



Manual 5
Electrocardiography Assessment
Visit 5

April 1, 2011- Version 2

Study website - <http://www.csc.unc.edu/aric/>

Electrocardiography Assessment

Table of Contents

1. OVERVIEW	3
2. FIELD CENTER PROCEDURES	3
2.1 ECG Acquisition	3
2.1.1 Electrocardiograph	3
2.1.2 Equipment and Supplies	3
2.1.3 Preparation for ECG Recording	4
2.1.4 Location of the ECG Electrodes	4
2.1.5 Attaching the Electrodes	8
2.2 Local ECG Reading	9
2.2.1 Rationale	9
2.2.2 Alert ECGs	10
3. READING CENTER TECHNICAL DETAILS	14
3.1 Data processing	14
4. QUALITY CONTROL PROCEDURES	15
4.2.1 Certification/Recertification Procedures	15
4.2.2 Quality Trend Monitoring	16
4.2.3 Quality Grades	16
4.2.4 Common ECG Problems	16
APPENDICES	21
Appendix 1 EPICARE Contact List	22
Appendix 2 MAC 1200 Programming and Setup	23
Appendix 2.1 12-Lead Setup	23
Appendix 2.2 System Setup	24
Appendix 2.3 Communication Setup	25
Appendix 2.4 Participant Data Setup	26
Appendix 2.5 Code Setup	26
Appendix 3 Transmission of ARIC ECGs to EPICARE	27
Appendix 4 ECG Form	28
Appendix 5 ECG Data Flow	29
Appendix 6 EPICARE Website User Guide	30

1. OVERVIEW

A resting standard 12-lead electrocardiogram (ECG) will be acquired on all ARIC study participants using the GE MAC 1200 portable electrocardiograph. The ECGs will be recorded according to a standardized study protocol developed by the ECG reading center (EPICARE) and used in previous ARIC exams. The records will be transmitted electronically via modem and a phone line to EPICARE for central reading. A local ECG screening of the ECG printout for specific abnormalities that require urgent referral will be conducted by trained personnel at the field centers. Similar to previous ARIC exams, ECGs will be recorded after a 12-hour fast and at least one hour after smoking or ingestion of caffeine.

The ECG recordings in ARIC exam 5 will serve to establish the distribution of cardiovascular disease findings and the development of new disease (including myocardial infarction, left ventricular hypertrophy, ischemia, prolonged QT interval, and arrhythmias) as well as the development of subclinical ECG findings that are determined to be associated with a poor prognosis. The ARIC ECG reading center will report classification of ECG abnormalities using Minnesota Code as well as providing continuous measures of the ECG waveforms on a monthly basis. The ECG reading center contact information is listed in **Appendix 1**.

2. FIELD CENTER PROCEDURES

The field center procedures include ECG acquisition, transmission of the recorded ECGs to the ECG reading center and local ECG reading by a physician.

2.1 ECG Acquisition

2.1.1 Electrocardiograph

The electrocardiograph to be used in the ARIC study is the GE MAC 1200 electrocardiograph. The MAC1200 is a portable device and can easily be moved from one location to another. Each machine will be configured specifically for the ARIC study ECG acquisition and transmission. The MAC1200 is to be used for resting ECG recording only. It is not intended for use as a vital signs physiological monitor. The MAC1200 has a customized menu specific to the ARIC study. **Appendix 2** includes the instructional charts that outline the set up for the ARIC MAC 1200 ECG machines. All ARIC ECG technicians should become familiar with the MAC 1200 Operator's Manual.

2.1.2 Equipment and Supplies

Equipment and supplies needed for recording and transmitting ECGs are summarized in **Table 1**.

Table 1

HeartSquare
Telephone jack cable
Scissors
Felt tip non-toxic washable markers
EPICARE contact list (Appendix 1)
Reference guides for "Patient Data Entry" (Table 2)
Reference guide for "Transmission of ECG" (Appendix 3)
ECG follow up form (Appendix 4)
GEMSIT MAC1200 operation manual
MAC1200 ECG paper
GEMSIT disposable silver chloride electrodes
Alcohol swabs and gauze pads
Cotton surgical tape
Examining table disposable paper

2.1.3 Preparation for ECG Recording

- All ECGs will be conducted on participants while fasting at least 8 hours (overnight fasting).
- Examination table/bed should be adequate to comfortably accommodate the participant.
- Supply drape for exposed upper torso.
- An additional covering may be needed to prevent the participant from becoming chilled.
- Make sure ankles and wrists are accessible for electrode application.
- ECG electrode placement should be performed with the technician standing to the participant's left side.
- Reference guide for "Participant Data Entry" instructions (**Table 2**) should be available to insure accuracy.
- Supplies needed for ECG acquisition should be assembled and arranged efficiently.

2.1.4 Location of the ECG Electrodes

This involves location of limb electrodes and chest electrodes

Location of Limb Electrodes (Figure 1)

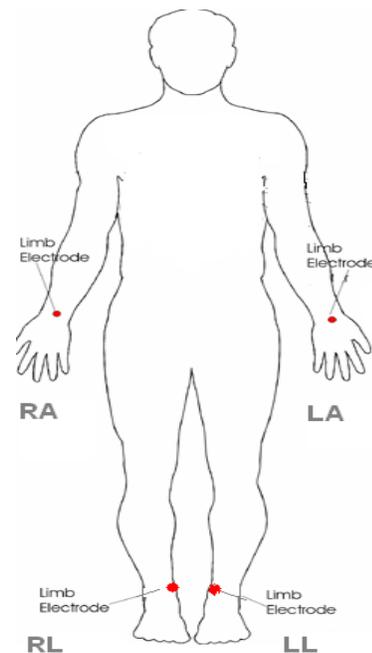
RIGHT AND LEFT LEGS:

- On the inner side of the right leg (RL), above the ankle, rub briskly an area about 1-2 inches in diameter with an alcohol swab using firm, circular motions
- Mark the position to place the electrode later.
- Repeat this procedure for the left leg (LL).
- In amputees, the leg lead electrode may be placed higher up on the torso.

RIGHT AND LEFT ARMS:

- Rub the inner side of the right arm (RA) above the wrist similar to what you did with the right and left legs.
- Mark the position to place the electrode later.
- Repeat the process for the left arm (LA).
- In amputees, the arm electrode may be placed on the shoulder, below the clavicle.

Figure 1



Location of Chest Electrodes

The order of locating chest electrodes is V1 and V2, then V4 and V6, and finally V3 and V5.

V1 AND V2:

- First, locate the sternal angle about the width of your 3 middle fingers below the sternal notch (**Figure 2**). Mark a dot over the sternal angle.
- Feel the sternal angle between the index and middle fingers of your right hand, keeping the fingers wide apart and moving your fingers firmly up and down. While feeling the sternal angle, move your fingers to the left side of the sternum and feel the 2nd rib between your fingers where it joins the sternal angle.
- Move your middle finger to the interspace below the second rib and with your index finger locate the interspace below the next rib (3rd) and again below the next (4th) rib. This is the 4th intercostal space. Mark an **X** at this level at the midsternal line. **X** is the reference level for V1 and V2. Mark their locations at the right and left sternal border (**Figures 2 and 3**).

Figure 2

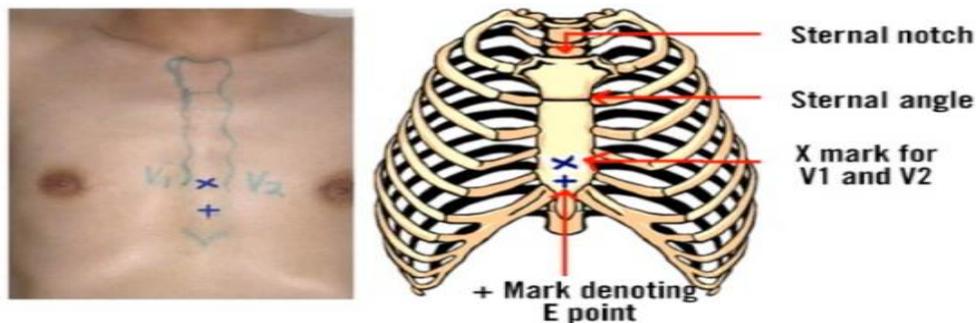
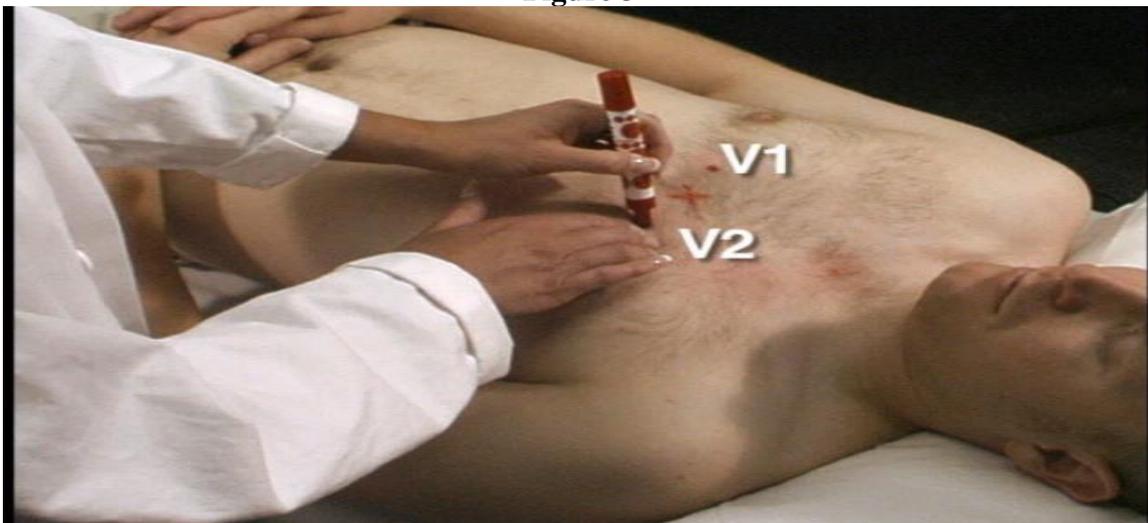


Figure 3



V4 AND V6

- From the location of V2, palpate with the middle finger of your right hand the intercostal space and follow it laterally outside the sternal border and at a slight angle down. Feel the 5th rib between your index and middle fingers and then feel the 5th intercostal space with your index finger.
- At the level of the 5th intercostal space, mark a + sign at the midsternal line below your X mark for V1-V2 level. This + is the reference level “E” for V4, V5, and V6 (**Figure 2 and Figure 4**).
- In overweight persons and in women with tender breast tissue, it is often difficult to locate the 5th intercostal space. In such a case, mark the + sign for E point 1 ¼ in (3 cm) below your reference level X for V1 and V2 (in smaller adults, 1 inch (2.5 cm) is enough).

