

Electrocardiography Assessment Manual

**The Glycemia Reduction Approaches in Diabetes: A
Comparative Effectiveness Study (GRADE Study)**

The GRADE Central ECG Reading Center
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I. INTRODUCTION

The Epidemiological Cardiology Research Center (EPICARE) is the GRADE Central ECG Reading Center (ECG Reading Center). It is located at Wake Forest School of Medicine, Winston Salem, NC.

II. BACKGROUND AND PURPOSE

A total of about 16,667 electrocardiograms (ECGs) will be recorded during the baseline and follow up visits of the Glycemia Reduction Approaches in Diabetes (GRADE). The ECG recording will serve to establish the distribution of cardiac disease findings at the study baseline and detect the development of new findings during follow up. In this regard, the ECG Reading Center will provide a standardized ECG reading using the Minnesota ECG Classification (Minnesota Code) for establishing myocardial infarction, myocardial ischemia, cardiac chamber enlargement including left ventricular hypertrophy, arrhythmias and conduction defects as well as subclinical ECG findings that are determined to be associated with a poor prognosis including measures of heart rate variability. The standard methods of ECG acquisition and reading/coding in GRADE will be similar to the methods currently used in other major diabetes- related studies such as DPPOS, ACCORD/ACCORDION and LookAHEAD.

III. FIELD CENTER PROCEDURES

The field center procedures include: **1)** ECG acquisition (section III.1), **2)** Local ECG screening/reading for certain alerts as a safety procedure during the study visit; and **3)** Filing a short form documenting the process of ECG recording. (**Appendix A**)

III.1. ECG ACQUISITION PROCEDURES

At each time point or when indicated, 3 sequential 12-lead ECGs will be recorded using standardized methods then transmitted to the Grade ECG Reading Center (EPICARE) on a regular basis (twice weekly is recommended). Multiple ECGs may be transmitted to the ECG Reading Center at the same time.

III.1.1 Electrocardiograph

The electrocardiograph to be used for ECG recording and transmission in the GRADE 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 GRADE 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 GRADE study and should be used ONLY for GRADE study ECGs.
- Appendix B includes the instructional charts that outline the setup for the GRADE MAC 1200 ECG machines.
- All GRADE ECG technicians should become familiar with the GE MAC 1200

III.1.2. Supplies

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

Table 1

- GE MAC1200 Electrocardiograph
- HeartSquare
- Telephone jack cable
- Scissors
- Felt tip non-toxic washable markers
- The ECG Reading Center contact list
- Reference guides for "Participant Data Entry" (**Table 2**)
- Reference guide for " ECG Transmission" (**Appendix C**)
- GE MAC1200 operation manual
- ECG paper
- Disposable silver chloride electrodes
- Alcohol swabs and gauze pads
- Cotton surgical tape
- Examining table disposable paper

Contact the ECG Reading Center to order more ECG tracing paper and electrodes.

Note that the ECG Reading Center does not provide supplies for removing chest hair (e.g. razors). Sites may choose to obtain these supplies, as needed and permitted, from their local institution.

III.1.3 Preparation for ECG recording

- Participant should be relaxed and comfortable in supine or semi-recumbent position.
- Examination table/bed should be adequate to comfortably accommodate the participant.
- If participant is uncomfortable or unable to move to the bed or lie in supine or semi-recumbent position due to a medical need (e.g. wheelchair bound, heart failure etc.), the ECG can be done in semi-sitting position.
- 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, if possible
- Reference guide for "Participant Data Entry" instructions should be available to ensure accuracy.
- Supplies needed for ECG acquisition should be assembled and arranged efficiently.

III.1.4 Location of the ECG electrodes

III.1.4.1 Location of limb electrodes (Figure 1)

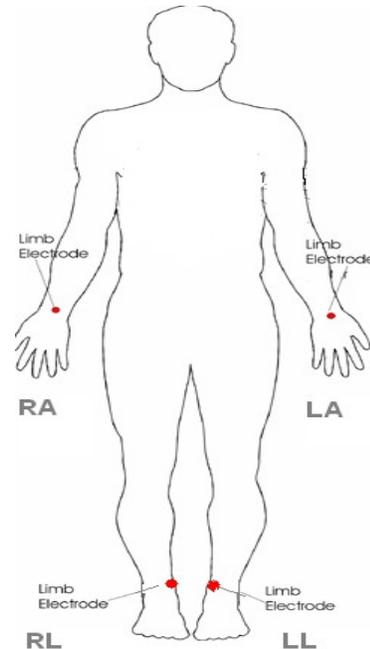
RIGHT LEG (RL) and LEFT LEG (LL):

- 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 1



III.1.4.2 Location of chest electrodes

V1 and V2:

- First, locate the sternal notch. About the width of your 3 middle fingers below the sternal notch, you will feel a slightly raised, bony area. This is the sternal angle. (**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 (**Figure 2** and **Figure 3**).

FIGURE 2

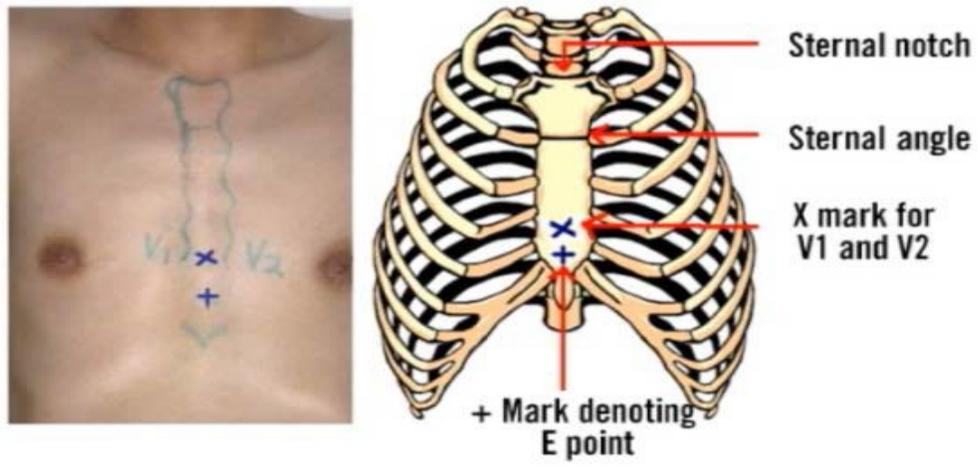
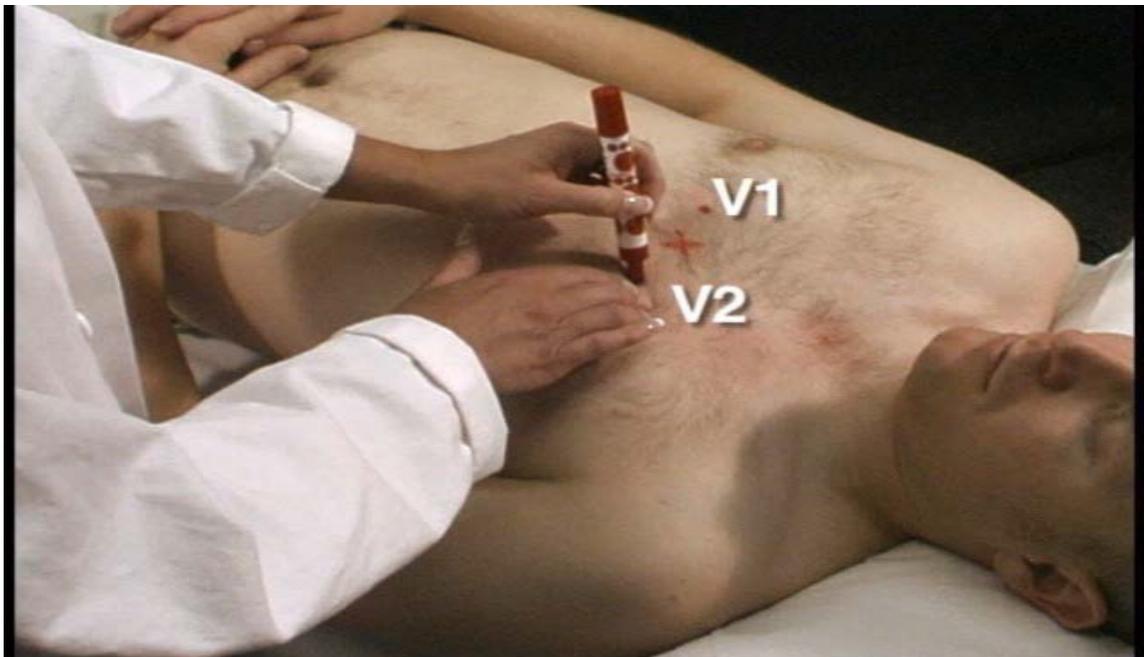


