Jackson Heart Study Visit 4

Manual 5

Electrocardiography Assessment

Version 2.1

May 20, 2022

Revised July 29, 2024

Preface

This manual describes the ECG acquisition for the Jackson Heart Study (JHS). Along with the HeartSquare DVD, which could be requested from EPICARE, this manual should be used as a reference for JHS ECG technicians throughout the study. For more information on topics or issues not covered by this manual, please contact the JHS Central ECG Reading Center (CERC), EPICARE, Wake Forest University School of Medicine, Winston-Salem, NC (see **Appendix A**):

EPICARE contact list:

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

For other questions or any concern, contact Elsayed Soliman or Oguz Akbilgic.

Note: This manual is not intended as a replacement for the Jackson Heart Study protocol, rather it is a handy reference that contains information only on ECG acquisition procedure that the ECG technicians need to know.

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1. BACKGROUND AND PURPOSE

The Jackson Heart Study (JHS) is a longitudinal investigation of genetic and environmental risk factors associated with the disproportionate burden of cardiovascular disease in African Americans. The JHS recruited 5306 African American residents living in the Jackson, Mississippi, metropolitan area of Hinds, Madison, and Rankin Counties. JHS participants received three back-to-back clinical examinations (Exam 1, 2000-2004; Exam 2, 2005-2008; and Exam 3, 2009-2013) that have generated extensive longitudinal data on traditional and putative cardiovascular disease risk factors and measures of subclinical cardiovascular disease. The ECG recording in the JHS in this exam visit (Exam 4) will continue to document the development of new cardiovascular disease (CVD) including silent myocardial infarction, myocardial ischemia, left ventricular hypertrophy, prolonged QT interval and arrhythmias as well as the development of subclinical ECG findings that are determined to be associated with a poor prognosis.

2. FIELD CENTER PROCEDURES

The field center procedures include ECG acquisition and transmission to the CERC, and local ECG reading by the clinic physician. The ECG transmission is detailed under data management procedures (Section **2.3**). Two categories of resting ECGs are collected in the JHS: 1) Standard 12-lead ECG on every participant at each exam visit using specific protocol. This updated manual focuses on this category of ECGs given the change in the ECG machine and some procedures, and 2) Hospital ancillary ECGs, which are recorded outside of the JHS exam visits, including ECGs recorded in-hospital and at local medical facilities. These are the ECGs that have been continuously collected in the JHS. Because there is no change in the process of collecting these ECGs, this updated manual does not discuss this category. Technicians can refer to prior manuals and documents.

2.1. Standard ECG acquisition

Each participant will have one resting 12-lead ECG recorded. It is recommended that the ECG be performed in the fasting state. The fasting ECG minimizes the impact of food ingestion and glucose levels on heart rate variability and repolarization measures. However, if the participant is not fasting, the ECG recording should still be done. The ECGs stored in the ECG machine will be transmitted to the EPICARE at least once a week. The ECG form (**Appendix B**) must be filled out after each recording to document the fasting status and the process of recording.

2.1.1. Electrocardiograph

The GE MAC 3500 and GE MAC 5 (added to the study in 2024) portable electrocardiographs (**Figure 1**) will be used for ECG recording and transmission. The MAC 3500 and MAC 5 are portable devices and can easily be moved from one location to another. The ECG machines will be configured specifically for the JHS. **Appendix C** includes the instructional charts that outline the SETUP for the JHS ECG machines. The machines are to be used for resting ECG recording only; they are not intended for use as vital signs physiological monitors. All of the JHS ECG technicians should become familiar with the machines operator's manuals. The educational materials provided with the ECG machines have tutorials on how to operate the machines. Contact the ECG Reading Center for advice about the machines if further help is needed.

Figure 1

2.1.2. Equipment and supplies needed for recording

Table 1 summarizes the equipment and supplies needed for recording and transmitting ECGs.

- GE MAC 3500/GE MAC 5 Electrocardiograph with its 10-lead acquisition module
- SD memory card
- MAC 3500/MAC 5 ECG paper
- Disposable silver chloride electrodes
- Felt tip non-toxic washable markers
- Reference guides for "Participant Data Entry" (**Table 2**)
- Machine operation manuals
- Alcohol swabs and gauze pads
- Cotton surgical tape
- HeartSquare

2.1.3. Preparation for ECG recording

Prior to electrode placement, there are some steps and precautions to be followed:
- Participant should be relaxed and comfortable in supine or semi-recumbent position.
- ECG electrode placement should be performed with the technician standing to the participant's left side.
- Examination bed should be adequate to comfortably accommodate the participant.
- Supply drape for exposed upper torso.
- An additional covering as needed to prevent the participant from becoming chilled.
- Make sure ankles and wrists are accessible for electrode application.
- "Participant Data Entry" instructions 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

2.1.4.1. Location of limb electrodes (Figure 2)

RIGHT LEG (RL) AND LEFT LEG (LL):
- The right leg electrode serves as a ground connection, and problems there will influence all other leads.
- 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 ARM (RA) AND LEFT ARM (LA):
- 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 2
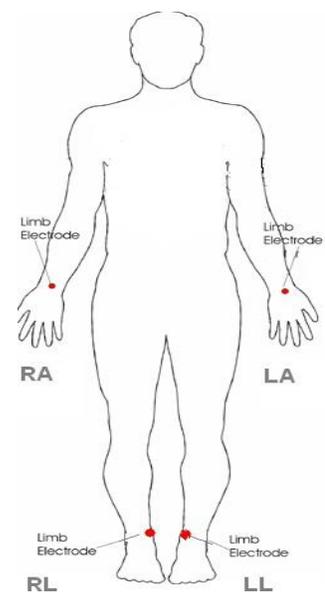
2.1.4.2. Location of chest electrodes

V1 AND V2:

- First locate the sternal angle about the width of your 3 middle fingers below the sternal notch (**Figure 3**).
- 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 (**Figure 3** and **Figure 4**).

Figure 3
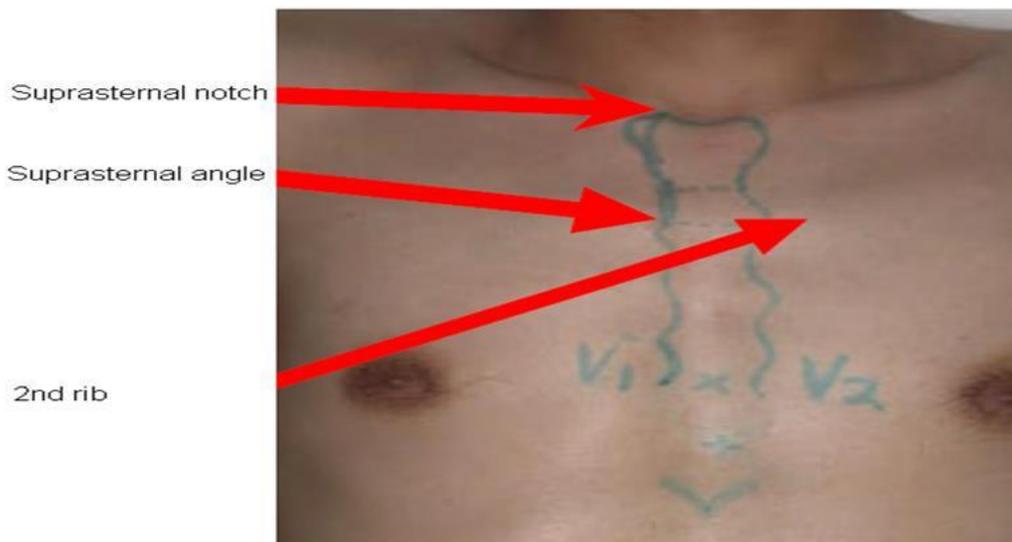
Figure 4
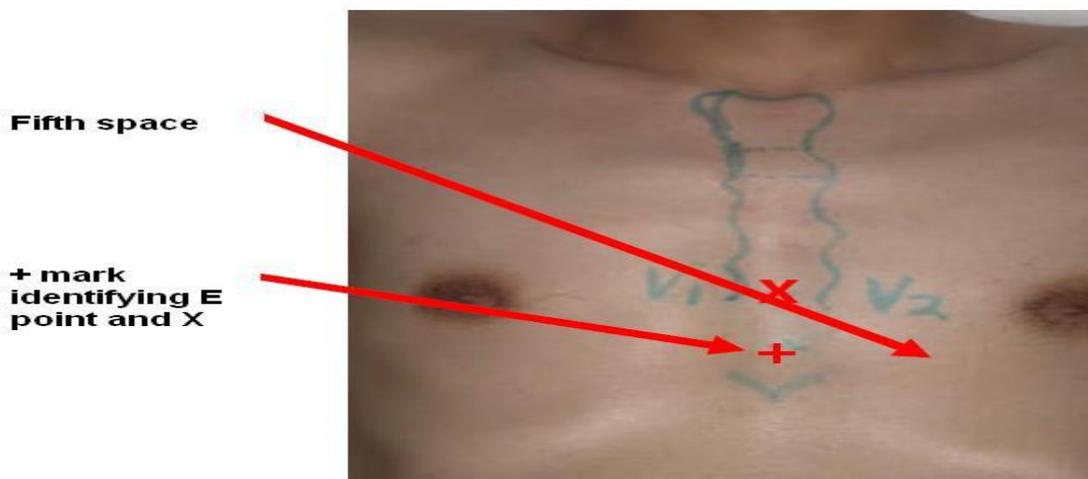
REFERENCE POINT "E" FOR LOCATING V4, V5, AND V6

- 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 feel the 5th intercostal space with your index finger.
- At the level of the 5th intercostal space, mark a + at the midsternal line below your X mark for V1-V2 level. This + is the reference level "E" for V4, V5, and V6 (**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 + for E point 1¼ inch/3cm below your reference level X for V1 and V2 (in smaller adults, 1 inch/2.5 cm).

