COMPARISON OF A DERIVED ECG FROM A CARDIOWARE HARNESS TO A STANDARD 12-LEAD ECG DURING REST AND EXERCISE

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ABSTRACT

**Purpose:** To determine whether a 12-lead electrocardiogram (ECG) using five dry electrodes in the modified EASI electrode position in the CardioWare harness can be derived from a standard 12-lead ECG during rest, ambulatory walking, and strenuous walking on a treadmill. **Methods:** Thirty healthy men (n=15) and women (n=15), ages 20-54 years, from Cleveland State University and the surrounding community participated in this study. Each subject served as their own control as they were connected to both types of ECG simultaneously (Modified EASI CardioWare and Standard Mason-Likar). Data was collected from both ECG placements for five minutes of rest (Trial A) and during Trial B for two intensities of exercise. The first half of Trial B included rest and ambulatory walking (Stage 1: standing rest and Stage 2: walking 1.7mph, 0% incline). The second half of Trial B consisted of strenuous walking and recovery (Stage 3: walking 1.7mph, 10% incline, Stage 4: walking 2.5mph, 12% incline, and Stage 5: standing recovery). Paired samples t-tests were used to compare the two electrode placements. **Results:** There was no significant difference between the root mean square error (RMSE) of the two different types of electrode placements during either the first half or the second half of Trial B (p ≥ .05). All correlations were robust (r range= 0.658 - 0.942) and significant (p =0.0001). The subjective goodness of fit measure based on the overlay of both types of ECGs was similar. **Conclusions.** It can be
concluded that the modified EASI derived 12-lead ECG is an acceptable alternative to the standard 12-lead ML system at rest, ambulatory, and strenuous walking.
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CHAPTER I
INTRODUCTION

1.1 Background Information

The number one leading cause of death in both men and women is heart disease, with more than 600,000 deaths per year. Many Americans suffer from coronary heart disease in which plaque deposits in the coronary arteries block blood flow to the heart which results in myocardial infarction. Heart disease may also lead to arrhythmias such as atrial fibrillation also known as Afib. Afib is a quivering or irregular heartbeat that can lead to stroke, heart failure, and other heart complications. Sometimes Afib does not have any signs or symptoms, which is why it can be so deadly. Afib is one type of arrhythmia that can be detected with an electrocardiogram (ECG).

ECGs are a fundamental tool of clinical practice and are one of the most common diagnostic cardiovascular tests conducted. ECGs record the electrical activity of the heart providing a record that shows a series of wave forms that relate to the electrical impulses that occur during each heartbeat. The wave forms in the ECG are labeled P, QRS and T and occur in alphabetical order (Appendix A). The contraction of the atria is
represented by the P wave, contraction of the ventricles is represented by the QRS complex, and ventricular repolarization is represented by the T wave.\textsuperscript{3}

A standard 12-lead ECG using 10 gel electrodes is commonly used in most clinical and ambulatory settings to record heart rate and rhythm during every day normal activities. This lead configuration of 10 gel electrodes is impractical for ambulatory patients using telemetry monitoring such as 24 hour Holter and other cardiac event monitoring. This also poses potential problems for the patient including aggressive skin preparation, possible dehydration of the electrode therefore causing it to fall off, and skin irritation.\textsuperscript{26} Inaccurate signals or interference in the ECG may also cause the clinician to misdiagnose a heart condition.

A novel dry electrode (Appendix B) has been developed by Orbital Research Incorporated (ORI, Cleveland, OH) and has been investigated to see if its signal quality is similar to that of a standard gel electrode for ECG use. The micro-anchors that penetrate the top layer of the skin on the dry electrode are projected to decrease interference, increase patient comfort and compliance, while still maintaining the signal quality of the traditional gel electrode.\textsuperscript{35} The ORI dry electrode has been tested in previous studies\textsuperscript{32,35} and found to produce a similar signal to that of the standard gel electrode.

With the dry electrode producing a similar signal as the standard wet electrode, ORI has developed a new CardioWare system where the dry electrode is embedded into a wearable harness that is capable of displaying a 12-lead derived ECG from the modified EASI electrode placement. Three bipolar ECG leads are recorded to derive a 12-lead ECG which is comparable to the standard Mason-Likar (ML) 12-lead ECG which uses 10 electrodes.\textsuperscript{7} The placement of the electrodes in the CardioWare system is modified
meaning the “E” and “S” electrodes are moved off the sternum. These electrodes are moved left of the sternum to accommodate patients who have undergone a midline sternotomy. Sternotomies are the most common form of surgery used for coronary artery bypass graft (CABG) and heart valve replacement surgery. During these surgeries, the cardiologist opens up the chest along the sternum to access the heart. These types of surgeries take months for the incision site to heal, and if the patients need to be monitored during this time, electrodes cannot be placed on top of the incision site. Therefore, the electrode placement needs to be modified.

The term derived electrocardiogram refers to when the standard limb leads are moved away from the extremities and placed on the torso and the precordial leads are reduced to a single lead that is calculated for the unipolar precordial V lead on the horizontal plane. Dower and colleagues developed the EASI lead system in the 1980s to address clinical issues of using 10 gel electrodes to obtain a continuous 12-lead ECG. The EASI system allows the clinician to derive an ECG from a reduced set of electrodes, using four sensing electrodes and one reference electrode (5-lead), whereas the standard 12-lead uses 10 electrodes in its configuration (Appendix C). Transformation coefficients are used in the EASI lead configuration to derive the standard 12-lead ECG.

The CardioWare harness is able to detect cardiac arrhythmias such as Afib and other arrhythmias, and allows for short and long term continuous monitoring for heart rate, rhythm, and a derived 12-lead ECG. Cardiac patients may benefit from long term continuous monitoring by the CardioWare harness. ORI has incorporated the coefficients published by Feild et al. to demonstrate that the standard 12-lead configuration can be accurately derived from the CardioWare harness during supine and standing recordings.
However, often patients are not supine or standing when they wear the CardioWare harness, but may be moving performing daily activities. Thus, the CardioWare harness needs to be validated under these conditions.

1.2 Statement of the Problem

A standard 12-lead ECG using gel electrodes poses numerous problems for clinicians and patients who use ambulatory telemetry monitors. Clinicians may have difficulty reading the signal, experience a cost increase to replace electrodes, and also experience a decrease in patient compliance. The ECG signal may be hard to read if the patient is moving in bed. This may cause interference in the signal, where it can become unusable for the clinician. Gel electrodes can dry out with extended wear and the adhesiveness can become un-sticky therefore causing the gel electrode to fall off. This will increase cost because clinicians have to replace the electrodes that dry up or fall off. Patients may experience skin irritation from the gel, aggressive/painful skin preparation, and additional time to place the electrodes.\textsuperscript{22, 26} When using dry electrodes, there is no skin preparation that needs to be performed, therefore skin irritation is less likely. Inaccuracy reading an ECG due to increased artifact and false arrhythmia alarms from placement of the gel electrodes may cause the clinician to overlook a dangerous abnormality which could cause severe consequences to the patient. A potential solution may be using fewer electrodes in strategically placed locations to produce an accurate restoration of the full 12-lead ECG. For this reason, the problem that was investigated in this study was whether a standard 12-lead ECG using 10 gel electrodes can be derived from five dry electrodes embedded in the CardioWare harness at rest and during exercise. The CardioWare harness needs to be investigated because there is a need to improve patient
compliance, and to reduce the associated costs of advanced monitoring and diagnostic capability in telemetry settings.

