

## RESTING ECG

### Resting ECG

#### 1. Background and Rationale

**Significance of Resting ECG:** The resting ECG collected at the MrOS Sleep Study visit may be needed in the future to help identify cases of incident myocardial infarction. Accurate identification of such events is essential to the primary aim of the MrOS Sleep Study: to determine the relationship between sleep disordered breathing and other sleep disorders with risk of cardiovascular disease events. The ECG will be printed and kept in the participant's chart until a possible myocardial infarction is reported, in which case the ECG will be provided along with other required adjudication documents for central adjudication at the Coordinating Center.

#### 2. ECG Collection

Standard 12 lead ECGs will be collected at the MrOS Sleep Study visit. It is important collect and retain a copy of the ECG in the participants chart to allow subsequent comparison of ECGs for detection of significant changes suggestive of myocardial infarction. Missing ECGs can jeopardize the diagnosis of myocardial infarction. Certification prior to study initiation will ensure high-quality data for the study duration. Certification is discussed below, and the certification form is included as Attachment A.

#### 3. Training and Certification of ECG Technicians

##### ECG Certification

Sites are required to certify ECG technicians before they are involved in the collection of electrocardiographic data for the MrOS Sleep Study. The certification procedure is as follows:

1. Five ECGs will be acquired using the methods described in section D: Resting ECG Acquisition.
2. The five resting supine ECGs will be obtained consecutively.
3. The ECGs will be printed and sent to the UCSF CC along with the certification form.
4. Upon receipt of the ECGs and certification form, the UCSF CC will evaluate the ECGs for quality parameters and provide the sites with certification confirmation.
5. Certification requires successful acquisition of five high quality ECGs. Quality ratings are outlined in section D.5.

Indicators of poor quality include:

- a) Excessive baseline wander
- b) Motion artifact or loose electrode contact
- c) Excessive muscle noise
- d) Excessive 60 Hz noise
- e) Valid calibration documentation
- f) Missing leads
- g) Check for lead reversal

The Request for Certification form is included as Attachment A. The field center should make several copies of this form and keep it on file. The Request for Certification form will accompany the certification ECGs. A technician number will be assigned by the UCSF CC to each person certified to perform MrOS Sleep Study resting ECGs. This number will allow tracking of ECG quality for the study duration.

#### 4. Electrocardiographic Equipment and Supply Specifications

**4.1 No specific ECG machine is required for use in the MROS study. However, if you do not already have a machine available and are going to purchase one for the study the following equipment is recommended.**

Marquette Electronic MAC PC Resting ECG Analysis System  
(Part # MACPC-AAA-ABCA)

The MAC PC is portable, weighing approximately 12 pounds, and is equipped with a validated 12SL ECG analysis program to provide the sites with a complete computerized analysis of the participants ECG in both morphology and rhythm. The 12SL program processes and evaluates ECGs in the same manner as the larger central ECG systems and produces a hard copy tracing for the participant's chart. This portable unit operates on rechargeable NiCad Batteries supplied with a line-operated charger.

The unit may be operated with the AC adapter or battery pack. Refer to the manual for specific information regarding care of equipment and optimal use/charge of the battery for optimal performance.

#### 4.2 Equipment Support and Troubleshooting Information

Please refer to the Operations Manual that was received with your ECG equipment for details on support and troubleshooting.

If you are using the Marquette MAC PC machine, the operations manual provides additional information and should be used in conjunction with this manual. It is an excellent resource and contains detailed information for troubleshooting equipment problems.

#### 4.3 Supply Information

The following is a sample supply list, provided for those using the Marquette MAC PC machine (Note: pricing may not be current). Those using equipment from a different manufacturer can adapt this list to specifications required for their machine.