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 – **Figure 5**) down where the line meets the horizontal plane of e point. Using your marker, make a vertical one inch long line there as an approximate location of V6.

EXACT LOCATION OF V6

- Exact location of V6 is determined by using the HeartSquare (Chest-Square).
- Place the HeartSquare horizontally with the wider arm (E arm) at level E point (**Figure 5**).
- 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 5

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.
- 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.
- Record the E and V6 measurements on the ECG Form (**Appendix B**).

Figure 6
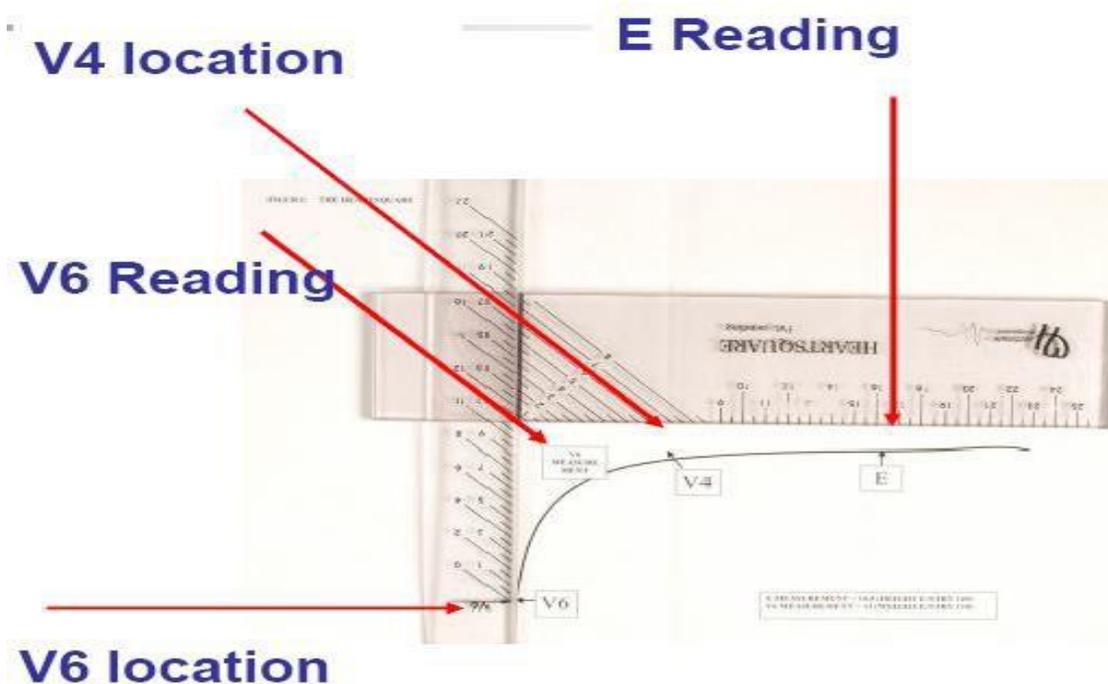
LOCATIONS OF V3 AND V5

- Mark V3 exactly halfway between V2 and V4.
- Mark V5 exactly halfway between V4 and V6. (**Figure 7**)

Figure 7
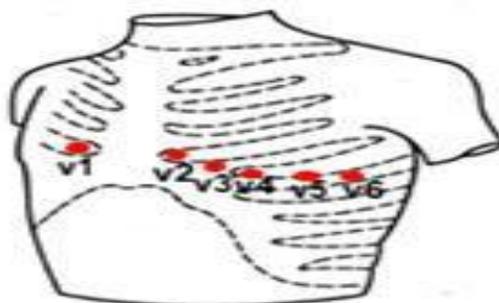
2.1.4.3. Attaching the electrodes

- After you have marked electrodes positions and rubbed them with Alcohol swabs, you may apply the electrodes.
- Do not place electrodes directly over bone.
- 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.

2.1.5. ECG recording

- Turn on the MAC 3500.
  Press F1 to get to patient information **Figure 8**.

  CAUTION – Patient data may be retained from a previous patient. To prevent from entering the subject ID twice, the user should check the patient info screen for each new patient.

Figure 8
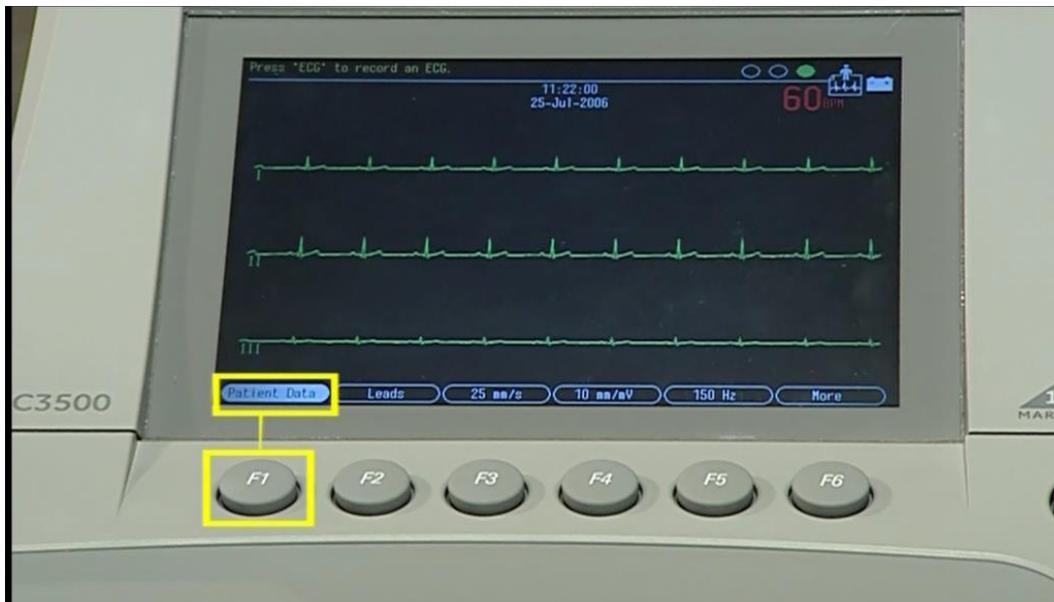
- Another screen with an ECG tracing will appear (**Figure 9**). Enter participant's data as mentioned in **Table 2**.

Figure 9
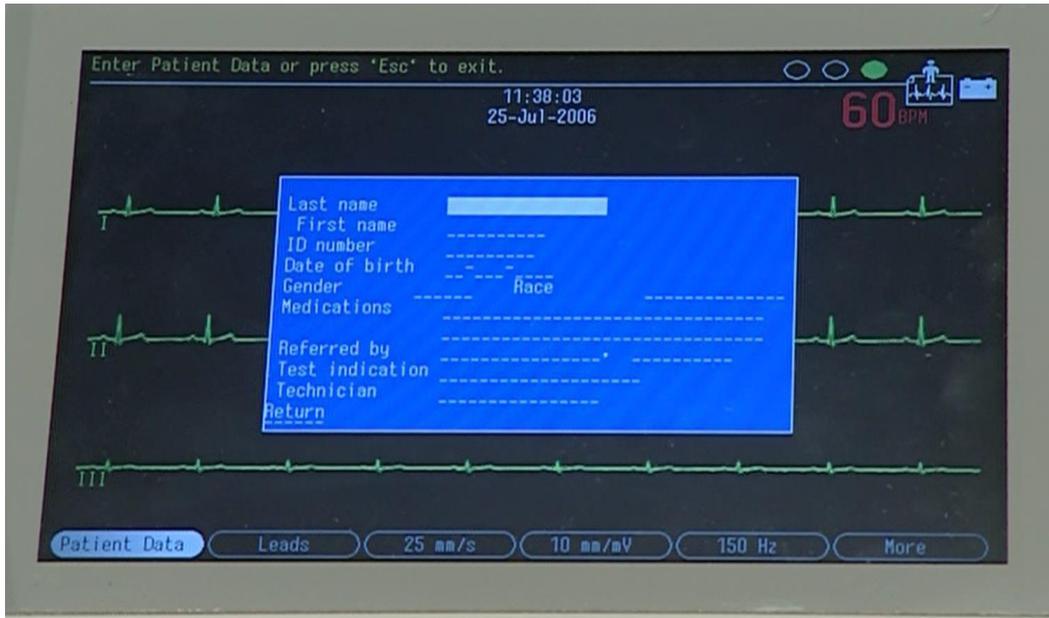
- Once the participant information is entered, check the display screen to verify ECG quality. The Hookup Advisor at the top right will not only indicate the quality of the displayed ECG signal, but will also give clear indications of the nature of the problem (**Figure 10**).

