**APPENDIX 12 -- MAC-PC Setup**

**FUNCTION KEYS**
Selects function from LCD display that is directly above key or alternate function (F1) key.

**DESTRUCTIVE BACKSPACE**
Deletes alphanumeric character immediately to the left of cursor.

**LCD DISPLAY**
Presents each prompt or menu for ECG test.

**STOP**
Returns ECG cart to main menu. Terminates printing of a report.

**RECORD RHYTHM**
Prints a 3-lead or 6-lead rhythm report.

**RECORD ECG**
Print a 12-lead report.

**SHIFT/ALTERNATE FUNCTION KEY**
Changes to character displayed on top of key or alternate function (F1) key.

**LEFT ARROW**
Moves cursor left one space at a time.

**RIGHT ARROW**
Moves cursor right one space at a time.

**SPACE BAR**

**SHIFTED CONTRAST KEYS**
Shifted down arrow pressed simultaneously with the shift key. Lightens the LCD display. Shifted up arrow pressed simultaneously with the shift key, darkens the LCD display.

* For most function key uses, pressing either the normal or the alternate function (F1) key produces the same results.

---

*Strong Heart Study II 7/01/93*
APPENDIX 12 (a) Cardiograph Setup

Although your MAC PC will operate perfectly when you first receive it from the factory, you’ll want to set up a lot of the details such as date and time, the name of your institution, types of reports you want printed, etc. Once these details are set, the cardiograph will retain them until you change the details again.

To turn on Power, press

To begin cardiograph setup, press to display the Main Menu:

<table>
<thead>
<tr>
<th>Task</th>
<th>V1 + II + V5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Info</td>
<td>Rhythm</td>
</tr>
</tbody>
</table>

25mm/s 10mm/mV 100Hz

Next, press and at the same time to display the System Functions menu:

<table>
<thead>
<tr>
<th>Storage</th>
<th>Setup</th>
<th>Diag</th>
<th>RevXmit</th>
<th>Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>F2 2</td>
<td>F2 4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Select Setup (F2) by pressing either or . The following display will appear if a Level 1 password has been entered:

Password: ____________

Press keys “L” and “1” (numeric one, not lowercase “l”), then press to display the first Cart Setup menu:
Each of the above steps is explained in the following pages.
Step A: Date and Time Setup

Press Backspace-Delete to erase.

Today's Date (DD-MM-YY):
DD=Day, MM=Month Name, YY=Year

Type day + dash + month + dash + year and press

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

Type hour + dash + minute and press

Press to return to the Main Menu.
Step B: Phone Setup

Phone Number
0-9#*=., 9=18005314784

Type phone number. Then press

Press to return to the Main Menu.

Step C: Lead Groups-Rhythm Leads Setup

These should never need to be changed.

Select a group. The previously chosen leads will appear. Then press

Strong Heart Study II 7/01/93

Cardiograph Setup
Number of Rhythm Leads: 3

Select the number of rhythm leads you want on writer reports. Then press ➔

F1 1  F1↑ 2  F2 3  F2↑ 4

Select 1 of 12 available leads for each of the 3 or 6 rhythm channels; press ➔ after each selection. In the example below, the displays for the 12 available leads are shown for channel 1:

Ch 1: V1
    I  II  III  More

Ch 2: V1
    I  II  III  More

Ch 3: V5
    I  II  III  More

After selecting a lead for each of the channels, the following will appear:

Rhythm  Lead Groups
        Standrd  RMR
        4 x 2.5

Press ➕ to return to the Main Menu.

Step D: Report Formats Setup

Do not configure confirmed.
Press F2 for unconfirmed.

For each of the following LCDs press either F1 keys for “YES”, F2 keys for “NO”; and press ➔ to store the report information.
Clinic choice here. Marquette interpretation may be printed on ECG.

Phoenix enters F1 or F2 for "YES".

Strong Heart Study II 7/01/93  II- A  56  Cardiograph Setup
This is the **ONLY** format to be printed.
### Step E: Modem Setup -- Auto Dial

<table>
<thead>
<tr>
<th>Modem</th>
<th>Cart Setup</th>
<th>Misc</th>
<th>Defaults</th>
<th>More</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1①</td>
<td>F1①↑</td>
<td>F2①</td>
<td>F2①↑</td>
<td></td>
</tr>
</tbody>
</table>

**Speaker On:**
- Dial
- Always

**Dialing:**
- Auto Dial
- Manual

**Dialing Format:**
- Touch Tone
- Pulse

When you return to the start, press to return to the Main Menu.

From here, Press "RETURN" key.

Or "PULSE", may vary by site.
### Dial Tone Required

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>F2↑</td>
</tr>
</tbody>
</table>

### Dial Tone Time

<table>
<thead>
<tr>
<th>1s</th>
<th>2s</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>F2↑</td>
</tr>
</tbody>
</table>

### Modem Transmit Power Level

-9dBm
-6dBm
-7dBm
-8dBm
-9dBm
More

<table>
<thead>
<tr>
<th>F1</th>
<th>F1↑</th>
<th>F2</th>
<th>F2↑</th>
<th>F3</th>
<th>F3↑</th>
<th>F4</th>
<th>F4↑</th>
<th>F5</th>
<th>F5↑</th>
<th>F5↑</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

### Transmit Synch Time

800ms
220ms
148.3ms
90ms
More

<table>
<thead>
<tr>
<th>F1</th>
<th>F1↑</th>
<th>F2</th>
<th>F2↑</th>
<th>F3</th>
<th>F3↑</th>
<th>F4</th>
<th>F4↑</th>
<th>F5</th>
<th>F5↑</th>
<th>F5↑</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

### Answer Tone Frequency

2025Hz
2100Hz

<table>
<thead>
<tr>
<th>F1</th>
<th>F1↑</th>
<th>F2</th>
<th>F2↑</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### Answer Tone Wait (in seconds)

180
5 - 600

### Step F: Password Setup

#### Cart Setup

<table>
<thead>
<tr>
<th>Cart Setup</th>
<th>Passwds</th>
<th>Misc</th>
<th>Defaults</th>
<th>More</th>
</tr>
</thead>
<tbody>
<tr>
<td>F2</td>
<td>F2↑</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

F2 3
F2↑ 4

#### System Passwords

- Level 1
- Level 2

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>F1↑</td>
</tr>
</tbody>
</table>

F1 2
F1↑ 3

F2 4

---

Passwords are preset as
L1 for Level 1 as all
aspects of programmability.

---

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II- A

Cardiograph Setup
Step G: Miscellaneous Setup

For each of the following prompts, type in an appropriate response or press a function (F) key. Then press \[ \leftarrow \] to store that information.