1.3 Purpose of the Study

The primary purpose of this study was to investigate whether a 12-lead ECG using five dry electrodes in the CardioWare harness (modified EASI) can be derived while subjects are at rest and when exercising on a treadmill by analyzing the root mean square error (RMSE) and using a subjective evaluation of the goodness of fit overlay of both types of ECGs.

1.4 Hypothesis

There will be no significant difference between the derived modified EASI 12-lead ECG and the standard Mason-Likar 12-lead ECG when comparing the RMSE of the first half of exercise (ambulatory walking) and the second half of exercise (strenuous walking) on the treadmill. The subjective evaluation of the goodness of fit will show a similar overlay of both types of ECGs.

1.5 Definition of Terms

Several terms used often are defined below:

*Arrhythmia:* An abnormal rhythm of the heart. Examples include bradycardia (HR < 60bpm), tachycardia (HR > 100bpm), and atrial fibrillation (quivering or irregular heartbeat).^2

*CardioWare Harness:* A comfortable wearable harness populated with ORI patented, FDA approved, ECG sensors.
**EASI:** A method of continuous ECG monitoring that uses a reduced electrode set of 5 electrodes. The EASI 12 lead ECG is derived from the reduced lead set using the methods described by Dower et al.\(^7\) and Field et al.\(^{12}\) The term EASI comes from the electrode placement of the four electrodes E-A-S-I. The “E” electrode is placed at the lower extreme of the sternum, the “A” electrode is placed on the left mid-axillary line, the “S” electrode is located on the sternum manubrium, and the “I” electrode is located on the right mid-axillary line.

**Electrocardiogram (ECG):** A diagnostic test to measure the electrical activity of the heart.\(^1\)

**Electrode:** A skin sensor used in ECGs that detects the electrical activity of the heart; senses ion distribution on the tissue surface area, and then converts the ion current to an electron current that can then be displayed on an electrocardiogram to record the signal.\(^{21}\)

**Goodness of Fit:** A subjective evaluation of both types of ECG waveforms (derived modified EASI and the true 12-lead) overlaid on top of each other. How well the model (true 12-lead ECG) fits the data (derived ECG).\(^{35}\)

**Modified EASI electrode placement:** The electrodes of the standard EASI lead placement are moved off the sternum.\(^{12}\) The CardioWare harness uses the modified EASI electrode placement by moving the “S” and “E” electrode off the sternum to accommodate patients who have had open heart surgeries.

**Root Mean Square Error:** A measure of the average deviation (in millivolts) from the derived signal to the true signal. It quantifies the size of the average difference between the measured signal and the true 12-lead signal to which it is compared.
**ST-segment:** Reflects the period of time from completion of ventricular depolarization to the start of ventricular repolarization. It is measured at the J point, which is the point in the ECG where the end of the QRS complex meets the beginning of the ST segment.²⁹
CHAPTER II
LITERATURE REVIEW

2.1 Standard Mason-Likar ECG

In 1966, Mason and Likar\textsuperscript{23} introduced a new lead system which modified the placement of limb leads traditionally used by Frank.\textsuperscript{15} Mason and Likar modified the limb leads on the arms and legs by moving them in the infraclavicular fossae and midway between the costal margin and the iliac crest respectively. This system is known as the Mason-Likar (ML) system and is widely used in hospital and ambulatory settings (Appendix C).\textsuperscript{23}

2.2 Derived EASI ECG

The EASI derived method of ECGs was introduced by Dower et al. in 1988.\textsuperscript{7} The name EASI comes from the placement of the electrodes. Each electrode E, A, S, and I are placed in defined anatomical landmarks (Appendix C). Five electrodes are used with this method to record three bipolar ECG leads to derive a 12-lead ECG which is similar to the configuration of the standard 12-lead ECG which uses 10 electrodes.\textsuperscript{7} ECG data is transformed using the vectorcardiography dipole hypothesis recorded by the three bipolar
ECG leads into the standard 12-lead ECG. Dower et al. made alterations to the EASI lead vectors and configured them into a converter box to obtain the derived ECG. As mentioned earlier, under the theory of the dipole hypothesis, the EASI lead method can be used to yield various leads depending on if the goodness-of-fit is acceptable between the standard and derived leads.

The placement of the EASI electrodes is unlike the standard placement using the Mason-Likar system (Appendix C). The S electrode is located on the sternal manubrium while A, E, and I electrodes are located in the horizontal plane at the bottom of the sternum at the fifth intercostal space. The A and I electrodes lie in the left and right midaxillary lines and E lies in the anterior midline. The fifth electrode serves as a ground. Advantages to the EASI lead system include that the electrodes are positioned on the upper body, therefore causing less ECG interference when patients move their arms, and the left precordium is free of electrodes so clinicians can have access for other types of tests such as echocardiograms and chest x-rays.

The US Food and Drug Administration (FDA) has approved the EASI lead system for monitoring all types of heart rhythms including normal and abnormal, as well as depression and elevation of the ST-segment. With the creation of the derived ECG, researchers and clinicians have compared the signal quality of the two ECGs to determine which is superior for diagnostic purposes.

2.3 EASI Derived ECGs vs. Standard ECGs: Waveforms

Welinder and colleagues investigated whether or not the EASI lead system is less susceptible to artifact than the standard 12-lead Mason-Likar (ML) ECG by comparing ECG baseline interference, wander and myoelectric noise amplitude during real-time
recorded derived EASI and Mason-Likar 12-lead ECGs. Twenty healthy volunteers, 15 females aged 30-58 years, and 5 males aged 40-64 years, were given a range of standardized physical activities to perform within an hour including holding a 3 kilogram load with both arms up at 45 degrees when supine, walking on a treadmill, slowly turning from supine to the left side and supine to the right side, and cycling on an ergometer (load and speed not specified). A simultaneous recording of the EASI and Mason-Likar ECG was obtained for each activity. The researchers used the algebraic transfer coefficients of Feild et al.\textsuperscript{12} to derive the 12-lead ECG from the EASI position.\textsuperscript{38}

Data was analyzed by computing the noise measurements at rest and during physical activity for both Mason-Likar and EASI electrode placements. The results were termed “equal” if the myoelectric noise was within 25\(\mu\)V or if the baseline wander was within 300 \(\mu\)V. A “winner” was chosen if the difference was greater. The Chi Square statistic was used to compare the proportion of “winners” in both ML and EASI conditions. The results showed that the EASI derived configuration was superior when walking on the treadmill, cycling, and turning from supine to the left because there was less myoelectric noise. However, the ML placement proved superior when turning from supine to the right. The authors contribute this to the fact that only the EASI placement had an electrode positioned in the right midaxillary line. They ultimately concluded that the EASI 12-lead monitoring system was a suitable alternative to the ML system in ambulatory settings.\textsuperscript{38}

Sejersten and colleagues\textsuperscript{33} considered whether or not the waveforms and clinical triage produced by the standard 12-lead configuration acquired by paramedics and EASI-derived ECGs were similar. Twenty patients, 12 males and 8 females, mean age of 70 ±
21 years, who reported angina had a pre-hospital 12-lead ECG in an ambulance. The standard precordial leads and EASI electrodes were applied at the same time to record both types of ECG data. The 12-lead EASI ECGs were derived using Feild et al.’s fixed coefficients. Computer QRS-T waveform factors were calculated and compared to the standard Mason-Likar ECG. Two emergency physicians compared the ECGs and determined that they were more prone to alter their patient care based on the derived EASI ECGs. However, this difference was not statistically significant. The reasons to recommend change of treatment were based on any signs of an inferior myocardial infarction (MI) and ischemia or a lack of ischemia. The researchers concluded that either method of ECG can be used for monitoring; however for diagnostic purposes, neither method was deemed equivalent to the standard 12-lead ECG.