Figure 10
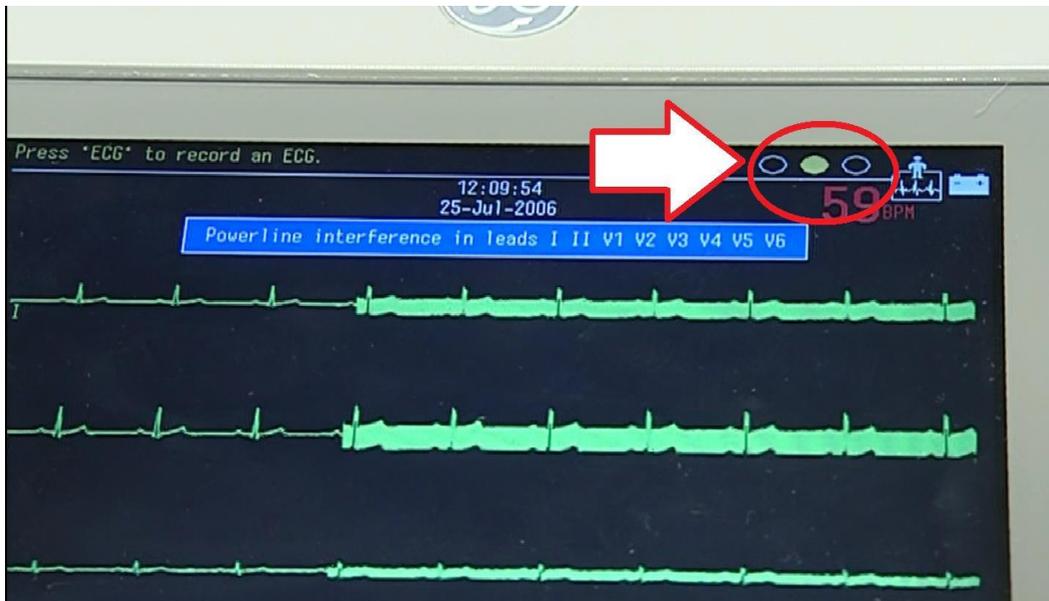
- Press the "ECG" key to print an ECG if you are satisfied with the quality (**Figure 11**).
- No need to print a "Rhythm strip", but if needed, you can press Rhythm Key then press stop once done (**Figure 11**)

Figure 11

Table 2 Participant data entry

Category Listed on MAC 3500	Entry to Machine by ECG Technician
Last name	Do not enter the participant's last name. Enter JHS.
First name	Enter JHS exam visit number (04)
ID number	Enter the ID number given by the JHS (Jxxxxxx)
Visit	04
Date of birth	Enter 01 and participant's month and year of birth (01-mon-yyyy)
Gender	M or F
Technician ID	Staff ID#
Secondary ID	Enter same as ID number (Jxxxxxx)

2.2. Local ECG reading

Because there are no available diagnostic statements from the CERC except as monthly measurement reports to the Coordinating Center and because the diagnostic statements printed on the ECG machine are not always correct, local reading/screening of the ECGs to detect alert findings during the exam is essential for safety purposes.

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

- Ventricular tachycardia (**Figure 12**)
- Idioventricular rhythm
- Acute MI (**Figure 13**)
- Complete heart block (**Figure 14**)
- Mobitz Type II AV block
- Sustained SVT (including multifocal atrial tachycardia and paroxysmal atrial tachycardia)
- Atrial fibrillation/flutter with HR > 100 bpm or < 50 bpm or new onset (**Figure 15** and **Figure 16**)
- Sinus bradycardia ≤ 44 bpm
- Sinus tachycardia ≥ 140 bpm
- ST changes consistent with ischemia

These "ALERT" ECGs should be further reviewed by the clinic physician for confirmation and possible cardiology referral. 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 above list.

Figure 12. Ventricular tachycardia

Diagnosis key points: Wide complex tachycardia (HR≥110) with QRS not preceded by P wave. The participant will be mostly restless
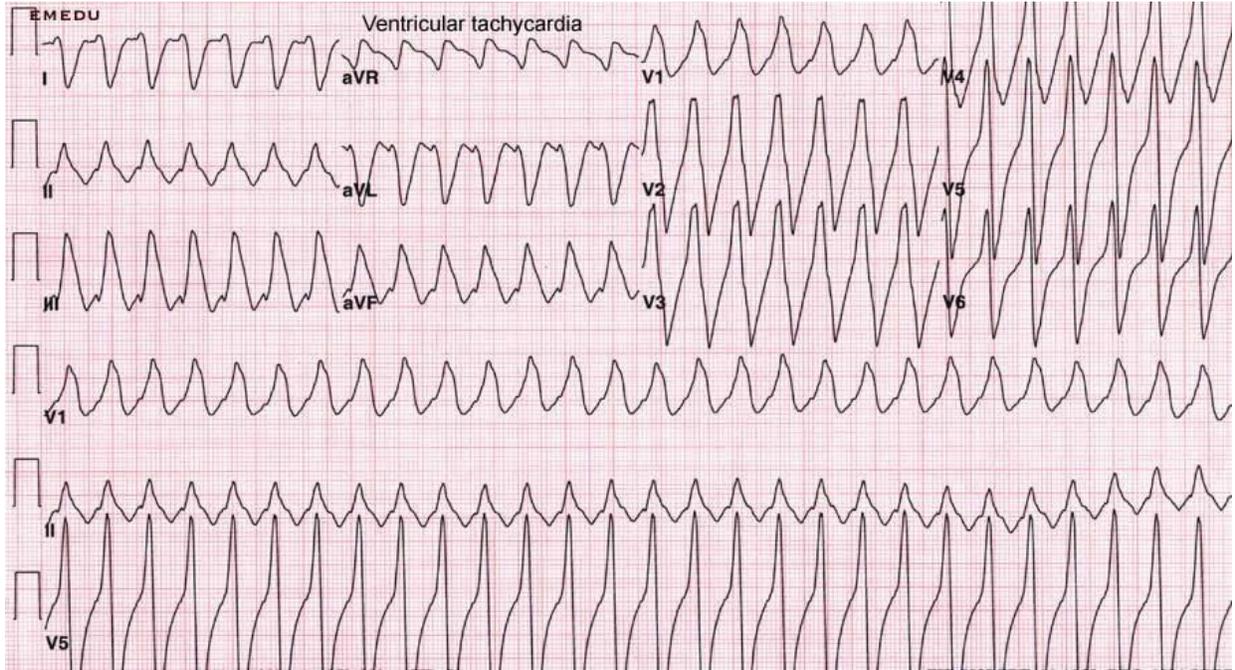
Figure 13. Acute inferior (upper panel) and acute anterior (lower panel) myocardial infarction

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
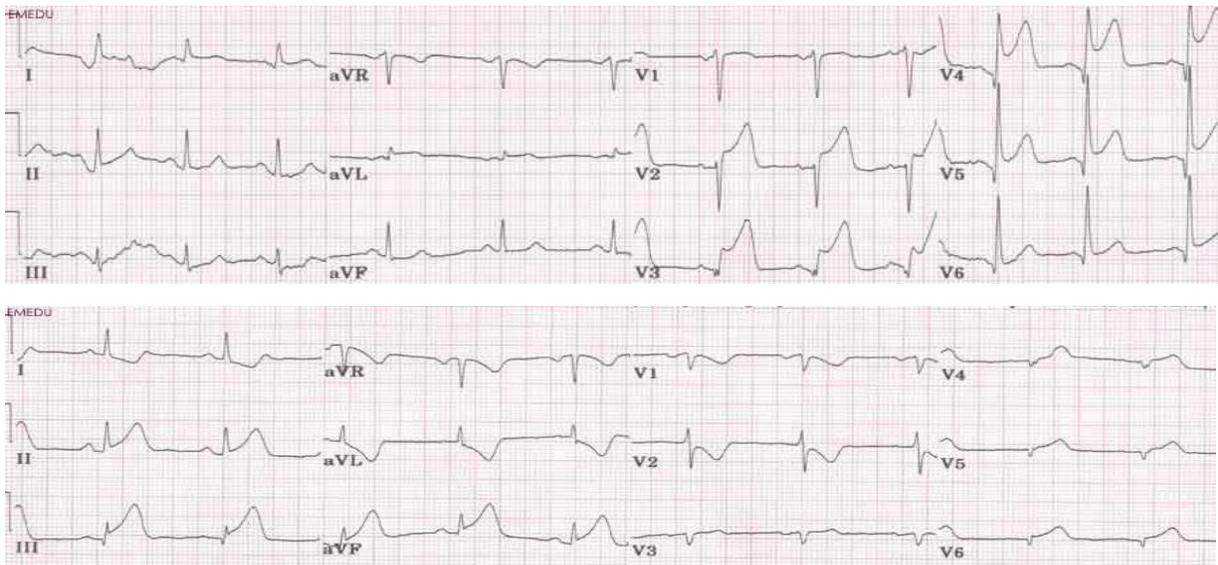
Figure 14. Third degree atrioventricular block.

