2. SPIROMETRY - MANUAL OF OPERATIONS

2.1 Forward

This manual serves three purposes:

- a study guide for training of technicians to perform pulmonary function testing
- a practical "how-to" reference guide to be used by clinic staff during the study
- documentation of the pulmonary function testing procedures for analyses and manuscript preparation.

2.2 Background

Rationale for Pulmonary Function Testing

1. According to the results of the Framingham study and many others, the Forced Vital Capacity (FVC) from the spirometry test is an excellent independent predictor of mortality from cardiovascular diseases, even after adjusting for cigarette smoking (1-2). It is hypothesized that this "lung test" predicts heart disease mortality because the FVC decreases when lung congestion occurs due to early (preclinical) left-sided heart failure (CHF). Addition of spirometry testing in the Strong Heart Study should, therefore, allow better prediction of CVD morbidity and mortality.

2. Measurement of the slow vital capacity (SVC) in the standing position will also be performed in those unable to perform high quality FVC maneuvers and those with a low FVC. This addition will allow us to better differentiate between the various causes of a reduced FVC. The FVC, but not the SVC, is reduced in moderate to severe airways obstruction (due to asthma or COPD). We estimate that about 15% of the participants will have some degree of airways obstruction. The high intra-thoracic pressures generated during the forced FVC maneuver in these participants makes their narrowed airways close completely towards the end of the maneuver, trapping air in the alveoli, causing an underestimation of the true vital capacity (as measured by the SVC). The measurement of a normal SVC in these participants will rule out the presence of a superimposed restrictive process (such as pneumonia, congestive heart failure, or obesity).

The SVC breathing maneuver is much easier to perform than the FVC maneuver. This is important in the 6-10% of participants who are not highly motivated to perform the athletic-type breathing maneuvers required by the FVC test.

3. The FEV1 from the spirometry test is the best predictor of morbidity and mortality from...
chronic obstructive pulmonary disease (COPD) due to cigarette smoking (3-4). COPD is one of the ten leading causes of morbidity and mortality in American Indians. Portions of an American Thoracic Society standardized respiratory questionnaire (5) regarding asthma, chronic cough, sputum production, and smoking cessation attempts have been added to the study questionnaires. These will allow the assessment of associations between cigarette smoking, respiratory symptoms, and respiratory diagnoses and pulmonary function results (and the later development of overt respiratory disease, if follow-up studies are later performed).

4. When the FEV1 results show airways obstruction in a current smoker, that individual has been demonstrated to be susceptible to the pathologic effects of cigarette smoking and is at very high risk for disability and death from COPD (6) or lung cancer. Participants who are smokers and have abnormal spirometry results will, therefore, be referred to a smoking cessation program (not funded by this study).

5. Predicted pulmonary function values for American Indians are not well established. In one study of nonsmoking, adult Navajo Indians without lung disease, spirometric values were found to be statistically different (but close) to larger studies of normal whites (7). The values of Navajo Indians, however, may be quite different from other Indian tribes. The normal population studies used by most PF laboratories did not test any Native American subjects (8). Rhoades states that "There is a great need for additional study of ventilatory function in American Indians, including the establishment of normal values" (9). Addition of PF testing to the Strong Heart Study will accomplish this, which in turn will allow more sensitive and specific diagnostic testing of Native Americans for asthma, COPD, and restrictive lung diseases.

6. American Indian mortality and hospitalization rates during the 1980s due to respiratory diseases were recently reviewed (9-10). The most prominent (in order of mortality rate) are pneumonia, lung cancer, COPD, and tuberculosis. Rates vary considerably between geographic areas of the country: Aberdeen, Billings, and Bemidji rates are higher, associated with higher cigarette smoking rates (11). Addition of the standardized respiratory questionnaire will help to quantitate the prevalence of these diseases in the Strong Heart Study participants when they have been diagnosed by a physician. Pulmonary function tests will add objective data concerning the prevalence rates of obstructive lung disease (COPD and asthma) in their early (preclinical) stages, and lung infections which leave permanent scarring resulting in an abnormally low vital capacity (FVC). (Spirometry, however, is NOT helpful in the detection of lung cancer.)

7. The addition of PF testing is an opportunity to bring more attention to other preventable respiratory diseases in this population. The death rate from TB in American Indians has declined dramatically during the last 30 years, but still appears high in Alaska and North Dakota, relative to whites (9). Lobectomies or other lung surgery for TB will frequently reduce the vital capacity, so this effect could be studied by spirometry.
Coccidioidomycosis (cocc, valley fever) is endemic in Southwestern Indians who live in or visit the Sonoran desert (including Arizona) and may affect pulmonary function when disseminated. Questions regarding tuberculosis and cocc exposure, and history of previous diagnosis and treatment (as currently done only at the Dakota clinic) will be added to the respiratory questionnaire.

Tuberculosis skin tests will be applied when appropriate (as specified by American Thoracic Society guidelines), and Cocci skin tests will be applied to participants in Arizona. The participant will return in 2-3 days to have the test reaction measured by community health workers. Those with positive results will be referred for appropriate treatment.

**Background references**


2.3 Definitions

*A/D CONVERTER* is a small electronic interface card mounted inside the spirometer which changes the analog voltages from the spirometer potentiometer and temperature sensor to digital numbers that the computer can understand. These are transferred to the personal computer via the RS-232 serial interface.

*ARCHIVAL FLOPPY DISK* is the floppy disk which stores a backup copy of participant test results, to be stored at the Field Center in case the PF Workstation's hard disk crashes or the Mailer floppy disk is misplaced by the U.S. Postal Service.

*ATPS* is the condition of air inside the spirometer - Ambient Temperature and Pressure, and Saturated with water vapor. The ambient temperature of the spirometer is usually lower than body temperature; this has the effect of cooling and contracting the volume of air exhaled into the spirometer.

*ATS* is short for American Thoracic Society, the scientific branch of the American Lung Association - the Easter Seal folks. The ATS promotes accurate spirometers by recommending spirometry standards.

*BACK EXTRAPOLATION* is the standard method used to determine "time zero" when measuring the FEV1. The amount of slowly exhaled volume at the start of the maneuver excluded from the FEV1 by this technique is called the back extrapolated volume (BEV or EV). The BEV should be less than 5% of the vital capacity, otherwise the maneuver is considered to have started too slowly.

*BTPS* stands for Body Temperature (usually 37 degC) and Pressure, and Saturated with water vapor (100% humidity), which is the condition of air inside the lungs before it is exhaled into a spirometer. ATS standards require that volumes and flows be reported as if they were under these conditions.

*CALIBRATION SYRINGE* is a large metal cylinder with a rubber sealed piston used to check the volume accuracy of spirometers. The ATS recommends that it be 3.00 liters in size and we use a sturdy aluminum model made by Hans Rudolph.

*COPD* stands for Chronic Obstructive Pulmonary Disease, a general term for lung disease
caused by cigarette smoking - a mixture of emphysema, bronchitis, and hyperreactive airways.

*EV* (see Back Extrapolation)

*FET* is short for Forced Exhalation Time. The FET should be at least ten seconds for the FVC maneuver to be considered acceptable, otherwise the FVC may be underestimated. The FET is displayed on the incentive screen as the Duration.

*FEVI* is the most important spirometry variable, short for Forced Expiratory Volume in one second. It is convenient to think of it as the average flow rate during the first second of the FVC maneuver. It is reduced with airflow obstruction.

*FEVI/FVC RATIO* is the most sensitive and specific index of airways obstruction measured by a spirometer. It is normally above 70%.

*FLOPPY DISKS* are removable, rather slow, computer storage media. The personal computer's floppy disk (drive A:) uses high density (HD) 3 1/2 inch floppy disks which can each store up to 1.44 million characters (Mbytes).

*FLOW-VOLUME CURVE* is the graph obtained from a forced exhalation maneuver plotted with flow on the vertical axis and volume on the horizontal axis. When compared with the traditional spirogram, it has the advantage of allowing easy recognition of unacceptable or poorly reproducible maneuvers and disease patterns.

*FVC* is the Forced Vital Capacity, the volume of air exhaled during the maneuver named after it. The subject takes as deep a breath as possible and then quickly exhales as much air as possible. The FVC is reduced with restrictive disorders.

*HARD DISK* is the personal computer's fast, mass storage device (drive C:) which stores millions of characters.

*OBSTRUCTION* is a decrease in maximal airflow rates caused by airway narrowing. The FEV1/FVC ratio and the FEV1 are both decreased.

