1 Electronic Case Report Forms

Data will be entered on study-specific electronic CRFs as part of a 21 CFR 11 compliant EDC system hosted and managed by the Clinical Research Unit, who follows protocol regarding weekly data back-ups, validation and security provisions. Therefore, any and all data collected in this study and entered into the EDC is protected by those same protocols. CRF data will be entered only by qualified site personnel. At the sponsor's discretion, when a study record is complete (has undergone both monitoring and source verification), the record may be locked to prevent further modifications. In general, the study coordinator oversees the process of data entry and cleaning. The site Principal Investigator will log on to the EDC system periodically to verify that each subject's EDC-recorded data is accurate.

14.2 Source Documents

Data entered into electronic CRFs will be compared with available source documents by the clinical monitor to ensure high data quality. Source documents include the reports of

tests/procedures, lab results, history and physical reports, progress notes and any other original medical document(s).

14.3 Investigator Records

21 CFR 812 (IDE regulations) require that the site Principal Investigator maintains accurate and complete records related to his/her participation in the study, including:

- All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports
- Records of receipt, use or disposition of an investigational device
- Records of each subject's case history and exposure to the device
- Signed and dated consent forms
- Relevant medical records and progress notes
- Records describing adverse device effects
- The protocol itself
- Any other records required by FDA or the local IRB or hospital/clinic

All records will be retained by the Investigator for a minimum period of two (2) years after the study is completed (21 CFR 812.140(d)). To avoid any possible errors, the Investigator must contact the Sponsor prior to the destruction of any study records. The Investigator will also notify the Sponsor in the event of unintended loss or destruction of any study records.

14.4 Investigator Reports

The reporting requirements and the timeframes for such reports are provided in **Table 4**.

Table 4. Reporting and Submission Timelines for Study Form/Report

Event	Report to	Timing
Unanticipated adverse device effects	IRB & Sponsor	As soon as possible, but no later than 10 working days after the investigator first learns of the effect
Withdrawal of IRB approval	Sponsor	Within 5 working days of withdrawal
Study progress reports	IRB & Sponsor	At least yearly
Deviations from investigational plan	IRB & Sponsor	If done to protect subject safety, within 5 working days after the emergency occurred
Use of device without informed	IRB & Sponsor	Within 5 working days

consent		
Final report	IRB & Sponsor	Within 3 months after termination or completion of study

15.0 Literature Cited

a. Steinberg Varma, N, Cygankiewicz I, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring / telemetry. Heart Rhythm 2017;14:e55–e96.

b. Davis BR, Friedman LM, Lichstein E. The prognostic value of the duration of the ambulatory electrocardiogram after myocardial infarction. Med Decis Making 1988;8:9–18.

16.0 Instructions for Use and Labelling

See the following section (pages 31 to 35).

HeartWatch 10 Information of Use Manual

Investigational Device/Instrument de recherche; To Be Used by Qualified Investigators Only/Réservé uniquement à l'usage de chercheurs compétents

DESCRIPTION

The HeartWatch 10 is a non-invasive ECG monitor that is worn on a patient's left bicep to extract electrocardiogram data. The device uses dry sensors to collect this information and relay it to a smart device via Bluetooth.

_____

INDICATIONS

HeartWatch is indicated for extended diagnostic evaluation of patients with symptomatic and transient symptoms such as chest pain, syncope, and palpitations, as well as patients at risk for arrhythmias, but without significant symptoms.

While the use of the device itself can be managed by both healthcare professionals and patients, interpretation of the collected data for diagnosis is restricted to healthcare professionals, as the data must be loaded and analyzed separately.

SETTING UP THE HEARTWATCH

1) Unpack the HeartWatch and ensure that the following 3 components (see Figure 1) are available: a) Main Enclosure, b) Sensor Strap and c) Disposable Strap.

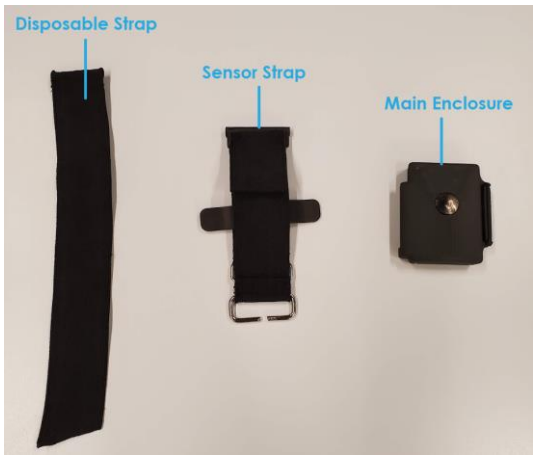


Figure 1: HeartWatch Components

2) Charge the device using a micro USB cable (see Figure 2).

Note: The phone application indicates when the device is charging with a lightning bolt in the battery symbol once this is done, the device is effectively turned on until the battery runs out (indicated on the HelpWear App).