FIGURE 3



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 - **Figure 5**) 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 6**).

FIGURE 5



FIGURE 6



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 7**).
- Slide the V6 arm of the HeartSquare towards the midaxillary line until the arrow points to an exact place on the midaxillary line. Mark this point. It is the exact location of V6.

FIGURE 7
E point

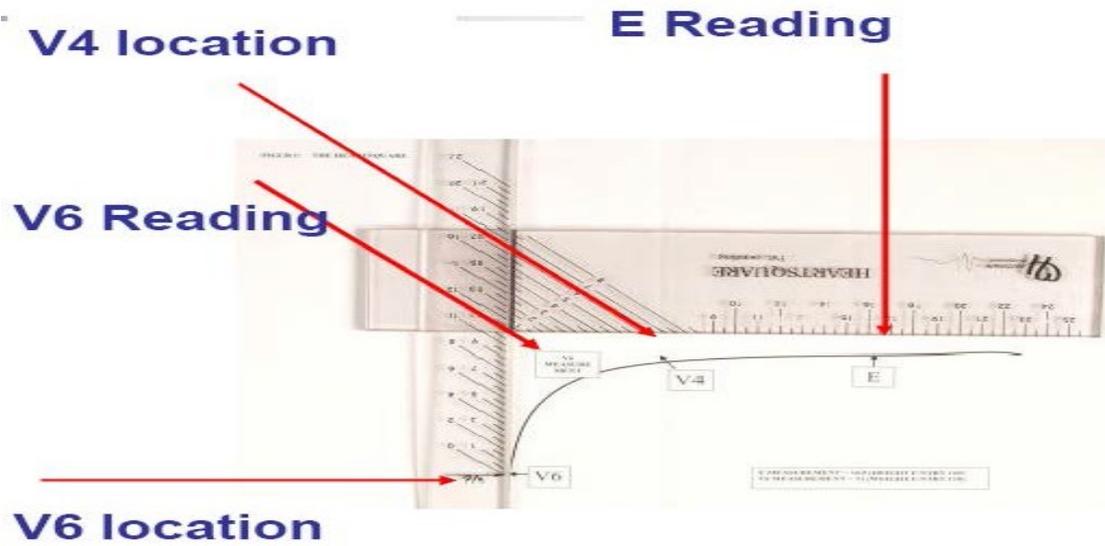


Exact V6 location

EXACT LOCATION OF V4

- While keeping the HeartSquare in the horizontal position with the arrow on the V6 arm pointing toward the exact V6 position, observe the reading at E point. (**Figure 7**)
- Find this E point reading on the V6 arm of the HeartSquare, 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.
- Enter the E and V6 measurements as three digits. **Figure 9** 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**).
- If the HeartSquare is too small for participant, enter 0 as the E and V6 measurements.

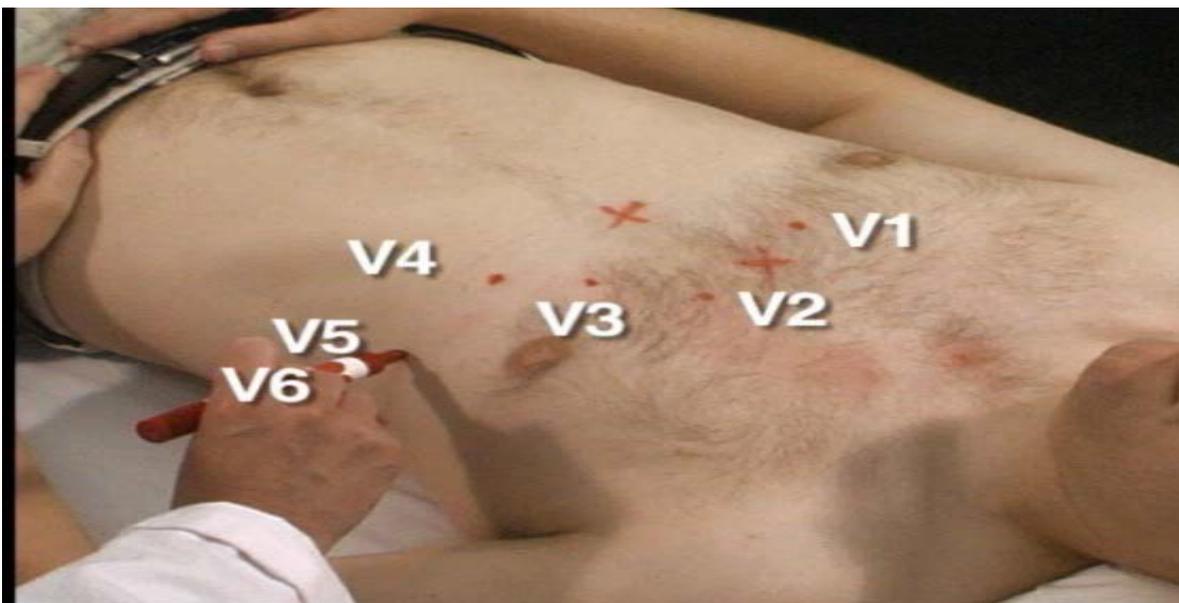
FIGURE 9



LOCATIONS OF V3 and V5

- Mark V3 exactly halfway between V2 and V4 (Figure 10).
- Mark V5 exactly halfway between V4 and V6 (Figure 10).

FIGURE 10



III.1.4.3 **Attaching the electrodes:**

- After you have marked electrodes positions and rubbed them with alcohol swabs, you may apply the electrodes.
- Lower limb electrodes should be facing up, while upper limb electrodes could be facing up or down
- Attach lead wires in the same, correct order every time to establish routine and to eliminate lead swaps.
- Position the MULTI-LINK (the junction at which all cables going to the chest and limbs are connected) 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 silver tab only 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.