*PEF* stands for Peak Expiratory Flow Rate, the highest flow measured during the FVC maneuver. It is a good index of effort used at the onset of the maneuver. It can be seen on a flow-volume curve but not on a traditional volume-time spirogram. Inexpensive $10 hand-held instruments can also measure PEF with better than 10% accuracy. These peak flow meters will be used to assess the lability of airways obstruction in a subset of the CHS population.
2.4 Methods Summary

Daily Procedures

Calibrate Instruments
- Power-up computer and spirometer
- Run leak and volume checks
- Wash your hands

Identify the participant
- Enter name, ID number, age, height, weight

Perform FVC maneuvers
- Demonstrate the FVC maneuver
- Obtain 3 acceptable FVC maneuvers
- Review maneuver quality
- Measure Slow VC if unable to perform FVCs
- Add comments
- Print and store the results

Clean Equipment at the end of the day
- Clean breathing hoses
- Rinse and dry hoses overnight

Weekly Procedures

Monday mornings
- Run leak and volume cal checks
- Perform a biologic control test

Friday afternoons
- Remove spirometer shell
- Clean internal compartment
- Rinse and dry overnight

2.5 Description of the PF Workstation

A dry-sealed volume spirometer is connected to a personal computer using a 12 bit analog to digital (A/D) interface. The spirometer is equipped with a potentiometer (pot) which changes the mechanical motion of the spirometer bell into a voltage which is proportional to exhaled volume. An electronic sensor measures the spirometer temperature for automated BTPS corrections. The A/D converter, mounted on a board inside the spirometer takes the analog voltages, converts them into digital numbers and sends them to the computer via an RS-232 serial interface. The computer
then calculates the exhalation time (FET) and airflow rates (FEV1) using a crystal controlled clock and stores all the results in RAM memory. The results are stored on the hard disk, printed, and copied to a diskette to be mailed to the PF Reading Center.

2.6 Main Menu

The MAIN MENU is automatically displayed when the computer's power is turned ON. If you are faced with the DOS prompt C:> type GO The MAIN MENU is the control center or hub of the system. Moving from one function to another is performed by going back to the MAIN MENU first.

You usually move forward within a program by pressing either the Enter key or the spacebar. Directions are often given at the bottom of the screen. If you obtain a program or screen by mistake, you can usually get back to the MAIN MENU by pressing the Esc key.

Select the desired program from the MAIN MENU by highlighting your selection using the cursor (arrow) keys. Then press the Enter key. An alternate method for experienced users is to merely press the three letter code for the program (not followed by Enter).

The first column of selections, under the heading PRE:Tests lists the most frequently used programs in the order in which they are usually selected:

INF - Enter patient information Used to enter the name, ID number, age, height, etc for a new participant. The name of the "current participant" is given in parentheses on this line.


EOS - End the Test Session Asks you for comments, then prints a report for the participant and his/her physician and a tabular report for the participant's on-site CHS chart. The data are then stored in a directory on the hard disk.

SVC - Slow Vital Capacity If the participant can't perform good FVC maneuvers, the slow VC test should be done. It requires very little effort.

TXT - Enter Comments You may go back and edit your comments about what happened during testing at any time.

2.7 Participant Information

Select "INF - Identify the Participant for the MAIN MENU." If you did not complete a leak and volume cal check today, you will be instructed to do so at this time, before testing a participant (see the CALIBRATION section of this manual).
Enter or verify the information requested in each box. End each entry by pressing the ENTER key. Every item must be entered in order to calculate predicted values.

Name: Enter the participant's last name, a comma, then his first name (up to a maximum of 22 letters). Use all capital letters. Don't add a space after the comma. Press F2 here to edit the currently selected participant’s data (instead of entering data for a new participant).

ID #: Enter the participant's 7 digit CHS ID number and verify that it is correct. If you enter it in error, use the backspace key to correct it.

Note: If you are not testing a participant, use 999 as the first 3 digits of the ID number.

Date: Verify that the computer knows the correct date.

Location: Your Field Center's name should be here.

Age: Enter the participant's age.

Sex: Press M for male or F for female.

Height: Enter the participant's measured standing height (in stocking feet) in inches.

Weight: Enter their weight in pounds. If computed BMI exceeds 27, you will be instructed to ask the participant to stand during spirometry maneuvers.

Race: Enter the ethnic code: N for Native American, A for Asian, B for Black, C for Caucasian, H for Hispanic

Note: Predicted values for Asians and Blacks are reduced by 12%, due to a shorter trunk to height ratio.

Baro: The average barometric pressure at your location (usually between 720 and 760) should be displayed here. It should NOT be changed.

Temp: The spirometer temperature is measured by an internal sensor and displayed here. Verify that it reads within 2 degC of the small MICRONTA thermometer mounted on the spirometer.

If the readings differ by more than 2 degC, call the PF Reading Center. If the spirometer temperature is below 17 degC (60 degF), the room is probably too cold for testing. Turn up the room's thermostat and blow into the spirometer yourself to warm it before testing participants.
Help. Each entry is verified to make sure it is within a reasonable range. If your entry is rejected, press the F1 key for a help message which explains the entry expected.

Editing. If a mistake was made when entering information, use the arrow keys to move the cursor to the error. Then begin typing the information. Press ENTER to complete the line.

The predicted PF values will be displayed in a box in the lower right hand corner of the screen. Ignore them and press the Enter key.

A comments screen is displayed next: Press the Enter key twice to skip over the two lines of general comments. (You will get a chance to enter these just before you print the report.) Indicate if the participant will stand for the maneuvers due to a large body mass index (above 27). Enter your 3 digit tech ID number (otherwise you will not be credited with high quality testing!) Press the Enter key at the bottom of the screen to return to the MAIN MENU.

2.8 Forced Vital Capacity Testing

You, the technician, are the critical part of the pulmonary function testing system, since you must guide the participant through breathing maneuvers which are highly dependent on participant effort. You must coach the participant to inhale maximally and then to exhale maximally. You also must judge the quality of his effort. To obtain accurate results, the testing must be done in a standardized fashion.

Note: This manual refers to the participant as "he" or "him" for easy reading, although participants will be both ladies and gentlemen.

Wash your Hands Participants will appreciate your consideration if you make a point of washing your hands before testing them. Do this as you enter the testing room if it has a sink, otherwise, just before you enter the room. Another thing you can do to minimize the risk of cross-contamination is to store the fresh mouthpieces in a sanitary plastic box and ask the participant to use a Kleenex tissue to remove one for their use. Then allow them to attach it to the clean breathing tube.

Explain the Procedure Explain that the purpose of the next test is to determine how hard and fast he can exhale air, "Like blowing out dozens of candles on a birthday cake." Explain that, as before, he should take in as deep a breath as possible, and when his lungs are completely full, quickly position the mouthpiece as before, and exhale his air as hard and fast as possible, until told to stop.

Position the Participant Testing should usually be conducted in the sitting position; however, obese participants (BMI>27) should stand. A chair (without wheels) should be positioned behind obese participants who stand for the test. Use the chair if the participant becomes light-headed or faint during testing. Ask the participant to sit erect with chin slightly
tight clothing, such as a tie, vest, or belt, which might restrict maximal breathing efforts, should be loosened. Dentures, if they are loose, should be removed and placed in a clean denture cup, since they will prevent a tight seal from being formed around the mouthpiece. If dentures are not loose, leave them in place.

**Always Demonstrate the Maneuver** Ask the participant to watch you perform the FVC maneuver. Again demonstrate correct placement of the mouthpiece. Stand up straight. Take a deep breath, throw back your shoulders, widen your eyes, and stand on your toes to emphasize the maximal depth of inhalation. Then place the mouthpiece and dramatically **BLAST** out all of your air as hard and as fast as you can.

Your vigorous demonstration will prevent time and effort from being wasted on unacceptable forced expiratory efforts which are caused by the participant's failure to understand a verbal explanation of the procedure.

**FVC Test Steps**

Step 1 From the MAIN MENU, select **FVL**. Move the silver lever to about the 1 liter position --- the FVC Incentive screen will then be displayed.

Step 2 Tell the participant to "take in as deep a breath as you possibly can, then put the mouthpiece in your mouth." Watch him as he does so and then coach him: "now inhale a little bit more," until you are sure that his lungs are full.

Step 3 Shout **"BLAST OUT!!!"**
Lower your voice a bit and say "keep going ... keep on pushing out all that air... a little bit more ..."

Step 4 After a couple of seconds, the tail of the flow-volume curve will be displayed in a box in the upper right-hand corner of the screen. Glance at it. Perhaps draw his attention to it and the horizontal bar. You will hear a beep when the EOT criterion is met, but keep coaching him to keep blowing out the air until only the green portion of the EOT plateau bar is showing (or 15 seconds has elapsed).

Watch the body language of the participant as he attempts to follow your instructions. **Pay attention to him, not the instrument.**

Encourage him to blow out smoothly without re-breathing.

Don't press the Esc key during testing until you are certain that you have performed enough good maneuvers. Press the spacebar to get the results screen. (You'll have to press it twice if you
didn't wait for 15 seconds to elapse.) Then save the maneuver by pressing the spacebar again. If you press the N key at this point, the maneuver will be erased forever. Do this only if the maneuver was terrible and you are sure that the participant can do a better maneuver. Analyze the flow-volume curve produced by this maneuver. Note the maneuver quality message in the box.