Item specification	Part #	Vendor	Cost	Quantity
Silver Mactrodes plus electrodes	9623-003P	GE Marquette Medical Systems	\$33/case	1,000/case

Mac PC Recording Paper	9402-023	GE Marquette Medical Systems	\$38/case	18 rolls/case
Alcohol/ pumice prep pads	4828-004	GE Marquette Medical Systems	\$10.56/ box	100/box
Prep Razors	3704-901	GE Marquette Medical Systems	\$21.12/ pack	100/pack
Replacement Lead Wire Set	900177-001	GE Marquette Medical Systems	\$136.40/ set	12 leadwires / set
Replacement Adaptors	900178-002	GE Marquette Medical Systems	\$74.80/set	set of 10
Felt Tip Pen		Supplied locally		

#### 4.4 Quality Control Checklist: Equipment and Supplies

Monthly Equipment and Supply Check—Every month do the following:

1. Drain and charge the battery according to the operators manual
2. Visually inspect the unit
3. Check the case and display screen for cracks
4. Inspect cords and cables for fraying or other damage
5. Inspect all plugs, cables, and connectors for bent prongs or pins
6. Verify all cords, socketed components, and connectors are securely seated
7. Inspect keys and controls for proper operation, i.e., toggle keys should not stick in one position, and knobs should rotate fully in both directions.
8. Clean the exterior surface with a damp soft cloth (wring excess water from the cloth) Do not drip water or any liquid on the writer assembly and avoid contact with open vents, plugs, and connectors. Dry the surface with a clean cloth or paper towel
9. Check supplies (ECG paper, and prep supplies). Order if necessary

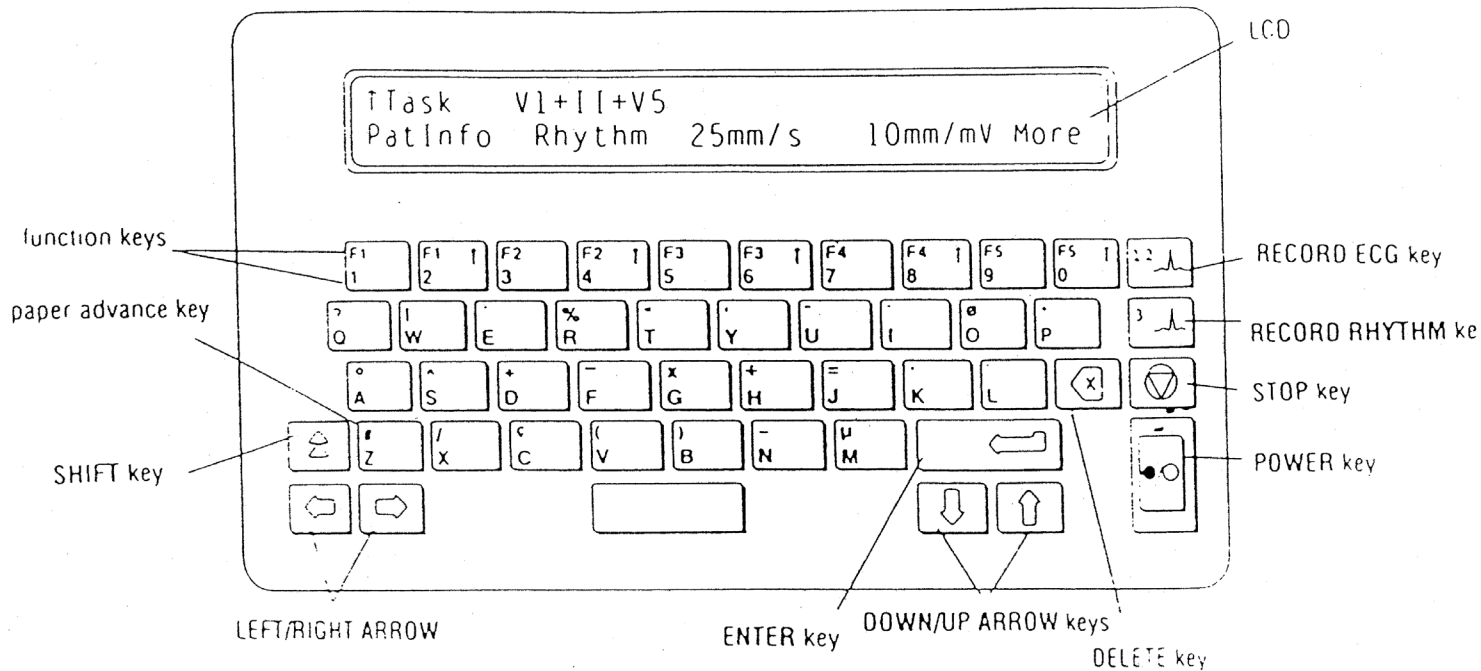
#### 5. Equipment Set-up Procedures (for MAC PC users only)

**(system setup stored for study duration; only change in time will need to be modified)**

The MAC PC is operational at delivery. For the MrOS Sleep Study, you will need to modify the set up to the following specifications (Refer to the Marquette Operators manual chapter 11-SETUP.) **Once these details are set, the system will retain them until they are manually modified.**

## 5.1 Overview: MAC PC Keyboard

The following diagram is from the Marquette MAC PC Operator's Manual and provides a brief overview to the MAC PC keyboard.



Note: Each of the 10 numerical keys on the keyboard has a number from 1-5 on it preceded by the letter F. These keys are dual purpose: They are used to either type in numerical data or as a function key to select an item from the LCD.

## 5.2 MAC PC Equipment Setup

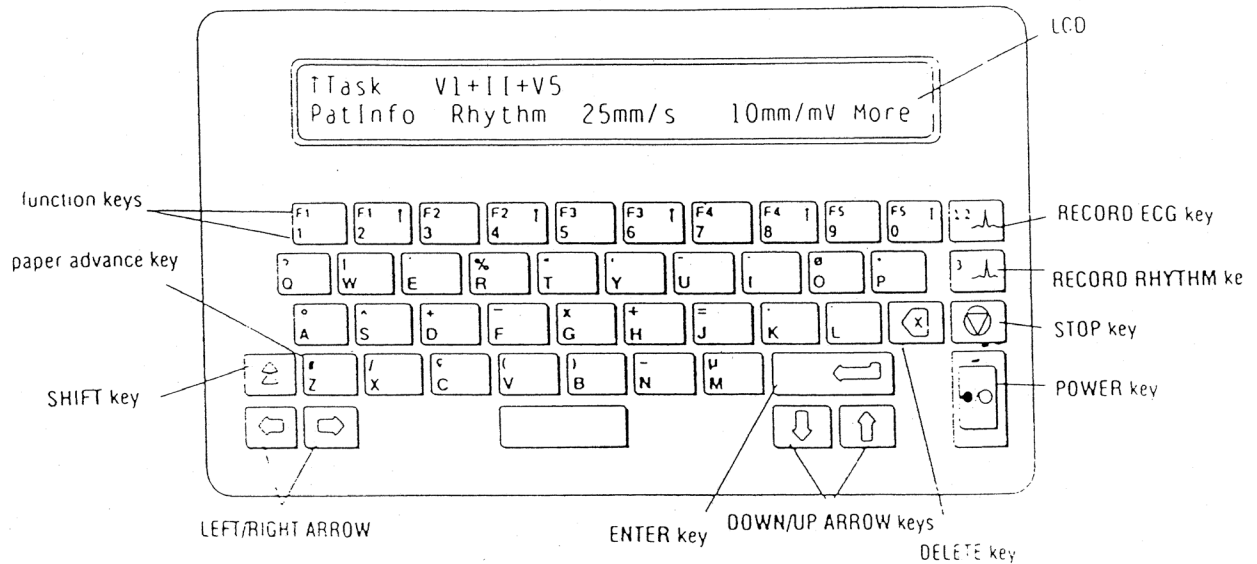
### 5.2.1 Setting Date and Time

To enter the setup menu:

- Press the **STOP** key to display the main menu.
- Hold the **shift** key down while pressing the **2** key for the system functions menu.
- Set up to enter the Cart Set up menu. Enter the date/time and phone numbers from this menu.
- Select **Date/Time**  
 Select **Date**: type the day, a dash, the month, a dash, and the year. (Press **enter**)  
 Select **Time**: Type the hour, a dash, and the minute (Press **enter**)
- Press the **STOP** key to return to the main menu.