III.1.5. **ECG recording**

- Turn on the MAC1200.
- Allow the machine to go through the “self-test.” Do NOT press “R.”
- Press “Pat info” key to enter the participant information
- Use the participant data entry sheet as a reference guide (**Table 2**).
- Press the START/STOP key to return to the ECG screen (you will see the waveforms)
- Press the START/STOP key to begin acquisition of the 1st ECG.
- Once the machine has collected, analyzed, printed and saved the 1st ECG, wait until the waveforms are again moving across the screen. Repeat this process for the 2nd and 3rd ECGs for each participant, making sure that the waveforms are again moving across the screen before turning off the machine. This insures all 3 ECGs are saved to the directory.

Table 2: Participant Data Entry into the MAC1200 for the GRADE Study

<u>Category</u> <i>[What shows on MAC1200 screen]</i>	<u>Entry</u> <i>[What you enter]</i>
NEW PATIENT	YES
LAST NAME*	Enter the 4 digit GCode per ECG form
FIRST NAME*	Enter the 2 digit Visit Number (00, 24, 48, or 72)
DATE OF BIRTH**	01/01/YYYY
PARTICIPANT ID	Enter 7 digit ID assigned by the study [Pat ids are 7 digits. The first 3 digits is the site number where the patid was created and the last 4 is a sequential number assigned to the patid (going from 0001 to 9999
SECONDARY ID	Same as Participant ID

PACEMAKER	NO [YES IF PACEMAKER]
GENDER	M OR F
HEIGHT (Do NOT Enter Height)	E Measurement of HeartSquare (e.g., if E=16.0, enter 160)
WEIGHT (Do NOT Enter Weight)	V6 Measurement of HeartSquare (e.g., if V6=12.0, enter 120)
RACE	Use Other and enter defined race codes
REFERRING PHYSICIAN	No action required
TECHNICIAN	highlight "Other", select technician
LOCATION	No action required

* Do not enter participant's name

** Do not enter participant's full date of birth. Enter 01/01 for month and day and enter the participant's actual birth year (01/01/YYYY)

III.2. LOCAL ECG READING (ALERT ECGs)

Rationale

Because there are no available diagnostic statements from the ECG Reading Center except as monthly reading report to the GRADE Coordinating Center, the local clinic screening for certain ECG conditions (i.e. reading the diagnostic statements on the printout of the ECG) is essential for safety of the participants during the study visits. This process is designed primarily to identify ECG abnormalities defined as "alerts" because of their potential importance in terms of the need for urgent action or notification. There are no specific directions to follow regarding management of these alerts; it is up to the judgment of the reviewing clinician.

Alert ECGs

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

- a) Heart rate below 40 or over 120 beats/minutes
- b) Atrial fibrillation (**Figure 11**) or atrial flutter (**Figure 12**) not known by the participant
- c) Ventricular tachycardia (**Figure 13**)
- d) Acute myocardial infarction (**Figure 14**)
- e) Ventricular preexcitation/Wolff-Parkinson-White (WPW) ECG pattern (**Figure 15**)
- f) Complete atrioventricular block (**Figure 16**)
- g) Any statement which includes a reference to **acute** injury or ischemia

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 GRADE study.