Hint: If you like traditional volume-time spiromograms, you can display them by pressing the F8 key at this time.

If after the initial demonstration, the participant fails to perform the maneuver correctly, again demonstrate both the error and the correct performance yourself. You may have to repeat the demonstration after every maneuver for some participants!

Your goal is to obtain at least 3 good maneuvers, 2 of which match each other closely. If the current maneuver did not match the best prior maneuver, a message like "Next time, take a deeper breath" will be displayed at the bottom of the screen. Quality grades from A-D will be displayed immediately after the FVC and FEV1 results. These indicate the reproducibility of the best and second best maneuvers.
Note: Try using a noseclip if you get the message "Deeper breath" indicating that the FVCs do not match.

To perform another maneuver, merely press the Spacebar and move the lever back to the 1 liter position to get the incentive display.

Review the Results

After the participant has performed three apparently good FVC maneuvers, review the results. **Press the F9 key** to see the three best maneuvers superimposed, each in a different color.

The blue maneuver with numeric results listed at the top right of the screen in blue is the "best" maneuver obtained so far. The Trial number is the order in which it was performed.

The "best" maneuver is the one with the highest sum of FVC + FEV1. Ignore the predicted and %predicted values displayed in the right-hand columns.

If you still don't have 3 good maneuvers, press the Spacebar twice to perform another maneuver. If the quality and reproducibility of the 3 maneuvers displayed looks good, and you think that you might be done testing, press the F10 key.

Maneuver Quality Review Window (F10)

The best three maneuvers are again indicated at the top of the columns. First look at the bottom row marked QC. Any letters there are maneuver Error Codes which mean that the maneuver was not acceptable or reproducible, and that more maneuvers should be performed. Press the F1 key for an explanation of these codes. Press the Spacebar twice to resume testing.

Numbers listed under the Stored Values column are the highest obtained from all maneuvers performed and will be printed on the report. The number listed under the (%) column for each maneuver (Trial) is the percent of the highest value. For the FEV1 and FVC parameters, a good match is 95% or more. For PEFR, a good match is 85% or more.

If all 3 maneuvers are "Good tests", you have obtained enough FVC maneuvers, and should press the Esc key to store the results. The hard disk light will illuminate as the results are stored, and you will be returned to the MAIN MENU.

FVC Maneuver Acceptability

According to the ATS standards, you should coach every participant to obtain at least three maneuvers that are "acceptable" and two that are "reproducible." The criteria for acceptability and reproducibility are described below. The accuracy of results depends much more on the quality of
the maneuvers than on the instrument calibration.

Acceptability Messages  Errors in FVC maneuver performance are identified by the computer and displayed in the F10 QC box:

<table>
<thead>
<tr>
<th>QC Message</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>S  Start faster</td>
<td>BEV &gt; 5% FVC</td>
</tr>
<tr>
<td>P  BLAST out harder</td>
<td>PEFT &gt;90 msec</td>
</tr>
<tr>
<td>C  Avoid coughing</td>
<td>&gt;50% drop</td>
</tr>
<tr>
<td>T  Blow out longer</td>
<td>FET &lt; 6 sec</td>
</tr>
<tr>
<td>A  Blow out more air</td>
<td>Abrupt termination</td>
</tr>
<tr>
<td>V  Try for 10 seconds</td>
<td>40 ml in last 2s</td>
</tr>
</tbody>
</table>

After the first maneuver, reproducibility messages are also displayed on a line at the bottom of the screen prior to the next maneuver if the current maneuver's result was lower than the previous highest value from an acceptable maneuver:

\[ d \quad \text{Deeper breath} \quad dFVC > 5\% \text{ and } 200 \text{ mL} \]
\[ f \quad \text{Blow out faster} \quad dFEV1 > 5\% \text{ and } 150 \text{ mL} \]
\[ h \quad \text{Blow out harder} \quad dPEFR > 15\% \text{ and } 1 \text{ L/s} \]

Notes: QC = error code displayed in the Review QC window - F10 key.
BEV = back extrapolated volume
dPEFR, dFVC, dFEV1 = difference between the current maneuver's value and the highest value from any other acceptable maneuver from the testing session.

Maximum Number of Maneuvers. Don't exhaust the participant by asking them to perform more than eight FVC maneuvers. If you haven't obtained 3 acceptable maneuvers by the time you have done 8 maneuvers, it is unlikely that you will. Make a note of the reason why the participant couldn't perform the maneuvers well in the Comment Screen later.

The following figures show examples of flow-volume curves from acceptable and unacceptable maneuvers.
EXHALED VOLUME (LITERS, BTPS)

AVOID COUGHING

EXHALED VOLUME (LITERS, BTPS)

GOOD MANEUVER

EXHALED VOLUME (LITERS, BTPS)

BLOW OUT LONGER

EXHALED VOLUME (LITERS, BTPS)

START FASTER

EXHALED VOLUME (LITERS, BTPS)

BLOW OUT HARDER

EXHALED VOLUME (LITERS, BTPS)

BLAST OUT HARDER
TAKE A DEEPER BREATH

BLOW OUT FASTER

THREE GOOD MANEUVERS
2.9 Slow Vital Capacity Testing

Participants who are unable (or unwilling) to perform three acceptable forced vital capacity maneuvers should be asked to perform two easy slow VC maneuvers. Select SVC.

**Demonstrate the SVC Maneuver**

Ask the participant to watch you perform the SVC maneuver. With an extra cardboard mouthpiece, not connected to the spirometer, demonstrate the correct placement of the mouthpiece. Stick out your tongue and place the mouthpiece on top of it. Then withdraw your tongue, pulling the mouthpiece inside of your mouth, and seal your lips around the mouthpiece. Breathe normally for a few breaths, then take a deep breath, throw back your shoulders, widen your eyes, and stand on your toes to emphasize the maximal depth of inhalation. Then slowly exhale all of your air for several seconds.

Sample SVC tracing:
SVC Maneuver Steps

1. Move the silver lever to about the 7 liter position. Ask the participant to hold their nose during the SVC maneuvers. Attach a noseclip only if you notice that the participant is leaking air through his nose during the maneuvers or if you cannot obtain reproducible results.

2. Instruct the participant to seal their lips around the mouthpiece and breathe normally from the spirometer. Press the spacebar to begin the test when they have begun breathing from the spirometer.

3. Note the blue tracing of their breathing pattern starting on the left side of the screen. Allow him to breathe normally for a couple of breaths. Then coach him to take as deep a breath as possible. Look at him to see if he is doing so. Tell him to strain to take in a little bit more air.

(SVC steps continued)

4. When you are sure that he cannot inhale any more air, tell him to let it all out slowly and then squeeze all the air out of his lungs. Point to the display. Tell him to keep blowing out until the bar graph on the right side of the display moves down into the green area (and you see a flat plateau on the blue tracing).

5. Press the Y key to accept the maneuver if it seemed OK. Then press the Enter key to view the numeric results. You don't need to adjust the FRC line.

6. After a short rest, repeat the maneuver a second time. When the results for the second maneuver are displayed, check to see that the SVCs from the two maneuvers match within 5% of each other. Press the F10 key to see the SVC result from all SVC maneuvers done so far.

7. After completion of the SVC tests, press the Esc key to store the results and return to the MAIN MENU.

2.10 End Test Session

After you have performed all of the maneuvers, congratulate the participant for a job well done and tell him that the results will be explained to him at the end of the visit. Do not attempt to explain them to him yourself.

Get the printer ready to print the report.
Select "EOS - End test session" from the MAIN MENU. The results will be added to the patient directory and database on the hard disk.

You will then be asked if you have any comments. If anything unusual happened during the testing, enter your comments on the two lines provided.

The reports will then be printed (see samples on the next pages).

2.11 Print-Screen

Anytime while you are testing a participant and you wish to make a copy of what is displayed on the screen, you may do so by pressing the <Print Screen> key located in the upper right-hand corner of the keyboard. A box will then be displayed near the bottom of the screen asking if you want a Small, Medium, or Large size print. Normally you should select a small print by pressing the S key. This will allow two such screens to be printed on a single sheet of paper.

To eject the page from the printer, following a Print-Screen, you may need to take it "off-line" then press the Form Feed button, wait for it to eject, then press the On-line button again. Sample report printed for the participant (or their private physician):

2.12 Leak and Calibration Checks

**Leak Check** Select "LEA - Leak Check" from the QC column of the MAIN MENU. The leak test must be performed BEFORE the Volume Cal Check, since a leak will affect the volume calibration.

1. Attach a breathing hose. Raise the spirometer bell by the silver lever knob to the 7 liter position. Cork the breathing hose with the #8 rubber stopper.