**Line Frequency:**
- 60 Hz
- 50 Hz

**Cart ID:**
- 0 - 255

The Cart ID is site specific:
- Phoenix MAC PC = 43
- Phoenix MAC 12 = 44
- Oklahoma MAC PC 1 = 48 (Lawton)
- Oklahoma MAC PC 2 = 49 (Anadarko)
- Rapid City: Eagle Butte = 59
- Pine Ridge = 60
- Fort Totten = 61

**Site ID:**
- 3
- 1 - 255

**Institution Name:** Strong Heart Study

**Number of Patient ID Digits:**
- 11
- 1 - 12
This may be omitted in the SHS.

Input Patient Age As: DOB
DOB Years

Ask Blood Pressure Questions: NO
Yes No

Ask Options Question: NO
Yes No

Suppress Normal Statement: NO
Yes No

Suppress Border & Abnormal Statement: NO
Yes No

ECGs to Store/Transmit: ALL
All Abnormal

Date Of Birth.
SAVE. It is very important to change this to SAVE. By default the machine deletes ECGs as soon as they are transmitted, without waiting for confirmation from Halifax.

<table>
<thead>
<tr>
<th>Delete ECGs After Transmission:</th>
<th>SAVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Save</td>
<td>Delete</td>
</tr>
<tr>
<td>F1 1</td>
<td>F1↑ 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Store/Transmit Control: Store Transmit</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Power Up Speed: 25mm/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>25mm/s 50mm/s</td>
</tr>
<tr>
<td>F1 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Power Up Filter: 100 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 Hz 100 Hz</td>
</tr>
<tr>
<td>F1 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screening Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
</tr>
<tr>
<td>Yes No</td>
</tr>
<tr>
<td>F1 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline Roll Filter: .16 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01Hz .02Hz .16Hz .32Hz</td>
</tr>
<tr>
<td>F1 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QC Baseline Drift:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
</tr>
<tr>
<td>Yes No</td>
</tr>
<tr>
<td>F1 1</td>
</tr>
</tbody>
</table>
Step H: Defaults Setup

Return to the Main Menu.

Never say yes to return original factory setup defaults, because that will set the machine to delete ECGs after transmission.

Return the MAC PC to its original factory setup defaults. Any setup changes that you made will be lost.

Setup I: Timeout Setup
Select F1 to set a 1-minute timeout, F2 to set a 5-minute timeout, F3 to set a 10-minute timeout, F4 to set a 30-minute timeout, or F5 to set an indefinite timeout length.

“Timeout” is the amount of time it takes for the LCD to go blank when the MAC PC is not being used.

If the “none(ac)” is selected, the timeout length will be indefinite only if a power module is attached to the MAC PC and the battery status (section 12) message indicates “OK” or “FULL.” Otherwise, if a power module is NOT attached, then the timeout length will be set to 10 minutes.

Press ☐ to return to the Main Menu.
APPENDIX 12(b)  Taking a Resting ECG
Entering Patient Information

Note: It is NOT necessary to enter any patient information in order to take a resting ECG. You can record an ECG at any time -- if the Main Menu is displayed by just pressing . If you do not enter the patient's name and identification number, the patient will be identified by the date and time when the ECG was taken.

Note: When a patient's age is entered and the patient is 15 years old or less, then a pediatric 12SL analysis is performed on the ECG data. However, if NO age is entered, then the MAC PC will always perform an adult analysis.

If the Main Menu is not already displayed, then press to return to it:

\[
\begin{array}{|c|c|c|c|c|}
\hline
\text{ Task } & V1 + II + V5 & \text{ PatInfo} & \text{ Rhythm} & 25 \text{ mm/s} \\ \hline
\text{ F1 } & \text{ F1↑} & 1 & 2 & 10 \text{ mm/mv} & 100 \text{ Hz} \\ \hline
\end{array}
\]

Hit either F1 or F1↑.

Next, press either F1 or F1↑ to select PatInfo (F1). One of the following two prompts will appear:

Patient Last Name:
A to Z, Space.

Enter names.

OR

New Patient:
Yes, No

This won't show up if the machine was just turned on. Hit either F1 button if it is a new person. Hit either F2 button if you want to correct an entry and/or take another ECG on the same person.

Patient First Name:
A to Z, 0 to 9, Space.

This is actually an 11 digit ID. Enter five (5) 0 followed by six (6) digits, Strong Heart Study ID.

Patient ID:
Digits 0 to 9.

Referred By:
(Physician Name)

Skip over

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Location Number:
0 to 99

Room Number:
Any 5 characters

Date of Birth (DD - MM - YY)
DD = Day, MM=Month, YY=Year

Height: (in cm)

Weight: (in kg)

Sex:
Male  Female

Race:
Cauc Black Oriental Hisp More

Race:
Unknown Indian

Medication:
none Unknown Add Scroll

To type dash press [ ] and [ ] at the same time. MM=letters of month (JAN, FEB, ...,etc.) YY=Year (89, 90, etc.)

Indicate Sex. Hit either F1 F2.

Choose "More". Hit either F5.

Choose "Indian". Hit either F3.

If on CARDIAC medication enter either F4. Find medication and enter. (This is not part of Strong Heart Study essential information)

The MAC PC is now ready to take a 12-lead ECG. Press [12] to start.
Fault Detection Procedures

Should problems with noise or drift be encountered, electrodes are replaced. The following is a guide for determining which electrodes may be faulty. The underlined electrodes are the predominant determinants of the appropriate lead and therefore are most likely to be the faulty electrodes for a given lead. After adjustment or replacement of suspect electrodes, the electrocardiograph should be able to record 10 seconds of good data.

<table>
<thead>
<tr>
<th>Lead</th>
<th>Affected</th>
<th>Possible</th>
<th>Faulty Electrode</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td></td>
<td>RL, RA, LA</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td></td>
<td>RL, RA, LL</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td></td>
<td>RL, LA, LL</td>
<td></td>
</tr>
<tr>
<td>aVR</td>
<td></td>
<td>RL, RA, LL, LA</td>
<td></td>
</tr>
<tr>
<td>aVL</td>
<td></td>
<td>RL, LL, RA, LA</td>
<td></td>
</tr>
<tr>
<td>aVF</td>
<td></td>
<td>RL, LL, RA, LA</td>
<td></td>
</tr>
<tr>
<td>V1</td>
<td></td>
<td>RL, LL, RA, LA, V1</td>
<td></td>
</tr>
<tr>
<td>V2</td>
<td></td>
<td>RL, LL, RA, LA, V2</td>
<td></td>
</tr>
<tr>
<td>V3</td>
<td></td>
<td>RL, LL, RA, LA, V3</td>
<td></td>
</tr>
<tr>
<td>V4</td>
<td></td>
<td>RL, LL, RA, LA, V4</td>
<td></td>
</tr>
<tr>
<td>V5</td>
<td></td>
<td>RL, LL, RA, LA, V5</td>
<td></td>
</tr>
<tr>
<td>V6</td>
<td></td>
<td>RL, LL, RA, LA, V6</td>
<td></td>
</tr>
</tbody>
</table>

Self-Evaluation of Technical Performance

This section allows technicians to monitor their own ECG technique. It is intended to help technicians who are having difficulty meeting the quality standards set by the ECG Reading Center. These data are not intended to be collected by the study.