Pahlm and colleagues also looked at waveforms of the conventional 12-lead ECG and compared them to derived EASI leads using Horáček et al.’s adult coefficients. However, the researchers also studied children of various ages from less than one year to 18 years of age. Along with comparing the standard Mason-Likar 12-lead ECG and EASI electrode position, the researchers wanted to determine age-specific coefficients for deriving EASI ECGs and study the goodness-of-fit between the standard and derived ECGs. ECGs were recorded simultaneously and root mean square differences were calculated beginning at the QRS-complex and ending at the T-wave. Goodness-to-fit was then the result of the root mean square difference. Optimal coefficients based on adults earlier described by Horáček et al. were used to evaluate the results of the age-specific coefficients determined in this study. Overall, using the age-specific coefficients produced a relatively better fit based on the goodness-of-fit expressed as a root mean
square difference compared to the adult coefficients. Further, the EASI electrode placement derived similar levels of goodness-of-fit as a standard 12-lead configuration.²⁷

As mentioned previously, Pahlm and colleagues²⁷ used Horáčeke et al.’s adult coefficients that were derived from converting the three bipolar EASI leads (AI, ES, and AS) data into an estimate of the standard 12-lead ECG. In Horáčeke et al.’s study, the authors wanted to revisit some of the diagnostic information that was potentially lost when deriving ECGs. The sample included 290 normal subjects, 163 males and 127 females, age 36 ± 12 years, and 497 subjects who previously had a myocardial infarction, 416 males and 81 females, age 60 ± 11 years. All subjects had a 15 second recording of both types of ECG. ECG data was uploaded into a computer and sorted into categories based on QRS morphology. From that data set, the researchers extracted ECG waveforms for the ECG leads of interest. The quality of the derivations was assessed by calculating the mean correlation coefficients. The researchers concluded that EASI-derived 12-lead ECG signals produce the same diagnostic information in terms of accurate waveforms as a standard 12-lead ECG. Thus, the derived ECG signal was deemed suitable for clinical use.¹⁶

Twelve-lead ECGs derived with an improved lead transformation matrix (coefficient) described by Feild et al.¹² from the EASI electrode placement were compared to a standard 12-lead ECG in Rautaharju et al.’s study.²⁸ Novacode computer classification algorithms were used on the three test files that included data from subjects (age and gender not specified) who had a percutaneous transluminal coronary angioplasty (PTCA) or had a previous MI based on elevated cardiac enzyme serum levels. All subjects had both the standard 12-lead ML and EASI-lead ECGs recorded. To derive the 12 leads
from the EASI electrode placement, the researchers used the improved coefficients for
derived lead transformation by Feild et al.¹² Trained electrocardiographers and the Philips
diagnostic ECG analysis program categorized the test files and differences were
determined by a student’s t-test. In regard to sensitivity and specificity of both types of
ECGs, no significant differences were found between the two types of lead sets. This
study supports previous studies¹⁶, ²⁷, ³⁸ that the derived EASI 12-lead ECG is an
acceptable substitute to the standard 12-lead ECG in clinical or ambulatory settings.²⁸

2.4 EASI Derived ECGs vs. Standard ECGs: ST-Segment Monitoring

ST-segment monitoring is a key non-invasive technique for diagnosing acute MI and
also for determining effectiveness of treatment.³⁴ It is valuable for detecting lumen
closure in coronary arteries caused by clots and other various blockages. The number of
patients who have nonsurgical revascularization continues to increase, so 12-lead ST-
segment continuous monitoring is needed in cardiac units. However, this is unrealistic for
patients in cardiac units because the majority of units do not have bedside monitors that
offer 12-leads of ST analysis, so double cardiac monitoring is necessary. Double
monitoring occurs when one monitor has the standard 5 electrode configuration to
monitor arrhythmias, while the other monitor has the standard 10 electrodes for 12-lead
ST-segment monitoring.⁸ Drew et al.⁸ indicated that the instrumentation for double
bedside monitoring is complicated for the following reasons: 1. mobility of the patient is
severely decreased; 2. muscle artifact from movement creates problems causing false
arrhythmia alarms; 3. multiple electrodes are hard to maintain because if one falls off, all
electrode signals are affected; and 4. it interferes with other tests such as chest x-rays,
listening to heart sounds, and other procedures that require access to the chest.⁸ Research
has been conducted comparing the derived EASI 12-lead ECG vs. the gold standard configuration of the 12-lead ECG for purposes of comparing ST-segment monitoring and cardiac rhythms.

Drew and collaborators\(^\text{10}\) evaluated both ST-segment and cardiac rhythm when comparing the standard ML 12-lead ECG and the derived EASI 12-lead ECG in 426 patients, average age of 67 years, 58% males, 42% females who presented with unstable angina or acute MI in the emergency department. EASI and standard ML ECGs were recorded simultaneously to allow the patients to serve as their own control using twin Mortara ST-segment monitors. The Mortara analysis computer program determined that there was a 100% concurrence between the two methods for the diagnosis of cardiac rhythm. Experts also evaluated the ECGs and determined that two ECGs were misdiagnosed by the derived EASI and standard ML 12-lead methods. ST-segment monitoring proved to have a 100% agreement between both ECG methods for presence and location of acute MI. Ischemia was correctly identified 93% of the time of the 238 events in all ST occurrences using the EASI 12-lead ECG. However, leads II and V\(_1\) in the ML ECG correctly identified ST changes in only 101 (42%) of the total 238 events. Drew and colleagues\(^\text{10}\) concluded that the EASI and standard ML 12-lead ECGs were in agreement for the greater part of cardiac diagnoses including cardiac rhythm and acute myocardial ischemia.

ST-segment monitoring and cardiac rhythm were also compared between derived EASI and standard ECGs in Chantad et al.’s study.\(^\text{6}\) The purpose was to establish the precision of the derived EASI ECG and compare it to the standard ML 12-lead ECG. Two hundred and eighty two patients (155 males, 127 females), 62 ± 14 years,
participated. Simultaneous ECGs were recorded with both electrode placements and trained cardiologists evaluated all recordings without knowing which ECG was from which electrode placement. The amplitude of ST-segment variation was quantitatively analyzed using Pearson correlation using the nearest 0.1 mV between both methods of ECG. Accuracy and reliability of the two types of ECG methods was determined by using ST-segment deviation, sensitivity, specificity, and $\kappa$ statistics. The results showed that ST-segment deviation significantly correlated between the derived (EASI) lead system and the standard ML 12-lead ECG. In terms of cardiac rhythm, all ECGs were in perfect agreement by the $\kappa$ test. The authors concluded that the EASI lead configuration provided precise and dependable information on ST-segment deviation and cardiac rhythm and has numerous advantages over the ML lead system including continuous bedside monitoring, location of easily identified anatomical sites, and a decrease in time and price due to only using 5 electrodes.\textsuperscript{6}