2. Attach the rubber band to the silver lever in order to provide pressure inside the spirometer. [A 3 inch long 3/8in wide rubber band stretched to the 7 liter mark will provide 2 cm H2O pressure inside the spirometer, per ATS specifications.]

3. Press the Enter key to start the leak test (for the default 30 seconds).

The Leakage Rate displayed after one minute should be less than 40 cc/min (or blank, indicating no leak at all).

If a Leak is detected, the message "unacceptably high leak rate ... " will be displayed. Determine whether the leak is in the breathing tube or a spirometer seal as follows:

1. Disconnect the breathing tube from the spirometer. Raise the lever midway and insert a #8 solid stopper into the breathing tube connector at the front of the spirometer. Attach the rubber band again.
Sample report printed for the participant
(or their private physician):

**Cardiovascular Health Study**
**Pulmonary Function Report**

<table>
<thead>
<tr>
<th>Patient:</th>
<th>Martin McInroe</th>
<th>Height: 77.0(in) - 196 (cm)</th>
<th>Sex: M</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID Number:</td>
<td>1233</td>
<td>Weight: 170(lb) - 77 (kg)</td>
<td>BMI: 20.2</td>
</tr>
<tr>
<td>Date:</td>
<td>06-11-93</td>
<td>Age: 45</td>
<td>BP: 760</td>
</tr>
<tr>
<td>Temp:</td>
<td>23</td>
<td>ATPS: .919</td>
<td></td>
</tr>
<tr>
<td>Clinic:</td>
<td>Arizona</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Predicted:</td>
<td>Knudson 83</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Actual</th>
<th>%Pred</th>
<th>Pred</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC (L)</td>
<td>5.44</td>
<td>85</td>
<td>6.38</td>
</tr>
<tr>
<td>FEV1 (L)</td>
<td>4.16</td>
<td>80</td>
<td>5.18</td>
</tr>
<tr>
<td>PEF (L/S)</td>
<td>10.5</td>
<td>97</td>
<td>10.8</td>
</tr>
<tr>
<td>FEV1/FVC (%)</td>
<td>76.5</td>
<td>94</td>
<td>81.1</td>
</tr>
</tbody>
</table>

Comments:

Good Test

Computer Impression:

SPIROMETRY is within NORMAL limits.
Sample report printed for the participant (or their private physician):

Cardiovascular Health Study
Pulmonary Function Report

Patient: James Garner  Height: 70.0(in) - 178 (cm)  Sex: M
ID Number: 12376  Weight: 190(lb) - 86 (kg)  BMI: 27.3
Date: 06-11-93  Age: 54  BP: 760
Temp: 22  ATPS: .918
Clinic: Arizona
Predicted: Knudson 83

<table>
<thead>
<tr>
<th></th>
<th>Trial 1</th>
<th>Trial 2</th>
<th>Trial 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pred. Selected</td>
<td>Actual (%)</td>
<td>Actual (%)</td>
</tr>
<tr>
<td>FVC</td>
<td>(L) 4.62</td>
<td>5.60</td>
<td>5.33</td>
</tr>
<tr>
<td></td>
<td>(L) 3.73</td>
<td>4.09</td>
<td>3.99</td>
</tr>
<tr>
<td>FEV1</td>
<td>% 80.9</td>
<td>73.1</td>
<td>74.9</td>
</tr>
<tr>
<td></td>
<td>(L/S) 8.8</td>
<td>11.8</td>
<td>11.7</td>
</tr>
<tr>
<td>Exp time</td>
<td>(sec) 12.0</td>
<td>11.9</td>
<td>12.0</td>
</tr>
<tr>
<td>PEFT</td>
<td>(sec) 0.06</td>
<td>0.06</td>
<td>0.06</td>
</tr>
<tr>
<td>BEV</td>
<td>(mL) 91</td>
<td>92</td>
<td>91</td>
</tr>
<tr>
<td>SEQ#</td>
<td>6</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>QC code</td>
<td>32</td>
<td>32</td>
<td></td>
</tr>
</tbody>
</table>

Flow - Volume Loop best trials

Best Flow HVAC Capacity

Strong Heart Study II  2/10/94  IV- 71  Spirometry
2. Repeat the leak test. If the leak is gone, then the breathing tube was the source of the leak. Discard it and check the new one for leaks. If, however, the Leakage Rate is still larger than 40 cc/min, a seal inside the spirometer is probably leaking.

3. Snap the top off the spirometer and examine closely the large black rubber "O" ring on the base. Is it seated in the round groove? Is it cracked or worn? Try applying a thin layer of some stopcock grease to the "O" ring and carefully resealing the spirometer, then see if that solved the leak. If not, call S&M Instruments for help.

**Volume Cal Check**

Select "CAL - Volume Cal Check" from the QC section of the MAIN MENU. You should have first done a leak check. You'll need the 3.00 liter calibration syringe.

**Carefully follow the directions at the bottom of the screen.**

1. Make sure that you have stored the 3.00 liter calibration syringe very close to the spirometer so that they remain at the same temperature. Flush the syringe and the spirometer at least 3 times with room air. Detach the white mouthpiece adaptor.

2. Pull back on the syringe plunger until it clicks (thereby filling it completely with room air).

3. Move the silver lever to the 2 liter mark. Firmly attach the calibration syringe to the breathing hose. Place the syringe flat on the table and don't move the tubing during the next step. Then press the Spacebar.

4. Empty the syringe into the spirometer; then press the Spacebar again.

5. Disconnect the cal syringe.

If the volume calibration error is too high (more than 2%) press the Y key to re-run the volume cal check.

Press Enter to return to the MAIN MENU.

**If the Volume Check Fails**

Possible reasons for the volume check to fail (in order of decreasing likelihood) include:

- Failure to completely fill and/or discharge the syringe into the spirometer. Make sure the syringe clicks against the stops with each stroke.
• Differences in the air temperature between the spirometer and the syringe. Reflush and repeat the check.

• An air leak in the calibration syringe. Fill the syringe, plug the end with the rubber stopper and try to empty the syringe. If the plunger moves inward, this indicates a leak in the syringe seal. Call the PF Reading Center to replace the syringe.

**ADJ** If the volume error was greater than 2% during the calibration check, you will be instructed to try the above 5 steps again. If the error remains too high, you will be instructed to adjust (ADJ) the A/D converter calibration constants by carefully following the directions at the bottom of the screen.

Note: Stroke the syringe in and out completely at least three times. Take about one second for each stroke. End up with the syringe completely full (shaft extended). Make sure you hear it click at the end of each stroke, but don’t "bang" it too forcefully.

2.13 Cleaning the Spirometer

**Clean the Breathing Tubes** at the end of each day of testing. First wash them in warm soapy water, rinse, roughly dry, then soak them in the disinfectant solution for at least 30 minutes. Be sure to wear protective rubber gloves (and a respirator?) when using this disinfectant since it causes a rash in some persons and the fumes are irritating. Rinse thoroughly and hang them to dry completely overnight before reusing.

**Clean the Spirometer every Friday afternoon.**

1. Unplug the spirometer power cord from the rear of the spirometer and disconnect the serial interface cable leading from the the spirometer to the rear of the computer. Detach the breathing tube.

2. Unlatch the top of the spirometer from the base using the four silver thumb latches. Lay the top on its side.

3. Wash the base of the spirometer and wipe the inside of the breathing tube connector with a mild detergent solution, rinse it with water, and allow it to dry overnight before re-assembly.

4. Reassemble the spirometer and latch the top to the base. Repeat a leak check before using the spirometer.
Calibration Syringe Care

The 3.00 liter calibration syringe should be stored next to the spirometer so that it remains at the same temperature as the spirometer. Store the syringe with the plunger pushed all the way in. Take care not to drop the syringes.

DO NOT attempt to make any adjustments to the syringe. Do not loosen the metal rings on the shafts, since this will spoil the factory calibration. The accuracy of each syringe will be verified by returning it to the manufacturer for measurement of its water displacement at the beginning of the last year of testing or whenever any evidence of physical damage to the syringe is noticed.

You should periodically check each syringe for leaks. Fill it with air, hold your palm against the outlet snout, and try to empty it. If you can expel any air with the outlet plugged, the syringe has a leak and must be repaired.

2.14 Tech Certification

The certification examination includes 40 multiple choice questions based on this Manual of Procedures, and a practical demonstration of skills including leak and calibration checks, cleaning, and testing of a naive subject (50 points). A passing score of at least 65 points is necessary for certification. Only certified technicians will perform pulmonary function testing in this study.

Certification of new technicians after the initial central training session may be performed by a centrally trained, certified PF technician. The written exam will be administered locally, and the first 20 PF tests performed will be observed by a certified PF technician and then examined by the PF Reading Center and found to be satisfactory before the new technician is certified. The results of the first 50 spirometry test sessions performed by each technician will be closely examined at the PF Reading Center. Copies of suboptimal quality test sessions with comments for improvements will be mailed to the technician on the same day as they are evaluated.