Figure 11 Atrial fibrillation

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

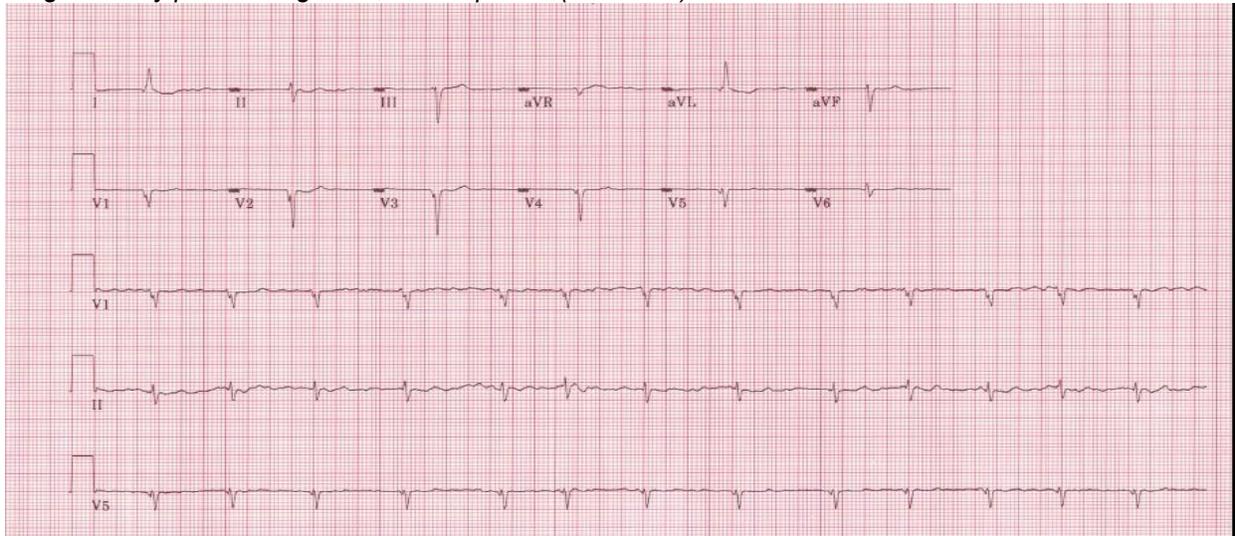


Figure 12 Atrial flutter

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

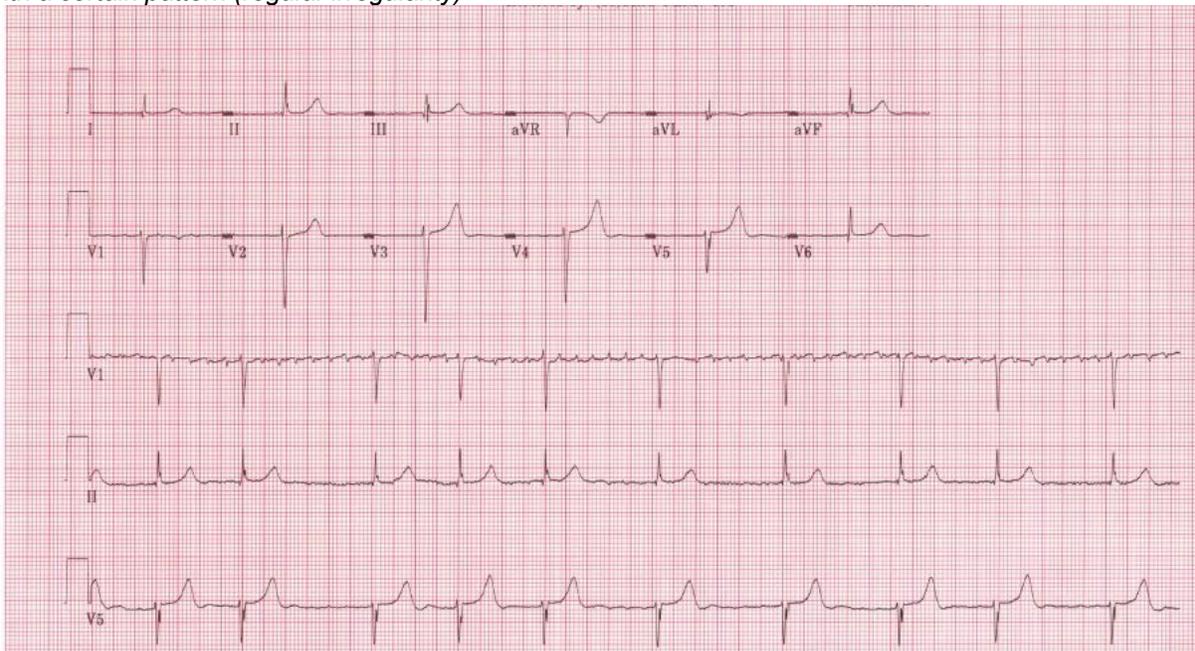


Figure 13 Ventricular tachycardia

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

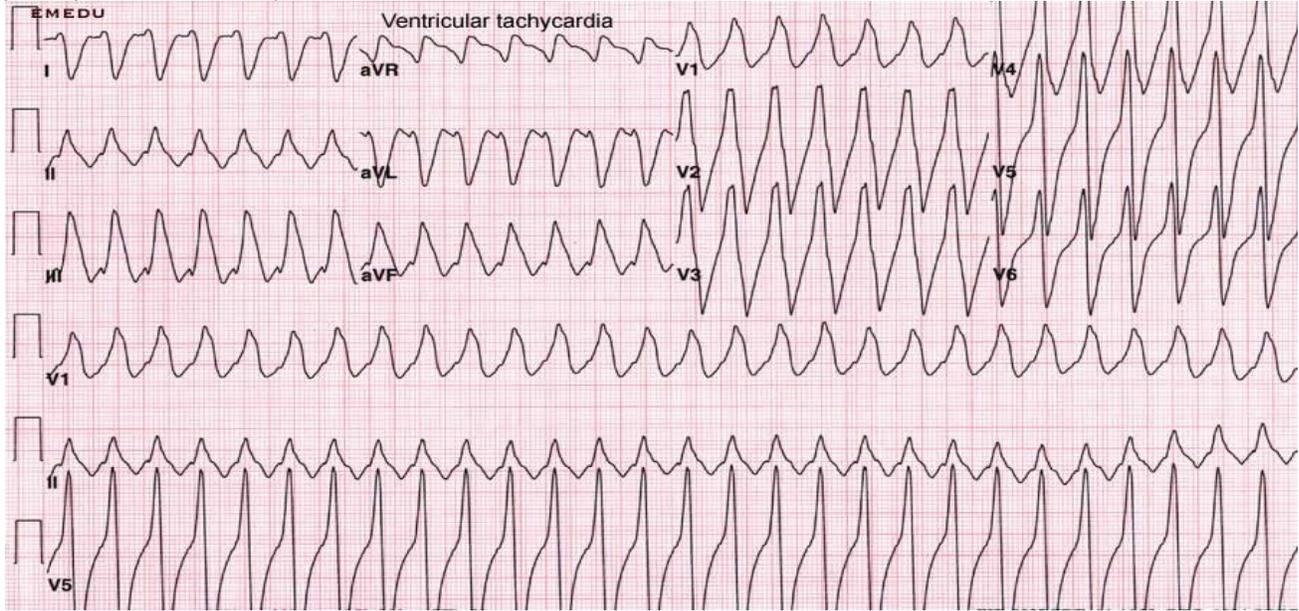


Figure 14 Acute inferior (upper panel) and acute anterior (lower panel) myocardial infarction

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

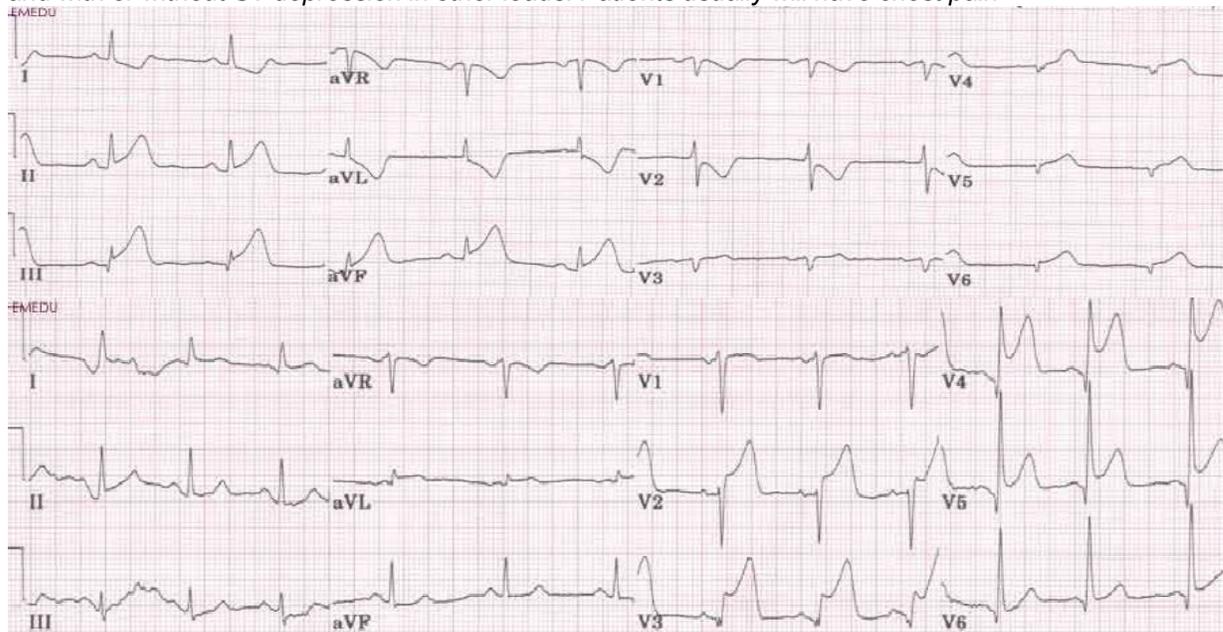


Figure 15 Wolf Parkinson White Syndrome

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)