Feldman et al.\textsuperscript{13} also evaluated cardiac rhythm and conduction abnormalities in 200 patients with angina who were being transported to two different hospitals by either the Durham County Emergency Medical Service (EMS) or the Palatine Fire Department EMS. For the Durham County EMS, there were 100 subjects, 63 ± 17 years, 49 females, 51 males. For the Palatine EMS, there were 100 subjects, 65 ± 19 years, 52 females, 48 males. They connected both EASI and standard 12-leads simultaneously, similar to previous studies\textsuperscript{6, 10} to monitor ST elevation. Again, sensitivity and specificity of the derived EASI was compared to the standard ML 12-lead ECG. The Duke University ECG Core Lab read all ECGs. Conduction abnormalities and rhythm comparisons were found to be similar for the ML and EASI ECGs. Overall, both methods agreed 96\%
during the time recorded, and the EASI lead system was found to be a suitable option for the ML 12-lead ECG for diagnosing ST elevation.\textsuperscript{9,28}

The EASI derived configuration was compared to the standard 12-lead configuration for recognition of acute ischemia. Sejersten et al.\textsuperscript{34} and Wehr et al.\textsuperscript{38} have both assessed whether a 12-lead derived ECG from an EASI electrode placement can produce similar diagnostic performance abilities compared to the standard ML 12-lead electrode placement. Sejersten and colleagues\textsuperscript{34} used 88 subjects, 61 males, 27 females, age 55 ± 16 years, who underwent a PTCA procedure to compare the two types of ECGs. Both ECGs were recorded simultaneously during the procedure and data was processed off line. Sensitivity and specificity of ischemia classification for detecting myocardial injury was determined to yield similar results. Therefore, Sejersten and coworkers\textsuperscript{34} concluded that there are clinical advantages to using a derived EASI 12-lead ECG with no significant loss of ECG quality.

Wehr et al.\textsuperscript{38} also investigated sensitivity and specificity for detecting myocardial injury. Standard and derived ECGs were recorded on 203 patients (age and gender not specified) with angina lasting longer than 30 minutes while they were being admitted to the hospital and 4 to 8 hours afterward. Subjects were excluded if they presented with bundle-branch blockages, cardiogenic shock, valve disorders, or pacemakers. Two cardiologists reviewed the ECGs and ST-elevation was diagnosed if either type of ECG showed ST-elevation more than 0.2 mV in at least 2 adjacent precordial leads. The EASI ECG final diagnosis of MI was correctly recognized with a specificity of 94% and sensitivity of 93% compared to the standard ML ECG, the gold standard. Of 118 patients who had cardiac enzymes analyzed, the standard ECG and EASI ECG correctly
diagnosed similarly, 73 and 72 respectively, for ST-segment elevation. Sensitivity and specificity were the same for both ECG types for detecting myocardial injury.\textsuperscript{38}

2.5 Misplacement of electrodes

There are numerous errors that may occur in routine 12-lead ECG acquisition. These errors have been documented by Schijbenaars et al.\textsuperscript{31} based on intra-individual variability in ECGs. The most common errors are misplacement of the chest electrodes and respiratory modulation.\textsuperscript{31} They documented previous studies of the inaccuracy of electrode placement by critical care nurses and it was found that accurate placement was only completed 13\% to 27\% of the time.\textsuperscript{5}

Electrode placement errors and their effect were evaluated on the EASI-derived 12-lead ECG by Finlay and colleagues.\textsuperscript{14} The researchers developed two electrode misplacement experiments along with a third experiment that moved the precordial leads in a 12-lead ECG. The first two experiments tested the placement of the EASI electrodes. These electrodes are commonly misplaced because of identifying the wrong anatomical landmarks. The first experiment moved the E, A, and I electrodes vertically, while the second experiment moved the A and I electrodes horizontally. Electrode misplacement was determined by the 117-lead body surface potential maps (BSPMs). BSPMs have been previously established according to Montague et al.\textsuperscript{24} The electrodes in experiment one and two were misplaced by having the regions around the electrodes interpolated using linear interpolation. In experiment one, the leads were inserted at 0.5 cm intervals up to 5 cm superior and inferior of E, A, and I. Interpolated leads were also placed anterior and posterior of I and A at the same intervals for experiment two.\textsuperscript{14}
For comparisons to be made, a third experiment was conducted with the 12-lead ECG precordial leads misplaced superiorly and inferiorly at interpolated intervals of 0.5 to 5 cm. Root mean square error (RMSE) analysis and variations in J-point amplitude were recorded at each trial of the 12-lead ECG and comparisons were made. The results showed that when the standard precordial leads were moved from their correct position, the error was greater compared to when the EASI leads were moved away from their correct position. The error obtained indicated that the standard ML leads could be misplaced at least 3 cm away from the correct location before the performance decreased below that of the EASI leads.\textsuperscript{14} The researchers indicated that the EASI precordial leads are more tolerant to the misplacement error (within $\pm 5$ cm) that was considered within the study and therefore are less sensitive to electrode placement.

The literature review provided shows an ample amount of evidence that the derived EASI electrode configuration produces similar signal quality to that of the standard M-L 12-lead electrode placement. The EASI electrode placement is a feasible alternative that can be used in ambulatory settings as well as clinical populations to monitor patients with heart irregularities.
CHAPTER III
METHODS

3.1 Research Design

An experimental research design was used within this study. The independent variable was the type of ECG recorded during each stage of the protocol; the Mason-Likar standard 12-lead ECG and the modified EASI derived 12-lead ECG from the CardioWare harness. The dependent variables were the RMSE and goodness of fit measure of each type of ECG.

3.2 Subjects

A convenience sample of 30 healthy volunteers (15 males and 15 females) aged 20-54 years from Cleveland State University (CSU) and the surrounding Cleveland community was obtained. The subjects were recruited by “word of mouth” and also by posted fliers (Appendix D). Only subjects who were considered healthy and low-risk according to the AHA/ACSM Pre-participation Screening Questionnaire (Appendix E) were included in the study. Each subject served as their own control as they were connected to both types
of ECGs simultaneously. An Informed Consent form (Appendix F) was signed by each participant. The CSU Institutional Review Board approved this study (Appendix G).

3.3 Instruments

The unisex CardioWare harness (Appendix H) is a comfortable ORI (Cleveland, OH) patented harness that has FDA- approved ECG dry electrodes embedded into the wearable device. It is easy to put on and take off and also does not require shaving or skin preparation due to the dry electrodes in the harness. The shoulder strap is universal depending on which type of harness is used. It can be placed over the left shoulder or right shoulder and the buckle is clipped at the right midaxillary line. All of the subjects wore the left sided harness during testing. The placement of the electrodes in the harness is in the modified EASI position using derived coefficients.\textsuperscript{12,13,16} The modified position moves the “E” and “S” electrodes of the sternum to accommodate patients who have had a median sternotomy (Appendix I).