The technician examines the ECG tracing to estimate the noise level and baseline drift. Based on the requirements of the Minnesota Code, acceptable and unacceptable levels of noise and baseline drift have been established. These levels are scored using the following table:

<table>
<thead>
<tr>
<th>Noise Grade</th>
<th>Overall (mm)</th>
<th>Beat-to-beat Drift (mm)</th>
<th>Quality Drift (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt; .25</td>
<td>&lt; 1</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>2</td>
<td>&lt; .50</td>
<td>&lt; 2</td>
<td>&lt; 1.5</td>
</tr>
<tr>
<td>3</td>
<td>&lt; 1</td>
<td>&lt; 3</td>
<td>&lt; 2</td>
</tr>
<tr>
<td>4</td>
<td>&lt; 2</td>
<td>&lt; 4</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>5</td>
<td>&gt; 2</td>
<td>&gt; 4</td>
<td>&gt; 3</td>
</tr>
</tbody>
</table>
The grade levels given in this table are related to the ability of the analysis program to achieve the required accuracy. Quality Grade 5 is unacceptable. ECGs of Quality Grade 5 must be deleted from the machine's memory and retaken immediately.

1. First, the tracing is examined for obvious errors such as right arm/left arm and other common lead misplacement (see Figure 4, negative p-waves in I indicate lead switch). These ECGs must be deleted from the machine's memory and retaken immediately.

2. The Quality Grade for noise is obtained by measuring the noise level as vertical peak-to-peak values in terms of number of small paper divisions (smallest grid squares). Note that recording sensitivity is 1 mV per centimeter, (one small paper division = 1 mm = 0.1 mV). A noise level of more than 2 small paper divisions (> 0.2 mV peak to peak) is unacceptable (Figure 5).

3. The Quality Grade for overall drift is obtained by searching each of the 12-leads for the maximum and minimum baseline levels within that lead (as determined by the PR and/or TP segments) over the 10 second recording and measuring the vertical distance between them. A distance of more than 4 small paper divisions is unacceptable (Figure 6).

4. The Quality Grade for beat-to-beat drift is determined by searching for the pair of successive QRS complexes having the largest amplitude difference (vertical distance) between successive PR segments. A difference of more than 3 small paper divisions (> 0.3 mV) indicates an unacceptable record (Figure 7).

Improvement in technical quality will indeed result if the prescribed procedure for electrode position marking, electrode and skin preparation, electrode replacement and equipment use are carefully followed. Baseline drift problems, which are essentially caused by poor electrode-skin contact are particularly easy to remedy, as is 60-cycle interference.

Sixty-cycle interference is characterized by perfectly regular fine oscillations occurring at the rate of sixty per second (Figure 8).

Electrical equipment of any kind may be the source of AC interference on an ECG in all leads or only certain ones. Check quality of skin preparation and electrode contact. Check leadwires and resecure attachment of the alligator clip to the electrode. Make sure participant does not touch any metal part of the bed or other equipment. Proximity to a wall with hidden wiring or a partially broken cable may also cause this problem.
Muscle Tremor causes irregular oscillations of low amplitude and varying rapidity superimposed upon the ECG waveform (Figure 9). Muscle tremor is the involuntary muscle activity of a participant whose state is tense, apprehensive, or uncomfortable. This is why a clear explanation of the electrocardiogram test and reassurance are necessary for the participant. The participant is asked if the temperature of the room is too low for her/him and is covered with a blanket if so.

Original Hard Copy Record

The original 12-lead ECG record is filed at the field center. If the clinic needs a second "original" ECG, it can be printed from the machine’s memory anytime before deletion of the ECG. The first hard copy ECGs are read locally by clinic physicians for notification and referral if needed. The records are then placed in participants’ local data files. Double-check that this participant is correctly identified.
Figure 5. Unacceptable Noise Level

Figure 6. Unacceptable Overall Baseline Drift

Figure 7. Unacceptable Beat-to-Beat Baseline Drift
Figure 8. Sixty-Cycle Interference

Figure 9. Artifact Caused by Muscle Tremor
Appendix 12 (c) Transmitting ECGs by Telephone

Note: Only a MAC PC equipped with a modem can transmit ECG reports by telephone.

1. Prepare the MAC PC as described in section 1.
2. Connect a telephone cord from a telephone wall jack to the backpanel jack on the MAC PC.
3. If the Main Menu is not already displayed, press [ ]:

<table>
<thead>
<tr>
<th>↑Task</th>
<th>V1 + II + V5</th>
</tr>
</thead>
<tbody>
<tr>
<td>PatInfo</td>
<td>Rhythm</td>
</tr>
<tr>
<td></td>
<td>25mm/s</td>
</tr>
<tr>
<td></td>
<td>10mm/mv</td>
</tr>
<tr>
<td></td>
<td>100Hz</td>
</tr>
</tbody>
</table>

4. Press [ ] and F1↑ to display the System Functions menu. Then press one of the two keys listed under each of the following displays:

System Functions

<table>
<thead>
<tr>
<th>Storage</th>
<th>Setup</th>
<th>Diag</th>
<th>RevXmit</th>
<th>Monitor</th>
</tr>
</thead>
</table>

Storage Functions

<table>
<thead>
<tr>
<th>Plot</th>
<th>Directory</th>
<th>Summary</th>
<th>Delete</th>
<th>More</th>
</tr>
</thead>
</table>

Storage Functions

<table>
<thead>
<tr>
<th>Transmit</th>
<th>Edit</th>
<th>Format</th>
<th>More</th>
</tr>
</thead>
</table>

Transmission Type

<table>
<thead>
<tr>
<th>Phone</th>
<th>Local</th>
<th>RS232</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>F1</th>
<th>F1↑</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F5</th>
<th>F5↑</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>9</td>
</tr>
</tbody>
</table>
** No Data in Storage **

OR

Phone Number:
0 - 9 # * = ,

5. If the second display appears, type in the phone number of the location where you will be transmitting and press \[arrow\].

The # and * are touch-tone symbols.

The , sign provides a 2-second pause and may be used repeatedly for longer parses. (For example, in the phone number 1,,8081112345 there will be a 6-second pause between the numbers “1” and “8” 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” first. A sample number would look like this: 9=1234567.)

6. Next, patient data on each stored ECG will be displayed similar to the following:

   Pressing No (F2) Bypasses this ECG.
   Pressing Yes... (F4) selects this ECG and all subsequent ECGs.