Diagnosis key points: Slow heart rate (around 40 beats per minute) with no relation between the P wave and the QRS
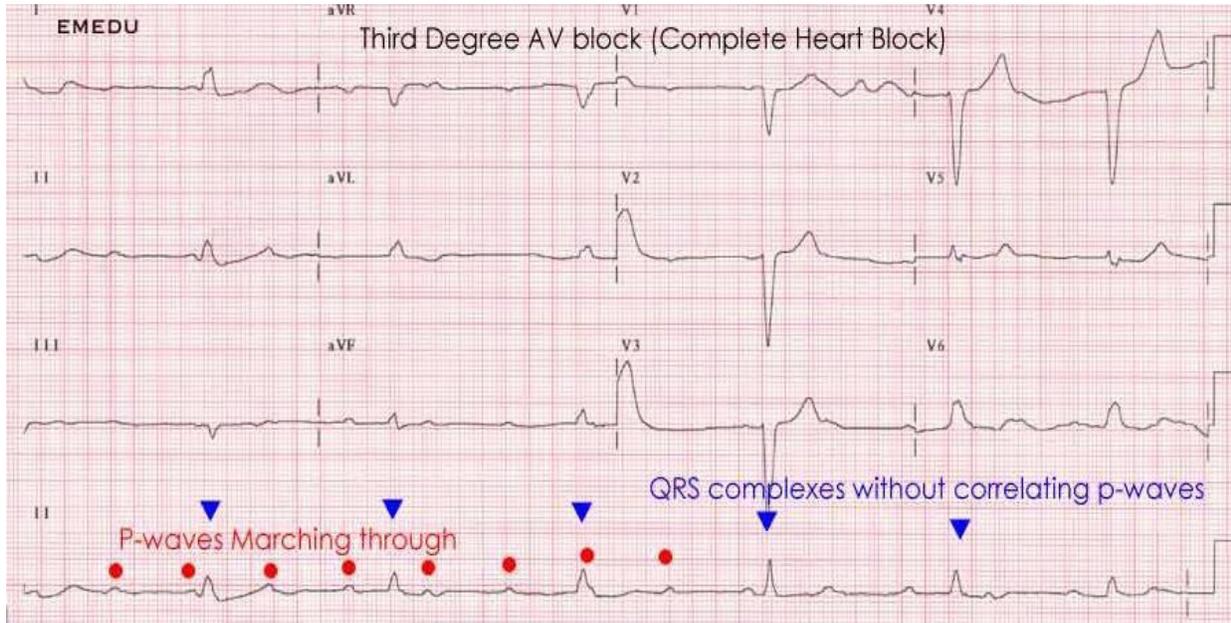
Figure 15. Atrial fibrillation

Diagnosis key points: irregular QRS complexes (heart rate) and absence of the P wave
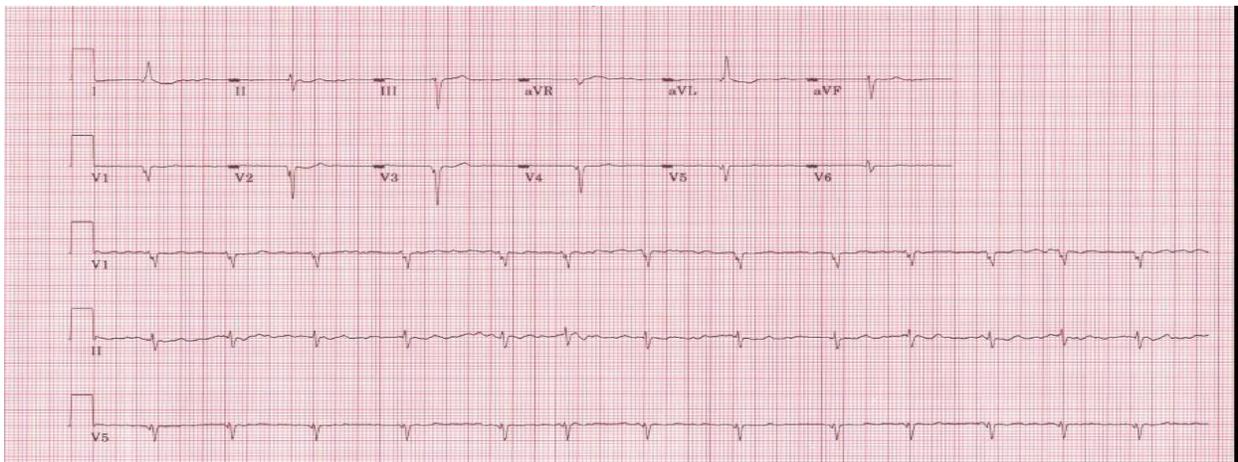
Figure 16. Atrial flutter

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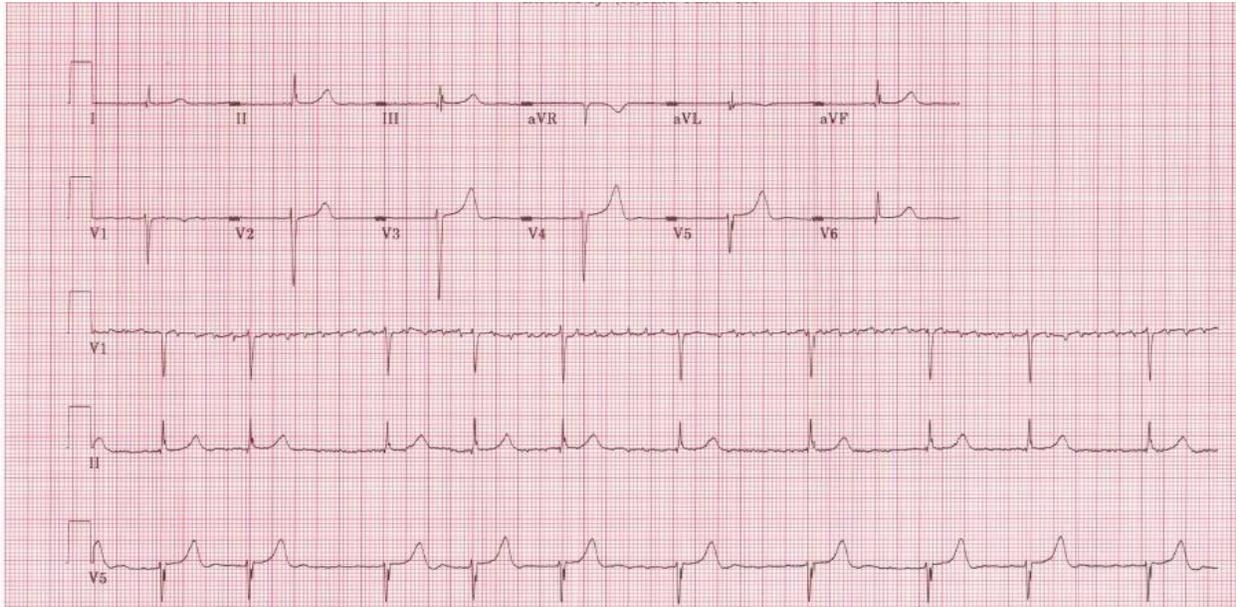
2.3. ECG Data management

2.3.1. Transmitting ECGs using a SD card

The MAC 3500 has the capability of storing the ECG digital data on SD cards **(Figure 17)**. The collected ECG data will be stored on the SD card as binary files to be sent to the ECG reading center via internet (email or FTP server). The binary digital ECG data cannot be opened except with the GE propriety software.

Figure 17

2.3.2. Machine set up for SD card ECG auto-save

To enable the use of the SD card, the machine must be set-up for auto save on the SD card as follows (**Appendix C**)

- Go to Main Menu > System Setup (default password is system).
- Go to Basic System > Miscellaneous Setup.
- Scroll down to the SD Card Storage Only field and press the Enter key.
- Scroll to Yes and press the Enter key.
- Scroll down to Return and press the Enter key.
- Scroll up to Return and press the Enter key.
- Go to Save Setup > To System.
- From File Manager select ECG records to transmit, print, edit or delete (**Figure 18**).

Figure 18
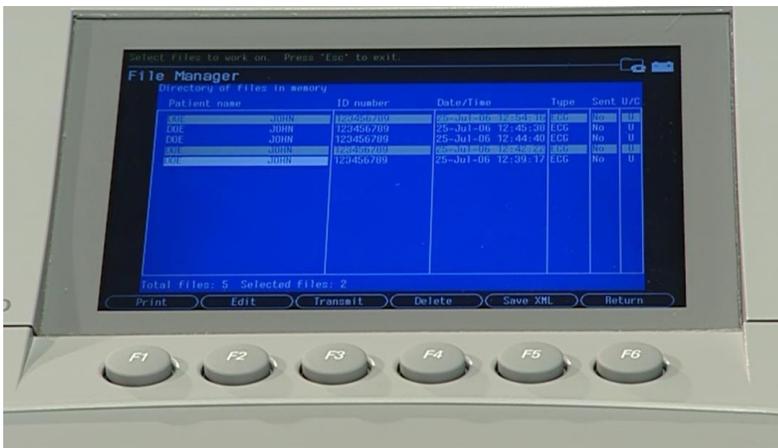
2.3.3. Data from the SD Card to the ECG Reading Center

- Remove the SD card from the ECG machine
- Place SD card into SD card reader and plug reader into USB slot on your computer
- Open FileZilla to the JHS FTP site
- Navigate to the SD card ECG directory using FileZilla Local Site

- Select All ECG files in folder ECG
- Drag to the FTP Remote Site within FileZilla
- Examine the FileZilla bottom tabs to verify Successful Transfers

2.3.4. SD CARD Data management

- Create a new folder with today's date in the SD Card and move the ECGs into it as follows:
- Open window explorer, and click on the Removable Disk (E:) under Computer
- Click on New folder on menu bar and rename it to today's date using format *mmddyyyy* (Ex: 05152019)

- Select all ECGs in folder ECG and file meidir.lst and move (not copy) them in today's folder
- Make sure to delete all unwanted ECGs like those with flat lines, poor quality or duplicates before sending the ECGs to the reading center. Also, correct any errors in participant data entry like ID numbers.
- Delete transmitted ECGs ONLY after confirming that EPICARE has successfully received the ECGs.