A site visit to the clinical center may be made early during recruitment. Complete calibration, leak, and complete PF testing of at least three participants by each PF certified technician will be observed. Copies of suboptimal quality test sessions will be reviewed. More efficient methods as well as protocol violations will be discussed during the site visits and later in a written report.

2.15 Quality Control

Need for Spirometry QC. Examination of spirograms from the Framingham study revealed that more than 18% were of clearly unacceptable quality (11). Two more recent studies, with over 12,000 adults each, found that 40 - 50% of the spirometry maneuvers were of unacceptable quality (12-14). Manual measurements from spirograms are tedious and prone to
error (15), and deviations in test performance and lack of regular leak checking and calibration can result in loss of study data (16-18).

The Epidemiology Standardization Project (19), the new American Thoracic Society spirometry standards (20), and recent evaluations of commercially available spirometers emphasize the importance of spirometry quality control procedures. Factors which affect spirometry quality (22) include:

1. Participant
2. Maneuvers
3. Technician
4. Equipment
5. Analysis

Feasibility of QC Procedures. This spirometry system has been developed and validated by an unbiased University testing program (21). The software assists the pulmonary technician with quality control of maneuvers, calculates the PF variables, suggests interpretations, formats and prints reports, and compresses graphics data for transmission and archival storage (23). The Lung Health Study (24), Cardiovascular Health Study, Framingham Study, and ARIC studies have used similar systems and procedures since 1987. The computerization of spirometry QC procedures dramatically decreases the overhead time associated with spirometry testing.

Implementation of QC Procedures. There are five separate levels of quality control implemented for spirometry testing which address the five factors known to influence the results:

1. Daily spirometer leak and calibration checks using a 3.00 liter syringe as the "gold standard" check the equipment accuracy.

2. Eight computerized checks of FVC maneuver acceptability and reproducibility check every maneuver immediately after it is performed.

3. The PF technician is trained to recognize the patterns of unacceptable maneuvers, watching the participant during the performance, and reviewing the colorfully displayed flow-volume curves on the computer monitor.

4. The results of the leak and calibration checks and of the best 3 FVC maneuvers are stored and sent to the PF Reading Center for review by the PF QC Supervisor. Monthly reports are compiled for each technician's performance.

5. Results from all of the above are taken into account during the analysis of the data by the PF Reading Center (3,24). The calibration factors, PF tech's impression of participant and maneuver quality, and the QC supervisor's impression of test session quality are all integrated to obtain the final FEV1 and FVC results reported to the Data Coordinating Center.
6. **Replicate testing** will be performed on a total of 30 participants scattered throughout the recruitment period. Choice of the participants will be by the Field Center staff, usually a participant who did not complete an exam and must return on another day to finish it. Spirometry should then be performed again by a different PF technician. The PF reading center will then examine the two sets of results for reproducibility.

7. After instrument QC checks, a **biologic control** subject (nonsmoker without asthma) will be tested each Monday morning (the Field Center Supervisor is preferred). The results will be compared with their prior mean values for FVC and FEV1.

**Weekly Biologic Control**

Type GET from the MAIN MENU. Use the same technician and the same ID number for all tests. It should be 999xxxxc where xxx is the tech's 3 digit ID code and c is the appropriate check digit. Press Enter to skipp all the comments. Perform FVC maneuvers as if testing a participant. Store the results and then review the trends by selecting TRD from the MAIN MENU. Ensure that your current FEV1 is within 5% of the mean of your previous values.

2.16 QC Analysis and Reporting

Each week you will mail a diskette to the PF Reading Center, using the BAK command which copies all the spirometry results for participants tested during the previous week onto a floppy diskette.

At the PF Reading Center, the result files are read by the PF QC workstation. The PF QC workstation displays the 3 best FVC maneuvers from a test session as differently colored flow-volume curves superimposed at the onset of each maneuver. The best maneuver is marked "B". The color of the maneuver sequence number (#1-8) corresponds with the color of that maneuver's flow-volume curve. The peak expiratory flow (PEF), FEV1, forced expiratory time (FET), and forced vital capacity (FVC) follow.

The Field Center and the PF technician who performed the testing are hidden from the QC Supervisor to avoid bias. The spirometer temperature is displayed and is highlighted if it falls outside the 17-33 degree C range, since BTPS corrections for volume spirometers become less accurate outside of this "normal" range (27).

After evaluating the flow-volume curves and the array of results, the QC supervisor indicates her choice of the single best maneuver, and enters a test session QC grade from A to F for both flow and volume. The flow grade is an index of reliability of the FEV1 from that test session. A flow grade of A is entered if at least 3 maneuvers demonstrate sharp PEFRs and if the best two have very reproducible PEFs and reproducible FEV1s (28).
The volume grade is an index of reliability of the FVC. A volume grade of A is entered if at least 3 maneuvers have maneuver durations of at least 10 seconds and the best two have very reproducible FVCs. A test session which just meets the minimum ATS recommendations of 3 acceptable maneuvers with the best two reproducible within 5% will generally receive a flow and volume QC grade of B.

After overreading a batch of test sessions, the QC grades are added to a QC database. All sessions with either a volume or flow grade of C or less or with a spirometer temperature outside the normal range are printed, comments are added by the QC Supervisor, and a cover letter is added and mailed to the technician who performed the test. The final, overread PF results are generated and sent by mail to the Data Coordinating Center at least monthly.

At the end of each month, a report is generated from the QC database, summarizing the performance of each PF technician. For each PF technician, the report includes the number of sessions reviewed and their average QC grades. The report is mailed each month to the Principal Investigators and to all PF technicians.

2.17 Annual Instrument Checks

Prior to the onset of the study, and at least annually thereafter, the following items will be checked to ensure spirometer accuracy:

1. **Spirometer temperature sensor accuracy** - A thermometer accurate to within 0.1 deg C is placed inside the spirometer bell and allowed to equilibrate for an hour. The temperature displayed by the spirometer on the INF screen is then compared with it. If there is more than a 0.3 deg C discrepancy, the correct temperature is entered by using the up arrow to move the cursor to the temp box and entering the correct temperature. The new temp cal factor is then noted using the EQU command.

2. **Volume linearity** - The linearity of the spirometer throughout its volume range is checked using a 1.00 liter calibrated syringe with internal one-way valves (Vitalograph). The LIN command invokes a program which directs the operation of this check. A worst-case linearity of 0.2% is the threshold of acceptability.

3. **Chart motor speed** - According to ATS recommendations, the chart motor's speed of 20 mm/sec should be accurate to within 1% to allow accurate manual calculations of the FEV1. This is verified by drawing two lines exactly 20 cm apart on the chart paper. A stopwatch is started and stopped as the pen passes the marks. This should be repeated a couple of times since eye-hand coordination often results in errors of more than 1%. The average elapsed time should be between 9.99 and 10.01 seconds.

4. **Calibration syringe volume and leak test** - The volume of the calibration syringe is checked by filling it with water, then emptying the water into a calibrated volumetric flask.
or cylinder. It is checked for leaks by pressurizing it while stoppered, as described previously.

5. **ATS waveform calculation accuracy** - The 27 standard ATS spirometer waveforms are available from S&M Instruments on a disk. These are "played into" the software (bypassing the A/D converter) to verify the accuracy of the software's calculations by comparing them to the published results. This check, however, doesn't check the spirometer or A/D converter nor the BTPS corrections.

2.18 References


2.19 Appendices

EQUIPMENT AND SUPPLIES

Attach the spirometer cable to the computer with the two screws on the connector, otherwise it will fall off easily. Attach the printer cable to the rear of the PC. Attach all power plugs to the switched outlet strip.

PF Workstation Major Components

1. Dry rolling seal spirometer with internal A/D converter
2. Toshiba T1850 laptop computer
3. Color VGA monitor (optional)
4. Canon BJ-200 bubble jet printer
5. Tamarac 3.00 liter calibration syringe
6. S&M Instruments Pneumocheck II software

Spirometry Supplies

The maintenance and supplies kit includes:
   Mouthpieces, 1 3/8 dia cardboard (qty 1000)
   Sanitary storage box for mouthpieces
   Noseclips
   Breathing hoses, 36" long (qty 20)
   Diskette Holder and 10 Diskettes, 3.5 inch
   Power strip with 6 surge protected outlets
   Denture cups
   Rubber stopper #8 size for leak checks

Other supplies to be purchased locally:
   Detergent and hose cleaning bucket
   Disinfectant solution (Cidex, Metracide, etc)
   Alcohol wipes, Cleaning cloths, Q-tips
PROGRAM FILES

The following files are distributed on 3.5 inch HD floppy diskettes and initially installed on the hard disk (Drive C:) in the subdirectory C:\CHS.