   123456789
   Yes
   No
   No...
   Yes...
   Expand

   Pressing Yes (F1) selects this ECG.
   Pressing No... (F3) bypasses this ECG and all subsequent ECGs.
   Pressing Expand (F3) provides additional patient information such as date and time of the ECG. Use this function to verify which single ECG to save and transmit on each participant.

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

b. Last name, first name of patient or the date and time when ECG was recorded.

c. Select to return to former display.

d. MUSE site number where ECG was recorded.

e. Location number where ECG was recorded.

f. Cart number of the unit where ECG was recorded.

g. Date and time of ECG acquisition. This is a unique identifier if more than one ECG was saved on a particular subject.

h. A U means that the ECG is unconfirmed. An C means that the ECG is confirmed. Use the Edit function described in section 6 to change an unconfirmed ECG to a confirmed ECG.

i. Type of Data. E stands for ECG.

8. Depending on which ECGs you want to transmit or bypass, press the appropriate function (F) key.

9. After selecting the ECGs you want to transmit, displays similar to the following will appear:

   ** Batch Transmission **

   Waiting for Dial Tone

   THEN

   ** Batch Transmission **

   Dialing 1112345

   THEN

   ** Batch Transmission **

   Waiting for an Answer Tone

   THEN

   ** Batch Transmission **

   123456789       JONES,    JACK

10. After the last ECG has been transmitted, a message indicating the number of ECGs that were transmitted vs the number you selected to transmit will be displayed similar to the following:

   5 of 5 Transmitted

   Type Any Key to Continue
11. Pressing any key displays the following:

<table>
<thead>
<tr>
<th>Transmission Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
</tr>
<tr>
<td>Local</td>
</tr>
<tr>
<td>RS232</td>
</tr>
</tbody>
</table>

Press to return to the Main Menu.

12. If, despite previously mentioned safeguards, you have still erroneously transmitted a tracing with improper ID #, time, or a non-SHS ECG, please FAX this data to Dr. Oopik immediately at (303) 674-4196.

13. All transmitted ECGs should be logged at the study field clinic.

A copy of this log page should be faxed to Dr. Oopik weekly on Monday to verify ECG authenticity before ECGs are sent to Minneapolis.

Erroneous ECGs consumed much time during Phase I.
<table>
<thead>
<tr>
<th>Patient ID #</th>
<th>Date (from ECG)</th>
<th>Time (from ECG)</th>
<th>Patient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Appendix 12 (d) Receiving ECGs by Telephone
Receiving By Telephone

Note: Only a MAC PC equipped with a modem can receive ECG reports by telephone.

Note: If 75% or more of the MAC PC’s memory is used, then the message “Plotter Output Only” will appear. This means that incoming data will be printed but NOT stored. In this case, if you want to store incoming data, then delete some ECGs from the MAC PC before you begin receiving data (refer to section 9).

1. Prepare the MAC PC as described in section 1.

2. Connect a telephone cord from a telephone wall jack to the backpanel jack on the MAC PC.

3. If the Main Menu is not already displayed, press \[ \text{\text{Menu}} \] :

\[
\begin{array}{|l|l|l|l|l|}
\hline
\text{Task} & \text{V1 + II + V5} \\
\text{Pat Info} & \text{Rhythm} & \text{25mm/s} & \text{10mm/mv} & \text{100Hz} \\
\hline
\end{array}
\]

4. Press \[ \text{Menu} \] and F1\[\uparrow\] to display the System Functions Menu:

\[
\begin{array}{|l|l|l|l|l|}
\hline
\text{Storage} & \text{Setup} & \text{Diag} & \text{RevXmit} & \text{Monitor} \\
\hline
\text{F4} & 7 & \text{F4}\[\uparrow\] & 8 \\
\hline
\end{array}
\]

5. Select RevXmit (Reverse Transmission) to display:

\[
\begin{array}{|l|l|}
\hline
\text{Phone} & \text{Transmission Type} \\
\hline
\text{Local} & \text{RS232} \\
\hline
\end{array}
\]

\[
\begin{array}{|l|l|}
\hline
\text{F1} & \text{F1}\[\uparrow\] \\
\hline
1 & 2 \\
\hline
\end{array}
\]

6. Select Phone (F1) and one of the following two message will appear:

\[
\begin{array}{l}
\text{No Data Storage - Plotter Output Only} \\
\text{Type Any Key to Continue} \\
\end{array}
\]

OR

\[
\begin{array}{|l|l|}
\hline
\text{Select Option:} & \text{Store} \\
\hline
\text{Plot} & \text{F1} \\
\hline
\text{F1}\[\uparrow\] & 2 \\
\text{F2} & 3 \\
\text{F2}\[\uparrow\] & 4 \\
\hline
\end{array}
\]

Strong Heart Study II 7/01/93 II- A 77 Receiving ECGs
7. If the second display appears, select Store (F1) to store and print out the ECG(s) you receive, or select Plot (F2) to just print out the ECG(s) without storing them. Then a display similar to the following will appear:

```
** Reverse Transmission **
Check the Phone Line
d
```

8. If the following message appears, then the telephone line is not attached:

```
** Reverse Transmission **
Phone Line Not Attached
```

9. Otherwise, the following series of message will be displayed for each ECG that is received:

```
** Reverse Transmission **
Ready to Receive
THEN
** Reverse Transmission **
Answer the Phone
THEN
** Reverse Transmission **
Receiving Data
THEN
** Reverse Transmission **
End of Data Packet
THEN
** Reverse Transmission **
Page xx of xx
```

10. After all ECGs have been received, following will appear:

```
** Reverse Transmission **
End of Transmission
THEN
** Reverse Transmission **
Ready to Receive
```

11. If no other ECGs will be received, then press 📧 to return to the Main Menu. NOTE: Use the Directory function (section 8) to check that all ECGs have been received.
APPENDIX 12 (e) Deleting an ECG

Since most ECG storage is only temporary, there will probably be times when you want to delete recordings from the MAC PC’s memory. Also, there may be times when the memory is almost full, and the MAC PC itself suggests that you delete ECGs. (Refer to the Section on “Forced Deletion”.) ECGs taken in the Strong Heart Study should be kept in memory until confirmed copy is returned. The machine will not automatically delete ECGs except that procedures are carried out as described in “Forced Deletion”.

Routine Deletion

ECGs are usually deleted after you print a paper copy of the ECG, when more than one ECG per patient has been stored or when the ECG is transmitted to another location. To delete one or more ECGs, follow these steps:

1. Prepare the MAC PC as previously described.

2. If the Main Menu is not already displayed, press $\Box$:

   | Task | PatInfo |
   | V1 + II + V5 | Rhythm |
   |   25mm/s | 10mm/mv | 100Hz |

3. Press $\Box$ and F1↑ at the same time to display the System Functions menu. Then press one of the two keys listed under each of the following displays:

   ![System Functions Menu]

   | Storage | Setup | Diag | Rev/Xmit | Monitor |
   | F1 1 | F1↑ 2 |

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

   Pressing Save (F2) saves this ECG. Pressing Expand (F5) provides additional patient information such as date and time of the ECG.