Figure 4



APPROXIMATE LOCATION OF V6

- Move the left elbow laterally without moving it anteriorly or posteriorly, while observing the anterior and posterior axillary folds. The left elbow must be supported properly.
- Follow a line exactly in the vertical midplane of the thorax (mid-axillary line) down where the line meets the horizontal plane of E point. Using your marker, make a vertical 1-2 inch long line there as an approximate location of V6 (**Figure 5**).

Figure 5



EXACT LOCATION OF V6

- Exact location of V6 is determined by using the HeartSquare.
- Place the HeartSquare horizontally with the wider arm (E arm) at level E point (**Figure 6**).
- Slide the V6 arm of the HeartSquare towards the midaxillary line until the arrow points to the mark at the midaxillary line.
- Mark the exact location of V6 at the level of the arrow on the V6 arm.

Figure 6
E point



Exact V6 location

EXACT LOCATION OF V4

- While keeping the HeartSquare in the horizontal position with the arrow on the V6 arm pointing toward the V6 position, observe the reading at E point. (**Figure 6**)
- Use this E reading on the centimeter scale on the V6 arm, and follow this same E reading along the 45 degree lines towards the torso to locate the exact position of V4. (**Figure 6 and Figure 7**)
- Now that you have located V6 and V4, secure the V6 arm with your thumb to prevent it from sliding. Note the V6 reading which is the distance from the arrow on the V6 arm to where this arm intersects the E arm at right angles. You may then remove the HeartSquare (**Figure 7**).
- Enter the E and V6 measurements as three digits. **Figure 7** shows that the E entry is 160 and the V6 entry is 120 for the readings of 16.0 cm and 12.0 cm, respectively. Enter the 160 for E in the height field of your Mac 1200 and 120 for the V6 measurement in the weight field (**DO NOT ENTER THE HEIGHT AND WEIGHT OF THE PARTICIPANT**)

Figure 7

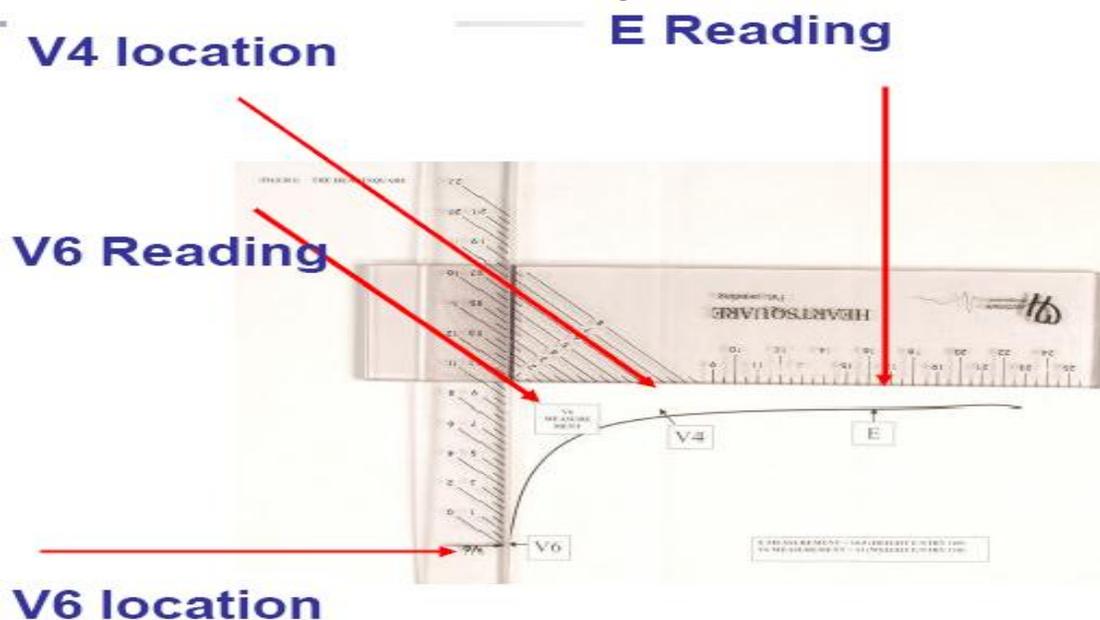
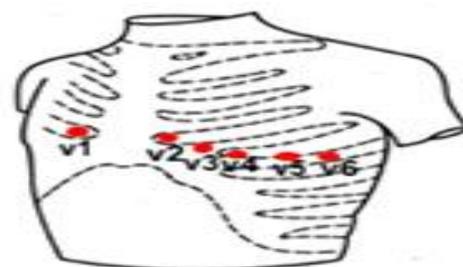


Figure 8

LOCATIONS OF V3 AND V5

- Mark V3 exactly halfway between V2 and V4.
 - Mark V5 exactly halfway between V4 and V6.
- (Figure 8)



2.1.5 Attaching the Electrodes

- After you have located electrode positions, rubbed them with alcohol swabs and gauze pads, you may apply the electrodes.
- Attach lead wires in the same, correct order every time to establish routine and to eliminate lead swaps.
- Position the MULTI-LINK on the participant's abdomen.
- Grasp each lead at the MULTI-LINK attachment point.
- Follow lead wire to the electrode attachment end.
- Attach wire to electrode, making sure clip is not in contact with electrode adhesive.
- Make sure lead wires have some slack and are hanging loosely.
- You may secure the lead wire to the skin by applying paper tape 1-inch below the clip, especially if the ECG shows baseline noise despite careful preparation.

2.1.6 ECG Recording

Once the Electrocardiograph is initiated, the machine will go into self-testing. The ECG machine is set up to simultaneously acquire 12 leads of ECG for a period of 10 seconds. However, before you start recording the ECG, participant data must be entered. **Table 2** summarizes the data entry process. After participant data entry, by pressing the “START” key, the machine will print a copy of the ECG and will automatically store the digital data for later transmission to EPICARE.

Table 2

CATEGORY LISTED ON MAC1200	ENTRY TO MACHINE BY THE ECG TECHNICIAN
NEW PATIENT	Yes
LAST NAME	Enter ARIC
FIRST NAME	Enter the City Code and Participant ID ex: J100123 (This is similar to what was used in ARIC visit 4)
PARTICIPANT ID	Enter the 6-digit PID number assigned by the ARIC CC
SECONDARY ID	Enter same as participant ID
PACEMAKER	Select YES or NO
GENDER	Select MALE or FEMALE
HEIGHT	Enter E measurement of HeartSquare (e.g., if E=16.0, enter 160) DO NOT ENTER HEIGHT
WEIGHT	Enter V6 measurement of HeartSquare (e.g., if V6=12.0, enter 120) DO NOT ENTER WEIGHT
RACE	Choose “Other” and highlight defined race codes (defined on the MAC1200)
REFERRING PHYSICIAN	No action, the data will be pre-programmed.
TECHNICIAN	Choose “Other” and highlight technician’s last name. Make sure that the technician’s name matches the technician performing the ECG
LOCATION	Clinic site name has been pre-programmed. Press Enter

2.2 Local ECG Reading

2.2.1 Rationale

Because there are no available diagnostic statements from the ECG reading center except as monthly reading report to the ARIC CC, the local clinic reading of the ECGs is essential for safety of the participants. A local clinical reading of the ECG at the time of ECG recording is designed primarily to identify ECG abnormalities defined as “alerts” because of their potential importance. Minor, clinically insignificant ECG findings are commonly found in samples drawn from the general population; most of these do not need immediate attention. “Alert” ECGs on the other hand should be reviewed by a clinician at the field center for possible referral. There are no specific directions to follow regarding management of these alerts; it is up to the judgment of the reviewing clinician.

2.2.2 Alert ECGs

The ECG technician should look for the following in the printed diagnostic statement on top of the ECG printout:

- a) Heart rate < 40 beats/minute
- b) Heart rate >120 beats/minute
- c) Atrial fibrillation (especially if new or with a fast hear rate) (**Figure 9**)
- d) Atrial flutter (**Figure 10**)
- e) Ventricular tachycardia (**Figure 11**)
- f) Acute myocardial infarction (**Figure 12**)
- g) Wolf Parkinson White (WPW) syndrome (**Figure 13**)
- h) Complete atrioventricular block (**Figure 14**)

Noteworthy, there are other significant ECG abnormalities that warrant treatment, but because they do not require prompt action or immediate notification to the participant, they are not included in the “alert” ECG list. Also, since local reading of the study ECGs for alerts is not part of the ECG reading center procedure, this list of ECG abnormalities may be modified by adding or deleting more ECG abnormalities to match the overall safety measures implemented by the ARIC study.

Figure 9 Atrial fibrillation

Diagnosis key points: irregular QRS complexes (heart rate) and absence of the P wave

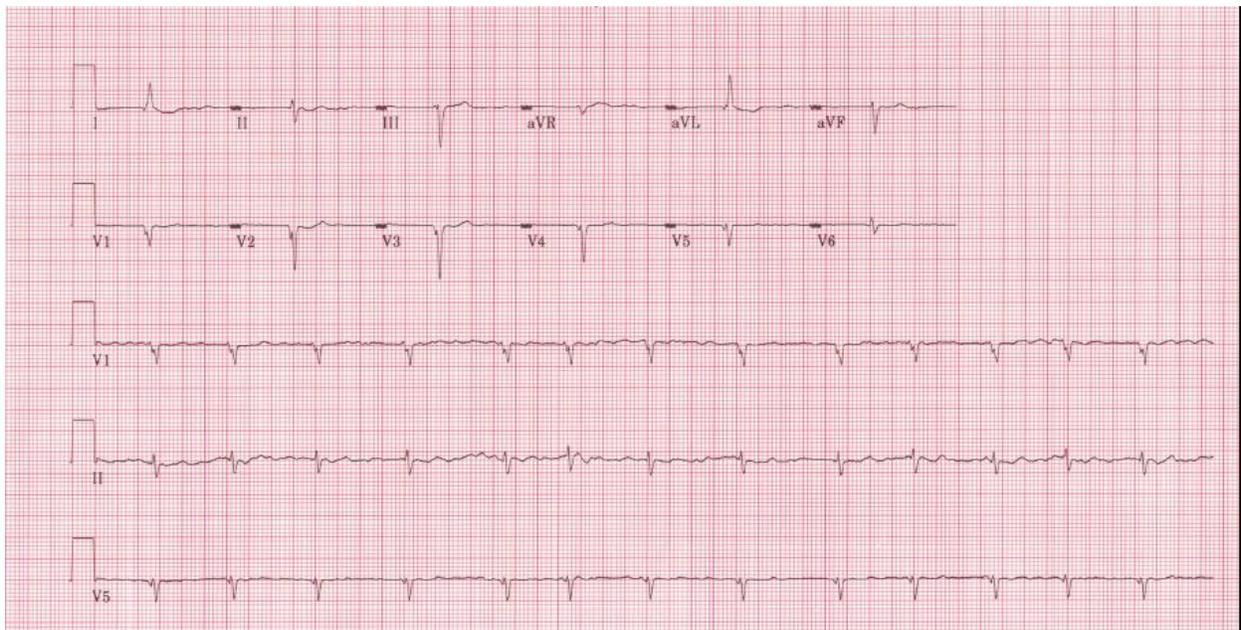


Figure 10 Atrial flutter

Diagnosis key points: multiple P waves; saw-teeth pattern (as in V1), mostly regular but could be irregular with a certain pattern (regular irregularity)