<table>
<thead>
<tr>
<th>File</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIRINF.EXE</td>
<td>The MAIN MENU shell program</td>
</tr>
<tr>
<td>FVL.EXE</td>
<td>FVC testing program</td>
</tr>
<tr>
<td>INF.EXE</td>
<td>Demographic information entry and calculation of predicteds</td>
</tr>
<tr>
<td>INF.REG</td>
<td>Predicted equations (text file)</td>
</tr>
<tr>
<td>DIS.EXE</td>
<td>Data File Management program</td>
</tr>
<tr>
<td>DISA.EXE</td>
<td>More data file management</td>
</tr>
<tr>
<td>ADJ.EXE</td>
<td>Recalibration of volume and flow</td>
</tr>
<tr>
<td>CONFIG.DAT</td>
<td>Custom configuration data</td>
</tr>
</tbody>
</table>

The *.EXE files are compiled using Quick BASIC version 6.0. Files with a .TXT extension are ASCII text files used to customize each program module. *.HLP files include the text in boxes displayed when the F1 key is pressed for help.

The software version number displayed at the top of the MAIN MENU is coded as follows: Ver. MMY.CCA.XX, where MM=month, Y=last digit of year, CC= Microsoft BASIC compiler version, A=major software version, and XX=the version of minor modifications.
RESULT FILES

At the end of each test session, the results for that single participant are stored on the computer's hard disk in the subdirectory C:PD93 as the following files:

<table>
<thead>
<tr>
<th>Filename</th>
<th>Description of contents (type)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FILE</td>
<td>Participant directory (A)</td>
</tr>
<tr>
<td>DATAxxxx.BST</td>
<td>3 best FVC maneuvers + 8 parameters (G)</td>
</tr>
<tr>
<td>DATAxxxx.LOP</td>
<td>1 best FVC maneuver (G)</td>
</tr>
<tr>
<td>DATAxxxx.MIP</td>
<td>5 best MIP maneuvers (G)</td>
</tr>
<tr>
<td>DATAxxxx.MEP</td>
<td>5 best MEP maneuvers (G)</td>
</tr>
<tr>
<td>DATAxxxx.TXT</td>
<td>Comments and other free text (A)</td>
</tr>
</tbody>
</table>

(A) = ASCII file,  (G) = Binary Graphics array

xxxx is an internal sequence number, unique for each participant's test session, starting from 0.

The total size of these 8 files for one participant is about 8 Kbytes. A maximum of 800 participants can be stored in a single PD subdirectory, but additional test result subdirectories may be created (the subdirectory name must start with the prefix PD, short for "Patient Directory").

The file confusingly called FILE includes each participant's name, ID number, and test date.

Every time a BAK command is performed, all "unmarked" files in the PD93 subdirectory are copied to Drive A: (but not deleted from the PD93 subdirectory). They are then "marked" as having been copied.

Two large database files also exist in the PD93 subdirectory: DATA.DOC is a redundant database file which contains the numeric results from the best single FVC maneuver for all participants ever tested on the workstation. INTERP.DAT is a large empty database file which enables other users to create and store multiple lines of free text comments or interpretations (in addition to those stored in the individual DATAxxxx.TXT files) for each participant. The CHS will not use the INTERP.DAT file, but it cannot be deleted.
QC FILES

An ACII file called SPIRO.LOG is also located in the PD93 subdirectory. It stores the results of CAL checks. It is formatted so that it may be printed using a simple DOS copy command on 8.5 x 11 inch paper. A comments line follows each cal check record. The Adjustments columns are used only when a recalibration (adjustment) was performed. C=A/D Channel number, V=Volume gain factor, F=Flow gain, I=MIP gain, E=MEP gain.

Temporary result files. Several result files are created temporarily during test sessions, but are overwritten whenever a new participant is selected by the INF program:

PRE.BAS
COM.DOC
PTA.DOC

The PTA.DOC is an ASCII file which contains the information necessary for the participant's summary report. When FIN is selected from the MAIN MENU, PTA.DOC is copied to a file called yyyyyyy.PU on the E:\DATA subdirectory of the print station's hard disk, where yyyyyy is the CHS participant ID number.

CUSTOM CONFIGURATION

SMI's commercial software has been customized for use by the CHS. The configuration is altered by a program called CON which displays the following screen and then creates a file called CONFIG.DAT to store the results. The CON program should NOT be altered by the PF technician. However, for reference purposes, the correct configuration setting for the CHS are as follows:
COMPUTER INTERPRETATION

The Printer Workstation will compare the observed values to those predicted by the CHS baseline data from the healthy participants (27), and then interpret them based on the American Thoracic Society recommendations for disability testing (28):

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal spirometry:</td>
<td>FEV1/FVC ratio ≥70% and FEV1≥80% pred and FVC ≥80% pred</td>
</tr>
<tr>
<td>Borderline obstruction:</td>
<td>FEV1/FVC ratio &lt; 70% but FEV1≥80% pred.</td>
</tr>
<tr>
<td>Mild obstruction:</td>
<td>FEV1/FVC ratio &lt; 70% and FEV1 60% to 79% pred.</td>
</tr>
<tr>
<td>Moderate obstruction:</td>
<td>FEV1/FVC ratio &lt; 70% and FEV1 of 41% to 59% pred.</td>
</tr>
<tr>
<td>Severe obstruction:</td>
<td>FEV1/FVC ratio &lt; 70% and FEV1 &lt; 40% pred.</td>
</tr>
<tr>
<td>Reduced vital capacity:</td>
<td>FVC &lt; 80% pred, in addition to obstruction.</td>
</tr>
<tr>
<td>Mild restriction:</td>
<td>FVC 60% to 79% pred, with FEV1/FVC ratio ≥ 70%</td>
</tr>
<tr>
<td>Moderate restriction:</td>
<td>FVC 51% to 59% pred, with FEV1/FVC ratio ≥ 70%</td>
</tr>
<tr>
<td>Severe restriction:</td>
<td>FVC 50% or less than pred with FEV1/FVC ratio ≥ 70%</td>
</tr>
</tbody>
</table>

The software calculates predicted values using equations stored in a file called INF.REG. The interpretation cutpoints and messages are stored in a file called DAT.TXT.
MAINTENANCE

Serial cable. The RS-232 serial interface cable uses standard 9 pin IBM PC AT connectors. Only pins 2,3,5,8,9 are connected.

A/D Converter Check. A program to check the A/D converter channels is easily obtained by pressing ADT from the MAIN MENU. Nine different options are then displayed on the A/D Check menu. The most useful is "6 Check S&M Channels" which gives a continuous display of the Volume, Flow, and Temperature readings in converted units. You may then move the spirometer bell up and down and watch the Volume and Flow change.

The "7 Check all Channels (Raw)" option on the ADT menu displays the instantaneous Actual inputs in raw A/D counts from 0 to 4000:
Press the R key to reset the "Difference" column to all zeroes and the drift or noise may then be measured by observing the maximum change for each channel.

Channel 1 is spirometer Volume. It should be near zero (0-50) when the pen is on the baseline, and increase to close to 4000 when the bell is raised to 8.0 liters. If not, the potentiometer or its connections may be bad.

Channel 3 is the Reference voltage (+5 volts DC). It should remain constant at about 4000 counts.

Channel 4 is the spirometer temperature. It should be between 150 and 250 at room temperature (higher at higher temperatures).

Channels 2 and 5-8 are not used and should all read 0.
3. SKIN TESTS FOR TUBERCULOSIS AND COCCIDIOIDOMYCOSIS

3.1 Rationale:

Tuberculosis (TB) has been a scourge of Indian people for many generations and only in the last decade have the rates of tuberculosis diminished to rates that are only several times higher than the U.S. rate. Until the 1960s tuberculosis was unquestionably the most serious health problem afflicting Indian people. With the advent of effective chemotherapy and the promotion of chemoprophylaxis, tuberculosis has diminished rapidly but still occurs three to four times more commonly than in the U.S. Diabetes and chronic renal failure are known to be risk factors for tuberculosis. The rationale for performing tuberculin skin tests on the Strong Heart Study cohort is: 1) to establish the prevalence of tuberculin positivity. 2) to refer Strong Heart Study participants with positive tuberculin tests to IHS for appropriate evaluation and treatment. 3) to establish a prevalence of history of TB.

This will be of special interest in the Pima population since they participated in a BCG vaccine trial in the 1930s. One half of the participating children received BCG and the other half received the placebo. John Hopkins University is currently doing a follow-up evaluation to ascertain the protective efficacy of the BCG vaccine as well as any potential complications especially with regard to increase or decreased incidence of cancer among those receiving the BCG. Coccidiodomycosis (Valley fever) is a pulmonary disease that is transmitted to humans through airborne organisms in the Sonoran desert environment. Thus the range of the disease is limited to Arizona and southern California. Exposure to this disease can be detected through a skin test similar to a tuberculin test. Although the disease is mild in most individuals, it can cause serious damage in some individuals. Systemic cocci disease occurs more commonly in diabetic patients and other patients with immunosuppression. The coccidiodomycosis skin test will only be done on Arizona participants.