   Pressing Delete (F1) Deletes this ECG. Pressing Save... (F3) saves this ECG and all Subsequent ECGs. Pressing Quit (F4) leaves the Delete function.

Strong Heart Study II 7/01/93 II- A 79 Deleting an ECG
5. To display additional patient information, press Expand (F5) and a message similar to the one below will be displayed:

a. Percentage of memory used by this ECG.

b. Patient identification number.

c. Last name, first name of patient or the date and time when ECG was recorded.

d. Select to return to former display.

e. MUSE site number where ECG was recorded.

f. Location number where ECG was recorded.

g. Cart number of the unit where ECG was recorded.

h. Date and time of ECG acquisition. This is a unique identifier if more than one ECG was saved on a particular subject.

i. A U means that the ECG is unconfirmed. An C means that the ECG is confirmed. Use the Edit function described in section 6 to change an unconfirmed ECG to a confirmed ECG.

j. Type of Data. E stands for ECG.

6. Depending on what you want to delete, save, or bypass, press the appropriate function (F) key.

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

```
Delete  2 ECG(s) ? :  Yes  No
        F1  F1↓  F2  F2↓
```

- Cancels the delete.
- Deletes the selected ECGs.
If the ECG you are recording requires more memory than the MAC PC is able to spare, a prompt will appear after the Processing ECG for Storage display:

**ECG storage: Insufficient Space Available**
**Type Any Key to Continue**

1. Pressing any key to continue causes this message to be displayed:

<table>
<thead>
<tr>
<th>Select Option:</th>
<th>Delete</th>
<th>Quit</th>
<th>Xmit</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1 1</td>
<td>F1↑ 2</td>
<td>F2 3</td>
<td>F3 5</td>
</tr>
<tr>
<td>F2↑ 4</td>
<td>F3↑ 6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Select Delete (F1) to display one of the ECGs stored in the MAC PC’s memory. A small explanation of how each function key affects ECGs stored in the MAC PC follows.
- Select Quit (F2) to return to the “ECG Storage: Insufficient Space Available” display.
- Select Xmit (F3) if you want the MAC PC to transmit the ECG you just acquired instead of storing it. (Xmit will only appear if your MAC PC is equipped with a modem.)

2. If you select Delete, a display similar to the following will appear:

```
(5%) 24% 123456789 ALLEN, BRADLEY
Delete Save Quit Expand
```

Pressing Delete (F1) deletes this ECG. Pressing Save (F2) saves this ECG. Pressing Quit (F4) return to the “Insufficient Storage” display.

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

```
(5%) 24% 123456789 ALLEN, BRADLEY
E U 23-MAR-88 09:53 C001 L001 S001 Cont
```

- a. Percentage of storage that must be deleted to provide room for the ECG just acquired. This number decreases as ECGs are selected for deletion.
- b. Location number where ECG was recorded.
- c. Cart number of the unit where ECG was recorded.
- d. ECG number.
- e. File number.
b. Percentage of memory used by this ECG.

c. Patient identification number.

d. Last name, first name of patient or the date and time when ECG was recorded.

e. Select to return to former display.

f. MUSE site number where ECG was recorded.

4. After you have either Saved or Deleted all stored ECGs, one of the following two displays will appear:

- Not enough ECG(s) selected for deletion
  Type Any Key to Continue

OR

- Delete 2 ECG(s) ? :
  Yes
  No

<table>
<thead>
<tr>
<th>F1</th>
<th>F1↑</th>
<th>F2</th>
<th>F2↑</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

If the first display appears, then you will return to the “ECG Storage: Insufficient Space Available” display. In this case, you will have to start the deletion process all over.

If the second display appears, or one like it, then select Yes (F1) to delete the selected ECGs or No (F2) to return to the “ECG Storage: Insufficient Space Available” display.

5. If you selected Yes (F1), the ECG you just recorded will be stored. The this message will be displayed:

- **ECG Storage Complete**
  Type Any Key to Continue

Pressing any key to return you to the Main Menu.
APPENDIX 13
THE STRONG HEART STUDY II

STANDARD ECG INSTRUCTIONS

1. BASELINE ECGs

1.1 Introduction

During the baseline examination, a standard supine 12-lead resting ECG is recorded at least one half hour after ingestion of glucose.

1.2 Procedure for Recording Baseline ECG

The standard electrocardiograph for the Strong Heart Study is the MAC PC Personal Cardiography by Marquette Electronics, Inc. The standard configuration for the MAC PC is shown in Appendix A. A 12-lead resting ECG tracing is obtained consisting of 2.5 seconds of each of the leads simultaneously (I, II, III, aVR, aVL, aVF, V1-V6) with a 10 second lead Rhythm Strip.

Procedures for charging the battery of the MAC PC: The MAC PC runs only from its battery. The battery can be charged by plugging the unit into a wall outlet. The MAC PC will record and print about 50 ECGs on one charge. The amount of charge left is displayed for one-half second when the machine is turned on. It takes about 10 hours to charge the battery.

Plug in the unit each evening after transmitting data to Fitzsimmons. Unplug the unit in the morning. It is not good for the machine to spend several days in either the fully charged or completely drained state. For weekends and holidays the machine may be left plugged in, or, if the brief charge display shows at least 25 ECGs remaining, it may be left unplugged.

1.3 Electrode Position Measuring and Marking

Because it is essential for the study to be able to compare baseline ECG data with subsequent records, a uniform procedure for electrode placement and skin preparation is required. The method and procedure for standardizing electrode locations are outlined below.
The participant, stripped to the waist, is instructed to lie on the recording bed with arms relaxed at the sides. The individual is asked to avoid movements which may cause errors in marking the electrode locations, but encouraged to converse with the technician. Prior experience with electrocardiograms is discussed, as is the purpose of the ECG recording. The participant should be told this is a research ECG to be used for statistical analysis later in the study. However, it can also be used by the clinic physician for general diagnostic purposes, and a copy can be sent to the individual's private physician.

For best electrode/skin interface, place the electrodes on the skin at least 2-3 minutes before taking the ECG. Patient information can be entered on the MAC PC during this time. This waiting time is not so critical with the suction electrodes, if it is anticipated that data entry will take > 3 minutes, you may want to enter data first when using these electrodes. It is recommended that the stick-on electrodes be applied 2-3 minutes prior to acquiring the ECG.

A good felt tip pen is used to mark the six chest electrode positions. Wipe the general area of the following 10 electrode sites with a sterile alcohol prep to remove skin oil and perspiration. It is extremely important that care be taken to locate these positions accurately. Therefore, the procedure given below must be meticulously followed. Electrode positions in women with large, pendulous breasts must be determined in relation to the anatomic points described below - as for all participants. The electrodes must then be placed on top of the breast (in the correct position).