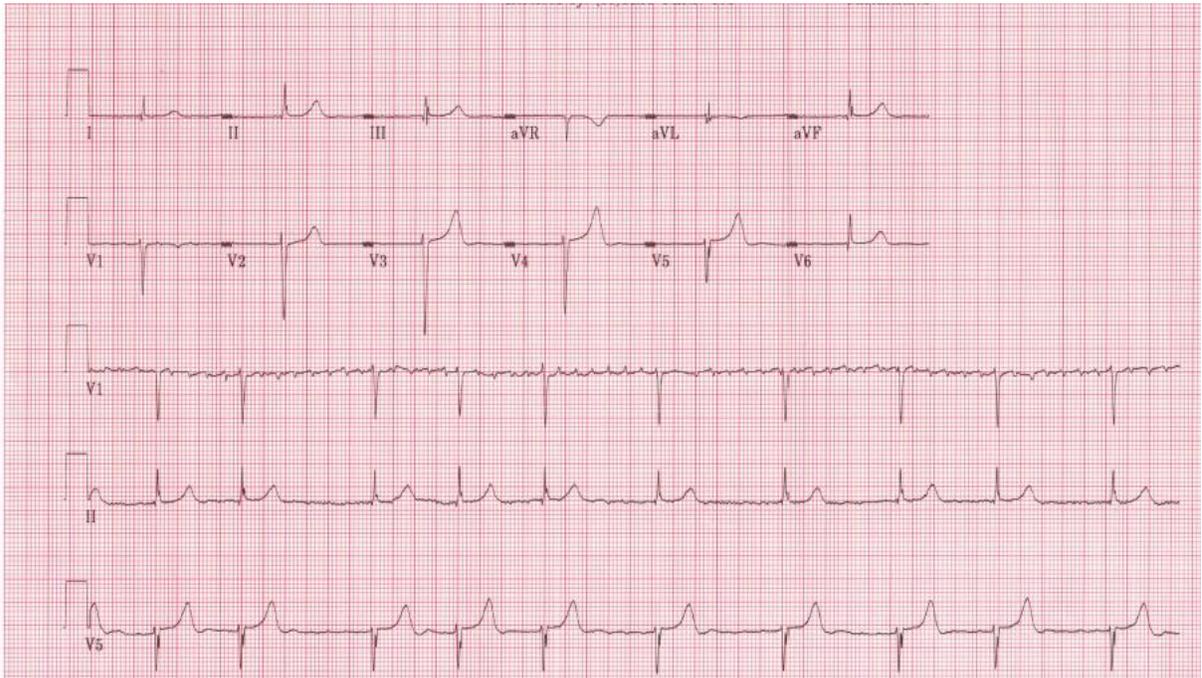


Figure 11 Ventricular tachycardia

Diagnosis key points: Wide complex tachycardia (HR \geq 110) with QRS not preceded by P wave. The patient will be mostly restless

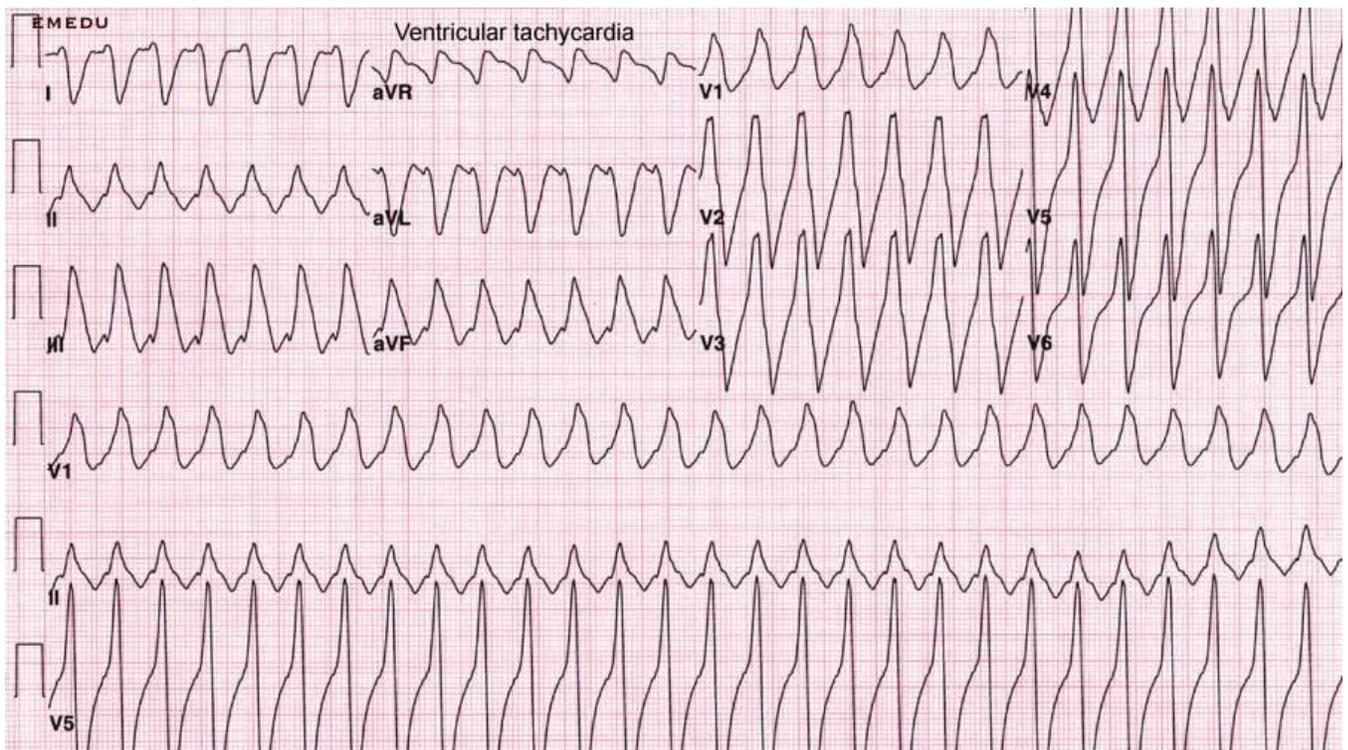


Figure 12 Acute inferior (upper panel) and anterior (lower panel) myocardial infarction

Diagnosis key points: Elevated ST segment in a group of adjacent leads with or without Q waves and with or without ST depression in other leads. Patients usually will have chest pain

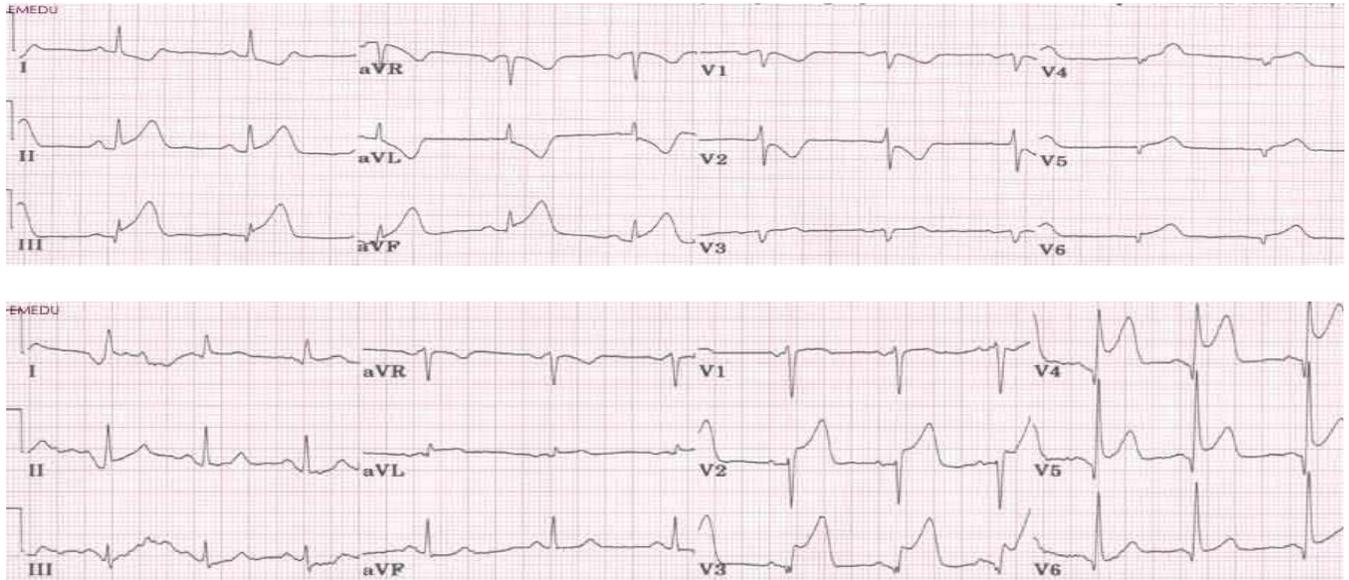


Figure 13 Wolf Parkinson White Syndrome

Diagnosis key points: Short PR interval (below 120 ms), slurred upstroke of the R wave (delta wave) with wide QRS complex (mostly above 110 ms)