3.4 Procedures

All testing was completed in the Human Performance Laboratory at CSU. Participants were asked to stand up to have both electrode placements applied. Before electrode placements were applied, the subject’s skin was prepped using NuPrep (Weaver and Company, Aurora, CO). NuPrep was applied by rubbing the gel on the subject’s skin with a cotton pad for 10 seconds in each electrode placement for the standard 12-lead ECG. NuPrep is an electrical impedance-lowering gel. Placement A (Appendix I) consisted of the CardioWare harness being placed on the subject and adjusted appropriately depending on subject size. The CardioWare harness was placed on the subject first to allow for adjustments so the ORI (Cleveland, OH) patented dry electrodes
had direct contact to the skin. The lead wires of the CardioWare harness were interfaced into a data acquisition unit (DAQ) developed by ORI (Cleveland, OH). The DAQ contains an electronic board that has the ability to derive a 12-lead ECG from the five-lead CardioWare harness. The DAQ unit was placed around the subject’s waist by a belt to hold it in place. Next, the 3M™ Red Dot™ 2560 gel electrodes were applied (Placement B, Appendix I) to the subject’s already prepped skin in a standard 12-lead Mason-Likar placement. Precordial electrodes V₃ – V₆ were placed directly under the CardioWare harness on the designated landmark to avoid interference between both types of electrode placements. Both types of ECGs were recorded simultaneously by the DAQ as shown in the overlay position in Appendix I. Once the subjects were finished with both types of electrode placements (the CardioWare harness and the 12-lead ECG), they were asked to stand still and the DAQ was turned on to record the 5 minute resting trial (Trial A).

3.5 Protocol

After instrumentation, the subjects were instructed on the exercise testing protocol as seen in Table I. Subjects were instructed to straddle the treadmill belt. Once the subject straddled the belt, the DAQ was turned on to begin recording the trial (Trial B). The first stage consisted of three minutes of standing rest followed by stages 2, 3, 4 of exercise and ending with the final stage of 3 minutes of standing recovery. The protocol included five, three minute stages, totaling 15 minutes (Table I).
Table I. Rest and Exercise Protocol on Treadmill.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Position</th>
<th>Time (minutes)</th>
<th>Running Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rest- Standing</td>
<td>3</td>
<td>0-3</td>
</tr>
<tr>
<td>2</td>
<td>Walk- 1.7mph @ 0%</td>
<td>3</td>
<td>3-6</td>
</tr>
<tr>
<td>3</td>
<td>Walk- 1.7mph @ 10%</td>
<td>3</td>
<td>6-9</td>
</tr>
<tr>
<td>4</td>
<td>Walk- 2.5mph @ 12%</td>
<td>3</td>
<td>9-12</td>
</tr>
<tr>
<td>5</td>
<td>Recovery- Standing</td>
<td>3</td>
<td>12-15</td>
</tr>
</tbody>
</table>

The first five minutes of standing rest was called Trial A. For data analysis, the exercise stages were split into two halves to compare rest and ambulatory walking to strenuous walking and recovery. The first half of Trial B consisted of the first 7.5 minutes, which included rest and ambulatory walking. The second half of Trial B was the last 7.5 minutes of the protocol, which included strenuous walking and recovery. From Trial A, a transformation matrix was generated using the computed fit between the 3 modified EASI channels and each one of the 12-lead channels. This transformation matrix from Trial A was used to derive a 12-lead ECG from the data on Trial B after data collection. The test was terminated when the 15 minute protocol was completed.

3.6 Data Analysis

A training set of true 12 Mason-Likar ECG leads recorded simultaneously with the three modified EASI channels (Trial A) were used to determine the transformation matrix that generated each respective Mason-Likar lead from a linear combination of the three modified EASI channels. The coefficient of determination was computed between each half of Trial B of Mason-Likar and modified EASI signals, from the same subject, which was not used in the training set (Trial A). RMSE (mV) was calculated between
the true ECG signal and the derived signal for each limb, augmented, and precordial lead set by using Matlab™ R2013b software (The Math Works Inc., Natick, MA).

Descriptive and inferential statistics were obtained using PASW/SPSS (version 18.0) with 0.05 used as the level of significance. Paired samples correlations were used to determine whether ambulatory walking and strenuous walking on the treadmill correlated to harness signal quality as measured by RMSE. Paired samples t-tests were conducted between each pair of limb, augmented and precordial leads during the first half of exercise during Trial B, (approximately 7.5 minutes of rest and ambulatory walking) and the second half of Trial B (approximately 7.5 minutes of strenuous walking and recovery). Subjective evaluation of the goodness of fit overlay was also determined.
4.1 Results

Thirty subjects, 15 males and 15 females (ages 20-54 years) volunteered to participate in this study to determine whether a 12-lead ECG using five dry electrodes in the CardioWare harness (modified EASI) can be derived from the standard 12-lead Mason Likar ECG while subjects are at rest and when exercising on a treadmill. The subject characteristics (age, weight, and height) are shown in Table II.

Table II. Subject Characteristics (mean ± SD)

<table>
<thead>
<tr>
<th></th>
<th>Age (year)</th>
<th>Weight (kg)</th>
<th>Height (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females (n=15)</td>
<td>26.0 ± 6.9</td>
<td>59.4 ± 9.9</td>
<td>164.8 ± 7.5</td>
</tr>
<tr>
<td>Males (n=15)</td>
<td>26.3 ± 7.9</td>
<td>83.3 ± 12.8</td>
<td>178.3 ± 6.2</td>
</tr>
</tbody>
</table>

The RMSE results are shown in Table III for standard and derived limb leads (Lead I, II, III), augmented leads (aVR, aVL, and aVF), and the precordial leads (V1 through V6) during the first half and second half of Trial B. There were no significant differences
between the RMSE of the two different types of electrode placements during either the first half or the second half of Trial B (p ≥ .05).

**Table III. Comparison of RMSE between first half and second half of Trial B.**

<table>
<thead>
<tr>
<th>Pair</th>
<th>Mean ± SD</th>
<th>Sig. (t-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lead I RMSE1 – Lead I RMSE2</td>
<td>0.042290 ± 0.517958</td>
<td>0.658</td>
</tr>
<tr>
<td>2. Lead II RMSE1 – Lead II RMSE2</td>
<td>0.082075 ± 0.453294</td>
<td>0.330</td>
</tr>
<tr>
<td>3. Lead III RMSE1 – Lead III RMSE2</td>
<td>0.082625 ± 0.396507</td>
<td>0.263</td>
</tr>
<tr>
<td>4. aVR RMSE1 – aVR RMSE2</td>
<td>0.049376 ± 0.360868</td>
<td>0.460</td>
</tr>
<tr>
<td>5. aVL RMSE1 – aVL RMSE2</td>
<td>0.054333 ± 0.410233</td>
<td>0.474</td>
</tr>
<tr>
<td>6. aVF RMSE1 – aVF RMSE2</td>
<td>0.080714 ± 0.346135</td>
<td>0.212</td>
</tr>
<tr>
<td>7. V₁ RMSE1 – V₁ RMSE2</td>
<td>0.099009 ± 0.621849</td>
<td>0.390</td>
</tr>
<tr>
<td>8. V₂ RMSE1 – V₂ RMSE2</td>
<td>0.115229 ± 0.443749</td>
<td>0.166</td>
</tr>
<tr>
<td>9. V₃ RMSE1 – V₃ RMSE2</td>
<td>0.053773 ± 0.307200</td>
<td>0.346</td>
</tr>
<tr>
<td>10. V₄ RMSE1 – V₄ RMSE2</td>
<td>0.020756 ± 0.762353</td>
<td>0.882</td>
</tr>
<tr>
<td>11. V₅ RMSE1 – V₅ RMSE2</td>
<td>0.096422 ± 0.648476</td>
<td>0.422</td>
</tr>
<tr>
<td>12. V₆ RMSE1 – V₆ RMSE2</td>
<td>0.070380 ± 0.441759</td>
<td>0.390</td>
</tr>
</tbody>
</table>

Pearson correlation coefficients were calculated for RMSE between each pair of limb, augmented, and precordial leads during the first half and the second half of Trial B as shown in Table IV. Very high, positive correlations (r range = .887 – .932) were found on all limb leads and all but three of the precordial leads, indicating a significant linear relationship (p = .0001). The precordial leads of V₁, V₄, and V₅ also showed high, positive correlations (r range = .658 – .785). The other precordial leads (V₂, V₃, and V₆)
showed very high, positive correlations (r range=.852 - .942). The coefficient of determination ($r^2$) ranged from 0.43- 0.88 suggesting a robust relationship between the CardioWare derived ECG and the standard 12-lead ML ECG.