1.3.1 Chest Leads (Figure 1)

1. Electrode V₂

Locate the sternal angle and second left rib between the index and middle fingers of your right hand. Count down to the fourth rib and identify the fourth intercostal space below it. Locate V₂ in the fourth intercostal space immediately to the left of the sternal border.

2. Electrode V₁

Locate electrode V₁ in the fourth intercostal space at the right sternal border. This should be at the same level as V₂ and immediately to the right of the sternum.
3. Anterior 5th Interspace Marker (E Point)

Identify the fifth rib and fifth intercostal space below V₂ by counting down ribs as described for V₂. Follow this space horizontally to the midsternal line and mark this point. This is the "E" point.

4. Electrode V₆

Locate the V₆ electrode at the same level as the E point in the midaxillary line (straight down from the center of the armpit). If breast tissue is over the V₆ area, mark the V₆ location on the breast.

Do not attempt to move the breast in order to mark V₆ on the chest wall, unless doing so is absolutely necessary to achieve better anatomic position.

5. Electrode V₄

Electrode V₄ is located using the E-V₆ Halfpoint Method. Using the medical tape measure employed in anthropometry, measure the distance between the E point and the V marking. The tape should be resting lightly on the skin, not pressing into the flesh. The E and V₆ marks should be clearly seen. Place electrode V₄ midway between E and V₆.

6. Electrode V₃

Using the medical tape measure employed in anthropometry, mark the location of electrode V₃ midway between the locations of V₂ and V₄.

7. Electrode V₅

Using the medical tape measure employed in anthropometry, mark the location of electrode V₅ midway between the locations of V₄ and V₆.
Figure 7. Precordial points from which chest leads are derived
Figure 8. Electrode and leadwire placement
1.3.2 Limb Leads (Figure 2)

Locate electrode LL on the left ankle (inside).
Locate electrode RL on the right ankle (inside).
Locate electrode LA on the left wrist (inside).
Locate electrode RA on the right wrist (inside).

1.4 Skin Preparation

Skin preparation is undertaken only in the presence of observed technical problems due to poor electrode contact. As a first step it may be sufficient to rub the skin lightly with a tongue depressor or piece of gauze to produce reddening. If this does not resolve the problem, then:

1. With the participant's consent, remove any excess hair from each electrode site on the chest using a shaver.

2. At each electrode location in turn the outer horny layer of the epidermis is removed by gentle dermal abrasion with a piece of gauze. Only three passes (in the form of an asterisk) at each site using light pressure are required.

If the skin preparation has removed the felt pen marking at any of the electrode sites, these are accurately re-established by carefully repeating the procedure described in Electrode Position Measuring and Marking. It is important that the electrode sites be marked using the exact technique described.

1.5 Application of Electrodes

Either disposable or suction electrodes are used in the Strong Heart Study. Adaptors are used with the leadwires to connect the "banana" plug from the MAC PC leadwire to the disposable electrode via a clip.

When placing each electrode, massage it in a small circular motion to maximize the pre-gel contact with the skin but avoid overlap of gel from one electrode to the next.

Center the four limb electrodes on the inside of the wrist or ankle with the tab for the clip pointing toward the head. Center the six chest electrodes on the chest markings with the tabs pointing down. Do not let the electrodes overlap or touch each other if possible.
Clip the appropriate leadwire to each electrode (Figure 1). Do not pull or jerk tangled wires. To untangle wires, disconnect lead wires from electrodes.

1.6 Recording the 12-lead ECG

Change the roll of paper as needed. Each roll is 75 feet long; each patient takes approximately one foot of paper.

Each ECG is automatically stored in memory until it is deleted. After placing the electrodes on the skin, enter the participant information into the MAC PC (Figure 3) according to Appendix B. Disposable electrodes particularly must be on the skin for at least 2-3 minutes before taking the ECG. Make a final check of the electrodes and lead wires. Ask the participant to relax and keep still, then press the RECORD key.

The machine will display "Acquiring Data" and the left side of the display will show a count. If there are technical problems the display will show which lead is involved and will keep counting until it gets 10 seconds of good data. Check electrode contacts and leadwires, then check the display again. If the display counts past 75, push the STOP key and remove the electrodes. Prepare the electrode sites as discussed in Skin Preparation and follow the above protocol for exact relocation of electrodes. Press RECORD ECG. The machine will tell you to "enter a new patient or press RECORD." Press RECORD ECG a second time to start the ECG. The machine will automatically print the ECG after it has acquired 10 seconds of good data (Appendix C).

Tear the ECG off the machine and file it in your records.
Press RECORD ECG. The machine will tell you to “enter a new patient or press RECORD.” Press RECORD ECG a second time to start the ECG. The machine will automatically print the ECG after it has acquired 10 seconds of good data (Appendix C).

Tear the ECG off the machine and file it in your records.

Figure 3. The MAC PC Keyboard and LCD Display by Marquette Electronics Inc.
APPENDIX 14 (a)
THE STRONG HEART STUDY II

PHYSICIAN REFERRAL FORM FOR DIAGNOSIS OF CONGESTIVE HEART FAILURE

ID Number:

While Mr./Ms. __________________ was participating in our examination, it appeared to us that he/she might have congestive heart failure. He/She thus has been referred to you for care. Listed below are the criteria that we are using for the identification of congestive heart failure in our study. We would very much appreciate it if you could complete the form below and send it to us, so that it may assist us in making the diagnosis. Record all that are present when you evaluate the patient.

I. Major Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Present</th>
<th>Absent</th>
<th>Not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxysmal nocturnal dyspnea or orthopnea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck-vein distention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiomegaly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute pulmonary edema</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S₃ gallop</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased venous pressure &gt;16 cm of water</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circulation time ≥ 25 seconds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatojugular reflux</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
II. Minor Criteria

<table>
<thead>
<tr>
<th>Present</th>
<th>Absent</th>
<th>Not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle edema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Night cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea on exertion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatomegaly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleural effusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital capacity decrease 1/3 from maximum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tachycardia (rate of ≥ 120/min)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

III. Major/Minor Criteria

<table>
<thead>
<tr>
<th>Present</th>
<th>Absent</th>
<th>Not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss 4.5 kg in 5 days in response to treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IV. Tests that were performed on this patient. (1=yes, 2=no)

<table>
<thead>
<tr>
<th>Echocardiogram</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest x-ray</td>
<td></td>
</tr>
<tr>
<td>Measurements of vital capacity</td>
<td></td>
</tr>
<tr>
<td>Measurements of venous pressure</td>
<td></td>
</tr>
</tbody>
</table>

In your opinion, does Mr./Ms. __________________ have congestive heart failure?
If yes, what is the underlying cause? 1=yes  2=no
(Please check the appropriate cause described below)

Valvular heart disease   ______
Atherosclerotic heart disease   ______
Cardiomyopathy   ______
Other   ______

Please specify. ____________________________

What is your specialty/subspecialty of medical practice?