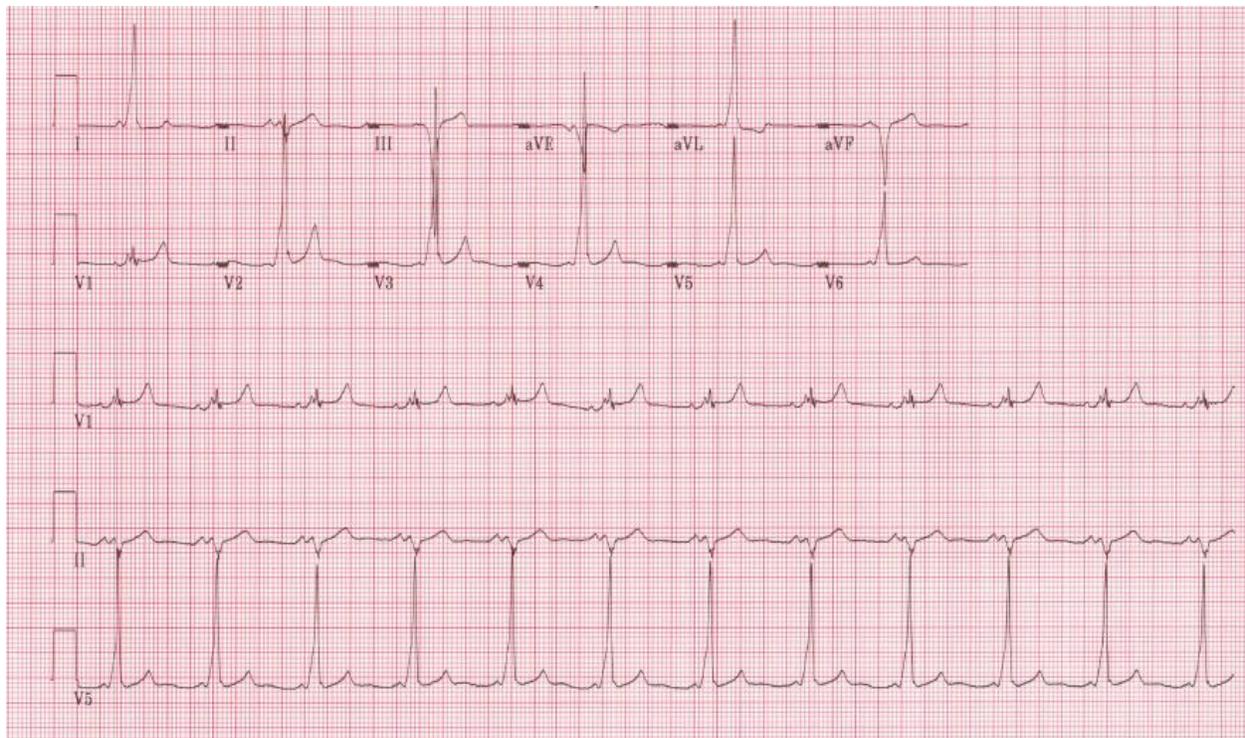
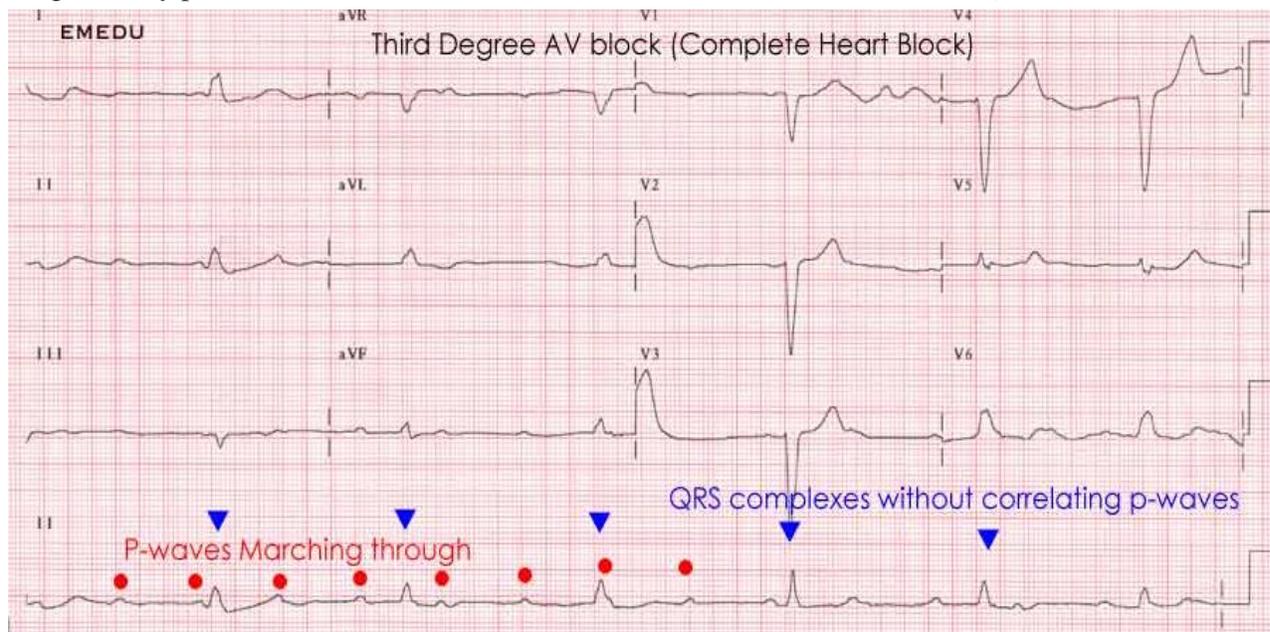


Figure 14 Complete atrioventricular block

Diagnosis key points: Slow heart rate with no relation between the P wave and the QRS



2.3 ECG transmission

Internal set up of the ECG machines must be done according to the instructions established by the ECG reading center (**Appendix 2**). Correct internal set up should enable the clinics to transmit the study ECGs via a phone line to the reading center. Adding 9 (or other number) to get an outside line and/or adding an access code for long distance are taken into consideration. A summary of the transmission process is in **Appendix 3**.

Before Transmitting ECGs to EPICARE

- Ensure that all previously transmitted ECGs are deleted but only after confirmation of receipt by checking the EPICARE website.
- Check to ensure that all IDs are valid. You can correct any variable from your participant data information by doing the following: While holding the “Shift” key down, press the Store/Retrieve key, move the cursor to the ID in question, highlight “Change” and then proceed to make corrections as needed

Transmitting ECGs to EPICARE

- Secure the modem cable into the 9-pin connector found on the right side of the MAC1200 and the 25-pin connector found on the rear of the modem.
- Plug one end of the phone cable into the connector marked “**LINE**” on the rear of the modem and the other end into any “analog” (fax) phone line.
- Start at the 12-lead screen. While holding the “Shift” key down, press the “Store/Retrieve” key. Press the down arrow 3 times and then hold the shift key and the down arrow together to get to the desired ECG to be transmitted. The screen will show black squares on the right and left sides of the ECG selected for transmission.
- To skip an ECG press the down arrow without using the shift key.

- Repeat this procedure until all ECGs that are to be transmitted have been selected.
- Once selections are made, press the “Enter” key. This will return you to the top of the screen.
- Use the right arrow to highlight “Send” and press the “Enter” key.
- Another screen will appear which states “to start transmission, press enter”. Once transmission is complete, press the “Start/Stop” key, located on the far bottom right of the keyboard, to return to the 12-lead screen.
- Confirmation of receipt of transmitted ECGs could be made by logging into the EPICARE website using a user name and password specific to each clinic. Allow 24 hours between transmission and confirmation of receipt through the website and deletion of ECGs from the ECG machine to allow system backup at EPICARE. Instructions on how to log into EPICARE website, along with screen instructions are summarized in **Appendix 6**.

3. READING CENTER TECHNICAL DETAILS

3.1 Data processing

The recorded ECGs will be electronically transmitted to the ARIC ECG reading center via phone lines connected to the ECG machines where it will be received by the GE-MUSE ECG management server. The digital ECGs are stored in an electronic database in a Marquette measurement matrix. This database will remain unaltered. Additionally, a second and third database will be created after technician editing of correct onset and offset of the waveforms. These two databases are then transformed into Minnesota Code categories by the EPICARE ECG coding program. A diagram of the data flow is outlined in **Appendix 5**

3.2 Classification of ECG abnormalities

Similar to the previous ARIC visits, the Minnesota ECG Code (*The Minnesota code manual of electrocardiographic findings. John Wright-PSG, Littleton MA, 1982*) will be used for classification of ECG abnormalities in ARIC visit 5 as well as comparing significant serial QSTT changes among ARIC visits.

The ECG reading center will also provide ECG classification using the Novacode (*The Novacode criteria for classification of ECG abnormalities and their clinically significant progression and regression. J Electrocardiol 1998; 31(3):157-187*).

To enable utilization of newly developed ECG criteria beyond Minnesota and Novacode, the ECG reading center will provide the continuous measurements of the ECG waveforms in each of the 12 leads. These continuous measurements have triggered lots of interest since the ECG reading center started to make the investigators aware of their availability. Noteworthy, in June 2010, the ECG reading center updated the ECG continuous measurements from the past visits using the same ECG software that will be used in the ARIC visit 5 ECG visit (Data have been already sent to the ARIC CC). This will enable looking into trends and changes in these measurements across ARIC visits without introducing bias due to changes in the ECG software throughout past years.

3.3 Data reporting

ECGs will be processed and reported within 30 days from receipt. Monthly reports will be sent to the ARIC CC via secured FTP server. The format and route of data transfer will be determined by agreement between the Coordinating Center (CC) and the ECG reading center.

4. QUALITY CONTROL PROCEDURES

4.1 Overview

The quality control plan for the ECG acquisition in the ARIC visit 5 consists of activities that will take place prior to collection of data (quality assurance) as well as efforts during the study to monitor the quality and correct errors during the collection and processing of data (quality control). As both quality assurance and quality control can sometimes overlap, they are both referred to here as quality control (QC). QC of ECG data collection and processing procedures requires attention in 3 areas: QC at the field center (clinic), QC of processing the study ECGs at the level of ECG reading center, and QC of ECG machines (electrocardiographs).

4.2 Quality Control of the Field Centers Procedures (Clinics)

The first step in quality assurance at the site level consists of the training and certification process. All ECG technicians will be trained on standard ECG recording including correct location of chest electrodes. Training on handling and programming ECG machines forms an integral part of the centralized training. Personnel turnover is anticipated and necessitates special consideration for training of new ECG technicians. Usually, new technicians will be trained by their clinic coordinator or by a previously certified ECG technician, and they will go through the standard certification process before being authorized to record ECGs for the study. ECG training materials (DVD video on how to use the HeartSquare, PowerPoint presentation explaining ECG recording procedures, and the ECG MOP) will be made available to all of the study ECG technicians. After training and certification, the ECG reading center will continuously monitor ECG quality and will identify errors in acquisition. Each tracing submitted will be graded for quality and used to compile continuous quality trend analysis data for each clinical site. QC grade reports will be sent to ARIC CC for review along with the monthly report of the ECG reading results.

4.2.1 Certification/Recertification Procedures

All ECG technicians must go through the certification process before they are allowed to acquire study ECGs. Each technician must acquire three (3) good quality ECGs. The 3 ECGs should be performed on 3 different volunteers or on one volunteer provided that there is at least 30 minutes between each recording. ECG technicians who meet the certification requirement will receive a certificate. Recertification process (if required) is the same as the certification process. The participant data entry should be done according to the instructions in **Table 3**, after pressing the “pat info key” on the MAC 1200 keyboard.