**Table IV. Correlations of RMSE between first half and second half of Trial B.**

<table>
<thead>
<tr>
<th>Pair</th>
<th>N</th>
<th>Correlation</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lead I RMSE1 – Lead I RMSE2</td>
<td>30</td>
<td>.887</td>
<td>.0001</td>
</tr>
<tr>
<td>2. Lead II RMSE1 – Lead II RMSE2</td>
<td>30</td>
<td>.891</td>
<td>.0001</td>
</tr>
<tr>
<td>3. Lead III RMSE1 – Lead III RMSE2</td>
<td>30</td>
<td>.932</td>
<td>.0001</td>
</tr>
<tr>
<td>4. aVR RMSE1 – aVR RMSE2</td>
<td>30</td>
<td>.909</td>
<td>.0001</td>
</tr>
<tr>
<td>5. aVL RMSE1 – aVL RMSE2</td>
<td>30</td>
<td>.913</td>
<td>.0001</td>
</tr>
<tr>
<td>6. aVF RMSE1 – aVF RMSE2</td>
<td>30</td>
<td>.910</td>
<td>.0001</td>
</tr>
<tr>
<td>7. $V_1$ RMSE1 – $V_1$ RMSE2</td>
<td>30</td>
<td>.769</td>
<td>.0001</td>
</tr>
<tr>
<td>8. $V_2$ RMSE1 – $V_2$ RMSE2</td>
<td>30</td>
<td>.854</td>
<td>.0001</td>
</tr>
<tr>
<td>9. $V_3$ RMSE1 – $V_3$ RMSE2</td>
<td>30</td>
<td>.942</td>
<td>.0001</td>
</tr>
<tr>
<td>10. $V_4$ RMSE1 – $V_4$ RMSE2</td>
<td>30</td>
<td>.658</td>
<td>.0001</td>
</tr>
<tr>
<td>11. $V_5$ RMSE1 – $V_5$ RMSE2</td>
<td>30</td>
<td>.785</td>
<td>.0001</td>
</tr>
<tr>
<td>12. $V_6$ RMSE1 – $V_6$ RMSE2</td>
<td>30</td>
<td>.853</td>
<td>.0001</td>
</tr>
</tbody>
</table>

A subjective evaluation of goodness of fit was also determined by an overlay of the two types of ECGs that were recorded. Overlays were taken during rest as well as during ambulatory walking and strenuous walking for each half of the protocol for a limb, augmented, and precordial lead. Figure 1 shows the overlay taken from subject 27 on limb Lead II during ambulatory walking midway through Trial B. Augmented Lead aVF
of the same subject was recorded during strenuous walking during the second half of Trial B (Figure 2). Resting data was recorded on precordial Lead V5 on the same subject during the first half of Trial B (Figure 3). Figure 4 shows a full 12-lead ECG overlay during the first half of exercise. By observation, all three overlays (Figure 1-3) showed similar ECG waveforms.

**Figure 1. Limb Lead II: Overlay of Derived ECG and Standard ECG During Ambulatory Walking.**

**Figure 2. Augmented Lead aVF: Overlay of Derived and Standard ECG During Strenuous Walking.**
Figure 3. Precordial Lead $V_5$: Overlay of Derived and Standard ECG During Rest.

Figure 4. Overlay of a Full 12-lead ECG During First Half of Protocol
4.1 Discussion

The results showed no significant differences in RMSE between electrode types during the two half of the exercise protocol. This indicates that derived ECGs from the modified EASI electrode placement were comparable to the standard 12-lead ECG. These results support Welinder et al.\textsuperscript{38} who showed that the EASI derived configuration was superior when walking on the treadmill, cycling, and turning from supine to the left because there was less myoelectric noise. However, the ML placement proved superior when turning from supine to the right.\textsuperscript{38} They ultimately concluded that the EASI 12-lead monitoring system was a suitable alternative to the ML system in ambulatory settings.\textsuperscript{38} They also found few differences at rest or during activity between the two types of ECGs which is similar to the current study. All limb, augmented, and precordial leads showed no significant difference. RMSE and goodness of fit was also assessed in Pahlm and colleagues\textsuperscript{27} study who sought to compare waveforms of the conventional 12-lead ECG to derived EASI leads using Horáček et al.’s\textsuperscript{16} adult coefficients. In accordance with the current study, ECGs were recorded simultaneously and root mean square differences were calculated. This is consistent with the current study in which the coefficients produced a relatively better fit based on the root mean square difference. The EASI electrode placement derived similar levels of goodness of fit as a standard 12-lead configuration\textsuperscript{27} which was also found in the current study through a visual overlay representation.

Very strong, positive correlations were found in the current study in all limb and augmented leads, while three precordial leads (V\textsubscript{1}, V\textsubscript{4}, and V\textsubscript{5}) exhibited strong positive correlations. Horáček et al.\textsuperscript{16} found a significant relationship in the goodness
of fit data correlated in resting cardiac patients. They showed that the proximity of the EASI electrodes is associated with better reproducibility of a given derived lead. The results of the current study support this finding due to fact that the proximity of the EASI electrodes did not show a difference in the correlations. All limb, augmented, and precordial leads, regardless of proximity, yielded a high or very high positive relationship. Feild et al. also found a greater correlation with the precordial leads compared to the limb leads of the derived ECG. The researchers evaluated original coefficients that were used to derive ECGs and modified them to be appropriate for a greater assortment of diagnostic applications. Drew and colleagues results resembled that of Horáček et al’s in that the electrodes with the largest proximity (i.e. limb leads) showed the poorest correlation with standard leads. Horáček et al. also assessed the quality of the derivations which was assessed by calculating the mean correlation coefficients. It was found that EASI-derived 12-lead ECG signals produce the same diagnostic information in terms of accurate waveforms as a standard 12-lead ECG.

The CardioWare harness was tested in a previous study and was found to accurately derive a 12-lead ECG from the harness during supine and resting recordings. This study was similar to the current study in which both types of ECGs were found to accurately derive a 12-lead ECG. However, Sparks et al. used a clinical comparison by having a trained cardiologist review the 12-lead ECGs. Goodness of fit was used as an overlay with the derived and true ECGs and the results showed very similar recordings between the two methods as did the subjective evaluations of goodness of fit recorded in the present study.
The novel dry electrode that Orbital Research Inc. incorporated into the CardioWare
harness has been validated in two studies. The novel dry electrode that was used in
those studies was the same electrode that was embedded into the CardioWare harness
that was used for this study. The dry electrodes were compared to a standard wet
electrode and proved to be just as good in signal quality using the signal to noise ratio.
With the current study, the novel dry electrode was validated again to show no
difference in the two types of ECG quality between a derived and standard 12-lead
ECG.