We thank you very much for your assistance.

Signature____________________ Date ________________
APPENDIX 15 (a)  
THE STRONG HEART STUDY II

Sample Letter to Participant after Physical Examination

Dear _____:

Thank you very much for taking part in the Strong Heart Study on _______ (date). The final results of your blood tests and other measurements are now available and this letter summarizes the important findings from your visit:

**Blood Pressure**

Your blood pressure was _____ (less than 140/90 and not taking medication for BP). This is within the normal range. It should be checked at least once a year.

Your blood pressure was _____ (greater than 140/90). This is above the normal range. You should make an appointment for follow-up with your medical care provider, since high blood pressure may cause heart problems and stroke.

Your blood pressure was _____ (less than 140/90, taking BP medication). This is within the normal range. Continue taking your blood pressure medication as directed by your medical care provider.

**Glucose Tolerance (Test for Diabetes)**

Your fasting blood sugar was _____ (less than 140) and your 2 hour blood sugar was (less than 140). This is within the desirable range.

Your fasting blood sugar was _____ (less than 140) and your 2 hour blood sugar was (less than 200). These values are slightly high and raise the possibility that you may develop diabetes in the next several years. Weight reduction and exercise may help to prevent you from developing diabetes, so be sure to get advise from a health care provider on what might be helpful to you.

Your fasting blood sugar was _____ (greater than 140) and your 2 hour blood sugar was (greater than 200). These values are above the normal range and suggest that you may have diabetes. Please see your health care provider for advice on appropriate follow-up if you have not already done so.

Your fasting blood sugar was _____ (known diabetic less than 200). On the day of the exam, your fasting blood sugar was under good control. Be sure to follow the advice of your
medical care provider for control of your diabetes.

Your fasting blood sugar was ______ (known diabetic greater than 240). Your fasting blood sugar was higher than the usual target for diabetic patients. See your medical care provider for advice on how to attain better control.

Measurements of Blood Fats (Cholesterol and Triglycerides)

Your blood cholesterol was ______ (less than 200). This is within the desirable range, and we encourage you to maintain a healthy diet so that your cholesterol stays low.

Your blood cholesterol was ______ (200 to 240). This is slightly above the desirable range. We advise you to reduce the fat in your diet and have your cholesterol checked again in 6-months.

Your blood cholesterol was ______ (greater than 240). Your total cholesterol is high and this may cause heart problems. We advise you to reduce the fat in your diet and have your cholesterol checked again in 3 months.

Your blood triglycerides were ______ (less than 200). This is within the desirable range.

Your blood triglycerides were ______ (200-400). This is above the desirable range. We advise you to reduce your amount of calories and alcohol (if you are drinking) and have your triglycerides checked again in three months.

Your blood triglycerides were ______ (>400) This is a high value. You should see your health care provider for follow-up.

Electrocardiogram

We have sent a copy of your ECG (heart tracings) to your physician and he/she will notify you if there are any problems.

Echocardiograph

We have sent a report on your echocardiogram (movies of your heart's motion and flow of blood within it) to your physician and he/she will notify you if there are any problems.

Pulmonary Function

You blew air quickly into a spirometer to measure how well your lungs work. The results were an FEV1/FVC ratio of 68% and an FEV1 of 55% of the expected normal value.
[If the FEV1 is normal, above 80% predicted]

This means that your lungs are of normal size and your airways are wide open and move air normally.

[If both the ratio and FEV1 are abnormally low]

This means that you have airways obstruction. This could be due to cigarette smoking, asthma and other lung diseases. If you currently smoke cigarettes, stopping now will probably prolong your life. You may wish to discuss this with your physician during the next few months.

[If the ratio is normal but the FEV1 is low]

This means that you can't take as deep a breath (or blow out as much air) as healthy people of your height. If you are overweight, this reduction in your vital capacity could be due to your weight, but your physician should examine your lungs and perhaps check your chest X-ray.

**Body Fat**

During the examination we measured the fat content in your body. The enclosed print out describes the results of this measurement, explains the normal values for your age and gender and suggests exercise programs and calorie recommendations.

**Gallstones**

The examination of your gallbladder did not show any gallstones.

The examination of your gallbladder showed that you have gallstones. If you are not having pain or other symptoms it is not necessary to seek any care at this time. However, we will include this information in your medical record and you should inform your doctor about the presence of the gallstones if you develop stomach cramps or other digestive problems. (Eliminate this section if the person has had gallbladder removed)

**Skin Tests**

Your skin test for tuberculosis was negative which suggests that you have not previously had or been exposed to tuberculosis.

You indicated that you had TB in the past and that you were treated for it. You don't need further evaluation for this unless you develop chronic cough, fever, weight loss or other symptoms.

Your skin test for tuberculosis was positive. This indicates that you were exposed to or have had tuberculosis in the past. If you have taken preventative treatment for 6-12 months, your
chances of getting TB are reduced. If you have not taken such treatment and are willing to take it, you should talk to your health care provider. This is especially important if you have had kidney or other organ transplants, diabetes, are currently undergoing dialysis.

Your skin test for valley fever was negative. This suggests that you have not previously had or been exposed to valley fever.

Your skin test for valley fever was positive. Although this means that in the past you were exposed to or had a case of valley fever, there is no need to receive any treatment unless you develop cough, fever, or weight loss, in which case you should see your healthcare provider. We will indicate this information in your medical chart so your health care provider will know about this test result.

The results of your tests will be sent to the IHS Hospital or Clinic as part of your hospital record. This will help the doctors take care of you if you get sick and go to the hospital or clinic. If your doctor does not work at the IHS Hospital or Clinic please let us know so we can send your test results to him or her.

We thank you again for participating in the Strong Heart Study. If you have any questions please call Dr. ______ at the ______ Hospital or Clinic or the medical care provider of your choice. You can also reach me at ______.

Sincerely,

SHS
APPENDIX 15 (b)
Interpretation of Examination Results and Suggestions

Blood Pressure: If your blood pressure was above 140/90, you should go to clinic to see your health care provider for advice on how to lower it.

Percent Body Fat: If your percent body fat is above the desirable range, you should lose weight. The desirable range is shown on the results.

Body Mass Index is also a measure of obesity. If you are more than 120% of body mass index, you should lose weight.

Physical Exam: The findings listed are those found by the exam done by the nurse practitioner. They will be available in your IHS medical record in case you need further evaluation.

Cigarette use: If you smoke, it is advised that you cut down or preferably quit. Smoking causes heart problems and cancer and you can improve your health by quitting.

Lipids: These are the fats measured in your blood.

Total cholesterol measures both good and bad cholesterol.

Triglycerides are another kind of fat in the blood. Sometimes they are high in diabetic patients who have high blood sugars. If your triglycerides are high, eat less food and drink less alcohol (if you drink) and have your triglycerides checked in 3 months.