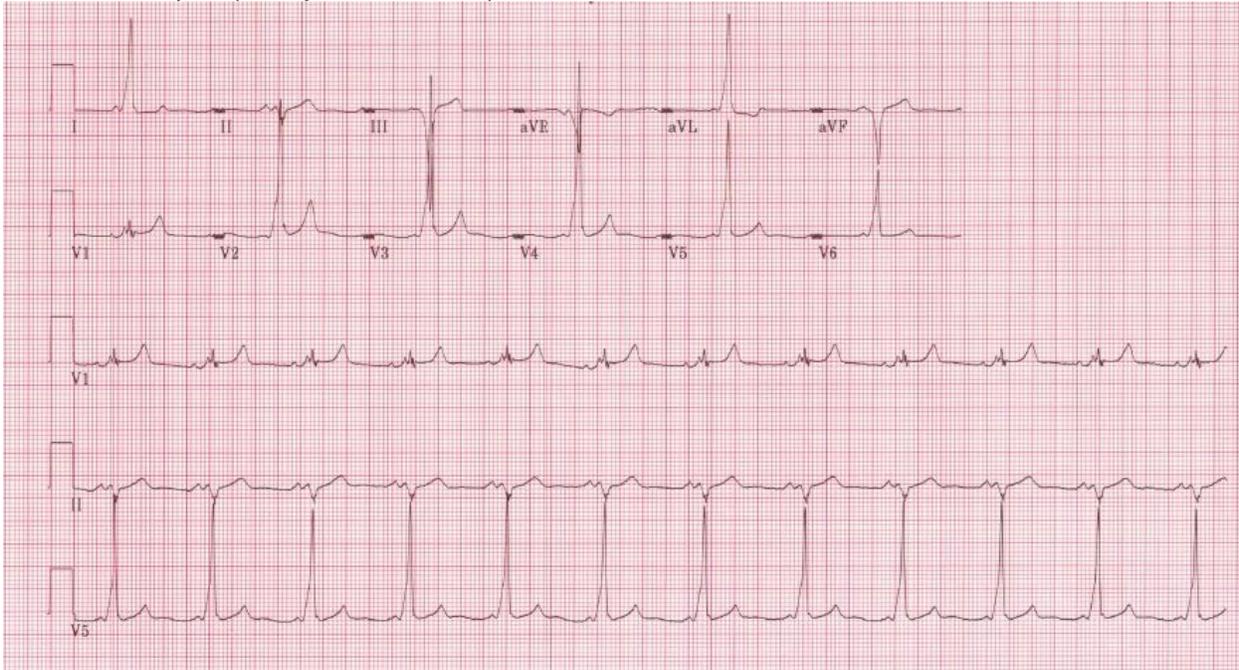
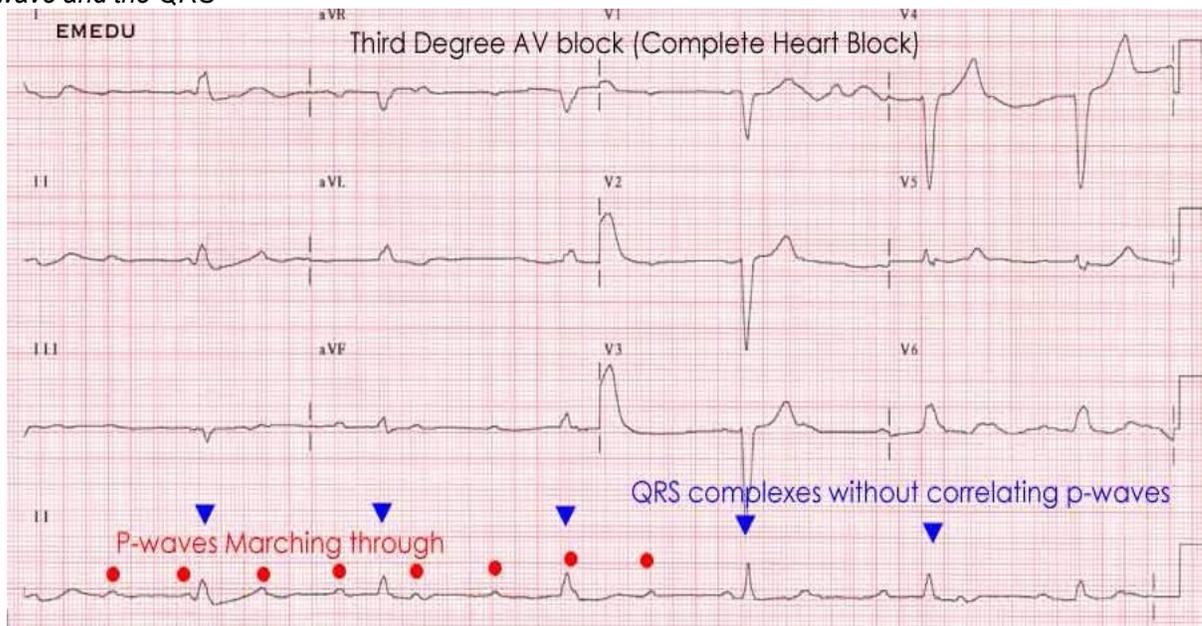


Figure 16 Complete (3rd degree) atrioventricular block

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



III.3. DATA MANAGEMENT PROCEDURES

III.3.1 Communications setup for transmission

Internal set up of the ECG machines must be done according to the instructions established by the ECG Reading Center. Correct internal set up should enable the clinics to transmit the study ECGs via an analog phone line from their clinic to the Reading Center. Contact EPICARE any time with questions.

III.3.2 Before transmitting ECGs to the ECG Reading Center

- Make sure the directory is up to date meaning all previously successfully transmitted ECGs (those transmitted and confirmed to have been received successfully by EPICARE) have been deleted from your directory.
- Check to ensure that all IDs are valid.

III.3.3 Transmitting ECGs to the ECG Reading Center (see also Appendix C)

- 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 “analogue” (fax) phone line.
- Multiple ECGs may be transmitted at the same time.
- 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.
- Delete transmitted ECGs ONLY after you have received, from EPICARE, confirmation of receipt of ECGs.

III.3.4 Directory management

Keep your directory correct and current by doing the following:

- *BEFORE TRANSMISSION*: Delete all unwanted ECGs like those with flat lines (no waveform) or duplicates. Correct any errors in participant data entry (e.g. ID, GCode or Visit number).
- *AFTER TRANSMISSION*: Delete transmitted ECGs ONLY after confirming that EPICARE has successfully received the ECGs.

III.4. ECG FORM

- A short form will be filled in by the GRADE ECG technician for each participant after recording their study ECGs. (**Appendix A**). This form is retained with the participant's records by the local clinic.

VI. READING CENTER TECHNICAL DETAILS

Set-up of the machines is done at the ECG Reading Center or by authorized study personnel assisted by EPICARE staff. Although rare, re-programming of the machine may be needed if a malfunction occurs or upon return of the machine to the clinic after repairs by GE. The machine set-up and programming instruction are listed in **Appendix B**.

V. QUALITY CONTROL PROCEDURES

V.1 Quality grades

Each GRADE study ECG is assigned 1 quality grade [0 (best), 1, 2 and 5 (poorest)]. Three of these grades [0, 1 and 2] are automatically determined by the GE ECG reading software. These automatically-assigned grades are based on information on muscle artifact, AC interference, electrode noise, etc. The last and most important grade is the ECG Reading Center quality Grade 5. Quality Grade 5, which overrides all other quality grades, is the poorest quality that could affect ECG reading. This would be mainly due to lead reversals, missing leads and marked background noise. The alarming threshold for poor quality ECGs in studies similar to GRADE is to have 5% or more of the total number of ECGs as grade 5. A monthly quarterly quality report will be sent to the GRADE Coordinating Center to share with the sites.

V.2 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 2 good quality ECG sets (3 sequential ECGs each-performed just as participants' ECGs).
- The 2 ECG sets should be approximately 20 minutes apart or recorded from 2 different volunteers.
- After evaluation of certification ECGs by EPICARE staff, the technicians will be notified of their certification status.
- Recertification process (required as needed based on ECG quality) is the same as the certification process.