3.2 The Procedure for Recording the Skin Test

The Procedure for recording the skin Test is as follows:

1) IHS medical records are reviewed and results of the skin tests (PPD at all 3 sites, cocci at Arizona) are recorded on the Strong Heart Study forms. Sometimes results are recorded as mm induration and sometimes the results are recorded as positive or negative.

2) All patients will be asked, "Have you ever had tuberculosis?", yes/no.

3) If yes, date diagnosed.

4) "Did you ever have a positive TB skin test (redness/swelling develop two days
after application) yes/no.

If participant has documented positive tuberculin test, or a history of tuberculosis, it is not necessary to repeat the tuberculin test. Strong Heart Study participants who deny history of tuberculosis, do not have documentation of a positive tuberculin test and do not have a history of a positive tuberculin test, should receive a tuberculin test in conjunction with the Phase II Strong Heart Study exam. If participants give a history of a positive skin test, their medical records should be reviewed to verify results if possible. If results cannot be verified, the participants should be offered a repeat skin test. If the patients give a history of active tuberculosis, the skin test should not be repeated. The Arizona participants will be asked whether they have ever had Valley Fever. If Arizona participants have a history of Valley Fever or a documented positive cocci skin test, it is not necessary to repeat the cocci test.

3.3 The procedure for administering tuberculin skin test

The procedure for administering tuberculin skin test is as follows:

1) Clean left forearm with alcohol swab.

2) Draw up five tuberculin units (0.1 cc) in a tuberculin syringe.

3) Inject 0.1 cc of tuberculin, intradermally in the left forearm with the bevel of the syringe facing upward (see diagram below). Taking care not to inject near a vein.

![Diagram of tuberculin skin test]

4) This should produce a small bubble 3-4 mm in diameter.

5) Strong Heart Study staff, CHRs, or nurses who are trained and certified in reading PPD’s should read the tuberculin test in 48-72 hours. The date and time should be recorded and any reactions to the test noted. The skin test should be measured in mm for the induration (raised/hard area) not the redness (10 mm or greater induration is considered to be positive) and recorded in the participants' medical
records. A tuberculin measuring device/caliper will be used to measure the induration.

6) A booster or two-step PPD is given to those participants who have not received a TB skin test in the past two years because their immune response may have waned over the years.

   a. First PPD given and read in 7 days unless the patient reacts in 2-3 days.
   
   b. If PPD is negative, second PPD will be given 1 week or more after the first one and read in 48-72 hours.

Participants with positive PPDs or cocci skin tests should be advised that they are at increased risk of developing TB or valley fever, especially if they have diabetes. They should seek medical care if they develop symptoms of these diseases (ie cough, weight loss, night sweats). PPD positive participants who have completed 6-12 months of preventive therapy or who have completed adequate treatment for active TB (6 or more months of therapy with 2 or more TB drugs) have a reduced risk of developing TB (about 80% reduced) Participants with positive PPDs may benefit from INH preventive therapy and should be advised to be evaluated by their health care provider if they have never received INH preventive therapy or been treated for TB. Referrel should be made if:

1) PPD positive and
2) Preventive therapy with INH for 6-12 months or adequate tratment for active TB has not been completed, and

3) Participant is willing to take preventive treatment if it is prescribed

   OR

   If the participants have a positive PPD or cocci test and develop symptoms of TB or cocci, results of both cocci and PPD skin tests will be reported to IHS so they can be recorded in the participants' medical records.

The procedure for administering and reading the coccidioidomycosis skin test is identical to the tuberculin test except it is administered on the right forearm and should only be done in the Arizona site, since exposure to the disease is not known to occur in the other two sites.

If participants have a severe reaction to the PPD or cocci skin test, they should be advised to use hydrocortisone cream to reduce the swelling and inflammation. Rarely severe swelling and induration may occur, but this occurs more often in younger individuals and responds well to hydrocortisone.
THE STRONG HEART STUDY II

TUBERCULOSIS AND COCCIDIOIDOMYCOSIS
TUBERCULIN SKIN TEST AND COCCI SKIN TEST

ID Number

A. TUBERCULOSIS AND TUBERCULIN SKIN TEST

1. History of Active Tuberculosis and Tuberculin Skin Test

   a. History of TB by medical record review:

      1=Yes      2=No
      3=Medical record not available or complete  4=Uncertain

   b. History of TB by personal interview, "Did a medical person ever tell you that you had active tuberculosis?"

      1=Yes      2=No      3=Uncertain

   c. If "Yes" in a or b, "what was the year of diagnosis?"
      Fill in year of diagnosis, 99=unknown. Skip to Section 4.

   d. If "No" or "Uncertain" in a or b, ask participant: "Have you ever had a positive TB skin test?"
      1=Yes      2=No      3=Uncertain

   Verify PPD results in medical record and fill out Section 2 below.

2. Results of tuberculin test - Recorded from chart review

   a. Date of last test

   b. If available, record induration (in mm). If not recorded, draw one line through the boxes.
      Comments regarding previous PPD testing: ________________________________

   c. Interpretation:
      1=Positive (≥10mm or PPD positive) (Go to section 4)
      2=Negative (<10mm or PPD negative)
      3=Uncertain (PPD not read)
If unable to verify positive results, offer to repeat PPD

If “Positive” in Medical Records, go to B if in AZ, or to next section if in OK or N/SD.

3. Results of Tuberculin Test - OFFER AS PART OF SHS TO PARTICIPANTS WHO HAVE NO HISTORY OF TB AND NEGATIVE PPD TEST OVER 2 YEARS AGO OR POSITIVE OR UNCERTAIN PPD HISTORY WITH NO MEDICAL RECORD VERIFICATION

a. Did participant refuse the TB skin test? 1=YES, 2=NO
   If participant refused TB skin test, GO TO Section B.

1st TB test:

b. Date of administration (left arm preferred)
   Initial site given right arm _____ left arm_____ 

c. Induration in mm. If unable to read skin test fill in 99.
   If <10mm induration, repeat PPD 7 days after the first test unless participant had negative skin test within the last 2 years..

d. Reading date

mo day yr

e. Reader’s initials: _____________________

2nd TB test (To be given at least 1 week after the first test):

b. Date of administration (left arm preferred)
   Initial site given right arm _____ left arm_____ 

c. Induration in mm. If unable to read skin test fill in 99.

d. Reading date

mo day yr

e. Reader’s initials: _____________________
4. If PPD is positive or history of TB is positive, did participant complete preventive therapy or curative therapy? *(Adequate preventive treatment is at least 6 months of INH. Adequate curative treatment is at least 6 months with 2 or more TB medication)*

1=Yes  2=No (Complete a & b)  9=Uncertain

   a. If no, would participant be willing to take preventive therapy prescribed by a medical professional?
      1=Yes  2=No  9=Uncertain

   b. Referral written for service unit follow-up?
      1=Yes  2=No

If PPD is positive and the patient never completed preventive therapy or was never adequately treated for active TB, refer for evaluation by TB control program if he/she is willing to take preventive therapy. A chest x-ray is indicated before starting a patient on preventive therapy but is not indicated for asymptomatic patients who have completed preventive therapy or therapy for active TB or for those who refuse preventive therapy, unless symptoms of TB develop.

5. Coder

6. Date completed

   mo  day  yr
B. Coccidioidomycosis and Cocci Skin Test (Arizona participants only)

1. Results of cocci test - Recorded from chart review
   a. Date of last test
      mo  day  yr
   b. If available, record induration (in mm). If not recorded, draw one line through the boxes.
      Comments regarding previous cocci testing:
   c. Interpretation:
      1=Positive (≥10mm or cocci positive)
      2=Negative (<10mm or cocci negative)
      3=Uncertain (cocci not read)

2. History of coccidioidomycosis by medical record review
   1=Yes  2=No
   3=Medical record not available or complete  4=Uncertain

3. Has a medical person ever told you that you had Valley Fever?
   1=YES  2=NO  9=Unknown/Uncertain

Offer cocci skin test to participants who have no history of coccidioidomycosis or Valley Fever and negative cocci skin test over 2 years ago.

4. Is Cocci skin test given? (Right arm preferred)
   1=Yes  2=No  3=Refused
   If "YES," Administration Date
   mo  day  yr

5. Induration of cocci skin test (in mm).
   left arm

6. Reading Date
   mo  day  yr

7. Reader's initials: ______________________

Participants with history of Valley Fever or positive cocci skin tests should be advised to seek medical care if they develop fever, cough or other pulmonary symptoms. No other specific treatment is indicated.