3. QUALITY CONTROL ISSUES AND PROCEDURES

The quality control plan for the ECG acquisition in the JHS 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. Given the technical nature of the QC of processing the study ECGs at the level of ECG reading center, which may not fit the purpose of this Manual, a brief description was placed only as an Appendix (**Appendix D**).

3.1. QC of ECG recording at the clinic

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 the ECG machine 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 the study coordinators or by a previously certified ECG technicians and they will go through the standard certification process before being authorized to record ECGs for the study. ECG training materials (video on how to use the HeartSquare to standardize location of chest electrode, 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. QC grade reports will be sent to the JHS CC for review along with the monthly report of the ECG reading results.

3.1.1. Certification/recertification procedures

- All ECG technicians **must go through the certification** process before they are allowed to acquire study ECGs.
- Each technician must acquire and successfully transmit three (3) good quality ECGs.
- The 3 ECGs should be performed on 3 different volunteers or on 1 volunteer provided that there is at least 30 minutes between each ECG**.**
- Recertification process is the same as the certification process and will be requested if deterioration of quality is observed.
- The participant data entry should be done according to the instructions in **Table 3** after pressing the "pat info" key on the MAC 3500 keyboard.

Table 3. Entry into the MAC 3500 for certification of technicians ONLY

Category	Entry
Patient ID	Enter 99999
Last name	Enter technician's last name
First name	Enter technician's first name
Date of birth	Enter volunteer's birth date
Technician	Choose "Other" and select technician's last name

3.1.2. Quality grades

The ECG reading center evaluates and ranks the ECG quality through an automated system with visual confirmation of the results if needed. 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 quality grade 3 or 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 quality issues that will not significantly interfere with appropriate reading.

Grade 5 is given to the ECGs that have significant quality issues that interfere with accurate automatic reading. The alarming level of poor quality in studies similar to the JHS is $\geq 5\%$ of the ECGs with quality grade 5. A monthly quality report will be sent to the JHS CC along with the ECG data results.

3.1.3. Examples of common ECG quality problems and possible solutions

- Excessive baseline drift (**Figure 19**): 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 20**): 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 21**): 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 22**): 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 23**): 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 (**Figure 24, Figure 25, Figure 26**): 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 19. Excessive baseline drift due to sudden movement of the participant
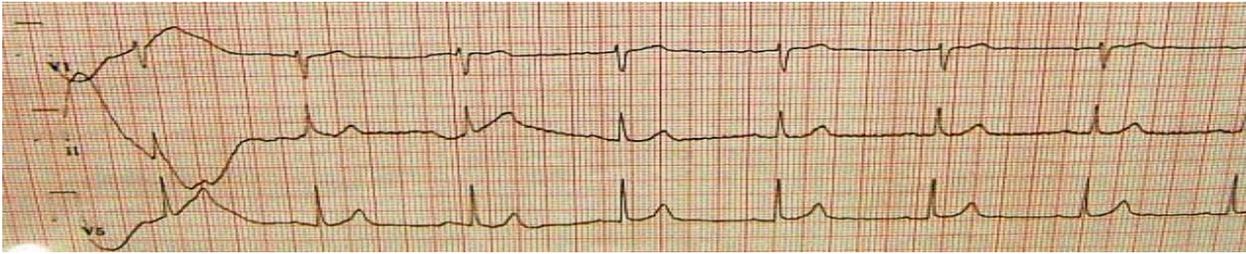
Figure 20. Excessive muscle noise
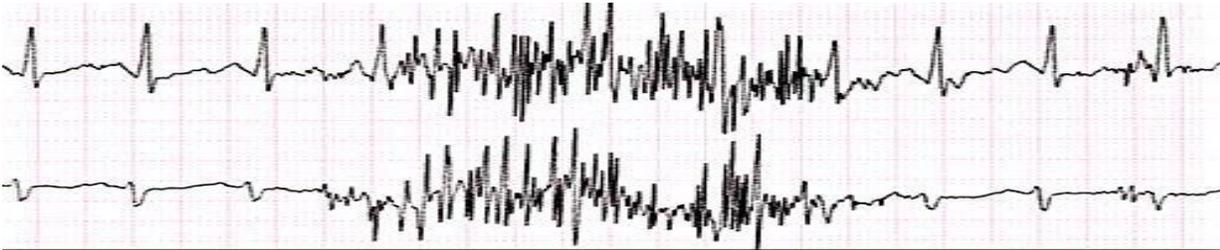
Figure 21. Baseline drift due to tangled wires
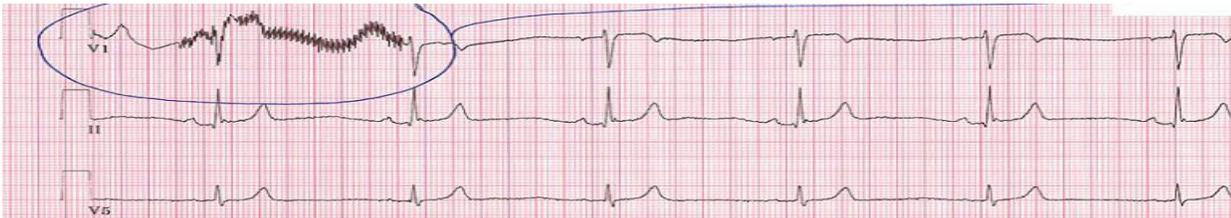
Figure 22. Wavy V1 baseline due to loose electrode
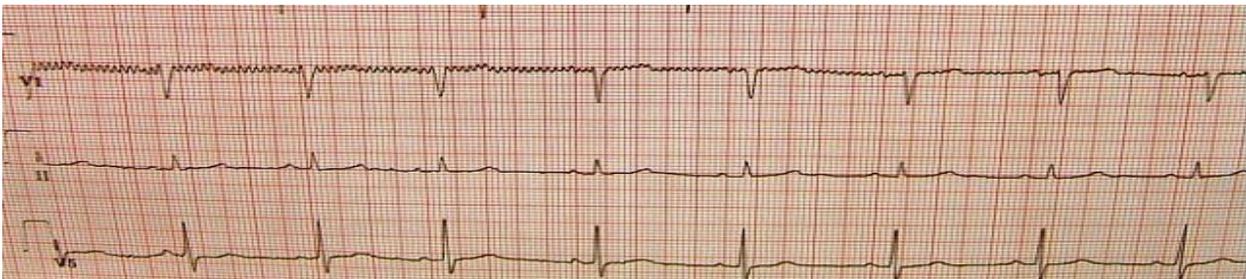
Figure 23. Sixty Hz electrical interference
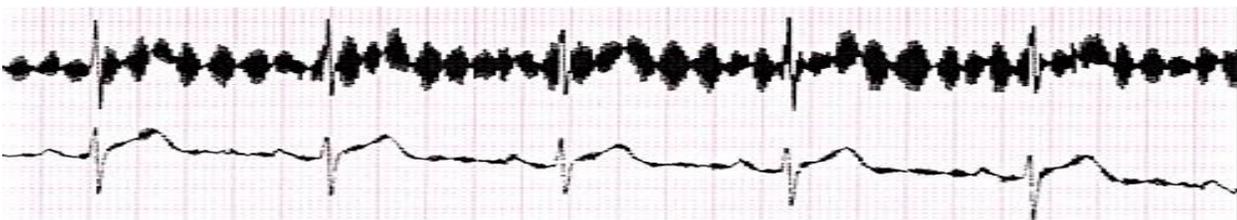
Figure 24. Flat line due to missing V1 lead
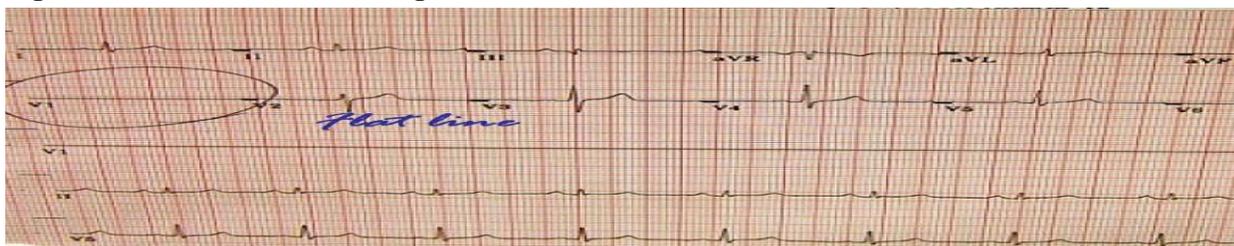
Figure 25. Lead reversal denoted by positive aVR (upper panel) compared to the normal (lower panel)
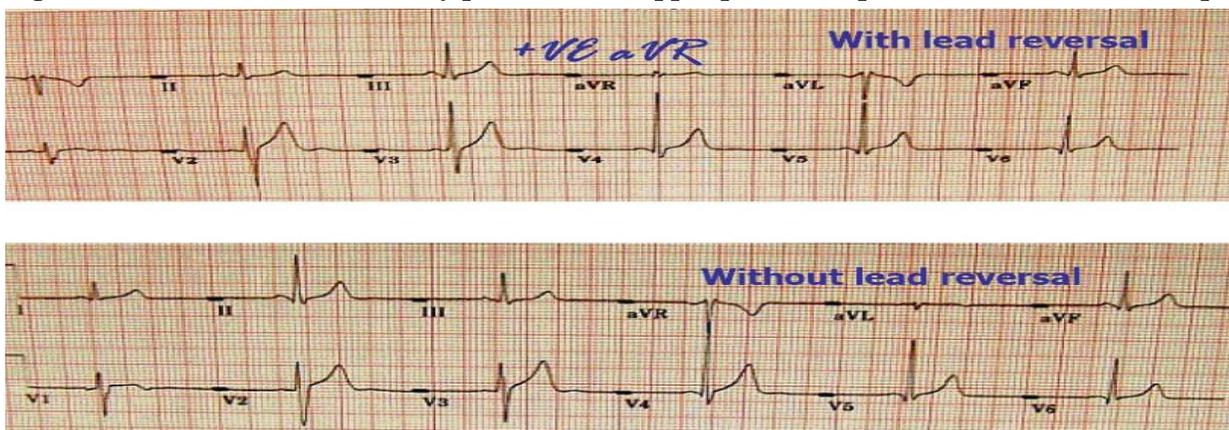
Figure 26. Lead reversal denoted by flat line in one of the limb leads (upper panel) compared to the normal (lower panel)
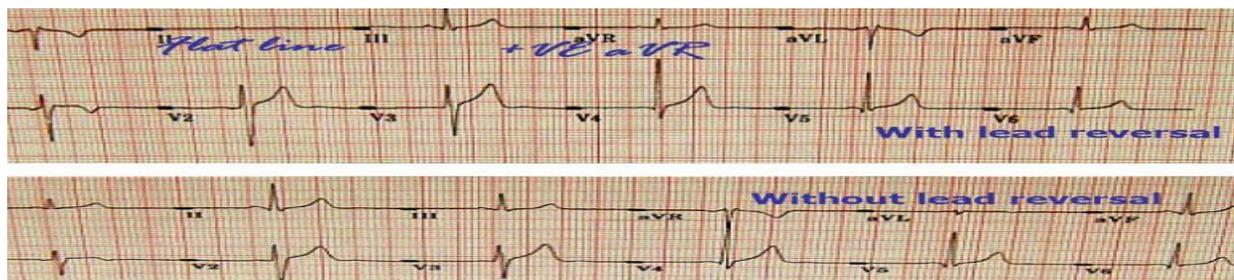
3.2.   Quality control of the ECG machine(s)