Table 3 Entry into the MAC1200 for certification of technicians ONLY

Category	Entry
New patient	YES
Last name	Enter technician’s last name
First name	Enter technician’s first name
Date of birth	Enter volunteer’s birth date (MM/DD/YY)
Participant ID	Enter 999999 (Press “Shift” key to enter numbers)
Secondary ID	Enter 999999 (Press Shift key to enter numbers)
Pacemaker	YES or NO
Gender	M or F (Note: Do not choose)
Height	E Measurement of HeartSquare (e.g., if E=16.0, enter 160)
Weight	V6 Measurement of HeartSquare (e.g., if V6=12.0, enter 120)
Race	Choose “Other” and choose defined race codes
Referring physician	No action required. Pre-programmed data
Technician	Choose “Other” and select technician’s last name
Location	Unit location ID (same as clinic No.)

4.2.2 Quality Trend Monitoring

Senior ECG technicians of EPICARE have been trained to continuously monitor ECG quality and to identify any procedural errors in ECG acquisition. Quality grades assigned to each ECG are used to compile continuous quality trend analysis data for each ECG technician to spot emerging problems, particularly with the change of ECG personnel over the duration of recruitment. A series of quality control (QC) reports will be sent monthly to the ARIC CC. These reports will be used as instruments to allow study management to be proactive. Sites can use these monthly reports to track the quality of their ECGs. Declining ECG quality should trigger the necessity for local, or central retraining, or fact-finding site visits by the CC or the ECG reading center.

4.2.3. Quality Grades

The ECG reading center evaluates and ranks the ECG quality through an automated system as well as manually. There are 4 grades; 0, 1, and 2 which are automatically assigned by the GE-MUSE, and 5 which is manually decided by EPICARE staff for poorest quality- No grade 4. The best grade is 0 and the worst is 5. Generally, grades 0 and 1 are difficult to separate visually and they are considered good. Grade 2 is given to ECGs that have problems that will not significantly interfere with appropriate reading. Grade 5 quality is given for ECGs that have major problems that interfere with accurate reading. The alarming level of poor quality is having more than 5% of the ECGs with quality grade 5 and 2 (combined). The CC and the sites will be contacted if alarming level of poor quality is reached, or there is a significant change in the quality.

4.2.4 Common ECG Problems

There is a number of ECG quality issues that may arise because of inappropriate preparation for the ECG recording. This includes:

- **EXCESSIVE BASELINE DRIFT (Figure 15):** This occurs if the participant is moving around or there is tension on the lead wires. Ask the participant to lie still for a few seconds. Drift in excess of 1 mm between baseline points (QRS onset) of any two successive complexes is a sign of significant drift.
- **EXCESSIVE MUSCLE NOISE (Figure 16):** The participant is either tense due to lack of body support or may be cold. Use a wide bed and blanket to cover the participant.
- **BASELINE DRIFT DUE TO TANGLED WIRES (Figure 17):** Ensure that the wires are not pulling. Be sure to establish a good electrode connection. Lay a towel across the wires, if necessary. Adjusting the angle of the clip at the electrode often helps. You may need to tape down the chest leads; use only hypoallergenic medical tape to prevent allergic reactions. Use a U loop (not a cross loop) with the electrode wires, i.e., the wire should not cross but remain open like a U; never crossover wires.
- **LOOSE ELECTRODE CONNECTION (Figure 18):** Loose electrode connection may cause a wavy baseline in some ECG leads. Check each electrode to ensure that it is secure.
- **SIXTY HZ NOISE (Figure 19):** Periodic 60 HZ noise is sometimes visible in the record. This may be caused by AC interference from a nearby machine. Make a visual check of this before recording the ECG. Unplug any unnecessary surrounding electric equipment *Note:* Jewelry does not cause 60 HZ noise.
- **MISSING LEADS AND LEAD REVERSAL (Figures 20-22):** To minimize the chances of having lead reversal and missing leads, always make sure that there are no flat lines in the ECG recording and/or mainly positive QRS in aVR lead. Also, always have a second look at the connections before recording