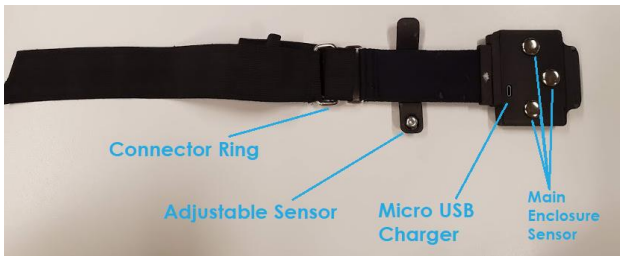


Figure 2: HeartWatch (bottom view).

3) The Sensor Strap (see Figure 1) comes in multiple sizes. Select a Sensor Strap based

on the circumference of the subject's upper left arm.

4) Connect the Sensor Strap to the left side of the Main Enclosure using the connector on the Strap Mate (see Figure 3).

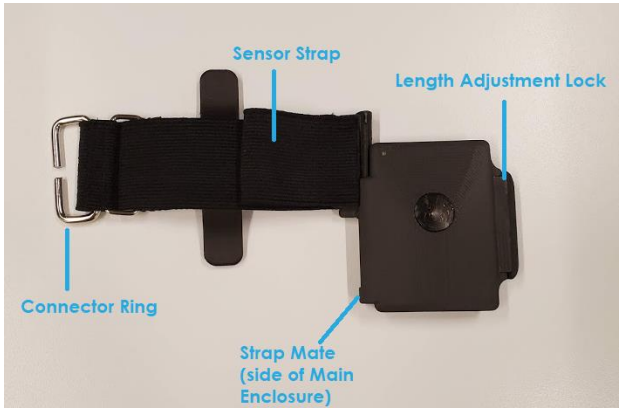


Figure 3: Connecting the Sensor Strap to the Main Enclosure

5) Attach the Disposable Strap to the Strap Connector Ring (see Figure 3) by inserting the Disposable Strap into the gap of the connector ring.

6) Put the remaining side of the Disposable Strap through the Length Adjuster Lock (see Figure 3).

7) Place the device on the subject's left bicep. Tighten the disposable strap and close the Forward Hinge (see figure _).

Figure 4: Securing Disposable Strap onto Length Adjustment Lock.

8) Check for signs of loss in circulation in the subject's left arm. If loss in circulation is detected, repeat step 7. If the issue persists, consider starting again from step 3 with a larger strap size.

Note: Loss in circulation can present through the subject feeling numbness, tingling, cold hands, change in skin color, pain, fatigue, or swelling.

9) Push down the Back Hinge (see Figure 4) of the Length Adjuster Lock. This secures the strap in place.

10) Pull the Finger Loop (see Figure 5) to open the Quick Release in the Sensor Strap and loosen the strap. This allows for the sensors under the Main Enclosure to be shifted into position. The Main Enclosure sensors typically go on the anterior region of the bicep.

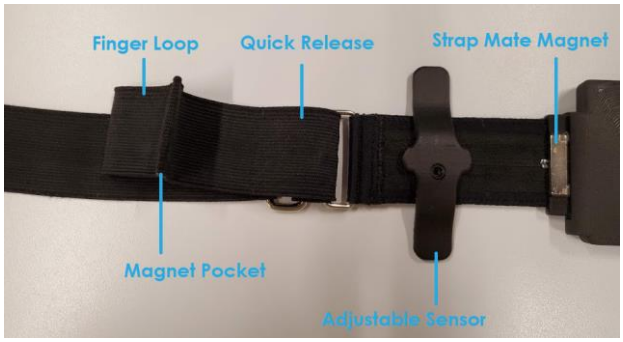


Figure 5: Sensor Strap with Quick Release open

11) Close the Quick Release by connecting the Magnet Pocket (see Figure 5) to the corresponding magnet on top of the Strap Mate.

12) Pull the Finger Loop to open the Quick Release (without loosening the Sensor Strap).

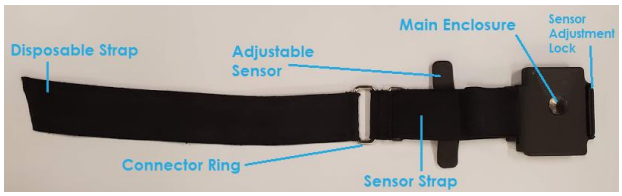


Figure 6: HeartWatch (top view)

13) Use one hand to secure the strap in place and another to move the Adjustable Sensor along the strap. The Adjustable Sensor typically goes along the Axillary Vein (between the inner bicep and tricep).

14) Once setup has been completed, take the scissor provided and cut the excess fabric on the Disposable Strap with about 0.5 – 1 inch of slack.

COLLECTING DATA

15) Open the HelpWear App and select which HeartWatch unit to pair the smart device to.

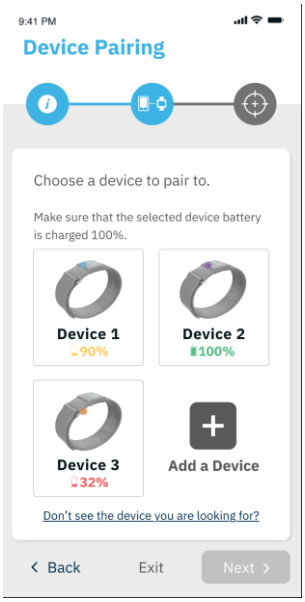


Figure 7: App Screen for Connecting to HeartWatch Devices

Note: Smart Devices with the HelpWear App Installed (and that already paired to the HeartWatch 10) are provided to users for HeartWatch 10.

Note: To connect the HeartWatch 10 to other smart devices, enable the Bluetooth settings of the device and select the HeartWatch 10 to establish the Bluetooth connections. Specific instructions on how to enable Bluetooth settings can be found in the instruction manual of the designated smart device.

16) HeartWatch 10 will assess the placement of the device on the subject. If placement is not correct, the app will guide provide direction on moving the device either left or right or up or down. Once successful, press 'start monitoring' to go into patient mode.

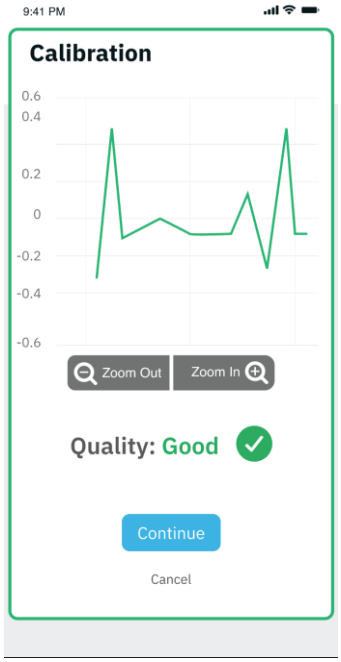


Figure 8: App Calibration Screen for assessing signal quality.

17) Going into patient mode, subjects can press the tag button on the HeartWatch 10 to report an event when experience symptoms or irregular activity.

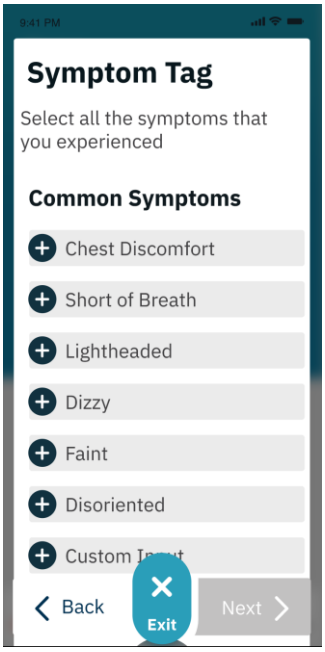


Figure 9: Reporting Screen for Patients to report symptoms after pressing the Tag Button

18) After monitoring is complete, users can extract data from the paired smart device via its document file manager.

REMOVING THE DEVICE

19) Press down on the Forward Hinge of the Length Adjuster Lock and then lift the Back Hinge.

20) Open the Forward Hinge and pull the Disposable Strap out of the Strap Mate.

21) Do the reverse of Step 5 to detach the Disposable Strap.

22) Remove Sensor Strap from its Strap Mate.

DATA QUALITY CHECK

If the data quality presented on the HelpWear app does not meet the requirements of either a member of the designated healthcare professional, repeat steps 3-11.

The ideal signal should show a strong T wave. Most of the time P wave and the QRS should be quite large inflict and not a large deflection.

In some cases, depending on the patient's arm size and shape, adjusting the positions of the Adjustable Sensor in either direction along the strap can help better data quality.

RECOMMENDATIONS

The HeartWatch works non-invasively via the patient's bicep and may require tightening. After wearing the HeartWatch, patients may notice some imprints on their skin from the sensors of the device. If the patient(s) feels any irritation or dryness, it's recommended that they apply a moisturizing lotion to the affected area.

TECHNICAL ASSISTANCE

For technical assistance, please contact HelpWear Inc. Support at the following numbers:

During the hours of 9:00 AM - 5:00 PM EST **647.884.3298**

24 Hours - **647.863.2420**

WARNINGS/CAUTIONS

WARNING - improper placement or alignment of the HeartWatch 10 can lead to inaccurate monitoring

WARNING - do not place HeartWatch 10 on injured skin as this may cause further discomfort.

WARNING - do not use HeartWatch 10 on the right bicep.

WARNING - do not use more than one unit of HeartWatch 10 on the left arm.

WARNING - do not use a damaged HeartWatch 10. This may result in inaccurate measurements or may damage the HeartWatch 10 further.