The JHS ECG machine(s) is covered by a manufacturer service/maintenance contract for 3 years. This will ensure that any equipment breakdown will be handled promptly. In addition, the ECG reading center "may" help with a loaner if the machine needs to go for repair.

Set up of ECG machine(s) for the need of the JHS is crucial to ensure that the ECG signals reach the Reading Center intact, standardized, and always go to their allocated directory at the center.

The software at the Reading Center regularly checks for changes in the machine settings and can detect most of the protocol breaches. Set-up of the machines is ONLY allowed to be done at the EPICARE or with assistance of one of the EPICARE staff or an authorized study personnel if it has to be done at the field. It may be necessary to re-program the machine after the start of the study if a malfunction occurs, or the battery has been allowed to become dead. The machine set-up and programming instruction are listed in **Appendix C**.

4. APPENDICES

Appendix A

The ECG reading center, EPICARE, contact list

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ELECTROCARDIOGRAM (ECG) FORM

ID NUMBER: J ☐☐☐☐☐☐

NAMECODE: ☐☐☐☐☐

VISIT: 0 4

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐ / ☐☐ / ☐☐☐☐

                           Month   Day   Year

0b. Staff ID: ☐☐☐

ECG

1. Time ECG performed: ☐☐ : ☐☐
                                    HH   MM

    1a. ☐$_1$ AM
           ☐$_2$ PM

2. Has it been 8 or more hours since you last ate and/or drank anything other than water, including candy and chewing gum?

Yes	☐$_1$
No	☐$_0$
Don't know	☐$_7$
Refused	☐$_8$
Missing	☐$_9$

3. ECG completed?

Yes ☐ 1 ──────▶ Go to Item 4

No ☐ 0

    a. Reason ECG incomplete or not done:

        ☐ 1   Hardware malfunction (contact EPICARE @ 336-716-0387)

        ☐ 2   Lack of supplies

        ☐ 3   Insufficient time available or room not available

        ☐ 4   Other

        b. Specify: _____

4. Electrode location measurements (approximated to the nearest 0.5")

    a. E measurement   ☐☐ . ☐   inches

    b. V6 measurement   ☐☐ . ☐   inches

5. Were any alert conditions noted on printout?

Yes ☐ 1

No ☐ 0 ──────▶ End of form

    a. Check all alert conditions that appeared on printout:

  ☐ 1 Ventricular tachycardia
  ☐ 1 Idioventricular rhythm
  ☐ 1 Acute MI
  ☐ 1 Complete heart block
  ☐ 1 Mobitz Type II AV block
  ☐ 1 Sustained SVT (including multifocal atrial tachycardia and paroxysmal atrial tachycardia)
  ☐ 1 Atrial fibrillation/flutter with HR > 100 bpm or < 50 bpm or new onset
  ☐ 1 Sinus bradycardia ≤ 44 bpm
  ☐ 1 Sinus tachycardia ≥ 140 bpm
  ☐ 1 ST changes consistent with ischemia

    b. Was alert condition confirmed by cardiologist on call?

        Yes ☐ 1

        No ☐ 0 ──────▶ End of form

c. What was recommended action by cardiologist on call?

Emergency department referral   1

Cardiology follow-up   2

Other   3

c1. Specify: _____

MAC 3500 SETUP FOR the JHS

In order to setup a MAC 3500 for the JHS, turn the ECG machine ON, select Main Menu.

Setting up to Store ECGs to SD card

1. Go to Main Menu > System Setup (default password is system).
2. Go to Basic System > Miscellaneous Setup.
3. Scroll down to the SD Card Storage Only field and press the Enter key.
4. Scroll to Yes and press the Enter key.
5. Scroll down to Return and press the Enter key.
6. Scroll up to Return and press the Enter key.
7. Go to Save Setup > To System.

Then select System Configuration for BASIC SETUP and RESTING ECG SETUP.

<u>**BASIC SETUP**</u>

Institution Block	
Name	enter JHS
Street	enter your JHS clinic number
City	enter city of your location
Technician	enter Yes
Site number	enter **170** This is the Site entry for all JHS study ECG machines
Cart number	1

Press Save to save your entries and leave the screen.

RESTING ECG SETTINGS

Gain	10
Speed	25
Line Filter	select
Enabled	
12 leads	4x3
Display format	12 leads: 4x3
Printer leads	12
Hookup Advisor	select
QTC calculation	Bazett
Sample Rate	500 Hz
Lead Sequence	Standard
Rhythm Leads	V1, II, V5, V2, V3, V4
10s ECG Report Format	4x 2.5 x3 R1
Report Copies	1
Auto Store ECG	select
File Manage-Sort by	Date

Press save to save entries and leave screen.

To continue with MAC 3500 SETUP FOR the JHS, select MORE

PARTICIPANT INFORMATION SETUP

Enabled	
Date of Birth	select
Required	
Patient ID	select
Secondary ID	select
Last Name	select
First Name	select
Enabled	
Patient ID Length	7
Sort by	Patient ID
Required	
Technician	select

Press save to save entries and leave screen.

USER SETUP

Select TECHNICIANS. Enter all ECGs technicians for your location.

Press save to save entries and leave screen.

Other Setup options should need no attention/changes. If you need help with any of these instructions, feel free to contact EPICARE for assistance.

Reading Center Technical Details

Data processing

All JHS scheduled ECGs (one per participant per scheduled visit) will be electronically transmitted to EPICARE. ECGs will be received via the GE- MUSE ECG management server. The digital ECGs are stored in an electronic database at the JHS EPICARE, in a Marquette measurement matrix, by participant ID. 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 and Novacode categories by the EPICARE ECG coding program. A diagram of the data flow is outlined in **Figure** below.