Figure 15 Excessive baseline drift due to sudden movement of the participant

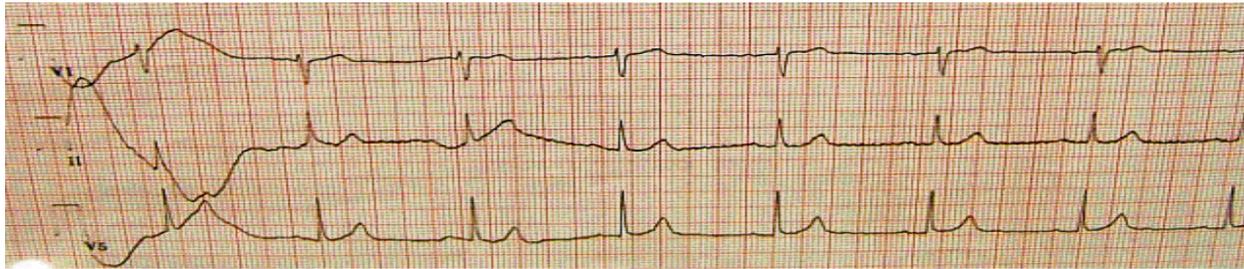


Figure 16 Excessive muscle noise

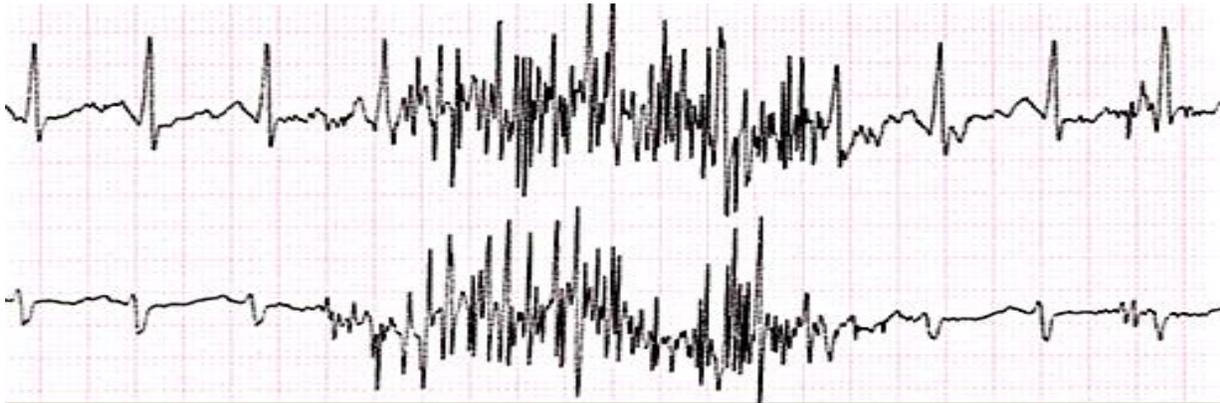


Figure 17 Baseline drift due to tangled wires

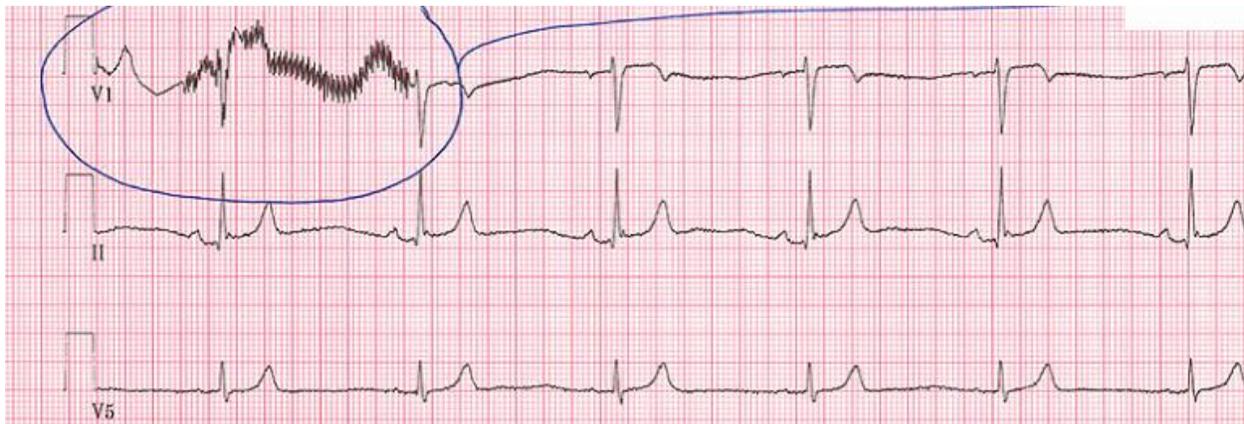


Figure 18 Wavy V1 baseline due to loose electrode

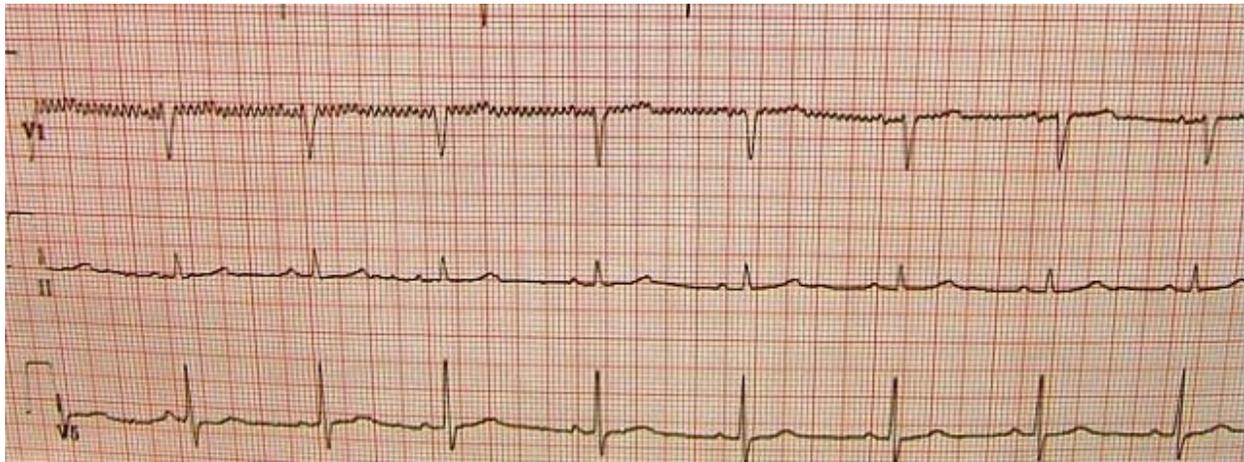


Figure 19 Sixty Hz electrical interference



Figure 20 Flat line due to missing V1 lead

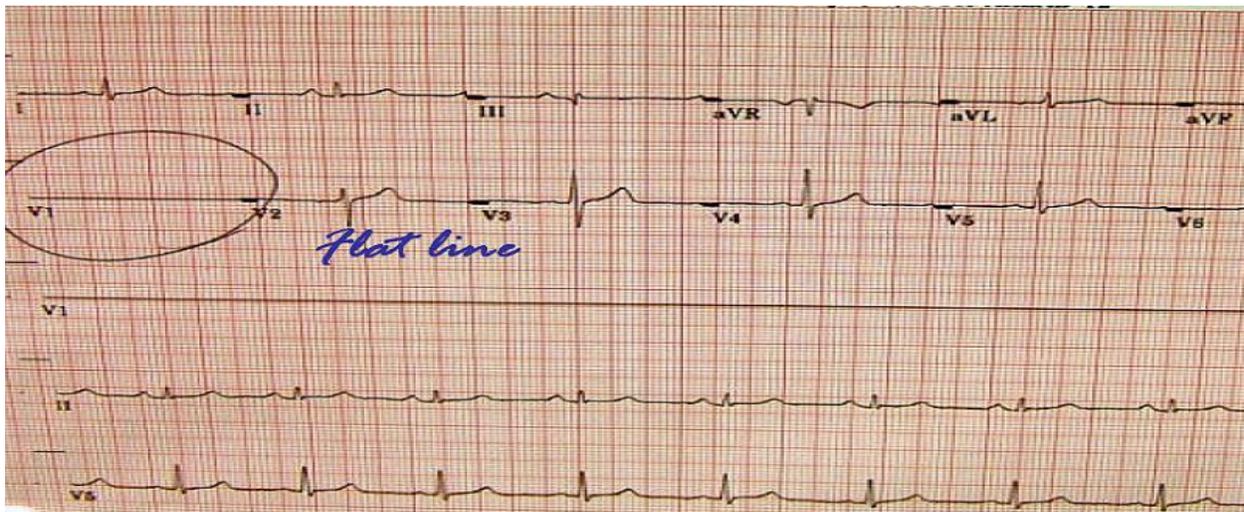


Figure 21 Lead reversal denoted by positive aVR (upper panel) compared to the normal (lower panel)

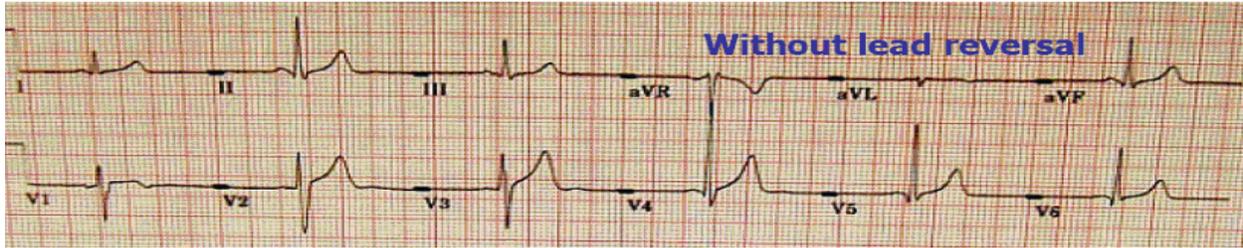
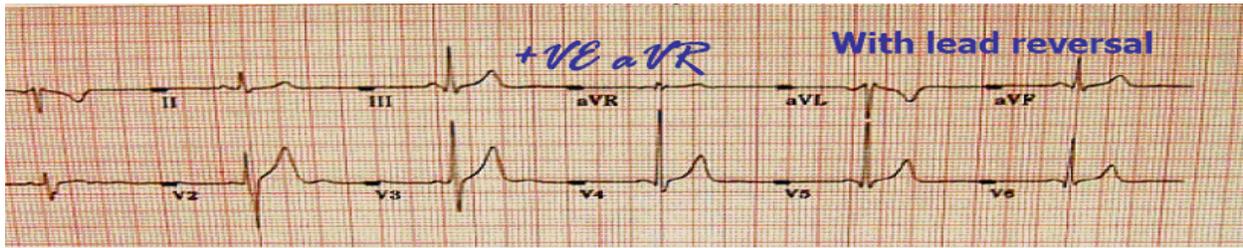
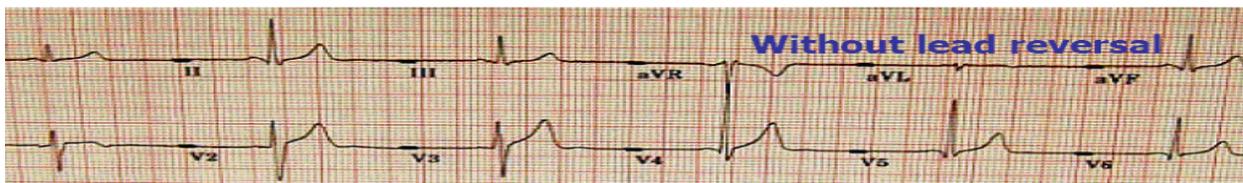
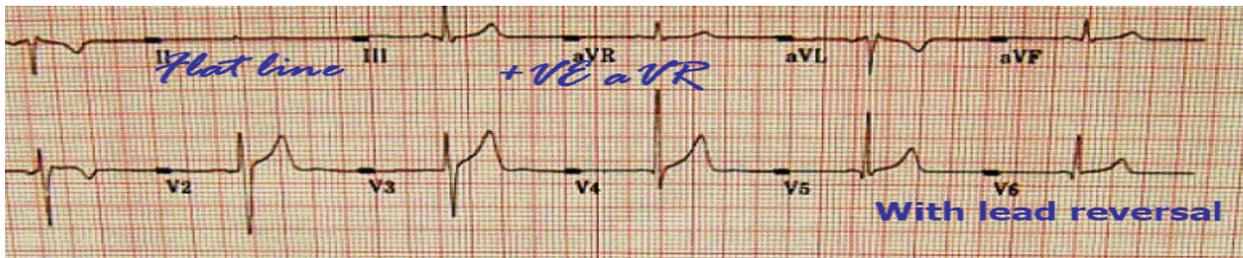


Figure 22 Lead reversal denoted by flat line in one of the limb leads (upper panel) compared to the normal (lower panel)



4.3 Quality Control of the ECG Reading Center Procedures

The ECG reading center has an extensive internal quality control protocol that monitors performance of ECG coding and measurement. This includes regular monitoring of the inter- and intra-reader variability in reading/coding visual (paper) ECGs, monitoring of the repeatability and accuracy of editing ECG waveforms of the digital (electronic) ECGs, and procedures to safeguard against change in trends due to change in ECG reading software. The ARIC CC can monitor performance of ECG coding and measurement within the ECG reading center by having access to the results of the center's internal quality control reports during site visits.

The variability of the electronically transmitted ECG source data should be 0% due to the digital nature of the stored and transmitted data. The median (most representative) P-QRS-T complex produced by the Marquette 12-SL ECG processing program is used by EPICARE to classify ECG findings according to the Minnesota Code and Novacode algorithms implemented by EPICARE on the GE MUSE system. ECG interval measurements by the program are ideal for the assessment of time trends. The

measurements are very robust, with the exception of rare occurrences of missed detection of low amplitude P waves and misplacement of the T wave at the end of the U wave when T-U fusion takes place. Every ECG is checked for these possible wave detection errors and an interactive computer graphics terminal with special software is used to correct these errors. It can be categorically stated that when the global onsets and offsets of ECG waves are properly detected, wave amplitude/duration measurements used to assign Minnesota codes are invariably done with a precision far superior to that possible with visual inspection.

Built-in safeguards have been in place to protect against software changes that may produce secular time trends in ECG measurements. In this regard, the ECG reading center continuously monitor the Marquette “raw” measurement for PR, QT and QRS interval durations to check for unsuspected technological, recording procedural changes, or editing changes that might occur during the course of the study. Any sudden unexplained departure in these parameters would signal procedural or software alteration that need to be investigated and corrected.

To minimize chances of errors due to inability of the software to detect some ECG abnormalities, each ECG received electronically is visually checked for a number of ECG conditions (e.g. arrhythmias including atrial fibrillation and ectopic beats, major conduction defects, and pacemakers). This visual supervision is done initially by an ECG coder, and then verified by another senior ECG coder. Further, all major ECG abnormalities (such as new myocardial infarction, significant QSTT serial changes, and major arrhythmias and conduction defects) are reviewed by the PI of the ECG reading center at the time of monthly report, and once again at the time of the final QC check at the end of the study.

To ensure consistency in the ECG acquisition/reading among ARIC visits which is crucial to examine trends and serial ECG changes, the field centers will use the same standardized ECG acquisition procedures similar to those implemented in the previous ARIC visits. Also, the main ECG classification used in the previous ARIC visits will be again used in ARIC visits 5; that is the Minnesota ECG Code. At the same time, the ECG reading center will take advantage of the new technology in the ECG management systems, and the accumulated experience on understanding the advantages/disadvantages of the automatic interpretation of ECG. For example, it has become clear that all automated ECG reading software cannot accurately detect all types of arrhythmias or some errors in ECG electrode application (lead reversals). Therefore, the ECG reading center has implemented visual review of all electronic ECGs for certain types of arrhythmias and lead reversals. This QC procedure was not implemented in the previous ARIC visits. Since these meticulous QC procedures may impact appropriate comparison of the ECG results in ARIC visit 5 with those from previous visits, the ECG reading center has budgeted for applying this QC step to all of the past ARIC visits. Reviewing the past ARIC ECGs has been made easy by using the most advanced ECG management system, GE MUSE 7, in which we have already uploaded all ARIC ECGs from the past visits. By using the GE MUSE, we can view and annotate any of the past ARIC ECGs from any authorized computer terminal in EPICARE.

4.4 Quality Control of Electrocardiographs

All ARIC ECG machines are covered by a manufacturer service/maintenance contract for 3 years. This will ensure that any equipment breakdown will be handled promptly. Also, the ECG reading center will keep an ECG machine that will serve as a loaner to any field center with malfunctioning ECG machine.

Calibration of ECG machines for a standard gain of 10 mm = 1 mV for MAC1200 electrocardiographs will be set invariably. More problematic for quality control monitoring is possible unauthorized local internal re-setting of software filters to give the appearance of adequate performance despite marked recording drift. The EPICARE ECG processing software regularly checks for filter settings used (which is indicated in the electronic signal) and so can detect any such breach of protocol.

APPENDICES

Appendix 1 EPICARE Contact List

Elsayed Z. Soliman, MD, MSc, MS, Director of the ARIC ECG Reading Center (EPICARE)

Phone: (336) 716-8632

Fax: (336) 716-0834

esoliman@wfubmc.edu

Susan Hensley, BS, Computer ECG Technician/ Trainer

Phone: (336) 716-9616

Fax: (336) 716-0834

shensley@wfubmc.edu

Lisa Keasler, AAS, Assistant Project Manager/ Trainer

Phone: (336) 716-0387

Fax: (336) 716-0834

lkeasler@wfubmc.edu

Charles Campbell, BS, AAS, Data Manager

Phone: (336) 716-3915

Fax: (336) 716-0834

chcampbe@wfubmc.edu

Contact Susan Hensley or Lisa Keasler with questions and/or comments pertaining to ECG acquisition and transmission as well as hardware malfunction.