**Note: remember to edit when the time changes**

## 5.2.2 Equipment Setup Continued



The remaining system setup items are entered as follows:

**Step 1:** Press the **STOP** key to display the main menu

**Step 2:** Hold the **shift** key down while pressing the **2** key for the system functions menu

**Step 3:** Select **set up** to enter the 1st Cart Set up menu

Step	LCD display	Your action
4	Cart Setup Date/Time Phone Ldgrps Reports More	Select <b>More</b>
5	Cart set up Modem Passwds Misc Defaults More	Select <b>Misc</b>
6	Line Frequency: 60 Hz 50 Hz	Select <b>60 Hz</b>
7	Cart ID: 0-255	Do not need
8	Site ID: 1-255	Do not need
9	Default Location: 0-999	
10	Institution Name: Up to 40 characters	Do not need
11	Number of Patient ID digits: 1-12	
12	ID required to record an ECG: Yes No	Select <b>Yes</b>
13	Height/Weight	Do not enter height/weight
14	Participant Age	Do not enter date of birth

15	Ask Blood Pressure Questions: Yes No	Select <b>No</b>
16	Ask Options Questions: Yes No	Select <b>No</b>
17	Ask order number questions: Yes No	Select <b>No</b>
18	Confirmation Text: Unconf Revd By	Select <b>Unconf</b>
19	Suppress Normal statements: Yes No	Select <b>Yes</b>
20	Suppress Border + Abn Stmts: Yes No	Select <b>Yes</b>
21	ECGs to store / transmit All Abnormal	Select <b>All</b>
22	Delete ECGs after transmission Save Delete	Select <b>Save</b>
23	Store/Transmit Control: Store Transmit	Select <b>Store</b>
24	Power up speed: 25 mm/s 50 mm/s	Select <b>25 mm/s</b>
25	Power up filter: 40 Hz 100 Hz	Select <b>100 Hz</b>
26	Screening Criteria: Yes No	Select <b>No</b>
27	Baseline Roll Filter: .01 Hz .02 Hz .16 Hz .32 Hz	Select <b>.16 Hz</b>
28	QC Baseline Drift: Yes No	Select <b>Yes</b>
29	QC Muscle Tremor Yes No	Select <b>Yes</b>
30	Disable Automatic Gain Check: Yes No	Select <b>No</b>
31	Pace Pulse Gain ( AM - 3): Normal Enhance	Select <b>Normal</b>
32	Bad Lead Handling (AM - 3) Use Flatline	<b>Flatline</b>
33	Cart Set Up Modem Passwds Misc Defaults More	Press the <b>STOP</b> key to return to the main menu

### 5.2.3 Report Format Setup

In the MrOS study, 12-lead ECGs will be printed with the 12 SL interpretation of the ECG. This is the ECG reviewed for alert conditions. After printing the copy with the interpretation, the machine will prompt if you want an extra copy. You should print a copy without interpretation for the participant to keep and provide to their physician if they wish. DO NOT give the

participant a copy with interpretation. A copy should be made of the printout with interpretation and kept in the file as the paper that the report is printed on tends to degrade with time. To set up the machine to print with interpretation follow these steps:

Enter the setup menu:

- Press the stop key to display the main menu
- Hold the shift key down while pressing the 2 key for the systems function menu
- Press setup to enter cart setup

In the setup menu do the following:

Step	LCD screen	Your action
1	Cart setup Dat/Time Phone LdGrps Reports More	select reports
2	Report formats for: Confirmed Unconf	select unconf
3	Ask for extra copies of plots: Yes No	select Yes
4	suppress orig Rpt Interpretation No Yes	select No
5	Suppress copy interpretation Yes No	Yes
6	Suppress Text page Yes No	select Yes
7	Rhythm and Morphology report Yes No	select No
8	1 Complex/Lead Yes No	select No
9	1 Complex/Lead with abnormalities Yes No	select No
10	Add tic to complexes Yes No	select No
11	Times 2 complexes Yes No	select No
12	Automatic rhythm (1 X 10) Yes No	select No
13	Automatic rhythm (1 X 10) with abnormalities Yes No	select No
14	12 lead (4 X 2.5) No Yes	select Yes
15	Separate Text page for (4 X 2.5) Yes No	select No
16	1 page (4 X 2.5) with rhythm Yes No	select No
17	12 lead (2 X 5) No Yes	select No
18	12 lead (2 X 10) Yes No	select No
19	12 lead (4 X 10) Yes No	select No
20	12 lead (4 X 10) with abnormalities Yes No	select No

21	12 lead (2 X 5 at 50 mm/s) Yes No	select No
22	Report formats for: Confrmd Unconfirmed	Press stop key to return to the main menu

## 6. Resting ECG Acquisition

Following an initial training session, all personnel involved in the collection of electrocardiographic data will be certified. The MrOS Sleep Study Staff # (assigned by the Coordinating Center) will be used to identify the ECG technician certified to collect ECG data. During the course of the study, any additional technicians at the field center involved in the collection of electrocardiographic data will need to perform the certification procedure.

### 6.1 Safety and Exclusions:

All study participants are eligible for a resting ECG. There are NO exclusions. Perform even if the participant has a chest deformity. The exam table should be secured (wheels locked if applicable) and a safe step stool should be available if needed for the participant to get on and off the table.

### 6.2 Pre-Examination Procedures

Complete the MrOS Sleep ECG Worksheet

- Assess history of a-fib/flutter, etc.
- Assess current medication use for conditions

Check the following:

- Clean sheets or exam paper on the table, and a pillow at the head of the table
- Exam table is locked or secured against a wall
- Prep supplies are available (felt tip pen, prep pads, disposable razor if needed, disposable electrodes)
- Unit is charged and has adequate paper supply

Explain the procedure to the participant:

Script: “The resting ECG is a test used to detect heart disease. This procedure is not painful and should take less than 10 minutes. First I will need to prepare your skin for the test which requires marking and preparing the sites for attachment of the electrodes on your chest.”

- Ask the participant to undress to the waist and put on a gown with the opening to the front.
- Position the participant.
- Ask the participant to lie in the supine position with head on one pillow, shoulders straight and arms relaxed at the sides. (If table has wheels, confirm the wheels are locked and it is safe for the participant to climb up on.)



### 6.2.1 Body Position and Lead Placement

To ensure comparability of data, the following uniform procedures for skin preparation, electrode placement, and quality control should be followed:

The participant should be supine with one pillow; the upper body is exposed; shoulders are straight and the arms are relaxed.

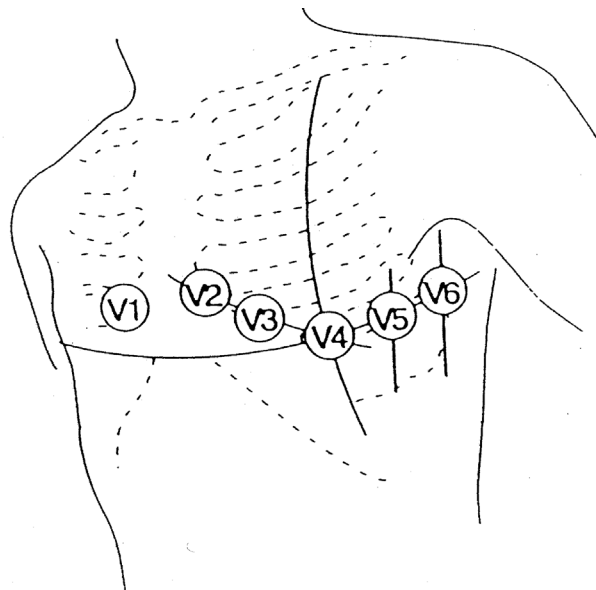
Ask the participant to avoid movements that may cause errors in marking the electrode locations, or artifact in the 12 lead ECG recording.

Mark each electrode site with an X using a felt tip pen, anatomical landmarks are used to determine lead placement (see Attachment B):

- Lead RA: Inner right arm above the wrist
- Lead LA: Inner left arm above the wrist.
- Lead RL: Right lower leg above the inner ankle or as close as the electrode will reach.
- Lead LL: Left lower leg above the inner ankle or as close as the electrode will reach.

*If the participant has an amputated limb, place the electrode on the body part closest to that limb*

Chest Electrodes (diagram from MAC PC Operators Manual):



- Lead V1: Fourth ICS\* space at the right of the sternal border.
- Lead V2: Fourth ICS\* space at the left of the sternal border.
- Lead V3: Position equidistant between lead V2 and V4
- Lead V4: Left Fifth ICS\* space in the midclavicular line
- Lead V5: Left Fifth ICS\* space at the level of the anterior axillary line.
- Lead V6: Left Fifth ICS\* space at the level of the midaxillary line.

\* ICS= intercostal space - space between the ribs To locate intercostal space:

- 1) *Locate the sternal angle (where the manubrium joins the sternum).*
- 2) *Move your fingers laterally along the sternal angle to the right (for V1) or left (for V2-V6). This is where the second rib joins the sternum.*
- 3) *You will feel the location of the second rib between your index and middle fingers. You now have your index finger in the second intercostal space and your middle finger in the third intercostal space.*
- 4) *Use your fingers to feel for and locate the fourth and fifth intercostal space for location of electrode placement.*

### **6.2.2 ECG Skin Preparation**

Prepare the skin for electrode attachment:

- If necessary, shave hair from the electrode site. Note: it is necessary to remove hair from the chest if the amount of hair is significant enough to either (1) interfere with adhesion of the electrode or (2) result in discomfort to the participant due to the chest hair pulling at point of electrode removal. Inform the participant before you shave the electrode site that removing the hair from the electrode area will result in a better quality tracing (because of better adhesion) and easier removal of the electrode (because the chest hair will not be pulled during electrode removal).
- Rub each electrode site with alcohol pumice prep pad; Dry with gauze or buff with sand paper; work in a single direction to remove the skin oils and epidermal layer at each site; the skin should appear slightly red, this removes dead skin and oil to enhance conduction.

### **6.2.3 Electrode Attachment**

- Place an electrode at each prepared site.
- Press on each electrode to promote good skin contact with gel.
- Attach clamp only to metal part of electrodes.
- Allow the gel to penetrate a minute before recording the 12 lead to enhance conduction.

### **6.2.4 Electrode Cable Attachment**

By following a uniform sequence of electrode attachment, the risk of wrong connections (lead reversals) can be minimized.

The following sequence of connecting electrode cables is recommended:

Right leg  
Right arm  
V1  
V2  
V3  
V4  
V5  
V6  
Left arm  
Left leg

Follow the electrode cable wires from the acquisition module to the electrode site prior to attaching electrodes to decrease the possibility of lead reversals. After attaching the lead wires, verify one by one that the connections to all electrode sites are correct.

### 6.3 Recording the 12 Lead ECG

Ask the participant to relax, breathe normally, and refrain from talking or moving while the 12 lead ECG is recorded. Record the 12 lead ECG. Two hard-copy printouts should be printed (one with interpretation for the participant's chart and review should a medical alert occur, the other copy without interpretation should be given to the participant. Remember to make a photocopy of the report with interpretation for the participant's file. The MrOS Sleep Study ECG form should be completed and sent to the UCSF Coordinating Center with other clinic visit forms.

The hard-copy printouts should be labeled with MrOS Study identifier and acrostic, staff ID#, and date of ECG.

### 6.4 Post Recording Quality Check

Inspect the ECG recording immediately for quality. If quality problems are detected, correct the source of artifact and repeat the recording. Check the following:

- a) Excessive baseline wander: Baseline wander is defined as 1.0 mm difference between the PQ baseline in three consecutive ECG complexes. The source of this artifact is usually inadequate skin prep.
- b) Motion artifact or loose electrode contact: These may cause sudden jumps in some ECG leads.
- c) Excessive muscle noise: Random noise in excess of 5 mm. The source of this artifact may be inadequate skin prep or a participant that is shivering or trembling.
- d) Excessive 60 Hz noise: 60 Hz noise is visible on the 12 lead ECG. This noise is usually associated with A-C interference from nearby machines. Other sources may include poor skin contact.
- e) Valid calibration documentation: Calibration standard should be recorded on each resting ECG. Invalid calibration exceeds  $\pm 1.0$  mm of the standard 10 mm pulse. Equipment should be calibrated if out of acceptance range. Please note, however, that in special cases when with standard calibration the ECG complexes run off the page, which interferes with ECG analysis, it is permissible to change the calibration.