Other research was conducted to compare derived ECGs and the standard 12-lead
ECG in clinical populations experiencing angina or induced ischemia during
percutaneous transluminal coronary angioplasty (PTCA). Even though the current study
was conducted on healthy individuals, the CardioWare harness is designed for clinical
populations in the hospital setting and can therefore be of use with that population.
Rautaharju et al evaluated derived ECGs from an improved transformation matrix while
acute ischemia was induced during PTCA. Of note, two experienced ECG readers
classified the ECGs along with the Philips ECG analysis program and found no
significant differences between the two lead sets. The authors concluded that the EASI
derived ECG deserves consideration as an alternative to the standard 12-lead ECG. The
results of the current study supported this. Sejersten and colleagues also found no
significant difference in the two types of ECG systems when used in the clinical setting
on patients with angina.
The CardioWare harness also has the potential to monitor ST-segment changes in the clinical setting. In Feldman et al.’s study, EMS providers recorded EASI derived ECGs prior to standard 12-lead ECGs in the field with patients who met the criteria for acute coronary syndrome. Specifically, they were looking at ST-segment changes with the EASI lead system. They concluded, overall, that the two methods matched 96% of the time when rhythm or conduction irregularities were present. The EASI lead system, whether in the field or in the clinical setting, is appropriate for ECG monitoring.²³ Chantad et al. also found the EASI lead system to be accurate and reliable for evaluating ST-segment deviation in cardiac patients. The analysis of ST-segment deviation showed significant correlations (range= 0.62-0.823) similar to those found in this study.
CHAPTER V
SUMMARY & CONCLUSION

Thirty subjects completed a treadmill protocol wearing the CardioWare harness as well as a 12-lead standard ECG simultaneously. Both types of ECGs were embedded into a data acquisition box invented by Orbital Research Inc. Data was analyzed to compare the RMSE of each limb, augmented and precordial lead during each half of the protocol. Goodness of fit was evaluated subjectively by reproducible overlays of each ECG during rest, ambulatory and strenuous walking.

There were no significant differences in the RMSE measurement between the derived ECG in the CardioWare harness and the standard 12-lead ECG in the ML position in all limb, augmented, and precordial leads. The goodness of fit measure was also qualitatively reviewed with an overlay of both types of ECGs. It was found that the overlay was very reproducible of the two types of ECGs during rest, ambulatory and strenuous walking. Therefore, the null hypothesis was accepted stating that there would be no differences between the derived ECG in the CardioWare harness and the standard 12-Lead ML placement. It can be concluded that the modified EASI derived 12-lead ECG is an acceptable alternative to the standard 12-lead ML system at rest, ambulatory and strenuous walking.
5.1 Application

The CardioWare harness may be very valuable in the future when implemented in the hospital setting for ambulatory monitoring. This study adds new knowledge to the field of derived 12-lead ECGs using the modified EASI electrode placement. Currently, conventional Holter/Event recorders and other cardiac event monitoring devices have limited application/wear periods and are uncomfortable to the patient due to the use of gel based and adhesive electrodes. When patients shower with these gel based electrodes, they take them off prior to their shower and can not put them back on because they no longer adhere to their body. The CardioWare harness can increase patient compliance because it uses dry electrodes that are embedded in the lining of the harness and it is convenient to put on and take off with the snap buckle. The CardioWare harness does not require any skin prep due to the dry electrodes that are embedded in the interior of the harness. There are no adhesives used so the patient does not have to worry about the electrodes not adhering to their skin. When applied to the hospital setting, the CardioWare harness with its reduced electrode set would be less likely to interfere with other clinical procedures, record less movement artifact, and increase patient comfort.

5.2 Limitations

Limitations of the study include:

1. Having a trained cardiologist review both the standard 12-lead ECG and derived ECG would have made the qualitative analysis stronger.

2. The subjects were a convenient sample size and were fairly homogeneous in race. Sample size (n=30) was small. Using a larger number of subjects and a more heterogeneous group would increase generalizability of the results.
3. The subjects were all young and healthy, which is not representative of the population for whom CardioWare is designed. CardioWare is designed for patients who have abnormal heart rate or rhythms to wear for an acute or extended period of time depending on the physician’s orders.

5.3 Future Research Recommendations

1. Research should be conducted on different populations such as the elderly due to the fact that most heart patients are older.

2. More research is needed to demonstrate a solution for data transmission, storage and analysis. The data that was recorded in this study was reviewed post-hoc after the testing was complete. Future research needs to be designed so real-time analysis can be displayed and analyzed. This will allow for immediate, on-demand, convenient, and cost-effective acquisition and analysis of the derived 12-lead ECG in areas of acute patient care.

3. Future research is needed on derived ECGs by comparing the EASI derived ECGs with gel electrodes to the modified EASI electrode placement using dry electrodes in the CardioWare harness.
REFERENCES


APPENDICES
APPENDIX A
ECG Waveform
ECG Waveform
APPENDIX B

ORI Dry Electrode with Micro-features.\textsuperscript{35}
ORI Dry Electrode with Micro-features.
APPENDIX C

EASI 5-lead vs. Mason-Likar 12-lead Electrode Placement
EASI 5-lead vs. Mason-Likar 12-lead Electrode Placement

EASI 5-lead electrode placement  
Mason-Likar 12-lead electrode placement

EASI 5-lead electrode placement  
Mason-Likar 12-lead electrode
APPENDIX D

Recruitment Flyer
Cleveland State University

Study Participants Wanted

The Cleveland State University Human Performance Lab is looking for healthy volunteers aged 18-70 years old from CSU or the surrounding community to participate in a study comparing derived electrocardiograms to standard electrocardiograms.

The study involves walking on a treadmill while being monitored for 18 minutes. Participants will only need to participate one time. The study lasts around 45 minutes.

Please contact Ken Sparks if interested at k.sparks@csuohio.edu or call 216-687-4831
APPENDIX E

AHA/ACSM Pre-participation Screen Questionnaire
AHA/ACSM Pre-participation Screen Questionnaire

Name: __________________________________________

Date: __________________________

AHA/ACSM Health/Fitness Facility Pre-participation Screening Questionnaire
Assess your health status by marking all true statements

History
You have had:

___ a heart attack
___ heart surgery
___ cardiac catheterization
___ coronary angioplasty (PTCA)
___ pacemaker/implantable cardiac defibrillator/rhythm disturbance
___ heart valve disease
___ heart failure
___ heart transplantation
___ congenital heart disease

Other health issues

___ You have musculoskeletal problems. (Specify on back)
___ You have concerns about the safety of exercise. (Specify on back)
___ You take prescription medication(s). (Specify on back)
___ You are pregnant.

Symptoms

___ You experience chest discomfort with exertion.
___ You experience unreasonable breathlessness.
___ You experience dizziness, fainting, blackouts.
___ You take heart medications.

If you marked any of the statements in this section, consult your healthcare provider before engaging in exercise. You may need to use a facility with a medically qualified staff.
Cardiovascular Risk Factors

___ You are a man older than 45 years.
___ You are a woman older than 55 years or you have had a hysterectomy or you are postmenopausal.
___ You smoke.
___ Your blood pressure is > 140/90.
___ You don't know your blood pressure.
___ You take blood pressure medication.
___ Your blood cholesterol level is > 240 mg/dl.
___ You don't know your cholesterol level.
___ You have a close blood relative who had a heart attack before age 55 (father or brother) or age 65 (mother or sister).
___ You are physically inactive (ie, you get < 30 minutes of physical activity on at least 3 days per week.
___ You are > 20 pounds overweight.

If you marked 2 or more of the statements in this section, consult your healthcare provider before engaging in exercise. You might benefit by using a facility with a professionally qualified exercise staff to guide your exercise program.


___

___ None of the above is true.

You should be able to exercise safely without consulting your healthcare provider in almost any facility that meets your exercise program needs.
APPENDIX F

Informed Consent
Informed Consent

Comparison of derived ECG obtained from Orbital Research, Inc. CardioWare to a standard 12-lead ECG

This study is being conducted by Dr. Kenneth Sparks, Director of the Human Performance Laboratory (CSU) and Nickie Lay in the Department of Health and Human Performance.

Purpose of the Study:

I understand that the purpose of this study is to obtain and evaluate a recording from a standard 12-lead ECG and a recording from the Orbital Research, Inc. CardioWare system.

I understand that I will be asked my age and required to complete the American Heart Association/American College of Sports Medicine prescreening questionnaire to determine whether I am at low risk for the occurrence of a cardiovascular problem as a result of exercise. If I am found to be at anything other than a low risk level, I will not be allowed to participate in this study.

Procedures:

I understand that I will be asked to come to CSU for one session.

I understand that all testing will occur in the CSU Human Performance Laboratory

Within the session, a resting and exercise trial will be performed, each being 3 minutes. I also understand that I will be wearing the CardioWare harness at the same time as 10 adhesive electrodes, placed at specific anatomical sites. During the resting trial I will be standing on a treadmill while the ECG is obtained. I understand that this is standard during ECG collection.

I understand that after the resting trial I will be asked to walk on the treadmill. I understand that I will be continuously monitored while walking on a treadmill for nine minutes with three minutes of recovery and that my heart rate will not exceed 85% of my maximal predicted heart rate during the exercise.
Risks and Benefits:

I understand the potential risks associated with this study include mild irritation at the sites where the adhesive electrodes are placed. I understand that every effort will be taken to minimize this risk. I also understand the potential risks associated with this study include mild muscle soreness resulting from walking on the treadmill. I also understand that during exercise testing there exists the possibility of certain changes occurring; these include abnormal blood pressure, fainting, disorders of the heart rhythm, and rare instances of heart attack, stroke or death (1:20,000 exercise tests). I understand the laboratory has emergency procedures in place and every effort will be made to minimize these risks. The laboratory is equipped with an AED. Dr. Sparks will be in charge of monitoring, and all lab personnel are trained in CPR and First Aid. Emergency procedures including calling EMS (x911) stating to the dispatcher:” We have a medical emergency in the Human Performance Laboratory PE Building- Room B60”. CPR/First Aid will be administered until EMS arrives. Emergency procedures are posted throughout the laboratory. I also know that I can voluntarily stop exercise if I experience any problems.

Responsibilities of the Participant

I will need to complete a medical history using the American Heart Association/American College of Sports Medicine prescreening questionnaire. This screening tool is used to ascertain that I am at a low risk of experiencing cardiovascular problems. The information I submit and that is contained therein will be used in the determination of my eligibility to participate in this study.

Confidentiality:

I understand that any information obtained during my testing will be treated as confidential and will not be revealed to any individual without my consent. However, information obtained during my test may be used for research purposes with my right to privacy retained.

The medical and research information recorded about me will be used within Cleveland State University as part of this research. Tests and procedures done solely for this research study may be placed in my file to indicate my participation in this study. Upon completion of the study, I will have access to the research information recorded about me. Any publication of data will only use group data and not identify me by name.
Freedom of Consent:

My participation in this study is voluntary. I know that I am free to stop at any time, if I so desire.

Contacts and Questions:

The researchers conducting this study are Kenneth Sparks and Nickie Lay. I may ask them any questions concerning this research study. If I have additional questions at a later time, I can reach Kenneth Sparks at 216-687-4831 or k.sparks@csuohio.edu

Participation:

I understand that participation in this study is voluntary and that I have the right to withdraw at any time with no consequences.

I understand that if I have any questions about my rights as a research participant, I can contact Cleveland State University's Institutional Review Board at (216) 687-3630.

Patient Acknowledgement:

The procedures, purposes, known discomforts and risks and possible benefits to me and to others have been explained to me. I have read the consent form or it has been read to me and I understand it. I have had an opportunity to ask questions that have been answered to my satisfaction. I voluntarily consent to participate in this study and I have been given a copy of this consent form.

________________________  ______  ______________________________
Signature of Participant    Date    Please Print Name

________________________  ______
Signature of Witness       Date
APPENDIX G

Institutional Review Board Approval of Additional Investigator
Institutional Review Board Approval of Additional Investigator

Cleveland State University

MEMORANDUM

Date: February 13, 2013

To: Kenneth Sparks
HPERD

From: Barbara A. Bryan
IRB Coordinator

Re: Renewal Notice of IRB Approval to Use Human Subjects

According to our records, the IRB approvals for the protocol listed below will expire as below:

Transaction No.: 29498-SPA-HS Approval Expiration: March 3, 2013
Title: Comparison of derived ECG obtained from Orbital Research, Inc Cardio Wear to a standard 12-lead ECG
Co-PI/Student: Aaron Rood

As such, the following items must be completed, and this form returned to Office of Sponsored Programs & Research (OSPR), Parker Hannifin Hall, 3rd floor, no later than ten (10) days from the date of this letter or our office will consider the protocol closed and remove it from our active files:

1. This project is ( ) Active and research will continue under this protocol.
   ( ) Inactive or Complete

2. Has there been any change of investigators conducting this study?
   ( ) Yes ( ) No

If yes, please indicate the additional or deleted investigator(s) below:

Addition of Investigator (form attached)

3. Has there been any change in procedure, design, tools, methodology, or subjects since the last review of your protocol? ( ) Yes ( ) No

4. Have any unexpected or adverse developments or problems occurred during the course of this research?
   ( ) Yes ( ) No

If yes, please give details on reverse side or attach a separate sheet.

Signature of Principal Investigator/Advisor

Renewal Approved By: John Jurkiewicz, Chair, IRB

Date: 2-18-13

Date: 2-18-13
APPENDIX H

Anterior and Posterior View of CardioWare Harness: Prototype 3
(Of note, the CardioWare harness is worn underneath the brassiere on females)
Anterior and Posterior View of CardioWare Harness: Prototype 3
APPENDIX I

Electrode Placement and Experimental Design
## Electrode Placement and Experimental Design

<table>
<thead>
<tr>
<th>Placement</th>
<th>Image</th>
<th>Description</th>
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<tr>
<td>A</td>
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<tr>
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<tr>
<th>Overlay And DAQ</th>
<th>Image 1</th>
<th>Image 2</th>
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<tr>
<td></td>
<td><img src="image3" alt="Experimental Design: Electrode Placement" /></td>
<td><img src="image4" alt="DAQ with CardioWare harness and 12-lead ECG" /></td>
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