ECG Data Flow
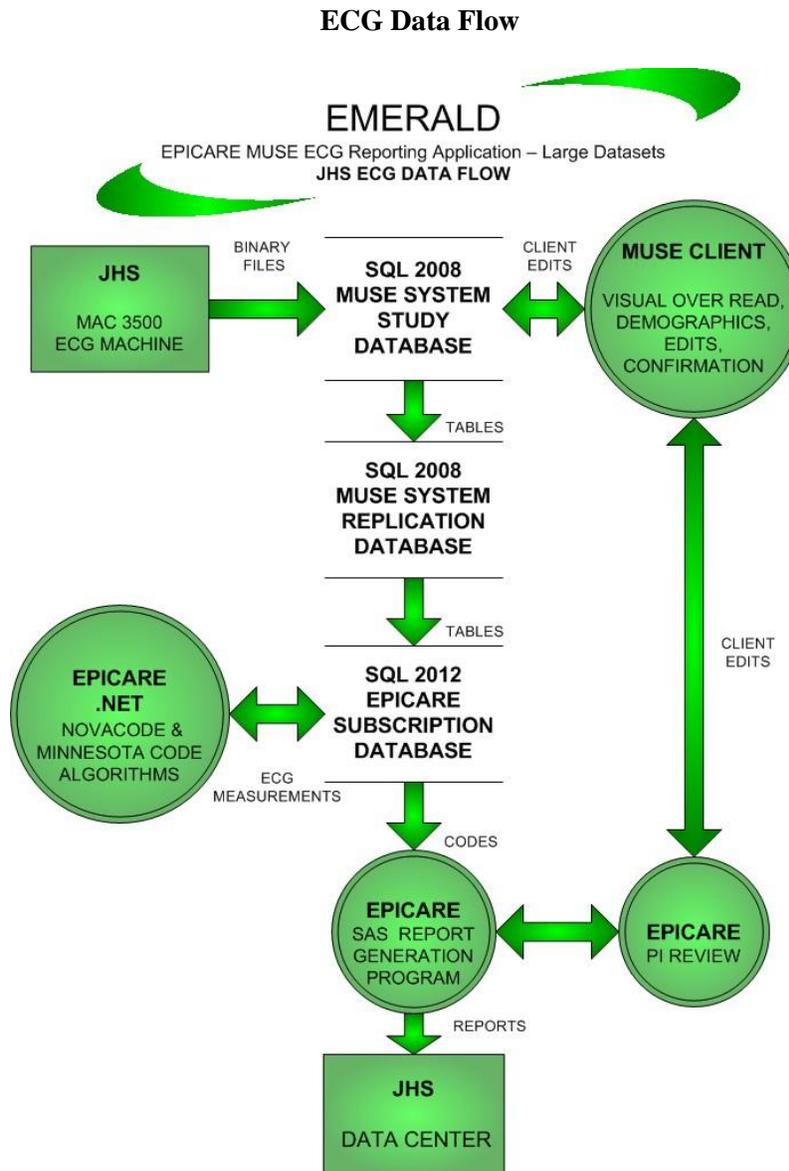
Data reporting

The format and route of data transfer will be determined by agreement between the Coordinating Center and the EPICARE Center. Monthly reports with the reading results will be sent from the EPICARE to the CC. All electronic ECGs will be processed and reported within 30 days from receipt. Note: Reporting results of the participants is not under the scope of the reading center and not discussed here. Instead, what is referred to here is the research reading results sharing with the CC.

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 JHS 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 JHS visits which is crucial to compare ECG findings, the field centers will use the same standardized ECG acquisition procedures similar to those implemented in other cohorts utilized digital ECG acquisition such as MESA, JHS, CHS, WHI, CARDIA, ARIC, HCHS-Sol, NHANES, and many others. Using the Minnesota ECG Code as the main method to classify abnormalities in the JHS study which was also used by studies that did not utilize digital ECG (paper ECG) will expand the comparison to these studies as well such as REGARDS, EDIC/DCCT and others.

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 some previous studies at its initial phases. Since these meticulous QC procedures may impact appropriate comparison of the ECG results in JHS with these studies, the ECG reading center keeps inventory of the studies that a better QC was applied and also a list of studies which underwent recent update for their QC and the center reprocessed their old ECGs aiming to improve quality.

Appendix E

Quick Reference Guide for the MAC 5

Log On to the Device

1. Enter the user name and password on the **Login** screen:
   The default username is **Admin**. The default password for the first login is **admin123**.
2. Reset the password to the default (**Transfer your data from the system before you start the procedure**):
   Press ↑ ↓ ← → ↑ ↓ ← → on the **Login** screen.
   Enter the serial number of the device in the **Enter the system serial number** field.
   Select **Restore**, then the device will reboot. You can access the device with the default username and password.

Acquisition Screen

Item	Name	Description
1	**Patient Information banner**	Displays Patient Information such as first name, last name, and gender.
2	Date and Time	Current local date and time in the configured date and time format.
3	**Orders/Patients, Files,** and **Queue** tabs	Select the appropriate tab to open the Orders list, files, or queue.
4	Brightness icon	Allows you to adjust the screen brightness.
5	Battery or AC Power icon	Shows the battery status. .
6	Network Status icon	Shows the wireless or LAN connection status.
7	User Menu	Displays the name of the user logged into the device.
8	**New Patient** icon	Select to enter patient data for a new patient test.
9	**Expand** icon	Expands the list of the Orders/Patient, Files, or Queue tabs.
10	Electrode Placement Image	Select the arrow to expand and view the image.
11	Notification Area	Displays the printing status, report transmission status, and **Hookup Advisor** lead quality status.
12	**Hookup Advisor** Lead Quality Status Indicator	Displays the overall lead quality status.
13	Filter, Speed and Gain	Displays the default waveform filter, speed, and gain.
14	**Start Rhythm** icon	Allows you to print or digitally record a rhythm report.
15	**Start ECG** icon	Allows you to start recording an ECG.
16	Lead Set and Display Format	Displays the default test type and display format.
17	**Restart** icon	Allows you to restart the Full Disclosure ECG.
18	**FD Report** icon	Allows you to generate the Full Disclosure report.
19	**Preview ECG** icon	Allows you to preview the recorded 10 seconds of ECG data.
20	**Select Lead** icon	Allows you to select the leads you want to display on the screen and the FD report.

21	**Full Disclosure** tab	Displays full disclosure ECG.
22	Home tab	Displays the live waveform for the current patient connected to the device.

Start a New Patient

1. Select **New Patient** on the acquisition screen.
2. Prepare and connect the leadwires to the patient.
3. Enter patient information on the **Patient Information** screen using any of these options:
   - Scan the patient's barcode
   - Perform order or ADT query
   - Attach a patient record from the **Patients** list
   - Attach an order from the **Orders** list
   - Use the device keyboard to manually enter the patient information.
4. Select **Save** to save the patient information.
5. Verify that the Hookup Advisor status is green and review the waveform.
6. Select **Start ECG** to record an ECG or **Start Rhythm** to record a rhythm.
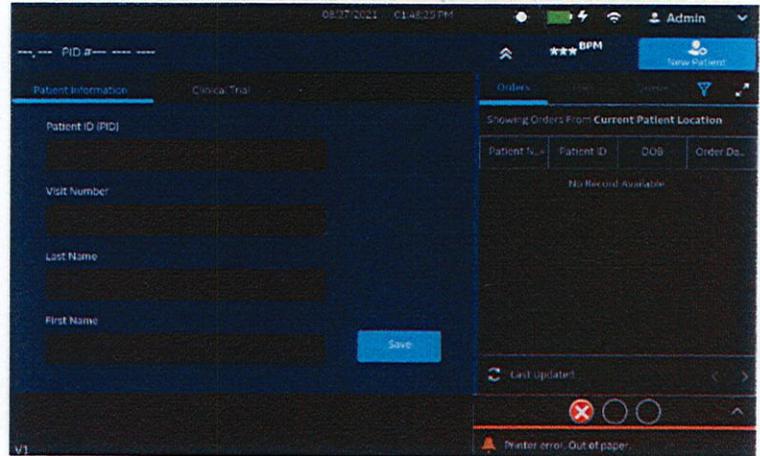
Record a Rhythm

1. Select **Start Rhythm** on the acquisition screen. If the rhythm mode is:
   - **Paper Only**, the rhythm is printed. Select **Stop Rhythm** at any time to stop printing the rhythm strip.
   - **Digital Only**, the rhythm is digitally recorded for a configured duration and saved in the **Files** list. The rhythm does not print. Select **Stop Rhythm** at any time to stop recording. The saved rhythm report displays in the **Rhythm** tab.
   - **Both**, the rhythm digitally records and prints for a configured duration and saves in the **Files** list. Select **Stop Rhythm** at any time to stop recording and printing the rhythm strip. The saved rhythm report displays in the **Rhythm** tab.
2. Review the rhythm report.
   To continue with the same patient, go to the **Home** tab and continue to record the ECG.
   To start a new patient, select **Done** or **New Patient** on the screen.
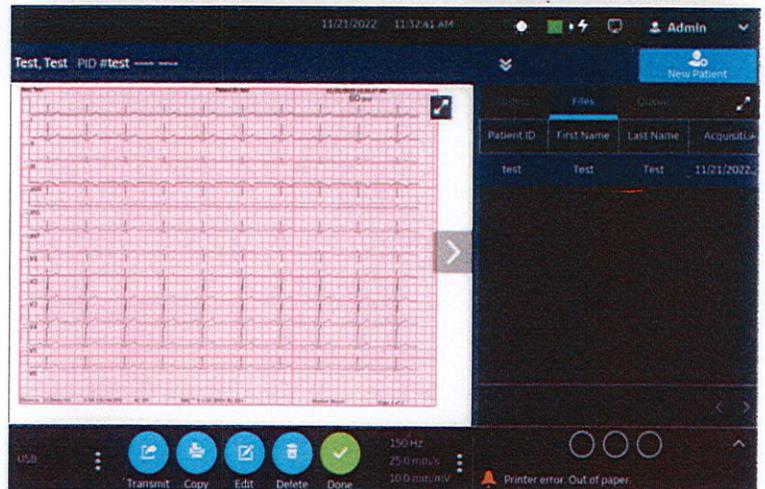
Record an ECG