- f) Missing leads: ensure all 12 leads are recorded, if a lead is missing, identify the missing lead, replace the lead, and obtain another ECG.
- g) Check for lead reversal: The 12 lead ECG should be inspected for possible lead reversals. Look for normal progression of chest lead patterns from V1 to V6. Inspect lead AVR for negativity, and lead I for mainly positive P, QRS and T wave. If any condition is suggestive of lead reversal, re-check the electrode cable attachment.

**Sources of artifact:** The most common cause of artifact is inadequate skin preparation.

Other sources of artifact include:

- Defective electrodes (check expiration dates; gel dries over time)
- Fractured lead wires (connects the electrodes to the acquisition module)
- Fractured wires in the acquisition cord interface (connects the acquisition module to the electrocardiograph)
- Participant not resting quietly and relaxed

### 6.5 Post Recording Alert Check

You are not expected to be able to interpret ECGs. However, you need to familiarize yourself with interpretative statements printed on the ECG hard copy by the automated ECG analysis program. These alert conditions include situations that may warrant referral because of the possibility of acute (new) cardiac injury (myocardial infarction) and certain arrhythmic events or cardiac conduction problems that may call for therapeutic actions.

The automated interpretation provided by the ECG machine should be considered a screening device that tends to be overly sensitive. Most of the interpretive statements such as “non-specific repolarization abnormalities” or even “myocardial infarction – age undetermined” are not considered acute events needing referral.

The following conditions are immediate and urgent alerts (as noted) identified in the protocol. The following statements would require clinic physician review:

- Indication of any of the following conditions on automated ECG interpretation:

QRS > 120 ms AND heart rate > 120 (with symptoms\*)

OR

ST segment elevation > 1 mm (acute infarction pattern) OR ST-T wave abnormalities consistent with ischemia, (with symptoms\*)

Heart rate > 140 or < 40 beats/min

3<sup>rd</sup> degree or complete AV block

\*Symptoms include chest pain, shortness of breath, dizziness or fainting spells.

- Indication of any of the following conditions on automated ECG interpretation

Heart rate  $\geq$  120 (tachycardia)

Wolff-Parkinson-White (WPW) ECG pattern or ventricular pre-excitation  
Mobitz type II AV block

Any abnormal result listed above as an **immediate** alert condition should be overread by a physician in the clinic before the participant leaves. The clinic physician will determine if immediate notification of the participant is required. If necessary, ECG will be faxed to the participant's physician (upon participant request) or sent with the participant to his physician. Results listed as **urgent** should be reviewed by the study physician within a week, with notification to the participant (if necessary) by phone or letter within 10 days. For any alert, whether immediate or urgent, the result should be indicated on the ECG form, and a **Medical Alerts and Adverse Events** form should be completed and sent to the Coordinating Center (see chapter on Medical Alerts and Adverse Events for further details).

Note that it is not advisable to alarm the participant by revealing these unconfirmed interpretative statements. However, it is helpful to casually inquire if the person has recently had chest pain or discomfort. If the answer is yes, it is particularly important that you notify the clinic physician. A negative answer does not mean that you can ignore the alert: heart attacks are often asymptomatic (silent).

## 6.6 Complete ECG form

The ECG form should be completed for all participants at the MrOS Sleep Study, regardless of whether or not they completed an ECG.

## 6.7 Quality Control Checklist: ECG Acquisition

### Prior to participant arrival:

- Confirm battery is charged
- Confirm adequate paper supply
- Skin prep supplies are available
- Exam table has clean sheets and gown is available for the participant; table is secured against a wall or the wheels are locked.