Table 3: Data Entry screen for technicians seeking certification

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 year (01/01/YY)
Participant ID	Enter 99999999 (Press "Shift" key to enter numbers)
Secondary ID	Enter 99999999 (Press Shift key to enter numbers)

Pacemaker	YES or NO
Gender	M or F
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.
Technician	Choose "Other" and select technician's last name
Location	No action required.

***Enter 01/01 for month and day for all volunteers and enter volunteer's actual birth year (01/01/YYYY)**

V.3. Examples of common ECG quality issued and possible solutions

- **EXCESSIVE BASELINE DRIFT (Figure 17):** 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 18):** 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 19):** 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 20):** Loose electrode connection may cause a wavy baseline in some ECG leads. Check each electrode to ensure that it is secure.
- **AC INTERFERENCE (Figure 21):** 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 22-24):** 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 (17) Excessive baseline drift due to sudden movement of the participant

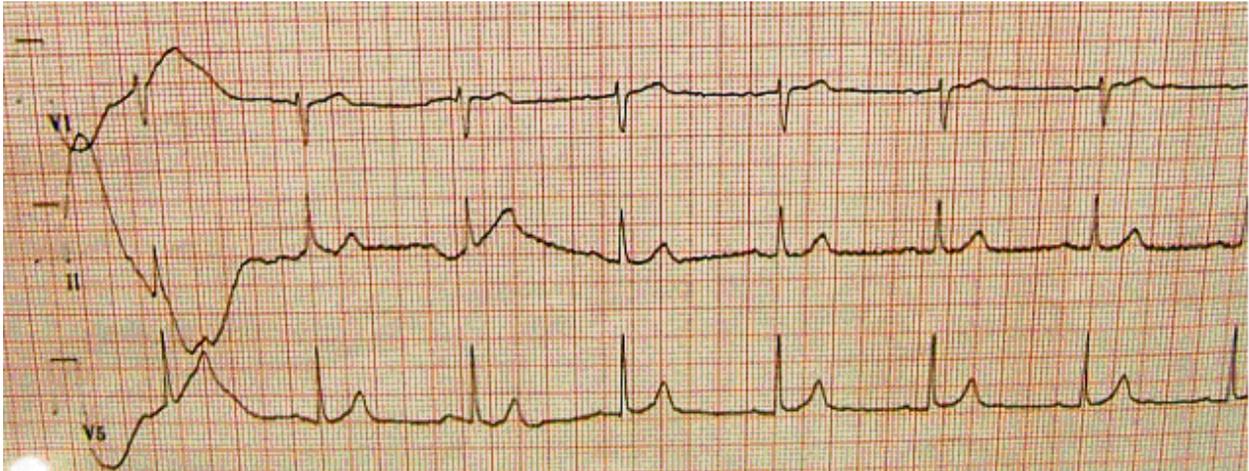


Figure (18) Excessive muscle noise

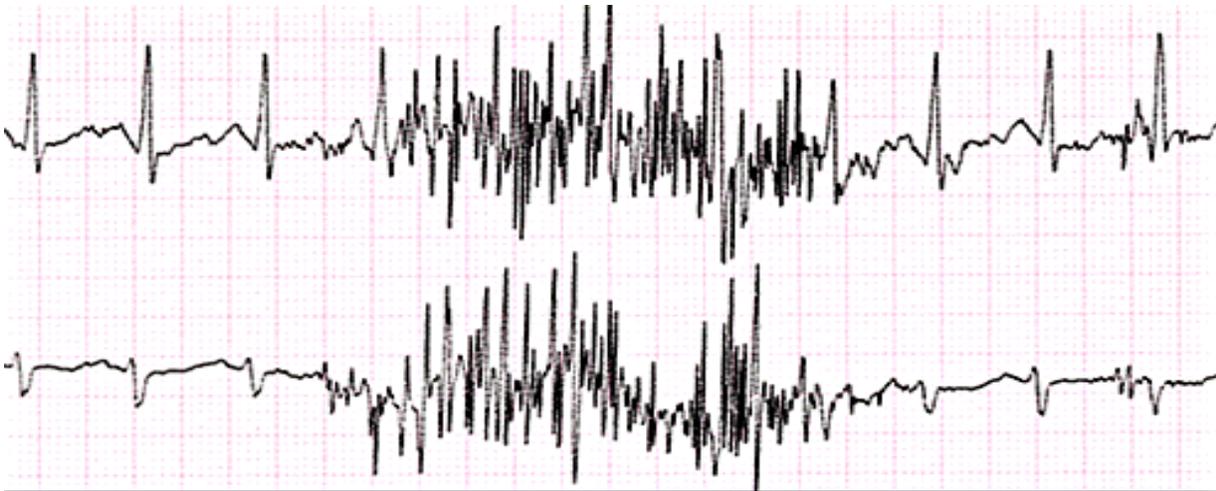


Figure (19) Baseline drift due to tangled wires

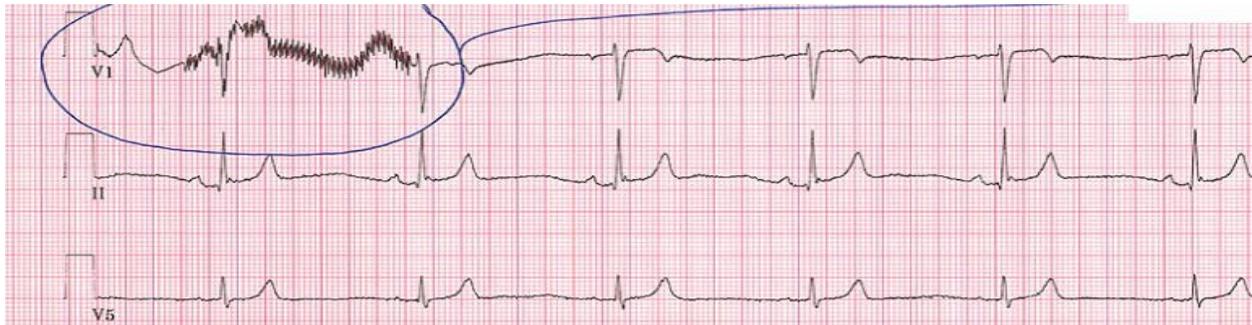


Figure (20) Wavy V1 baseline due to loose electrode

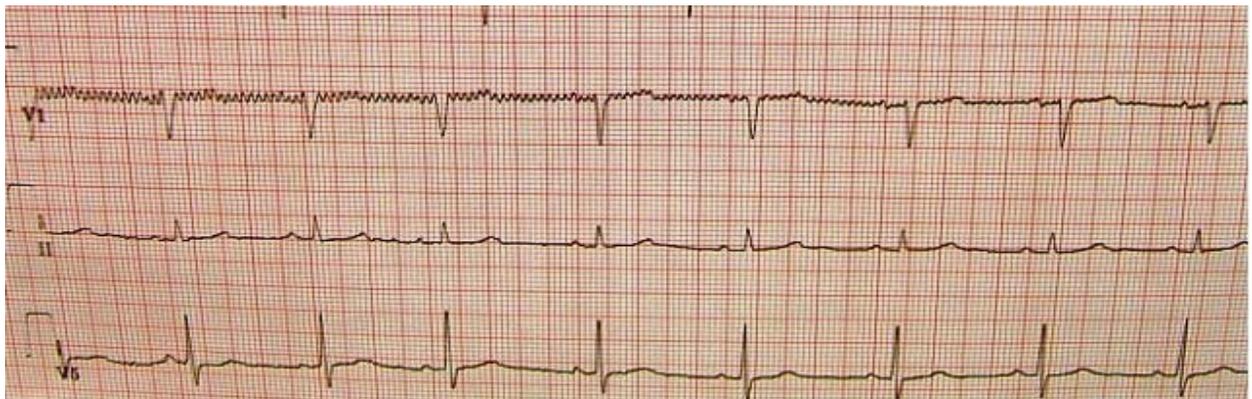


Figure (21) Sixty Hz electrical interference

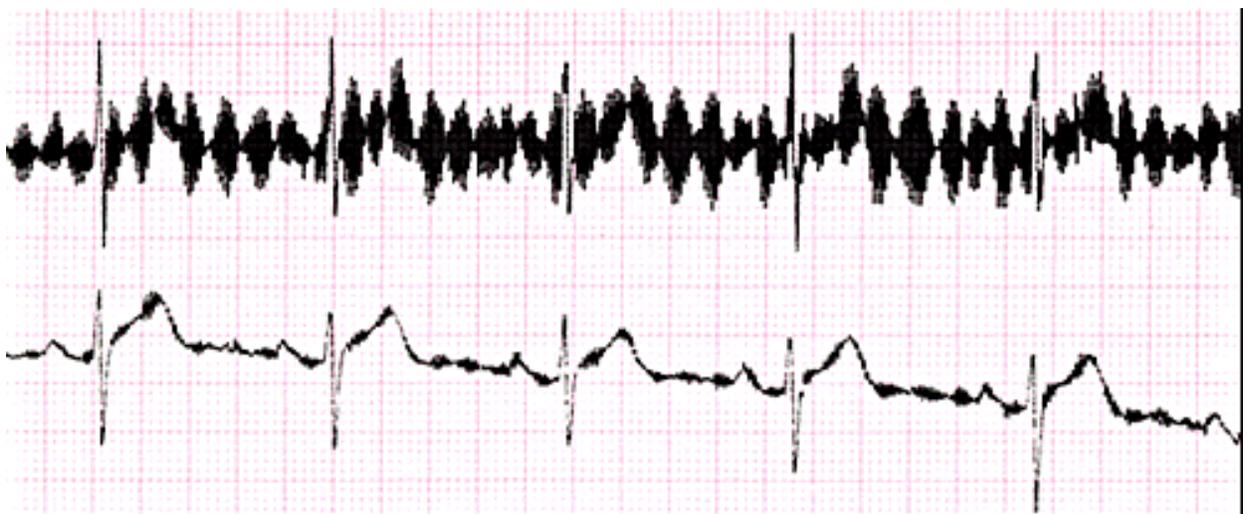


Figure (22) Flat line due to missing V1 lead

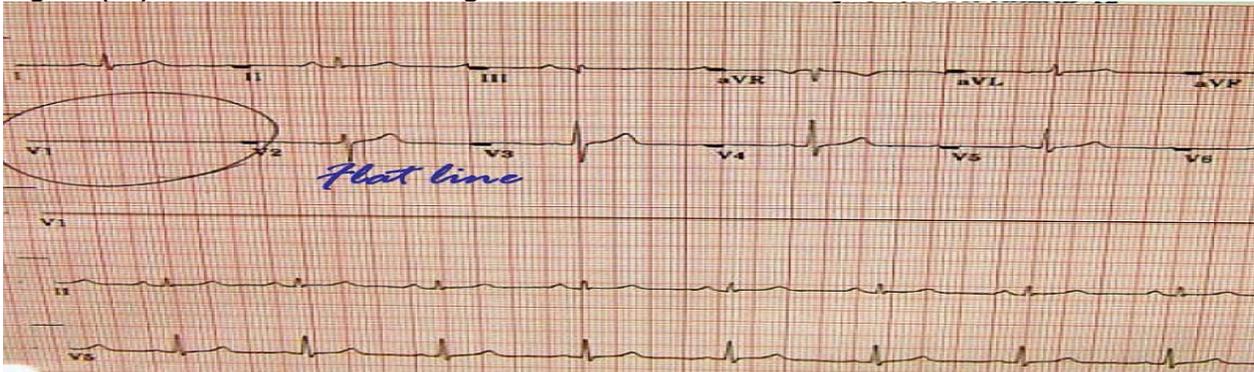


Figure (23) Lead reversal denoted by positive aVR (upper panel) compared to the normal (lower panel)

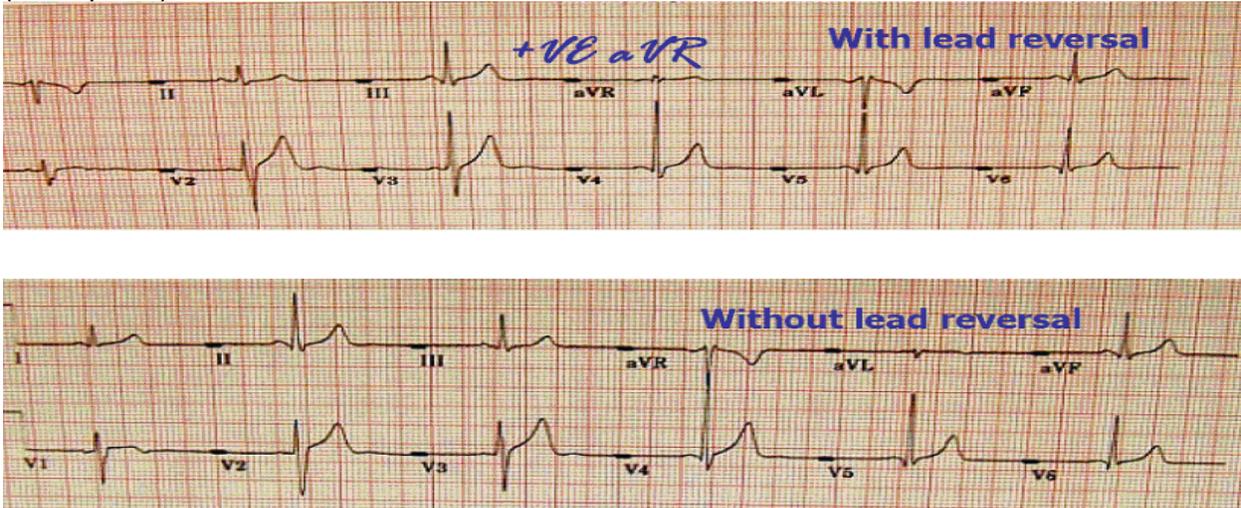
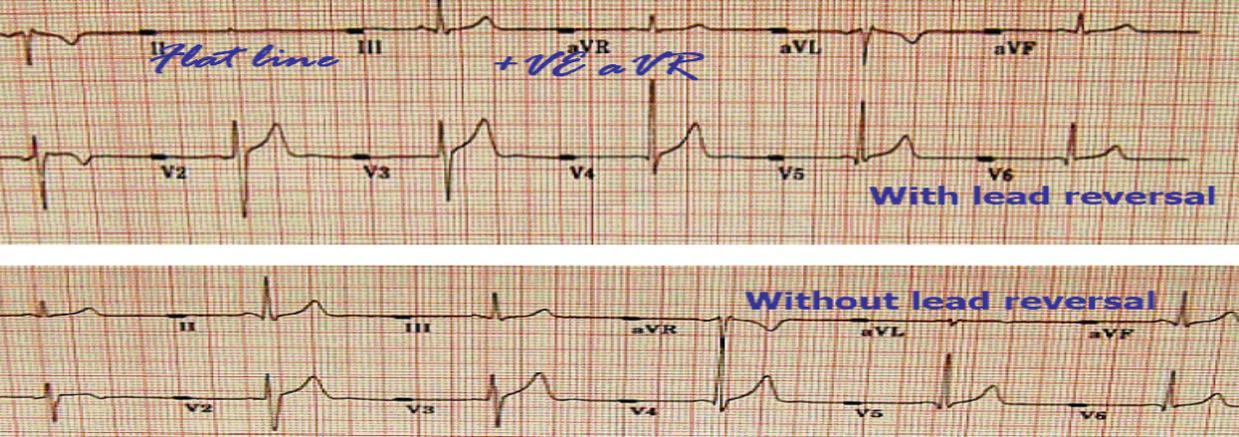