Appendix 2 MAC 1200 Programming and Setup

In order to setup a MAC1200 for the ARIC study, turn the ECG machine ON. After the self-test completes, the ECG machine will be at the 12-lead screen (3 flat lines). Press the Setup key. Press “Enter” to select either 12-lead setup, system setup, communication setup, participant data setup, or code setup. To make a selection, use the four arrow keys to highlight any selection and press “Enter”.

Appendix 2.1 12-Lead Setup

The lead setup should be conducted as in Table 1 below. When finished, press the STOP key

Appendix 2 Table 1

CATEGORY	SELECTION
Report sequence	[STANDARD]
Rhythm leads	[II]
Gain	[10]
Report format	[4x2.5R1]
Detailed results	[NO]
Muscle filter	[NO]
Muscle filter frequency	[40 Hz]
AC filter	[YES]
Manual copy to	[HOST]
No. of copies	[1]
Delete ECG after transmission	[NO]
Auto save ECG	[YES]
Use screening criteria	[NO]
Suppress normal statements	[NO]
Suppress abnormal statements	[NO]
Interpretation	[YES]
Print interpretation	[YES]
Override function	[YES]

Appendix 2.2 System Setup

After completing the 12-lead setup and pressing “STOP” key, press the down arrow key to highlight “System Setup”, and press ENTER. The system setup should be conducted as in Table 2 below. When finished, press the STOP key.

Appendix 2 Table 2

CATEGORY	SELECTION
Ordering physician	Name of the clinic study coordinator
Referring physician	ARIC then clinic #. Press ENTER; then Stop key.
Technician	Choose OTHERS, press ENTER. Press ENTER until the cursor is under the LAST NAME; type the technician’s LAST NAME then press ENTER. Type the technician’s FIRST NAME then press ENTER. Press the Stop key.
Institution name	The name of the university holding the clinic
Cart number	30, 40, 50 or 60; depending on the clinic
Site number	ENTER (7). This is EPICARE’s Study Number for ARIC
Location number	[1]
Date (mm/dd/yyyy)	ENTER the correct date using the mm/dd/yyyy format.
Time (hh:mm)	ENTER the correct time in the hh:mm format.
Lead fail beep	[NO]
High hr beep	[NO]
Lead labels	[AAMI]
Pace enhancement	[NO]
Baseline roll filter	[0.08]
Date	[MM/DD/YYYY]
Time	[24]
Units	[Cm, Kg]
Mains	[60 Hz]
LCD light off after	[5 MINS]
Low battery beep	[0 sec]
Default mode	[12 LEAD]
Language	[ENGLISH]
Enable password	[NO]
Test data	[NO]
Restore defaults	[NO]
Print setup lists	[NO]

<u>Field Clinic</u>	<u>Field Clinic #</u>	<u>Transmission Telephone #</u>
Forsyth County, North Carolina	30	13367131102
Jackson, Mississippi	40	13367131103
Washington County, Maryland	50	13367131104
Minneapolis, Minnesota	60	13367131102

**When finished, press the STOP key
Press the Down Arrow key to highlight Communication, and press ENTER.**

Appendix 2.3 Communication Setup

After completing the system setup and pressing “STOP” key, press the down arrow key to highlight “Communication Setup”, and press ENTER. The communication setup should be conducted as in Table 3 below. When finished, press the STOP key.

Appendix 2 Table 3

CATEGORY	SELECTION
Baud rate (pc)	[9600]
Protocol	[CSI]
Modem	MultiTech 56k
Dial mode	TONE
Phone no.	<p>13367131102, 13367131103, 13367131104, or 13367131105</p> <p>If an access code is required to dial a long distance number, enter the access code and the transmission telephone number at EPICARE, the same way you would dial a long distance number from your institution (using your access code), as follows:</p> <p>If the access Code is needed AFTER entering the transmission number, enter 13367131102,,,123456789 where 123456789 is the access code. If the access code is needed BEFORE entering the transmission number, enter 123456789,,, 13367131102 where 123456789 is the access code</p> <p>Note: Access codes are separated from the EPICARE transmission telephone number by three commas. This allows the MAC1200 to pause before another telephone number is entered.</p>
Outside line	If you need an outside line to obtain dial tone, please enter that digit. If not, leave it blank

Appendix 2.4 Participant Data Setup

After completing the communication setup and pressing “STOP” key, press the down arrow key to highlight “Patient Data Setup”, and press ENTER. The patient data setup should be conducted as in Table 4 below. When finished, press the STOP key

Appendix 2 Table 4

CATEGORY	SELECTION
New patient	[YES]
Pacemaker	[YES]
Gender	[YES]
Height	[YES]
Weight	[YES]
Race	[YES]
Systolic BP	[NO]
Diastolic BP	[NO]
Ordering physician	[YES]
Referring physician	[YES]
Technician	[YES]
Phone no.	[NO]
Medication	[NO]
Comments	[NO]
Id required	[YES]
Patient id length	[6]
Secondary id	[YES]
Secondary id required	[YES]
Last name (required)	[YES]
First name (required)	[YES]
Location #	[NO]
Room #	[NO]
Order number	[NO]
Extra questions	[Leave Blank]

Appendix 2.5 Code Setup

This option requires NO action. If this is the last option remaining, press the STOP key. Press the STOP key once again to exit the setup menu.

Appendix 3 Transmission of ARIC ECGs to EPICARE

Before transmitting ECGs to the CERC

1. Ensure that all previously transmitted ECGs are deleted only after confirmation of receipt by the CERC.
2. Check to ensure that all IDs are valid.
3. You can correct any variable from your participant data information by doing the following:
 - a. While holding the “Shift” key down, press the Store/Retrieve key,
 - b. Move the cursor to the ID in question,
 - c. Select ECG
 - d. Press “Enter” to return to top screen
 - e. Highlight “change/edit”
 - f. Proceed to correct information

Transmitting ECGs to the CERC

1. Plug one end of the phone cable into the connector marked “LINE” on the rear of the modem and the other end into any “analog” (fax) phone line.
2. Start at the 12-lead screen.
3. While holding the “Shift” key down, press the “Store/Retrieve” key.
4. Use arrow keys to move the cursor to the ECG to be transmitted. While holding down uppercase key, use up or down arrow key to select more ECGs (Black box will appear at either side of a selected ECG). Repeat this process until all ECGs that are to be transmitted have been selected. Press the enter key to return to the top of the screen.
5. Select “Send” and press the enter key to start the transmission.
6. Once transmission is complete, press the “Start/Stop” key, located on the far bottom right of the keyboard, to return to the 12-lead screen.
7. Confirmation of receipt of transmitted ECGs could be made by logging into the ARIC/EPICARE website using a user name and password specific to each clinic.

Appendix 4 ECG Form

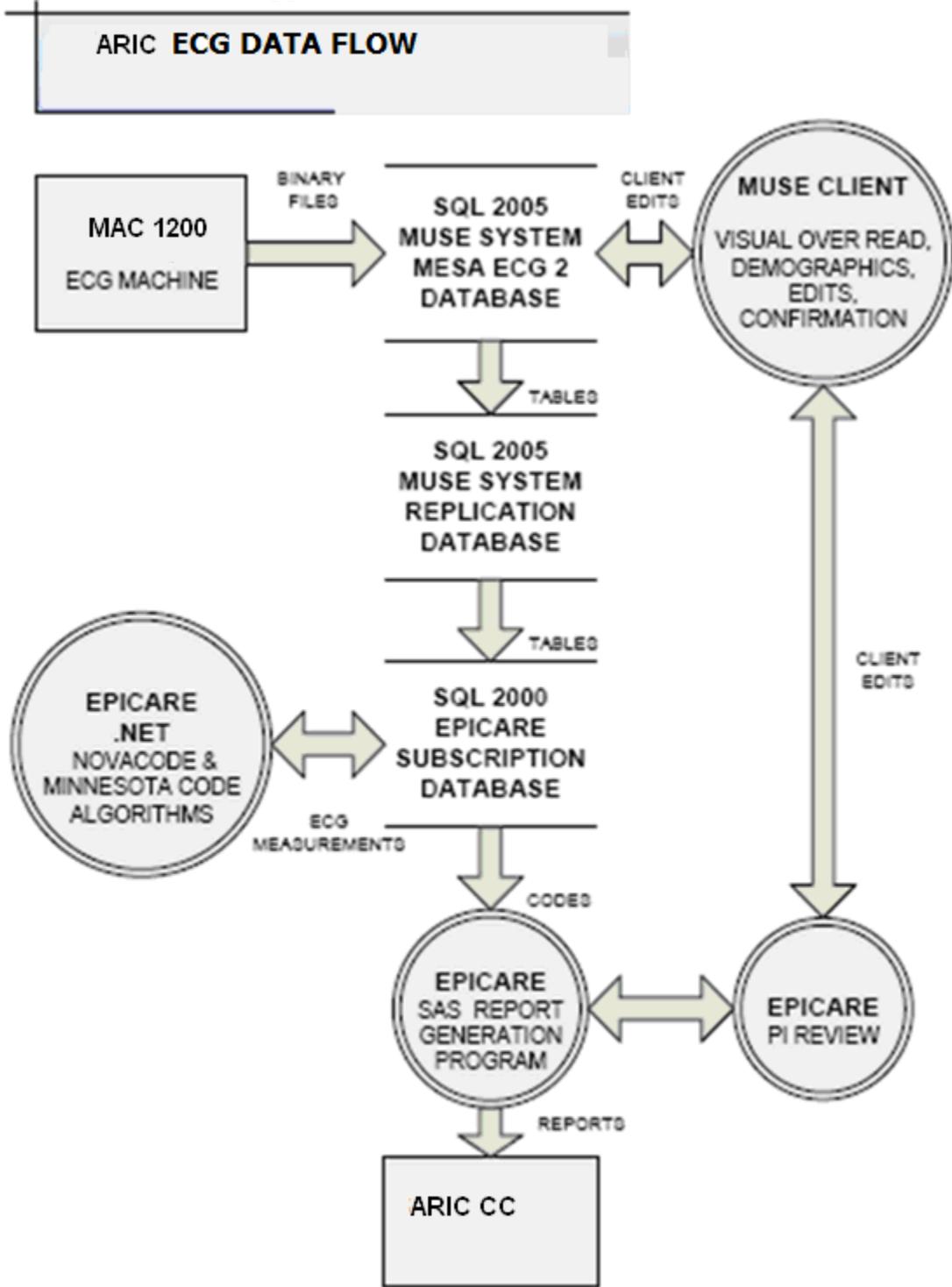
ELECTROCARDIOGRAM FOLLOW-UP

Patient ID	<i>[affix ID label here]</i>	Date Form Completed	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>
Administration Type <input type="text"/>	Visit Code <input type="text"/>	Reviewed by <input type="text"/>	Language <input type="text" value="E"/>