HDL cholesterol is the good cholesterol. The higher your HDL cholesterol, the less chance of heart disease.

LDL cholesterol is the bad cholesterol which may cause heart disease if it is high: 130-159 is moderately high, over 160 is very high.

All persons with high LDL should go on a low fat, low cholesterol diet and have a follow-up check-up in several months.

Creatinine measures kidney function. If it is high, you should go to clinic to see a health care provider.

Glucose is blood sugar. Patients with diabetes have high blood sugars.
  Fasting glucose 140 or higher = Diabetes
  Fasting glucose less than 140 = Normal
Two hour post 75gm glucose load

Some persons were given sugar water to see if they have diabetes. The reading two hours after drinking the sugar means:

- Blood glucose 200 or higher = Diabetes
- Blood glucose 140-199 = Impaired glucose tolerance
- Blood glucose less than 140 = Normal

People with impaired glucose tolerance are more likely to get diabetes than people with normal levels. Healthy diet, losing weight if you are overweight, and exercise are an important way to prevent or control diabetes.

Urinary albumin-creatinine ratio measures kidney function. If above 30, it indicates there may be some kidney damage.

Glycated hemoglobin reflects the blood sugar over the past 6 weeks.

The levels of glycated hemoglobin are interpreted in diabetic patients as follows:

- Poor control - 9.6% and above
- Fair control - 7.6% - 9.5%
- Good control - 6.0% - 7.5%
- Normal Value - 5.9% and below
APPENDIX 16
THE STRONG HEART STUDY II
INFECTION CONTROL POLICY

Human Immunodeficiency Virus (HIV) and Hepatitis B

INTRODUCTION:

The virus that causes AIDS is a human retrovirus that has been named HIV (human immuno deficiency virus). The virus primarily infects cells of the T-lymphocyte system, but is also able to infect other cells such as macrophages and those of the central nervous system. The virus destroys the cellular immunity of infected people, leaving them susceptible to a variety of opportunistic diseases.

It has been established that the virus can be transmitted: (1) through sexual contact; (2) through parenteral exposure, including sharing needles and syringes when injecting illicit drugs, transfusion of blood or its components, and infusion of clotting factors concentrates; and (3) through perinatal exposure, probably both transplacental and intrapartum transmission and postpartum transmission.

To date, there is no evidence that the HIV virus can be transmitted by casual social contact, not even among people living in the same house-hold. Recent reports by the CDC suggest that exposure of skin or mucous membranes to contaminated blood may rarely result in transmission of HIV. The magnitude of the risk is not known.

Hepatitis B virus (HBV) is transmitted in ways similar to HIV.

PURPOSE:

To stress the importance of following recommended precautions to prevent exposure to the AIDS and HBV virus.

PREVENTION:

1. Before initiating work, all bench areas should be cleaned and sanitized daily with an appropriate disinfectant.

2. All laboratory specimens should be treated as if they were contaminated with either HIV or HBV. Any specimens specifically taken from known AIDS or hepatitis patients should clearly marked as isolation and transported in a leak proof container.

3. Specimens leaking from their containers should be discarded after requesting a
replacement. In those cases in which the specimen is not replaceable, the outside of the soiled container should be disinfected with either a 1:10 sodium hypochlorite solution (household bleach) or lysol spray and left standing for at least ten minutes before performing any laboratory procedure(s).

4. Every laboratorian should wear gloves and be dressed in a laboratory gown or uniform when handling and processing specimens. This will minimize the risk of contamination to exposed body parts or street clothing. Gloves should be worn and disposed of in accordance with the "Gloves (Proper Use and Disposal)" policy. Hands and other skin surfaces should be washed thoroughly and immediately after coming into contact with blood or body fluids.

5. Wear masks, gowns (of aprons), and goggles (or glasses when there is a possibility that blood or body fluids may splash or splatter on you.

6. All laboratory specimens that must be manipulated before processing (i.e., body fluids to be diluted, caps on tubes of blood to be opened, specimens to be split or transferred, etc.) should be handled cautiously.

7. Centrifuge carriages should be sanitized daily (or after each use if possible HBVs or AIDS specimen is being centrifuged) with a germicide. After weekly use, centrifuge interiors should be sprayed with an appropriate disinfectant.

8. To prevent needle stick injuries, needles should never be recapped separated from syringes or otherwise manipulated. Instead, used needles should be place intact into puncture-resistant containers. The same criteria should be applied to used scalpel blades and any other sharp device that may contaminated by a patient.

9. To prevent transmission of HIV or HBV the platform on the finger prick device (Autoclik, etc.) should be changed between patients.

10. Reusable devices, such as tissue grinders, pipettes, etc, should be placed into vesicles containing an appropriate germicide prior to being autoclaved and cleaned.

11. Mouth Pipetting of blood or serum or plasma is forbidden for any clinical laboratory procedure. Mechanical pipetting devices are available and must be routinely used.

12. All laboratory specimens and disposables should be discarded in biohazard bags and autoclaved prior to final disposition by either incineration or sanitary carting.

13. Accidental spillage of a specimen should be promptly cleaned up with any of the previously mentioned disinfectants. This solution should be freshly prepared and
kept in its diluted form no longer than one week.

14. If accidental contamination occurs to an exposed area of the skin, wash first with a good liquid antimicrobial detergent soap (i.e., hibiclens, chlorhexidine gluconate, etc.). Rinse well with water, then apply a 1:10 dilution of household bleach or 50% isopropyl or ethyl alcohol. Leave preparation on skin surface for at least one minute before final washing with the liquid soap and water.

15. All work bench areas should be cleaned and sanitized with an appropriate germicidal agent at the end of each work shift.

16. Before workers leave the laboratory, all protective clothing should be removed. In addition, all laboratory personnel should wash their hands and arms with an appropriate germicidal detergent soap (i.e., chlorhexidine gluconate with alcohol).

FIRST AID AFTER CONTAMINATION OR LIKELY CONTAMINATION

1. SKIN: Wash the skin well with soap and water.

2. EYES: Flush eyes with water by using the safety eye wash.

3. NEEDLE STICK: Squeeze the affected part gently to somewhat cleanse the wound by bleeding. Cleanse with soap and water.

4. MOUTH: Immediately rinse out the mouth with large amounts of clean water. Do not swallow the water. (mouth pipetting is strictly forbidden)

5. For all incidents:
   a. Notify the supervisor and report to the Employee Health Unit or in the event Employee Health is closed, go to the Emergency Room.
   b. As incident report form must be filed.
   c. The decision to administer hepatitis immune globulin is made by the Employee Health Unit.
   d. The hepatitis B surface antigen (HBsag) vaccine HAS BEEN AND IS AVAILABLE to high risk personnel (laboratory, ICU, etc.)
REFERENCE:

