

SECTION 13

ECG PROCEDURES

INTRODUCTION

Standard 12-lead ECGs are obtained at baseline for all Clinical Trial (CT) participants. This will enhance the accuracy of estimating the prevalence of cardiovascular disease (CVD) in the study population and characterize the cardiovascular status regarding conditions such as left ventricular hypertrophy and cardiac arrhythmias. See *Figure 2.1 - Frequency of CC Tasks* for schedule of ECGs at follow-up visits.

A standard 12-lead ECG (12 SL ECG) is performed in a supine or semi-recumbent position for all participants. The safety and comfort of the participant are the highest priorities. The MACPC electrocardiograph is used to record the ECGs and transmit the readings to the ECG Center for diagnostic classification.

Extra effort is required to achieve accurate electrode placement than in routine clinical ECG laboratories, and to reduce the occurrence of incorrectly connected electrodes (*lead reversals*). In the event of inadequate ECG quality (grades 4 or 5), immediate corrective action is needed to correct technique. See *Form 311 - ECG Quality Assurance Checklist*.

13.1 General Requirements and Set-Up

13.1.1 Storing Supplies

Storing the ECG Paper

The thermal paper used in the MACPC can be stored for an indefinite period of time with the following precautions. These precautions apply to both unused paper and to paper that has already been run through the MACPC printer.

- Store the thermal paper in a cool, dry, and dark place, where the temperature is below 27.6°C (80°F) and the relative humidity is between 40% and 65%.
- Do not store thermal paper in a location where it will be exposed to bright light or ultraviolet sources such as sunlight, fluorescent light, or similar lighting. Ultraviolet light causes yellowing of paper and fading of tracings.
- Avoid contact with cleaning fluids and solvents such as alcohol, ketone, ester, ether, etc.

Storage of Adult Disposable Electrodes

The adult disposable electrodes are made with a unique conductive adhesive hydrogen. Their performance may be adversely affected if individual cards of electrodes are exposed to air or liquids for long periods of time. Always store unused cards of electrodes in their pouch or in a sealable plastic bag. Store unopened products in a cool, dry place.

13.1.2 MACPC Description

The MACPC is a widely used piece of equipment approved by the Underwriter's Laboratory and represents the most advanced technology in electrocardiography. In a matter of seconds, the MACPC is capable of delivering a complete computerized analysis of an ECG, both in morphology and rhythm.

For WHI, you will use the MACPC to obtain and store data before transmitting it to the ECG Center. The MACPC can store up to 12 ECGs before transmission. Complete instructions for operating the MACPC are provided with your machine. Read the manual thoroughly and become familiar with your model machine.

Equipment Precautions

The MACPC Unit is grounded so that the risk of electrical shock is highly unlikely. However, if at any time a "short" occurs or you discover frayed wiring or a potentially dangerous situation, do not use the equipment. Do not attempt to remove the cover or back of the unit. Notify your supervisor immediately of any equipment malfunction or damage. The safety of the participant during the recording is of utmost importance. Clean the ECG equipment at regular intervals. Use a dust-free cloth to clean the keyboard and the liquid crystal display.

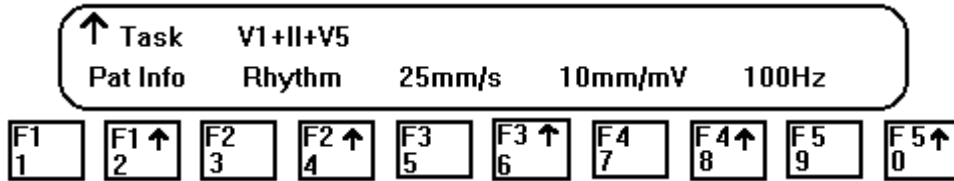
13.1.2.1 MACPC Keyboard Description

The Liquid Crystal Display (LCD) is on the top part of the MACPC keyboard and is used for entering information and displaying messages. The keyboard descriptions listed in the following sections correspond to the MACPC keyboard pictured in *Figure 13.1 - Liquid Crystal Display and Keyboard Description*.


Function Keys

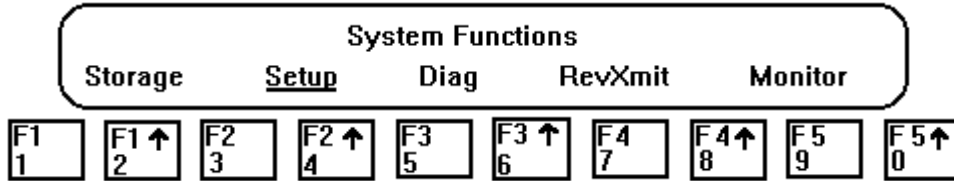
Notice that the keyboard has a set of 10 numerical keys. Each key has a letter F with a number from 1 to 5 on it (**F1, F2, F3, F4 or F5**), as well as a single number (1, 2, 3, 4, 5, 6, 7, 8, 9, 0). The keys serve as dual-

purpose keys. The keys are used to type in numerical data or to select an item from the LCD display. For example, in the *Main Menu* display below, pressing either the **1** or **2** key would select the *Pat Info* function because that *Pat Info* is directly above these two keys.



The *Task* function, on the other hand, appears next to an arrow in the display. To select this function, press the **SHIFT**

key  and either the **1** or **2** key at the same time. This causes *Main Menu* display to change to:



If you press the **1** or **2** key now, then you would be selecting *Storage* since the *Storage* function is directly above these two keys.



Figure 13.1
Liquid Crystal Display and Keyboard Description
THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-1.DOC

13.1.2.2 MACPC Set-Up



(See Marquette MACPC Operator's Manual, Chapter 12 - Cart Set-up for further information.)

To begin set-up, press  to display the **Main Menu**:

↑ Task	V1+II+V5
Pat Info	Rhythm 25mm/s 10mm/mV 100Hz



Next, press  (shift) and  at the same time to display the **System Functions** menu.

System Functions				
Storage	<u>Setup</u>	Diag	RevXmit	Monitor



Follow the steps below to set up the MACPC. Repeat the steps any time you need to reset the MACPC, for example, after running out of power.

13.1.2.3 Date and Time Set-Up

Select **Setup** (F2) by pressing either  or  to set the date and time. The following display will appear if a Level 1 password has been entered: [Enter L1 (password)press return.]

Date and Time Setup Enter:

Date	Time
------	------


 



↓

Today's Date [DD-MMM-YY]: DD=Day, MMM=Month Name, YY=Year	Type day + dash + month + dash + year and press
---	---

↓

Date and Time Setup	
Date	Time

 (return).

↓

Press either 3 or 4.

Time (HH-MM)
HH=Hour, MM=Minute [24 Hr Clock]

Enter:
Type hour +
dash + minute
and press




Date and Time Setup
Date Time

13.1.2.4 Phone Set-Up

Cart Setup
Dat/Tim Phone LdGrps Reports More

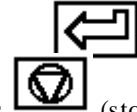
F2 3 F2 ↑ 4


Press  (stop) to
return to the
Main Menu.

Press either 3 or 4.

Phone Number
0-9 # * = ,

*Type phone number.
Then press



Press  (stop) to return to
the
Main Menu.

* The # and * signs are touch-tone symbols.

The "," sign provides a 2-second pause and may be used repeatedly for longer pauses.
(For example, in the phone number 1,,,8082345 there will be a 6-second pause between
the 1 and 8 numbers when dialing.)

The "=" sign is used to wait for a dial tone. (For example, in order to dial an outside
number, your phone system may require you to dial 9 before dialing the 7-digit phone
number. In this case, you would type in 9 = before the 7 digits. A sample number would look like this: 9=1234567.)

You may need a telephone repair person to arrange a direct line to the ECG Center's transmission number (910) 716-0837. This often occurs when an authorization number is needed to obtain an outside line.

13.1.2.5 Miscellaneous Set-Up

See Marquette MACPC Operator's Manual, Chapter 12 - Cart Set-up for further information.


To complete MACPC set-up follow this format:

Enter:


More

1.

Cart Setup
Dat/Tim Phone LdGrps Reports More

2.	<div> <div>Cart Setup</div> <div> Modem Passwds Misc Defaults More </div> </div>	Misc																																																				
3.	<div> <div>Line Frequency</div> <div> 60 Hz 50 Hz </div> </div>	60 Hz																																																				
4.	<div> <div>Cart ID:</div> <div>See Server (CC) Numbers Below</div> <div>0-255</div> </div>																																																					
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5.	<div> <div>Site ID:</div> <div>1-255</div> <div>50</div> </div>	“50” identifies the ECG as belonging to WHI																																																				
6.	<div> <div>Institution Name:</div> <div>Up to 40 Characters</div> </div>	Type your own Institution Name/State																																																				
7.	<div> <div>Number of Patient ID Digits</div> <div>1-12</div> </div>	7																																																				
8.	<div> <div>Height/Weight:</div> <div>in/lb cm/kg</div> </div>	cm/kg																																																				

9. **Input Patient Age As:**
DOB Years Years
10. **Ask Blood Pressure Questions:**
Yes No No
11. **Ask Options Question:**
Yes No No
12. **Confirmation Text**
Unconf RevdBy Unconf
13. **Suppress Normal Statements:**
Yes No Yes
14. **Suppress Border + Abnorm. Stmts:**
Yes No Yes
15. **ECGs to Store/Transmit**
All Abnormal All
16. **Delete ECGs after Transmission:**
Save Delete Save
(After transmission print a directory, then manually delete all ECGs.)
17. **Store/Transmit Control:**
Store Transmit Store until you need to transmit.

18. **Power Up Speed:**
25mm/s 50mm/s 25mm/s
19. **Power Up Filter:**
40 Hz 100 Hz 100 Hz
20. **Screening Criteria:**
Yes No No
21. **Baseline Roll Filter:**
.01Hz .02Hz .16Hz .32Hz .16Hz
22. **QC Baseline Drift:**
Yes No No
23. **QC Muscle Tremor:**
Yes No No
24. **Disable Automatic Gain Check:**
Yes No No
25. **Pace Pulse Gain (AM-3):**
Normal Enhance Normal
26. **Bad Lead Handling (AM-3):**
Use Flatline Flatline
27. **Cart Setup**
Modem Passwds Misc Defaults More
- Press  (stop) to return to Main Menu

13.2 Preparing for ECG Recording

The bed for ECG recording must be stable and properly supported. A stepping stool should be provided for safety if there is not a step with the table. Maintaining the participant's safety is imperative. The ECG technician needs to be attentive to special disabilities that may cause serious injuries, especially for older women (hip fractures, etc.). Make sure that the legs of the exam table are seated firmly on the floor (or on holders if a folding type of bed is used). Place a pillow at the head of the exam table and cover it with clean examination paper. The participant can be supine (flat on her back) or semi-recumbent.

1. Check the following:
 - Clean sheets or examination paper are on table/bed.
 - Bed is wide enough to support the participant's arms comfortably.
 - Participant is comfortable and relaxed.
2. Introduce yourself:
 - Ask the participant to relax, and explain a bit about what you are going to do, for example:
"Have you ever had an electrocardiogram recorded before?"
"It does not hurt, so just relax."
"This will not take long—less than ten minutes."
 - Explain why we are doing this:
"We are trying to learn more about heart disease in women."
3. Ask the participant to undress to the waist and put on a gown with the opening in the front. Ask her to sit or lie in a supine or semi-recumbent position on the recording bed with shoulders straight and arms relaxed at the sides.
4. Keep the participant covered as much as possible during lead placement and close the gown opening in front when lead placement is completed.
5. Ask her to avoid movements which may cause errors in marking the electrode locations, but encourage her to talk.
6. Use a bed that is wide enough to properly support her elbows.
7. Use felt tip pens or wax pencils for marking chest electrode locations.
8. Wipe the general area of each electrode position with an alcohol prep to remove skin oil and perspiration.

13.2.1 Limb Lead Electrode Placement

To assure comparability of data, follow the uniform procedures for electrode placement, skin preparation, and quality assurance below. Refer to *Figure 13.2 - Placement of Limb Leads* for placement of the leads.

Note: Electrode positions in women are determined with respect to anatomical landmarks on the thorax. In women with large pendulous breasts, leave breast in place while placing electrodes. Gently move the breast if participant appears uncomfortable with electrode placement.

1. Begin with the RIGHT LEG. This is an important connection as it is the ground connection. A careless skin electrode connection here will influence all ECG leads. Mark a dot or X with a marker on the inner side of the right leg. Use firm circular motions with the alcohol gauze, rubbing about ten times or until skin becomes red. For women with dark skin, rub ten times.
2. Repeat this procedure for the RIGHT ARM.

3. LEFT LEG. Prepare the skin, and mark the position.
4. Repeat this procedure for the LEFT ARM.
5. Place the limb electrodes on the four sites prepared and marked. The connector edge of the electrodes should face up towards the head. Do not connect the electrode cables until you have completed locating and preparing the chest electrodes.
6. Use of the newest type disposable silver chloride electrodes is highly recommended for hygiene, easy application and removal after recording, and ECG quality. These disposable electrodes do not need electrode paste.
7. If the participant has an amputated limb, place the electrode on body part closest to that limb. For example, in amputated arms, place electrode near shoulders; and in amputated legs, place electrodes above the hip. See *Figure 13.2 - Placement of Limb Leads*.

Figure 13.2
Placement of Limb Leads

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13.2.2

Locating Chest Electrodes

Refer to *Figure 13.3 - Anatomy of the Sternum*, *Figure 13.4 - Anatomic Structure of the Thorax*, and *Figure 13.5 - Location of Chest Electrodes* for placement of the chest electrodes and to the Heart Square in *Figure 13.6 - Heart Square*.

1. Location of electrodes V1 and V2.

Standing on the left side of the participant, locate the sternal angle (where the manubrium joins the sternum) firmly in between the index and middle fingers of your right hand at the mid-sternal line. Move your fingers along the sternal angle laterally to the right sternal border. This is where the second rib joins the sternum. Locate the second rib firmly in between your two fingers. You now have your index finger in the second intercostal space at the right sternal border. Replace your index finger position by your middle finger and move your index finger to the third intercostal space. Make sure that you feel the third rib in between your two fingers. Replace the position of your index finger by your middle finger and move your index finger to the fourth intercostal space at the right sternal border. Your index finger is now at the location of V1. Make an X with your pen.

Now locate V2 at the level of V1 at the left sternal border. Feel the fourth intercostal space there firmly and mark V2 location with your pen.

At this point, mark a dot in the midsternal line in between V1 and V2. This mark will serve as a reference level for V1 and V2 and the fourth intercostal space in case you lose the location marks of V1 and V2 during skin preparation.

2. Location of the horizontal reference level for electrodes V4, V5 and V6 (point E).

Starting from the V2 location, keep the middle finger of your right hand firmly in the fourth intercostal space and move it laterally and slightly diagonally downwards in the fourth intercostal space towards the nipple. Feel the fifth rib with your index finger and move your middle finger to the fifth intercostal space. Move your finger in the fifth intercostal space laterally to where the left midclavicular line intersects the fifth intercostal space. (The midclavicular line starts where you feel a bend in the clavicle. The midclavicular line is like a longitude line on the globe at a 45 degree angle towards the center of the thorax.) Now mark the exact transverse (horizontal) level of the point of intersection of the midclavicular line with the fifth intercostal space at the midsternal line below V1 and V2. It will be approximately one inch below the dot between V1 and V2. This is E. It is a reference level for the locations of V4, V5 and V6.

3. Location of electrode V6.

Move the participant's elbow laterally away from her body. Note the starting point of the left midaxillary line halfway between the axillary folds formed by the anterior and posterior axillary lines. Follow the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of E. This is the exact location of the V6 electrode. Note that it is a common mistake to locate the midaxillary line too far anteriorly, towards V5 location.

4. Location of V4, V5, and V3 electrodes and Heart Square Measurements.

The Heart Square accommodates all expected dimensions of thorax diameters. It simplifies the procedure by eliminating the need for calculating the difference between E and V6 measurements.

- Place the Heart Square firmly on the lower sternum at position E (see *Figure 13.6 - Heart Square*). Verify that the E and V6 arms of the Heart Square are exactly horizontal and vertical in the horizontal plane of the thorax at the level of the E position. (If the Heart Square does not slide easily, a small amount of a lubricant, such as WD-40, can be used. Lubricant must not come in contact with skin.)

- Slide the V6 arm of the square so that the arrow pointing to V6 is exactly at the marked V6 location (0 cm arrow on V6 arm).
- Read measurement at E to the nearest 0.5 cm. Identify this same number along the V6 arm and follow the corresponding 45° line to mark V4 position. (See *Figure 13.5 - Location of Chest Electrodes*.)
- Record the E measurement in the ECG Recording Log, dropping the decimal point (e.g., 14.0 cm = 140). Record the V6 measurement (at the V6 scale where it intersects the E arm) as you do for the E measurement. (e.g., 7.0 = 070.)
- Proceed to mark location V3, which is equidistant between V2 and V4, and V5, which is equidistant between V4 and V6.
- Enter measurements on *Form 91 - ECG Log Sheet* as follows:
e.g. E = 140 in the Height field (three digits)
V6 = 070 in the Weight field (three digits)

Wash Heart Square with gentle soap and warm water (one part detergent to 10 parts water) after each participant is measured. Gently wipe dry with a soft cloth. Lubricate as necessary. Do not drop the Heart Square.

13.2.2.1 Locating Chest Electrodes in Large Chested Women

Women who have a BMI of >40 may have a chest width greater than the Heartsquare can accommodate. In these situations, use the following guidelines for lead placement:

1. Follow instructions given in section 13.2.2 - *Locating Chest Electrodes* to determine location of V1, V2, V4, and V6 (point E).
2. Keep the Heartsquare strictly horizontal and vertical in the reference frame of the thorax at the level of E and V6. Use a steady and firm pressure against soft tissues.
3. Make a mark on the participant at the last Heartsquare measurement. (The last marking available on the Heartsquare arm for either E or V6 arm.)
4. Use a tape measure to measure this distance (in centimeters) between the last Heartsquare marking and the actual E or V6 mark on the participant.
5. Add this distance to the initial E or V6 readings for the correct values and record them in the appropriate "Height" and "Weight" columns respectively of your log.
6. To locate V2-V5 lead sites, measure the distance between E and V6.
 - V4 will be located at the midpoint in the horizontal plane of E and V6.
 - V3 will be located at the midpoint between V2 and V4.
 - V5 will be located at the midpoint between V4 and V6.

NOTE: V2, V3, and V4 must be on a straight line in a 45 degree angle to midsternal line. V4, V5, and V6 should be on a straight line in the same plane as E.

Figure 13.3
Anatomy of the Sternum

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Figure 13.4
Anatomic Structure of the Thorax

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Figure 13.5
Location of Chest Electrodes

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Figure 13.6
Heart Square

THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-6.DOC

13.2.3 Skin Preparation for Chest Electrodes

Rub each chest electrode location briskly with alcohol and gauze (or sandpaper wipes) in a circular motion up to 10 times or until the skin becomes slightly red. This removes dead skin and oil.

If the rubbing of the skin removes the marks of electrode locations, remark each location. Never rub location E or the spot between V1 and V2. Use these as landmarks for remarking V1 and V2, V4 and V6, and finally, V3 and V5, in that order.

Place electrodes now in their sites in the order V1, V2, V3, V4, V5 and V6.

13.2.4 Attachment of Electrode Cables

The optimal sequence of electrode cable connecting is determined by the design of the ECG Acquisition Module of the MACPC. Follow the same order to minimize the risk of wrong connections (lead reversals).

Figure 13.7 - Acquisition Module 3 (AM3) and *Figure 13.8 - Acquisition Module 4 (AM4)* indicate two different types of acquisition modules for the MACPC. AM3 facilitates connecting leg electrodes first (RL, LL, RA, LA). AM4 facilitates connecting RL, RA, LL, LA. Most CC sites will have AM4 modules.

Start by placing the ECG Acquisition Module on the participant's left side or lower chest. (Place a small towel under the module for participant comfort.)

The correct sequence for connecting the electrode cables is:

1. Right Leg (RL)
2. Right Arm (RA)
3. Left Leg (LL)
4. Left Arm (LA)
5. V1
6. V2
7. V3
8. V4
9. V5
10. V6

Make sure that you do not mix up what is your right and left and what is the participant's right and left. This happens easily and more often than you think.

Electrode cables should come in reasonably straight lines along the body toward the electrodes. Avoid looping cable wires. Place wires so that there is as little tension as possible on the electrodes.

With disposable electrodes, the silver dot on the connecting wire must touch the electrode. In newer models of the MACPC, this is facilitated by an alligator clip with a button on the top side and the silver dot on the down side.

Figure 13.7
Acquisition Module 3 (AM3)

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Figure 13.8
Acquisition Module 4 (AM4)

THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-8.DOC

13.2.5

ECG Preparation Summary

*Table 13.***Error! Bookmark not defined..** - *ECG Preparation Summary* lists the steps and sequence to follow in locating and marking the electrode sites, skin preparation, electrode placement, and electrode cable attachment.

Table 13.1
ECG Preparation Summary

A.	Locate and Mark	1. RL	3. LL
		2. RA	4. LA
B.	Prepare Skin	1. RL	3. LL
		2. RA	4. LA
C.	Attach Electrodes (connector facing head)	1. RL	3. LL
		2. RA	4. LA
D.	Locate and Mark	1. V1	
		2. V2	
		3. Spot between V1 and V2	
		4. E	
		5. V6	
		6. V4 using Heart Square Measurement	
		7. V3	
		8. V5	
E.	Prepare Skin and Re-mark Locations	1. V1	4. V4
		2. V2	5. V5
		3. V3	6. V6
F.	Attach Electrodes (if disposable electrodes)	1. V1	4. V4
		2. V2	5. V5
		3. V3	6. V6
G.	Connect Electrode Cables to Limb Leads	1. RL	3. RA
		2. LL	4. LA
H.	Connect Electrode Cables to the Chest Electrodes	1. V1	4. V4
		2. V2	5. V5
		3. V3	6. V6
I.	Verify one by one that the connections to all electrode sites are correct. Recognize the letter code on the cable before connecting each electrode.		

13.2.6 Registering Participant in the ECG Log

Before recording the tracing, record the following information on *Form 91 - ECG Log*. Remember to write in your CC number on each log sheet. (The name in parenthesis is the name of the MACPC field into which you will enter the data.)

- Date of Recording
- Participant's Last Name
- Participant's First Name
- First 7 Digits of Participant's ID Number
- Last Digit (character) of Participant's ID Number
- Baseline or Follow-up number (Location Number field):

Screening Visit	00
AV3	01
AV6	02
AV9	03
Closeout	04

- Technician Staff ID (Room Number field)
- Participant's Age
- Measured E Value (Height field)
- V6 Measurement (Weight field)

13.2.7 Entering Participant ID

For each tracing, enter the following information into the MACPC from *Form 91 - ECG Log* in the order listed.

Select "Pat Info" by pushing 1 or 2. For several items the MACPC message does not correspond to the value you should enter. The list below gives the MACPC message followed by the value to enter in parenthesis.

<u>MACPC Message (WHI Value)</u>	<u>Enter</u>
1. New Patient	Yes/No
2. Patient's Last Name (Acrostic)	Enter first four letters of the last name <u>only</u> . If the last name is less than four letters, use asterisks at end of name to complete four characters.
3. Patient's First Name (Check digit)	Enter the last digit (a letter) of the participant's ID number.
4. Patient's Identification Number	Enter first seven digits of participant's ID number.
5. Referred by	Enter WHI
6. Location Number (Baseline or Follow-up Number)	Enter follow-up number (see list in 13.2.6 - <i>Registering Participant in the ECG Log</i>)

- | | | |
|-----|--------------------------------------|---|
| 7. | Room Number
(Staff ID) | Enter 3-digit WHI employee number. |
| 8. | Patient greater than one year of age | Yes. |
| 9. | Age | Enter participant's age in years (2 digits). |
| 10. | Height
(E value) | Enter E measurement (3 digits, no decimals). |
| 11. | Weight
(V6 measurement) | Enter V6 measurement (3 digits, no decimals). |
| 12. | Sex | Enter female. |
| 13. | Race | Press Enter. (Answer not necessary for WHI.) |
| 14. | Medications | Press Enter. (Answer not necessary for WHI.) |

13.3 Recording the 12-Lead ECG

Ask the participant to relax, breathe normally and to remain still (without talking) while the tracing is recorded.

Record the ECG following the instructions and the format provided in the Marquette MACPC Operator's Manual, Chapter 3 - Taking a Resting ECG.

13.3.1 Error Messages

Observe the display panels on the MACPC for indication of an error, either a lead reversal, poor quality, or a missing signal from a lead. Common problems are listed in *Section 0 - 13.3.2 Quality Check After Recording* below. *Chapter 15 - Troubleshooting* in the Marquette MACPC Operator's Manual gives a listing of other possible messages. If any of the listed displays occurs, the problem should be corrected before transmission to the ECG Center.

13.3.2 Quality Check After Recording

It is extremely important that the electrocardiograms have a clean baseline and are free of drift, muscle tremor, and A-C interference. Enough variables influence the tracing without introducing unnecessary technical ones. It is the responsibility of the examiner to produce high quality ECGs, using uniform techniques from tracing to tracing every day. ECGs will be given a quality grade of 1-5. Grades of 4 and 5 are not acceptable.

After running, inspect the ECG record immediately for quality. Repeat the ECG recording if you spot any quality problems.

Use the following checklist to identify any potential problems:

1. Excessive baseline drift in any lead.

Drift in excess of 1 mm between baseline points (QRS onset) of any two successive complexes is a sign of excessive drift (see *Figure 13.9 - Excessive Baseline Drift*). This often occurs with poor skin preparation.

2. Excessive muscle noise.

Random noise in excess of 1/2 mm may cause coding problems and requires a repeated recording (see *Figure 13.10 - Excessive Muscle Noise*).

3. Motion artifacts, loose electrode contact, or electrodes falling off. These may cause sudden jumps in some ECG leads (see *Figure 13.11 - Motion Artifacts or Loose Electrode Contact*).

Electrodes falling off is common particularly when electrodes are placed on hairy arms or legs; loose skin can also be a problem and certain precautions can save time.

1. Establish a good connection by parting the hair before attaching the electrode.
2. Lay a towel across the wires to prevent the weight of the wire from tugging at the electrode. A twisted wire may tend to pull at the electrode. If necessary, re-position the electrode by slightly adjusting the angle of the clip away from the patient-cable box.
3. It may be necessary to tape down the electrodes on the arms and legs of participants with extremely hairy arms and legs.
4. Excessive 60 Hz noise.

Periodic 60 Hz noise visible in the record is often associated with poor skin-electrode contact, participant not being relaxed, or unfavorable recording location. The latter can be caused by A-C interference from nearby machines and is a common problem in a CC or hospital setting. It can be caused by poor

electrode contact or interference from nearby equipment. The technician should try different instructions from Chapter 15 - Trouble-Shooting Guide in the MACPC Operator's Manual to track down the source of the interference. Watches, eye glasses, rings, or bracelets do not cause interference. Make a visual check of this before recording.

5. Possible lead reversals.

Look for normal progression of chest lead patterns from V1 to V6. Normal progression of QRS-T patterns does not occur in many abnormal conditions but the absence of normal progression always warrants ruling out possible electrode reversal problems. Most common lead reversals involve leads V2 and V3, V3 and V4, V1 and V3 (see *Figure 13.12 - Lead Reversal, V1-V3*), and left arm/right arm. LA/RA lead reversal is easy to spot (*Figure 13.13 - Lead Reversal, LA-RA*) and should be suspected if P, QRS and T are all mainly negative in lead I.

Lead reversals such as RA-RL reversal are difficult to detect and can cause critical diagnostic classification errors. They often go unnoticed. Therefore, the procedures recommended for double-checking electrode lead connections are extremely important (see *Table 13.1 - ECG Preparation Summary* in *Section 0 - ECG Preparation Summary* above). The expected incidence of true CVD events in the trial is fairly low.

Figure 13.9
Excessive Baseline Drift

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Figure 13.10
Excessive Muscle Noise

THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-10.DOC

Figure 13.11
Motion Artifacts or Loose Electrode Contact

THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-11.DOC

Figure 13.12
Lead Reversal, V1 - V3

THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-12.DOC

Figure 13.13
Lead Reversal, LA-RA

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13.3.3

Post-Examination Procedures

1. Remove the tracing from the MACPC.
2. Remove the lead wires and electrodes. Care should be taken when removing electrodes since this procedure can cause some discomfort and skin irritation. You may apply body cream after the ECG recording if the participant's skin appears irritated after removal of electrodes.
3. Place the lead wire cable in a protective covering and store in the carrying case overnight.
4. Turn off the MACPC unit at the end of the day by pressing the power switch located on the right lower side of the keyboard.
5. Complete *Form 86 - ECG*.
6. Place the ECG tracing in the participant's file flagged for CC physician review. If the quality of the ECG does not meet the standard evaluation criteria, repeat the ECG at the next possible visit.

13.3.4 Definition of Alerts

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 12SL ECG analysis program of the MACPC. 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 12SL ECG program should be considered a screening device that tends to be overly sensitive. Most of the interpretative 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 (see *Vol. 1 - Study Protocol and Policies, Section 1 - Protocol, Section 5.5.5.1 - Immediate and Urgent Referrals*). Refer to the referenced figures in this section for examples. (Individual CCs may establish additional alert conditions.)

- Heart rate ≤ 40 beats/min. (see *Figure 13.15 - Sinus Bradycardia*), or ≥ 130 beats/min. (See *Figure 13.17 - Sinus Tachycardia ≥ 130 bpm* and *Figure 13.18 - Sinus Tachycardia ≥ 140 bpm*; **Urgent**).
- Sustained ventricular tachycardia. (**Immediate**)
- Ventricular pre-excitation mobitz type II AV block, or Wolff-Parkinson-White (WPW) ECG pattern. (*Figure 13.19 - Ventricular Pre-Excitation Wolf-Parkinson-White (WPW) or Mobitz Type II AV Block*; **Urgent**.)
- Atrial fibrillation (see *Figure 13.14 - Atrial Fibrillation*) or flutter (new onset); note the ECG video only mentions atrial fibrillation. (**Urgent**.)
- Third degree AV block or complete A-V block. (see *Figure 13.16 - 3° AV Block*; **Urgent**.)
- An ECG pattern that indicates acute injury or ischemia. (**Immediate**.)

Note: The ECG video states that LBBB is an alert. This is not true for WHI.

In the case of any of these alert statements, the CC physician will decide if it is a true alert and confirm if any further action is required.

- Immediate referrals require immediate notification of the participant during the CC visit and immediate notification of the participant physician via telephone by the CC physician, nurse practitioner, or physician assistant before the participant leaves the CC. Also a follow-up letter documenting the information discussed by phone should be sent as soon as possible.
- Urgent referrals require notification of the participant before she leaves the CC or immediately upon receipt of the finding from the ECG Center and urgent notification of the participant's physician within the week.
- 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 a CC physician. A negative answer does not mean that you can ignore the alert; heart attacks are often asymptomatic (silent).

Figure 13.14
Atrial Fibrillation

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Figure 13.15
Sinus Bradycardia

THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-15.DOC

Figure 13.16

3° AV Block

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Figure 13.17

Sinus Tachycardia ≥ 130 bpm

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Figure 13.18

Sinus Tachycardia ≥ 140 bpm

THIS FIGURE CAN BE FOUND IN I:\MOP\VOL2\FIG13-18.DOC

Figure 13.19
Ventricular Pre-Excitation Wolf-Parkinson-White (WPW) or Mobitz Type II AV Block

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13.4 Transmitting ECGs

You may store up to 12 records in your MACPC. Once you have 12 ECGs stored, transmit them to EIPCARE. The MACPC continues to process ECGs when its memory is full but will not store them. You may transmit as many times a day as necessary.

Before transmitting the ECGs to EIPCARE,

- print the directory (see *Section 13.4.1 – Directory*)
- delete any duplicate ECGs (see *Section 13.4.2.1 – Routine Deletion*)
- verify the participant ID numbers and make any needed corrections (see *Section 13.4.2.2 – Editing an ECG*)

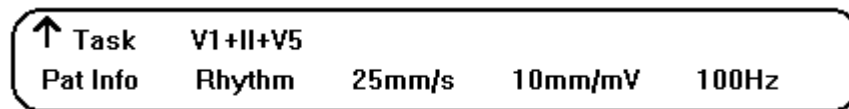
13.4.1 Directory



(See Chapter 8 - Directory, MACPC Operator's Manual.)

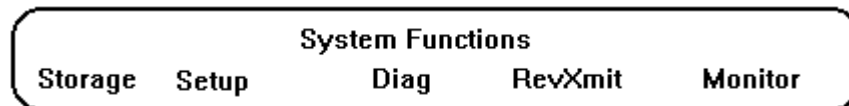
The directory (**Dirctry**) function allows you to look at what ECGs are stored in the MACPC's memory. This function gives you information such as the participant acrostic and ID number, date when the ECG was taken, how many ECGs are stored in memory, how much of memory is left to store ECGs, etc.

To print a directory, follow these steps below:

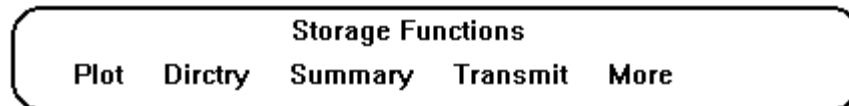
1. If the *Main Menu* is not displayed, press  to return to it:



2. Press  and  at the same time to display the **System Functions** menu. Then press one of the two keys listed under each of the following displays:

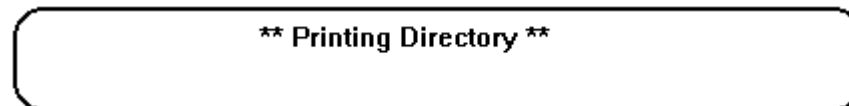


Storage



Directory

- 3.
4. Selecting **Dirctry** (F2) causes this message to be temporarily displayed:



A directory similar to the following one will be printed:

MACPC-Storage Directory 01-JAN-87-12:37

ID	Name	Date	Time	Type	U/C	Cart	Loc	Site	Room	Size
276778100	GLEN, BRADLEY	01-JAN-87	12:06	ECG	U	001	02	001	806	5%
123456789	WALABIZINSKI, STACHIO	01-JAN-87	12:13	ECG	U	001	01	001	234	4%
332987702	CRUCIAN, ROSE	01-JAN-87	12:22	ECG	C	001	00	001	23	3%
3 ECG(S) 12% Used 88% Free										

Compare this to your handwritten log to assure correct information before transmission.

You **MUST** print a directory before transmission so you can delete ECGs which you recorded more than once. Print a final directory after deletions and corrections and attach this to your daily log.


13.4.2 Deleting an ECG and Editing an Invalid ID Number

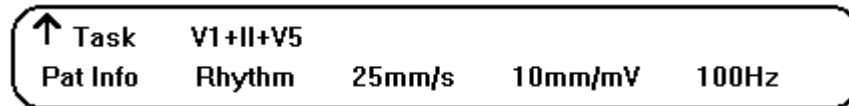
See Chapter 9 - Deleting an ECG, MACPC Operator's Manual.



13.4.2.1 Routine Deletion

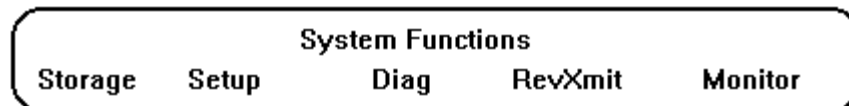
ECGs are usually deleted after you print a paper copy of the ECG, if it is a duplicate record, or when the ECG has been transmitted to the ECG center. When deleting a duplicate ECG, check that you are in fact deleting the correct ECG. The recording time is a good clue.

To delete one or more ECGs, follow these steps:

1. If the Main Menu is not already displayed, press  :

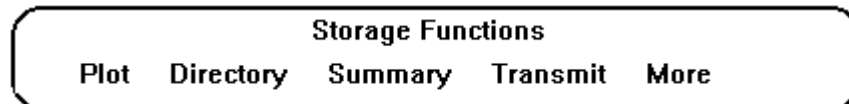


2. Press  and  at the same time to display the **System Functions** menu.



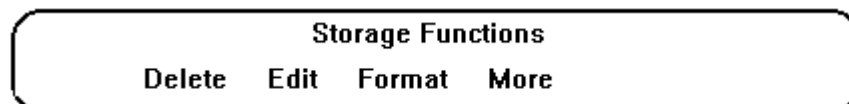
Storage

- 3.



More

- 4.



Delete

5.

Select by Patient ID?:

Yes

No

No

6. After selecting **Delete** (F4) a message similar to the following one will be displayed:

A message box with a title bar and five buttons. Above each button is a circled letter: A, B, C, D, and E. The buttons are labeled: Yes, No, No..., Yes..., and Expand. The text '123456789' is on the left and 'ALLEN, BRADLEY' is in the center.

- | | | |
|----------|---------------|---|
| A | <i>Yes</i> | selects this ECG. |
| B | <i>No</i> | bypasses this ECG. |
| C | <i>No...</i> | bypasses this ECG and all subsequent ECGs. |
| D | <i>Yes...</i> | selects this ECG and all subsequent ECGs. |
| E | <i>Expand</i> | provides additional patient information such as date and time of the ECG. (See step 6.) |

7. To display additional participant information, press **Expand** (F5) and a message similar to the one below will be displayed:

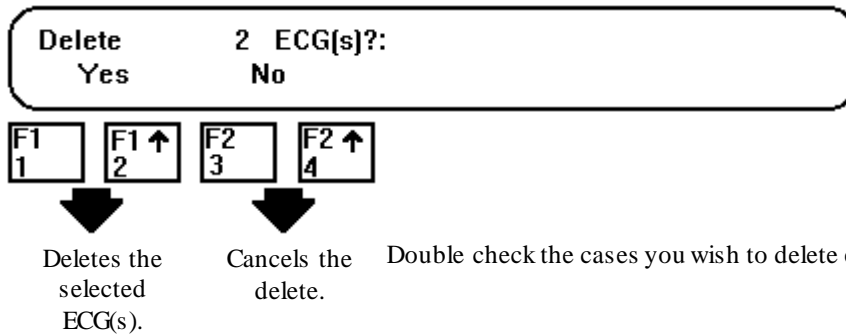
A message box with two rows of data. The first row contains: 123456789, ALLEN, BRADLEY. The second row contains: E, U, 01-JAN-89, 12:13, C001, L001, S001, and Cont. Above the first row are labels A and B. Above the second row are labels C, D, E, F, G, H, and I. Lines connect the labels to their corresponding data fields.

- | | | |
|----------|-------------------------------|--|
| A | Patient identification number | |
| B | Patient name | Last name, first name of patient or the date and time when ECG was recorded. |
| C | Cont | Select to return to former display. |
| D | Site | MUSE* site number where ECG was recorded. (This is 50 for WHI.) |
| E | Location | Location number (baseline vs. follow-up). |
| F | Cart number | CC number of unit where ECG was recorded. |
| G | | Date and time when ECG was recorded. |
| H | | U = unconfirmed ECG
C = confirmed ECG (use edit function described in Chapter 6 of MACPC Manual to change an unconfirmed to a confirmed ECG). |
| I | Type of data | E = ECG |

*MUSE

Marquette Universal System for Electrocardiography.

After you have decided which ECGs you want to delete, you have another chance to change your mind. For example, if you have decided to delete two ECGs, this message would be displayed:



Double check the cases you wish to delete especially before transmission.

13.4.2.2 Editing an ECG Report

(See Chapter 6 – Editing ECG Reports, MACPC Operator's Manual.)

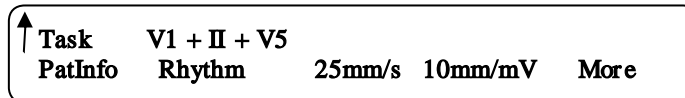
Before transmitting the ECGs to EPICARE, verify the ID numbers in the directory to ensure they are correct and there has not been a key-entry error. Also ensure that the check digit is in the first name field and the acrostic is in the last name field.

To edit one or more ID numbers:

Enter:

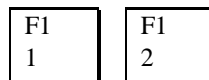
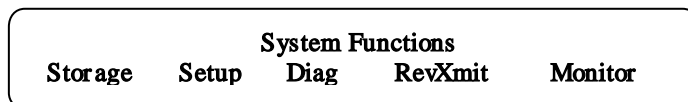
Press Shift F1

1. Display the Main Menu.

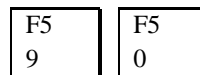
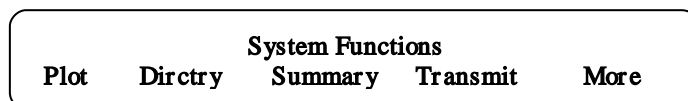


2. Display *System Functions* menu. Then press one of the two keys shown under each of the following displays:

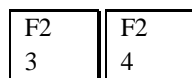
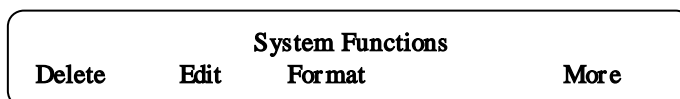
Storage



More



Edit



Enter:

PatData

Full		Edit Function	
		Pat Data	

F2 3	F2 4
---------	---------

↓

3. Selecting *PatData* (F2) displays the following message:

Yes

Select by Patient ID?:			
Yes		No	

F1 1	F1 2	F2 3	F2 4
---------	---------	---------	---------

Continue to press Enter until you reach the invalid ID you want to correct.

4. Press the ENTER Key and a display similar to the following will appear:

Patient	Last Name:	ALLEN
↑ OK	↑ Kill	↑ Print

You may now edit the ECGs one at a time until the last message is displayed:

<<End of Measurement Data>>		
↑ OK	↑ Kill	↑ Print

↑ OK Stops editing process and changes an unconfirmed report to a confirmed report.

Press Shift F1

↑ Kill Deletes most recent edits and restores information to what it was before the editing process began.

Press Shift F2

↑ Print Prints a preliminary copy of the ECG report you are editing.

Press Shift F3

13.4.3 Transmitting an ECG

Transmit records at the end of each day. To transmit, follow the instructions described below:

1. Send to the ECG Center using the transmitting number 1-910-716-0837. See *Section 0 - 13.1.2.4 Phone Set-Up*.
2. The ECG Center will eMAIL confirmation to you.
3. To confirm all ECGs you sent were received call 1-910-716-0840 for verification. This is not mandatory.
4. Those records with invalid participant ID numbers will be flagged.
5. eMAIL the correct participant ID to the ECG Center. Do not retransmit the record.
6. Proceed to delete the ECGs which were successfully transmitted.
7. The ECG Center's internet address is: EPICARE@PHS.BGSM.WFU.EDU. (No spaces)

13.4.4 Procedures at the End of Each Working Day

- Charge the ECG machine by connecting the power module to the main terminal on the side. This power module must be left plugged in all night and over the weekend when the machine is not in use.
- At the end of the day, the technician should take inventory of the equipment used for the ECG procedures. Any pieces of equipment that are missing should be reported to your supervisor.
- Regularly check and restock needed supplies.

13.5 ECG Quality Assurance Procedures

The ECG quality assurance will follow the well established procedures implemented by the ECG Center for large clinical trials. The implementation of computerized and semi-automated procedures for quality assurance has substantially economized the human effort in visual verification of computer coding.

13.5.1 ECG Quality Assurance at the Clinical Centers

CC Lead Practitioners will all participate in centralized (regional) training sessions in ECG acquisition procedures. Each Lead Practitioner and ECG technician will be individually certified. The certification will require the recording of five consecutive high quality ECGs (Grades 1 or 2).

Quality grades will be coded automatically for all ECGs transmitted. The quality grade is assigned lead by lead on the basis of random noise and worst beat-to-beat drift. Monthly summary reports will be compiled and forwarded to the CCC. Paper ECGs are not acceptable for coding due to lost data points in visual measurement analysis.

The ECG Center will also notify the CCC of all possible combinations of ECG lead reversals that still take place with unexpected frequency. A report specific to each CC will be sent monthly with requests to re-record when necessary or when the possibility of lead reversal is not certain enough to justify automatic correction by ECG software.

13.5.2 Certification in ECG Procedures

The ECG Center will assume the responsibility for Lead Practitioner and ECG technician training and certification. The ECGs recorded by the trainees are transmitted to the ECG Center and graded for quality on the basis of baseline drift and random noise. Each technician has a WHI staff ID coded with the transmitted ECG. Certification requires a successful acquisition and transmission of five successive high quality (Grade 1 or 2) recordings to the ECG Center.

Please note that certification and test ECGs that are transmitted must be clearly marked so as to distinguish them from the actual ECGs transmitted from participants in the study. **For certification and TEST ECGs, use an ID of 9999999** (seven 9s). In the "Referred By" field of the MACPC use the word CERT or TEST. Do not forget to enter the technician's name in the name field and her or his staff ID in the Room No. Field. The ECG Center can then distinguish test and certification ECGs from ECGs on participants. If the recording is to be used for study purposes, it should be retransmitted with the appropriate ID numbers. All Lead Practitioners will receive standardized training from the ECG Center staff and will then train ECG technicians at the CCs, if appropriate. Both Lead Practitioners and ECG technicians must receive certification from the ECG Center.

Each CC should have a copy of the video, "Procedures for Recording an Electrocardiogram," supplied by the ECG Center, and a training video for the MACPC, supplied by Marquette. Review these videos before to recording your first ECG.

13.5.3 Quality Assurance Summary

All CCs **MUST** adhere to the following rules:

- Store only ≤ 12 ECGs. If at the end of the day ≤ 12 ECGs were recorded, transmit them to the ECG Center (daily). If you have need, you may transmit to the ECG Center more than once a day.
- Print directory
- | • Delete any duplicate ECGs
- Edit incorrect participant IDs (See Chapter 6 - Editing ECG Reports, MACPC Operator's Manual)
- Transmit to the ECG Center
- Print Directory - file

- Edit invalid flagged participant IDs and eMAIL corrections to the ECG Center
- Print final directory - file
- Delete all ECGs from MACPC (Chapter 9 - Deleting an ECG, MACPC Operator's Manual)

Note: All these steps take up to 5 minutes to complete at the end of each day.

Tables 13.2 – Checklist for Recording ECGs and 13.3 – Checklist for ECG Processing are provided to help remind staff of key points. Post copies of these tables near the MACPC as a reminder.

At least once each month, completely drain and then fully charge the MAC PC's battery. Performing this battery maintenance procedure on a routine monthly basis is strongly recommended to extend battery life and ensure the validity of the LCD "fuel gauge." The procedures for draining and charging batteries can be found on the MAC PC Battery Maintenance document provided to clinics by EPICARE.

Table 13.2

CHECKLIST FOR RECORDING ECGs		✓ Done?
1	Review WHI Manual of Operations, Vol. 2, Sec. 13.	
2.	Make sure the bed is wide enough to support the participant, especially the left elbow, to help prevent muscle tremors.	
3.	Make sure the participant is comfortable and relaxed, to help prevent muscle tremors.	
4.	Use a blanket to cover the participant if she is cold, to help prevent muscle tremors.	
5.	Make sure the skin is properly prepared. If the skin is oily or scaly, rub vigorously to assure good contact.	
6.	Position the electrodes properly and accurately. Always attach electrodes in the same order. (See Vol. 2, Sec. 13.2.2 – Locating Chest Electrodes and Sec. 13.2.4 – Attachment of Electrode Cables.)	
7.	Make sure there is little or no tension on the connecting wires. (Use narrow strips of Velcro around limb leads to help keep wires in place.)	
8.	Ask the participant to remain relaxed and quiet while you are recording.	
9.	Review the recording for drift, muscle tremor, switching left and right leg leads (tracing shows flat line), or other artifact while the participant is still connected to the machine (see Vol. 2, Sec. 13.3.2 – <i>Quality Check After Recording</i>). Make corrections and re-record.	

Table 13.3
CHECKLIST FOR PROCESSING ECGs

		✓ DONE?																												
1.	Review <i>Vol. 2, Sec. 13 – ECG Procedures</i> for correct ECG data entry and lead placement techniques.																													
2.	Record participant information on ECG log (<i>Form 91</i>) as each ECG is performed.																													
3.	Enter participant data in the correct MACPC fields.																													
	<table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 50%; text-align: center;">MACPC FIELD</th> <th style="width: 50%; text-align: center;">PARTICIPANT DATA</th> </tr> </thead> <tbody> <tr> <td>• New Patient</td> <td>Enter Yes/No.</td> </tr> <tr> <td>• Patient's Last Name</td> <td>Enter first 4 letters of last name only.</td> </tr> <tr> <td>• Patient's First Name</td> <td>Enter the last digit (letter) of the participant's ID number.</td> </tr> <tr> <td>• Patient's Identification Number</td> <td>Enter first 7 digits of the participant's ID number.</td> </tr> <tr> <td>• Location Number</td> <td>Enter baseline or follow-up sequence number For: Enter: Screening visit AV3 AV6 AV9 Closeout</td> </tr> <tr> <td>• Room Number</td> <td>Enter WHI staff ID number.</td> </tr> <tr> <td>• Patient greater than one year of age</td> <td>Enter Yes.</td> </tr> <tr> <td>• Age</td> <td>Enter participant's age in years.</td> </tr> <tr> <td>• Height</td> <td>Enter E measurement.</td> </tr> <tr> <td>• Weight</td> <td>Enter V6 measurement.</td> </tr> <tr> <td>• Sex</td> <td>Enter female.</td> </tr> <tr> <td>• Race</td> <td>Press enter.</td> </tr> <tr> <td>• Medications</td> <td>Press enter.</td> </tr> </tbody> </table>	MACPC FIELD	PARTICIPANT DATA	• New Patient	Enter Yes/No.	• Patient's Last Name	Enter first 4 letters of last name only.	• Patient's First Name	Enter the last digit (letter) of the participant's ID number.	• Patient's Identification Number	Enter first 7 digits of the participant's ID number.	• Location Number	Enter baseline or follow-up sequence number For: Enter: Screening visit AV3 AV6 AV9 Closeout	• Room Number	Enter WHI staff ID number.	• Patient greater than one year of age	Enter Yes.	• Age	Enter participant's age in years.	• Height	Enter E measurement.	• Weight	Enter V6 measurement.	• Sex	Enter female.	• Race	Press enter.	• Medications	Press enter.	
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4.	Print a directory (see <i>Vol. 2, Sec. 13.4.1 – Directory</i> or MACPC operator's manual, Chapter 8 – Directory) and check it against your log entries before you transmit. <ul style="list-style-type: none"> • <u>Edit any invalid ID numbers</u> (see <i>Vol. 2, Sec. 13.4. – Transmitting ECGs</i> or MACPC operator's manual Chapter 6 – Editing ECG Reports), and • <u>delete any duplicate records</u> before transmission. If you transmit duplicate records, contact Epicare the same day to delete the duplicate. It is very important that this is done the same day. 																													
5.	Transmit on a regular schedule, or before you have 12 records stored in your MACPC.																													
6.	Delete the transmitted records after receiving e-mail confirmation of receipt from Epicare (see <i>Vol. 2, Sec. 13.4.3 – Transmitting an ECG</i> or MACPC operator's manual, Chapter 9 – Deleting an ECG). If you can't wait for e-mail confirmation, call Epicare directly. DO NOT re-transmit the same records unless directed to by Epicare.																													

Section 13
ECG Procedures

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