1. Select **Start ECG** on the acquisition screen.
   - The patient report preview displays in the **ECG** tab if you enable Print Preview. Select **Accept** to accept the ECG and save the patient report in the **Files** list. Select **Reject** to return to the live waveform display.
   - The patient report displays in the **ECG** tab and saves to the **Files** list if you disable print preview.
   The patient report automatically prints in the report format configured on your device.
2. Review the ECG patient report.
   To continue with the same patient, go to the **Home** tab and continue to record the ECG.
   To start a new patient, select **Done** or **New Patient** on the screen.
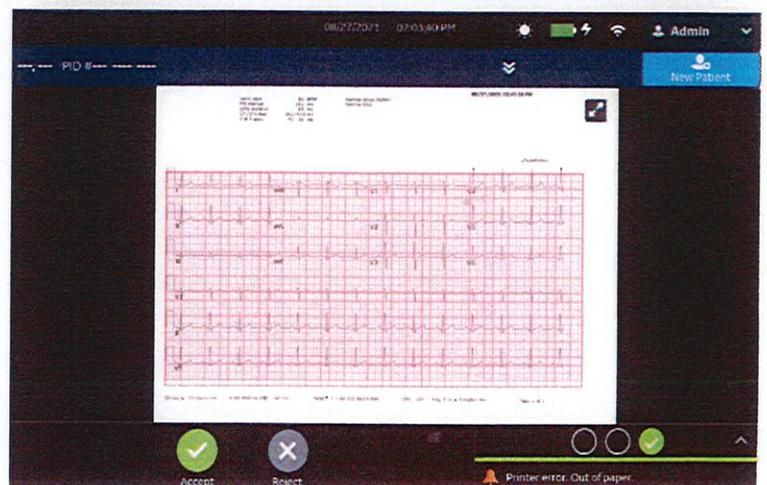
Record a Full Disclosure ECG

The Full Disclosure ECG option shows one lead of the patient waveform for a maximum of 5 minutes.

1. Enable the **Full Disclosure** option in the **Settings** screen.
2. The device automatically records the full disclosure ECG when you start a new patient test. It runs in the background.
3. Select the **FD** tab on the Acquisition screen to view the Full Disclosure ECG.
4. Select the **Preview ECG** tab on the Acquisition screen to preview the recorded 10 seconds of ECG data.
5. Select the **FD Report** tab to generate the full disclosure ECG report.
   To continue with the same patient, go to the **FD** tab and continue to record the full disclosure ECG.
   To start a new patient, select **Done** or **New Patient** on the screen.
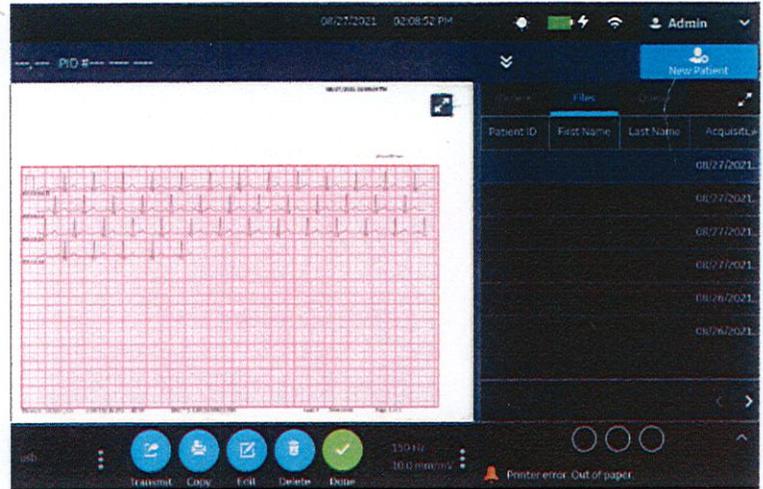
Review Patient Reports

1. From the Acquisition screen, select the **Files** tab.
2. In the **Files** list, select a patient report. The patient report displays in the **ECG** or **Rhythm** tab.
3. Review the patient report and perform any of these tasks:
   - To transmit the report, select a destination from the **Destination** menu and select **Transmit**.
   - To print a copy of the report in the displayed format, select **Copy**.
   - To edit patient information, select **Edit**, or select anywhere in the **Patient Information** banner.
   - To delete the report, select **Delete**.
   - To close the report, select **Close**.
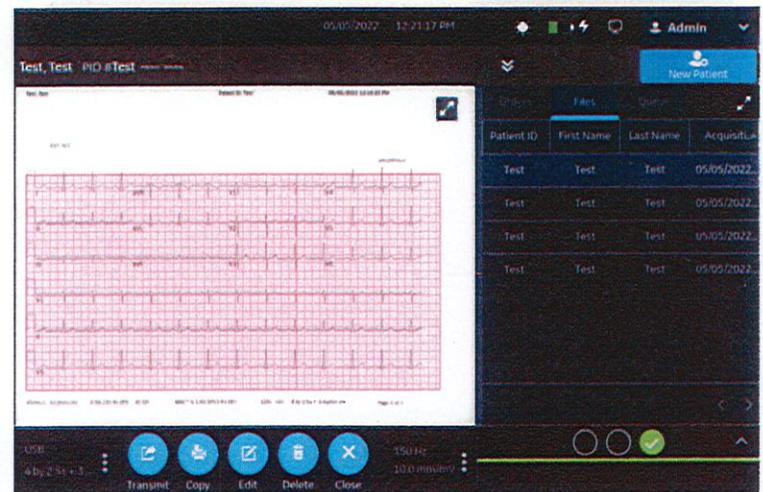
Query Orders or ADT Data

Make sure that you configure remote patient query and you have the required privileges to query patient demographics.

1. Start a new patient test.
2. Scan the patient's barcode, or enter the **Patient ID** or **Visit Number** on the **Patient Information** screen. Press the **Search Icon** to initiate the query.
   - If multiple orders for one patient are found, they are listed in the **Orders** list. Double-tap an order to attach.
   - If one matching order is found, it populates the **Patient Information** screen.
   - If no orders are found, the system will query for ADT.
   - If an ADT record is found, it populates the **Patient Information** screen.
   - If no matching order or ADT information is found, the data scanned or entered is used to populate the **Patient Information** screen.
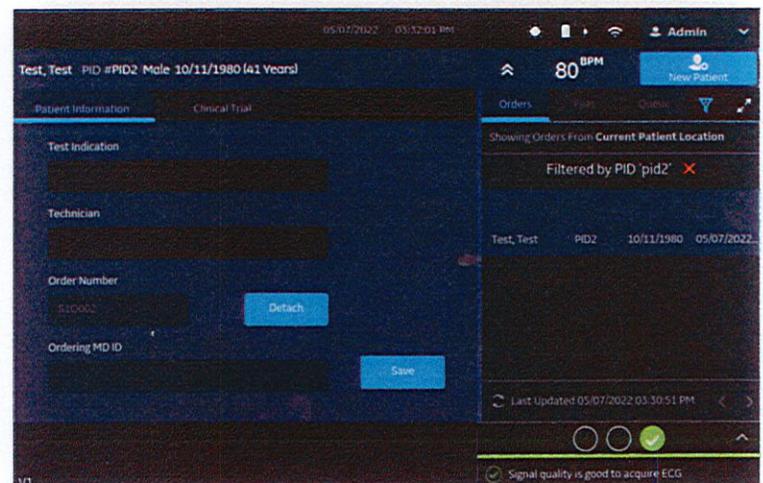
Attach an Order to a New Patient Test

1. Double-tap the correct patient order found from the patient query to attach it to the patient test.
   Data from the order is populated in the **Patient Information** screen and the screen expands. Some populated fields are read-only.
2. Edit the remaining fields and save the patient information.
3. In the **Orders** list, verify that the order status is **Attached**.
4. Record the ECG.
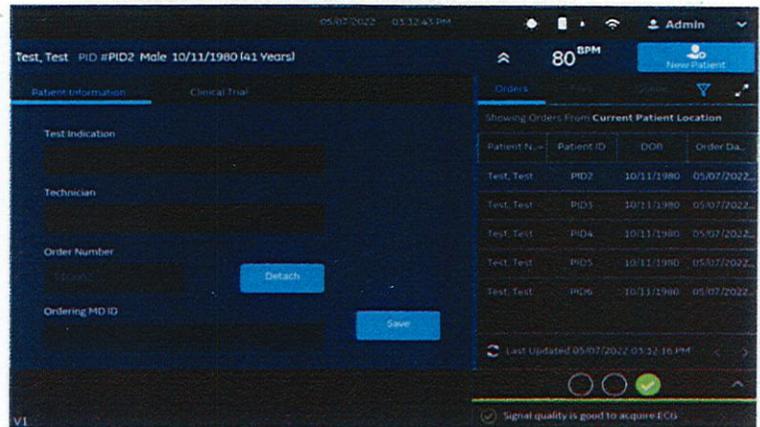
Related Manuals

Part Number	Document Title	Description
5864335-001	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Operator's Manual	Reference manual for details of how to use features of the device and software.
5864335-002	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Service Manual	Information for servicing of the device, updating the software, overview of the device hardware, FRU parts, and part numbers.
5864335-003	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Privacy and Security Manual	Required privacy and security information.
5864335-004	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System XML Technical Reference Manual	Reference manual for usage of xml fields.
5864335-006	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Quick Setup Guide	Guide for quick setup of the device.
2102946-001	Supplies and Accessories Guide Diagnostic Cardiology	All required supplies and accessories information.
2056246-007	Marquette™ 12SL™ ECG Analysis Program	Reference manual for the Marquette™ 12SL™ Program
NA - Refer to OEM Manual	Compact Trolley Instruction	Reference manual for the compact trolley.

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