Electrocardiogram	
1. Time of day	<input type="text"/> : <input type="text"/> <input type="checkbox"/> A.M. <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="checkbox"/> P.M. <small>month day year</small>
2. What time and date did you last eat and/or drink anything other than water, including candy and chewing gum?	<input type="text"/> : <input type="text"/> <input type="checkbox"/> A.M. <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="checkbox"/> P.M. <small>month day year</small>
3. Results of examination	<input type="checkbox"/> completed <input type="checkbox"/> not completed → <div style="border: 1px solid black; padding: 5px; margin-left: 20px;"> a. Reason test incomplete or not done: <input type="checkbox"/> hardware malfunction or lack of supplies <input type="checkbox"/> insufficient time available or room not available <input type="checkbox"/> other, specify <input style="width: 150px;" type="text"/> </div>
4. Heart square measurements:	O-E <input type="text"/> . <input type="text"/> O-V6 <input type="text"/> . <input type="text"/>
5. Were any alert conditions noted?	<input type="checkbox"/> Yes → <div style="border: 1px solid black; padding: 5px; margin-left: 20px;"> Specify: <input style="width: 150px;" type="text"/> Action taken: <input style="width: 150px;" type="text"/> </div> <input type="checkbox"/> No

Technician ID: <input style="width: 50px;" type="text"/>
--

Appendix 5 ECG Data Flow



Appendix 6 EPICARE Website User Guide

EPICARE Web-site:

http://epicare.phs.wfubmc.edu/public/Epicare_Home.cfm

EPICARE WEBSITE OVERVIEW

Each technician must have a user account created, with valid e-mail address.

On creation, the WFU PHS authentication service will automatically send an email notification.

WFU-PHS authentication credentials

USER EMAIL NOTIFICATION EXAMPLE

```
username: testPW  
Context: epicare  
Reset Password: d3cztHq
```

EPICARE LOGIN SCREEN

Use this username and EXPIRED password at the LOGIN screen

<https://epicare.phs.wfubmc.edu/Secure/LOGIN/login.cfm>

Please enter your login information below:

[Instructions home](#)

Username:

Password:

TO RESET PASSWORD: Please contact the site administrator. Have your userID and e-mail address available for verification for password resets.

For questions concerning your account contact chcampbe@wfubmc.edu

- On the login page enter your user name as listed in the email
- From the e-mail, copy the expired password (must be exact, no spaces)
- Paste the password you have copied
- You should then be directed to the expired password page

EPICARE EXPIRED PASSWORD SCREEN

testPW

Your password has expired. Please enter a new one below.
[\(Instructions home\)](#)

*Note: Passwords will display in the clear for entry ease/accuracy.
Guard your visual environment appropriately.*

Old (expired) password:

New password: Confirm it:

For questions concerning your account contact chcampbe@wfubmc.edu

- Re-Paste the expired password.
- Select a New password that meets the minimum requirements (See HELP file)
- After entering, look for the “User Record Updated” message below the username

testPW

User record updated.
Please return to the [login page](#) and use your new credentials to login.

CONFIRMED PASSWORD CHANGE

- Select the login page link to go to the login page
- Use your user select password to login
- On successful login you will go to the RptSel (Report Selection) page
- RPTSEL Contains Menus of available SCREENS

REPSEL

USERID: testPW	EMAIL ADDRESS: chcampbe@wfubmc.edu		
FIRST NAME: Test	STUDY NAME: ARIC		
LAST NAME: User	CLINIC ID: 999		
LOG OUT	Confirmation	HelpFile	DataEntryRes

CONFIRMATION REPORT ARIC

USERID: testPW	EMAIL ADDRESS: chcampbe@wfubmc.edu
FIRST NAME: Test	STUDY NAME: ARIC
LAST NAME: User	CLINIC ID:

[LOG OUT](#) [Confirmation](#) [HelpFile](#) [DataEntryRes](#)

SELECT ECG CONFIRMATION REPORT BEGINNING DATE.	<input type="text" value="01/29/2009"/>	BEGIN LOG DATE
SELECT ECG CONFIRMATION REPORT END DATE.	<input type="text" value="01/29/2009"/>	END LOG DATE
PRESS BUTTON TO RETRIEVE CONFIRMATION REPORT.	<input type="button" value="VIEW ECG CONFIRMATION REPORT"/>	

This form allows users to view the ECGs logged to the EPICARE ECG system database within the last 30 days. By selecting a BEGIN LOG DATE and END LOG DATE, users can view the ECGs transmitted to EPICARE within this time period.

The ECGs available for your queries are those processed at approximately 10 minutes after each hour. Depending on when the ECGs are transmitted, it could be up to 1 hour before they will be available for the report.

Once a beginning and end log date is chosen, click on the VIEW ECG CONFIRMATION REPORT button. You will be presented with a page that lists all ECGs logged within this time period, in table format. This information can be downloaded for your records by pressing the DOWNLOAD TO TEXT FILE button. Click save in the pop-up window and select your file location.

Once the confirmation report is saved, please allow one full business day before deleting the ECG(s) from your MAC1200. This will allow EPICARE's database server to be backed-up.

- ECGS Logged to Database
- Selected using BEGIN DATE and END DATE
- Website Database is **NOT REAL TIME**
- Updated 10 min after each hour
 - If ECG transmitted 15 after the hour, then it won't be available for confirmation for almost an hour
- Based on USERID and Clinic# (MAC1200 CART# AS ASSIGNED BY ICC AND EPICARE)

CONFIRMATION REPORT

USERID: testPW	EMAIL ADDRESS: chcampbe@wfubmc.edu
FIRST NAME: Test	STUDY NAME: ARIC
LAST NAME: User	CLINIC ID: 999

[LOG OUT](#) [Confirmation](#) [HelpFile](#) [DataEntryRes](#)

SELECT ECG CONFIRMATION REPORT BEGINNING DATE. BEGIN LOG DATE

SELECT ECG CONFIRMATION REPORT END DATE. END LOG DATE

PRESS BUTTON TO RETRIEVE CONFIRMATION REPORT.

PATID	FNAME	LNAME	ECGDATE	TECH LNAME	LOG DATE LOCAL	LOG DATE GMT
00001324	AMY	abc	28 Jan 2009 10:48:09	EVELYN	29 Jan 2009 23:31	30 Jan 2009 04:31
00130511	ESTELLE	LEE	29 Jan 2009 08:57:20	EVELYN	29 Jan 2009 23:51	30 Jan 2009 04:51

DOWNLOADED FILE

DOWNLOAD TO FILE

PATID	FNAME	LNAME	ECGDATE	TECH LNAME	LOG DATE LOCAL	LOG DATE GMT
00001324	AMY	abc	28 Jan 2009 10:48:09	EVELYN	29 Jan 2009 23:31	30 Jan 2009 04:31
00130511	ESTELLE	LEE	29 Jan 2009 08:57:20	EVELYN	29 Jan 2009 23:51	30 Jan 2009 04:51

testPW_2_17_2009[1].txt - Notepad

```
File Edit Format View Help
ID      FNAME    LNAME    ECGDATE      LOG_LOCAL    LOG_GMT    TECH
00001324  AMY      abc      28Jan2009 10:48:09 29Jan2009 23:31 30Jan2009 04:31 EVELYN
00130511  ESTELLE  LEE      29Jan2009 08:57:20 29Jan2009 23:51 30Jan2009 04:51 EVELYN
```

Ln 1, Col 1

- Download all confirmation reports to clinic files for your records
- Fixed length text file

HELP FILE ARIC

USERID: testPW	EMAIL ADDRESS: chcampbe@wfubmc.edu		
FIRST NAME: Test	STUDY NAME: ARIC		
LAST NAME: User	CLINIC ID: 999		
LOG OUT	Confirmation	HelpFile	DataEntryRes

1. [FREQUENTLY ASKED QUESTONS HELP FILE](#)
2. [TRANSMIT ECGs HELP FILE](#)
3. [TO SET/RESET DATE AND TIME](#)
4. [TO EDIT PATIENT DATA ENTRIES](#)

DATAENTRYRES

USERID: testPW	EMAIL ADDRESS: chcampbe@wfubmc.edu
FIRST NAME: Test	STUDY NAME: ARIC
LAST NAME: User	CLINIC ID: 999

[LOG OUT](#)
[Confirmation](#)
[HelpFile](#)
[DataEntryRes](#)

Review the table for Data Entry Issues. You may request Updates on ID, ACROSTIC, and/or VISIT information.

Choose only the record(s) for which you wish to request Database corrections, edit the desired field(s) to be updated, and place a check mark in the CHECKBOX(s) to the right of the record(s). Please leave records with no changes needed **UNCHECKED**.

When complete, press the RQST UPDATE ON RECORD button at the bottom of the table. You will be taken to a screen confirming your record(s) have been placed in a table for future action.

CURRENT ID	CORRECT ID	ECGDATE	CURRENT ACROSTIC	CORRECT ACROSTIC	CURRENT VISIT	CORRECT VISIT	
00001324	00004321	2009-01-28 10:48:09.0	abc	xyz	AMY	YMA	<input checked="" type="checkbox"/>
00130511	00130511	2009-01-29 08:57:20.0	LEE	LEE	ESTELLE	ESTELLE	<input type="checkbox"/>

[RQST UPDATE ON RECORD](#)

- Data Entry Resolution Page
- Request updates on ID, Acrostic, and/or Visit
- Choose only records for which you wish to request database corrections
- Leave records with no changes **UNCHECKED**
- Records placed in table to later action, changes are **NOT REAL TIME**

DATAENTRYUPDATE

USERID: testPW	EMAIL ADDRESS: chcampbe@wfubmc.edu
FIRST NAME: Test	STUDY NAME: ARIC
LAST NAME: User	CLINIC ID: 999

[LOG OUT](#) [Confirmation](#) [HelpFile](#) [DataEntryRes](#)

Record(s) inserted into the Resolution Request Table for Later Updates

CORRECT ID	CORRECT ACROSTIC	CORRECT VISIT
00004321	xyz	YMA

[GET ANOTHER RECORD](#)

VIEWCERTDATE

VIEW TECHNICIAN CERTIFICATION

CLINIC

UserID	Firstname	Lastname	CertDate	ClinicID
chma	Charlotte	Matt	26 Feb 2009	995
mpc	Mary	Pear	26 Feb 2009	995

- View Technician Certification
- Select CLINIC from list. Must be their assigned clinic #
- Select 'Get Technicians' to retrieve all certified users' certification history