### After participant arrival:

- Explain procedure.
- Request the participant disrobe to the waist and provide a clean (or disposable) gown with the opening to the front.
- Have the participant assume a semi-recumbent position on the exam table. with head on one pillow and the arms relaxed and to the side.
- Mark electrode positions with felt tip pen.
- Skin prep the electrode sites.
- Attach the electrodes.
- Attach the lead wires to the electrodes.
- Enter the participant information in the MAC PC.
- Record 12 lead ECG.
- Visually inspect the 12 lead for quality (including baseline wander, excess artifact and lead reversal).

- Repeat ECG if quality is poor.
- Inspect the ECG for alert conditions ( if alert conditions present contact the study physician).
- Disconnect the leadwires in the same order to check for possible lead reversal.
- Remove the electrodes.
- Wipe marks and goop off skin.

## 6.8 Deleting ECGs

ECGs can be deleted once the ECG has been reviewed for medical alerts, printed and placed in the participants chart.

## 7. Quality Assurance

### 7.1 Training Requirements

Previous clinical experience in acquiring ECGs is required to perform this assessment. Training should include:

- Read and study manual
- Attend MrOS Sleep Study training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Discuss problems and questions with local expert or QC officer

### 7.2 Certification Requirements

- Complete training requirements and examinations
- Recite alert diagnoses
- Submit five consecutive resting ECGs to CC for certification before MrOS Sleep Study participants are seen

### 7.3 Quality Assurance checklist

#### **Before participant arrival:**

- Confirm battery is charged
- Confirm adequate paper supply
- Skin prep supplies are available
- Exam table has clean sheets and gown is available for the participant.
- Table is secured against a wall or the wheels are locked.

#### **After participant arrival:**

- Explain procedure

- Request the participant disrobe to the waist and provide a clean (or disposable) gown with the opening to the front
- Have the participant assume a semi-recumbent position on the exam table with head on one pillow and the arms relaxed and to the side
- Mark electrode positions with felt tip pen
- Correct prep procedure for the electrode sites
- Correct lead placement
- Attach the lead wires to the electrodes
- Record 12 lead ECG
- Visual inspection of the 12 lead for quality (including baseline wander, excess artifact and lead reversal).
- Repeat ECG if quality is poor
- Inspect the ECG for alert conditions and report as instructed
- Disconnect the leadwires
- Remove the electrodes
- Unneeded ECGs deleted from directory

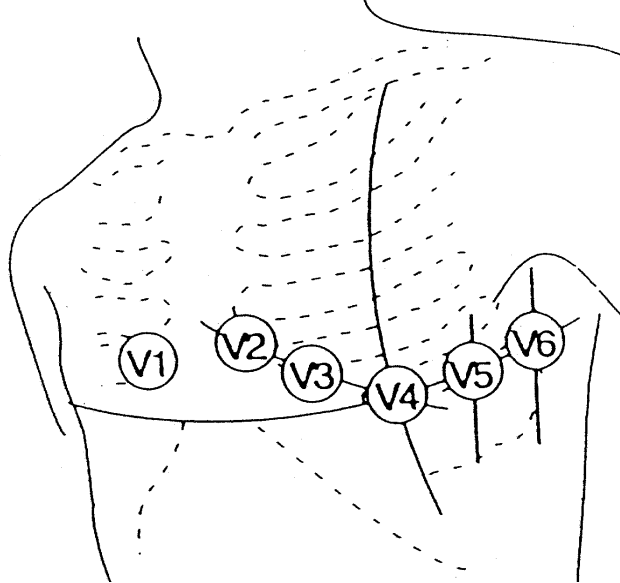




**Attachment B: 12 Lead ECG electrode lead placement****Limb Electrodes:**

- Lead RA: Inner right arm above the wrist  
 Lead LA: Inner left arm above the wrist  
 Lead RL: Right lower leg above the inner ankle or as close as the electrode will reach  
 Lead LL: Left lower leg above the inner ankle or as close as the electrode will reach

*(If the participant has an amputated limb, place the electrode on the body part closest to that limb)*

**Chest Electrodes (diagram from MAC PC Operators Manual):**

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