Figure (24) Lead reversal denoted by flat line in one of the limb leads (upper panel) compared to the normal (lower panel)



Appendix A

-
Site

Participant ID

GCode

Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE)

Electrocardiogram Form - ECG FORM

Date of visit:
mm dd yyyy

Visit number:
(F1, F2, 00, 24, 48, or 72)

INSTRUCTIONS: This form is completed for all participants at the time of ECG at the Final Run-In or Baseline visit, and Annual visits in GRADE years 2, 4, and 6. (Note: If ECG conducted at a later visit, record visit number at which the ECG is completed.)

A. ECG Information

1. Was the ECG completed? (Check only one)

- Yes, completed and transmitted successfully using the GRADE ECG machine..... 1
- Yes, completed and transmitted successfully using "other study" ECG machine..... 2
- Yes, completed and paper tracing only obtained for the ECG..... 3
- No, ECG was not completed..... 4

If NO, record reason below and try to reschedule the ECG.

a. Specify reason (e.g. not done, not recorded, deleted from machine, machine problems, etc.):

If YES,

b. Date of ECG:

mm dd yyyy

c. E point HeartSquare measurement:

.
.

d. V6 measure HeartSquare measurement:

e. Were any safety alerts* noted on the ECG machine printout?

1 Yes 2 No

If YES,

1) Specify:

2) Action taken:

*Safety Alerts requiring prompt action or immediate notification to the participant (refer to ECG MOP):

- Heart rate below 40 or over 120 beats/minutes
- Atrial fibrillation or atrial flutter not known by the participant
- Ventricular tachycardia
- Acute myocardial infarction
- Ventricular preexcitation/Wolff-Parkinson-White (WPW) ECG pattern
- Complete atrioventricular block
- Any statement which includes a reference to **acute** injury or ischemia

2. Were there any problems related to the conduct of the ECG?

1 Yes 2 No

If YES, a. Specify:

Initials of staff reviewing completed form: <input type="text"/> <input type="text"/> <input type="text"/>	Form entered in MIDAS? <input type="checkbox"/>
Initials of staff completing form: <input type="text"/> <input type="text"/> <input type="text"/>	Date form completed: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (mm/dd/yyyy)

**Appendix B
MAC 1200 PROGRAMMING AND SETUP**

**Minor changes in the set up below may occur during the course of the study- Call
EPICARE for assistance**

In order to setup a MAC1200 for the GRADE 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”.

12-Lead Setup

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]
AUTOSAVE ECG	[YES]
USE SCREENING CRITERIA	[NO]
SUPPRESS NORMAL STATEMENTS	[NO]
SUPPRESS ABNORMAL STATEMENTS	[NO]
INTERPRETATION	[YES]
PRINT INTERPRETATION	[YES]
OVERRIDE FUNCTION	[YES]

When finished, press the STOP key

Press the Down Arrow key to highlight System Setup, and press ENTER.

System Setup

CATEGORY	SELECTION
ORDERING PHYSICIAN	No
REFERRING PHYSICIAN	Highlight OTHERS press ENTER. Press ENTER until the cursor is under the LAST NAME; type GRADE. Press ENTER until the cursor is under the FIRST NAME; type the GRADE field unit location (city, state) and 3 digit field clinic identifier.
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	GRADE city, state of clinic
CART NUMBER (GRADE site # with no dashes))	3 digit field clinic identifier
SITE NUMBER	ENTER 110 This is EPICARE's Study Number for GRADE
LOCATION NUMBER	1
Enable ease of clock setting	No
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]- Time Out Mechanism
LOW BATTERY BEEP	[0 sec]
DEFAULT MODE	[12 LEAD]
LANGUAGE	[ENGLISH]
ENABLE PASSWORD	[NO]
TEST DATA	[NO]
RESTORE DEFAULTS	[NO]
PRINT SETUP LISTS	[NO]

When finished, press the STOP key

Press the Down Arrow key to highlight Communication, and press ENTER.

Communication Setup

CATEGORY	SELECTION
BAUD RATE (PC)	[9600]
PROTOCOL	[CSI]
MODEM	MultiTech 56k
DIAL MODE	TONE
PHONE NO.	Enter your site-specific transmission Telephone number <i>To be assigned later by the ECG Center.</i> 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) 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.
OUTSIDE LINE	If you need an outside line to obtain dial tone, please enter that digit here, e.g. 9

When finished, press the STOP key

Press the Down Arrow key to highlight Patient Data Setup, and press ENTER.

Participant Data Setup

CATEGORY	SELECTION
NEW PATIENT	[YES]
PACEMAKER	[YES]
GENDER	[YES]
HEIGHT	[YES]
WEIGHT	[YES]
RACE	[YES]
SYSTOLIC BP	[NO]
DIASTOLIC BP	[NO]
ORDERING PHYSICIAN	[NO]
REFERRING PHYSICIAN	[YES]
TECHNICIAN	[YES]
PHONE NO.	[NO]
MEDICATION	[NO]
COMMENTS	[NO]
ID REQUIRED	[YES]
PATIENT ID LENGTH	7
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]

When finished, press the STOP key. Press the STOP key once again to exit the Setup menu. The Option Code Setup requires NO action.

Appendix C

Transmission of GRADE study ECGs to the ECG Reading Center

Before transmitting ECGs to the ECG Reading Center

1. Ensure that all previously transmitted ECGs are deleted only after confirmation of receipt by the ECG Reading Center.
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 ECG Reading Center

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.
5. 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. Never delete an ECG before confirmation of receipt from EPICARE. Confirmation could be made via EPICARE website or GRADE website (*under discussion- to be determined later*). Call the ECG center for confirmation anytime.