8. Coder

9. Date completed (mo/day/yr)

Strong Heart Study II 8/01/93  IV-93  TB and Cocci Skin Test
Instructions for the Form of Tuberculosis and Coccidioidomycosis

1. History of active tuberculosis and tuberculin skin test

The first of this section (Part A) involves medical record review for history of active tuberculosis (class III tuberculosis). Case definition for class III tuberculosis involves having a positive culture for myco bacterium tuberculosis from a body fluid or tissue or having a clinical picture suggestive of tuberculosis that responds to treatment with antitubercular medications. Information on treatment could be found on the patients problem list and discharge summaries or consultant reports that are filed in the patient’s chart. If there is no evidence in the IHS medical record or other medical records that may be available, place 2 in the box. If the patient has active TB listed on a discharge diagnosis or on a problem list place 1 in the box. If the diagnosis is suspect tuberculosis or there is uncertainty about whether the lab results meet the case definition, photocopy the information and send this for review by Dr. Tom Welty. The box number 4 could be checked in those situations until clarification is obtained.

In part B the person is asked whether he ever had active tuberculosis. Sometimes patients might be confused by a positive skin test. If the patient has questions about the interpretation of this, please probe them about whether sputum or other AFB cultures were obtained in working up the problem and whether they were positive for TB or not. If patient had TB 10 or 20 years ago, it is almost certain that they would have been hospitalized. Currently TB patients are often treated as outpatients. Patients with active TB always receive 2 or more TB medicines. Again probing about the medication is encouraged if the patient is uncertain about the TB history.

On Part C record the year (last 2 digits) of diagnosis of TB and if the information is available in the medical record this date listed there would be preferable to the patients history.

If there is no evidence of active TB by chart review or history (Part D), ask the participants whether they have ever had a positive tuberculin skin test. If the answer is NO, and if the latest recorded PPD is negative (<10 mm induration) the participant should be offered a two-step tuberculin test as described below. If the answer is YES, try to verify the results of tuberculin test through the medical record. If the results cannot be verified, offer the participant a two-step tuberculin test.

Section II requires medical record review for results of the latest tuberculin test. If the latest tuberculin test is negative, the PPD should be repeated. In some cases the latest tuberculin test will be negative but previous tuberculin tests will be positive. The tuberculin test should probably be repeated in such situations since it would be unlikely that a bad reaction would occur to the tuberculin and clarification would be needed as to the correct
interpretation of the tuberculin status which should be possible through a two-step test. This situation occurs occasionally due to waning immunity of individuals as they age. It can also occur in individuals who have previously received BCG, which we know was given in the Sacaton area, to our cohort when they were children.

2. Tuberculin Test

All Strong Heart Study participants who have no history of TB should be offered a two-step tuberculin test if they meet the following criteria:

a. Had negative PPD test over 2 years ago,

b. Positive of uncertain PPD history with no medical record verification.

Participants who have consistently had negative PPD tests recorded in their medical record with the latest results less than 2 years ago, do not need to have a repeat test done. If there is only one PPD test recorded in the medical record within the past 2 years, it would be advisable to do a repeat one-step test as part of the Strong heart Study exam. If a history is questionable or medical records are not available there is minimal risk involved in repeating the skin test and this should be done in such cases. In approximately 5% of positive skin tests, a large red reaction will occur. These reactions are self limited and gradually disappear over a period of several weeks or a month. The resolution of the reaction can be hastened by application of hydrocortisone creme 2% twice a day. Serious complications from these reactions rarely if ever occur. Since immunity wanes with age, it is unlikely that we will have a serious reactions occurring in our cohort of study participants that are all over 45 years of age.

Preventive therapy reduces the risk of developing tuberculosis in persons who have positive tuberculin tests. Recommended therapy is 6 to 12 months of INH. Once this preventive therapy is completed, no further follow-up or evaluation is necessary unless symptoms of tuberculosis develop such as cough, fever, weight loss, poor appetite, night sweats, etc. Patients with a history of active tuberculosis (Class III disease) do not need any special follow-up, if they have completed the recommended therapy. Currently therapy for active TB involves 2 or 3 medications for six months. In the past TB has been treated for 12 to 24 months routinely. Frequently duration of therapy is noted on the problem list under the problem of active tuberculosis or positive PPD and notation will be made that treatment is completed or adequate. This will help to answer question number 4 and assist you to know whether a referral if necessary. if treatment is not adequate, it will be helpful to determine whether the individual is willing to take preventive therapy. If the participant is not willing to take preventive therapy, there is no need to make a referral for follow-up unless the participant develops symptoms of active tuberculosis as described above. In the past patients with positive PPD's have been advised to have annual chest X-rays to rule out active disease. However, at present this is no longer recommended because it is not a cost
effective screening approach. If the participant has a untreated PPD and is willing to consider taking INH preventive therapy, if this is recommended by the health care provider, a referral should definitively be written. if the participant is not willing to take preventive therapy, a notation should be made on the PCC form as follows (PPD positive patient not interested in preventive therapy at the present time).

When measuring induration of tuberculin tests, it is advised that the reaction be felt with the index finger a line drawn at the edges of the induration. The induration area then can be measured in millimeters and recorded on the Strong heart Study data collection form. The two-step testing procedure involves intraderinal administration of a mantoux tuberculin test (0.1 cc) which can be read in 48 to 72 hours. A health care provider or a CHR should be trained to make these readings in a consistent manner if the initial tuberculin test is negative, a repeat test should be administered one week to one year after the first test and the result recorded. Thus persons with a initial negative PPD could be restested during the summer months by a health profession student trained to carry out this aspect of study. Results of the tuberculin test should be recorded in the patients chart on the blue immunization sheet.

3. Coccidioidomycosis history and skin testing

In a similar manner the medical records should be reviewed for history of coccidioidomycosis (valley fever) and results of cocci skin tests. This infectious disease has clinical symptoms very similar to tuberculosis and is transmitted to humans through dust in the Sonoran desert area of the United States (southern Arizona and California). No preventive therapy is available for coccidioidomycosis so patients do not need to be referred for evaluation if they have a positive test. However, results of skin testing should be recorded on the immunization sheets in each individuals chart. Persons with a positive skin test should be advised that if they develop symptoms of cough, fever, weight loss, they should be evaluated for valley fever. Persons with a history of coccidioidomycosis or positive skin test that is verified in the medical chart do not need to have a coccidioidomycosis skin test applied.
4. ANCILLARY STUDY OF ULTRASONOGRAPHY OF THE GALLBLADDER

4.1 Introduction

This document discusses the importance of performing gallbladder ultrasonography, data collection, quality control, and data analysis.

Gallstones are a common condition and their treatment is a major medical expense. Cholecystectomy is the fifth most common non-obstetric, therapeutic hospital procedure in the United States; in 1990 there were 522 thousand cholecystectomies compared with 392 thousand coronary artery bypasses and 285 thousand percutaneous coronary artery angioplasties. Gallstones are the second most costly digestive diseases in the U.S. (behind gastrointestinal infections) with a yearly direct and indirect cost of well over $5 billion.

Gallstones are a particularly important condition for American Indians. The first ever population study of gallstones using oral cholecystography in 1967-1968 found a prevalence of gallstones among Pima Indians that was remarkably high, particularly among women. About 50 percent of all Pima Indians and more than 70 per cent of women were found to have gallstones or to have undergone cholecystectomy. This study was largely unable to define factors other than sex that were associated with gallstone disease. Since then much has been learned about the pathophysiology of gallstones, some of it from Pima Indians, but no further prevalence studies have been performed among American Indians in the United States. Besides being a common affliction, gallstones also greatly increase the risk of gallbladder cancer among American Indians. Cancer registry data have demonstrated that American Indians in New Mexico have the highest reported gallbladder cancer incidence in the world, more than 10 times the rate in the United States population as a whole. One study estimated that among American Indians gallstones increased the risk of gallbladder cancer 20-fold.

Ultrasonography has greatly facilitated epidemiologic studies of gallstone disease. It is safe, accurate, relatively inexpensive, and can be accomplished in a few minutes. Diagnostic criteria for gallstones are simple and have allowed standardization across studies. A great deal of experience with gallbladder ultrasonography has been gained from the third National Health and Nutrition Examination Survey (NHANES). Over 10,000 ultrasounds have been performed to date. By its completion, United States population estimates will be available for whites, blacks, and Mexican Americans. Much of the present protocol has been pulled from the NHANES because that study has been highly successful and because it would be valuable to compare the results of the two surveys.
4.2 Data Collection and Interpretation

4.2.1 Ultrasonography

Each person undergoing cardiac echocardiography will also have gallbladder ultrasonography. This examination will be performed either immediately before or after the echocardiogram. The examination protocol is as follows. Brackets ([ ]) indicate a feature of the NHANES protocol that may not be applicable here.

A. Eligibility Criteria

All persons eligible for echocardiography are eligible for ultrasonography of the gallbladder. Participants should be asked to fast for at least six hours prior to arriving at the clinic in preparation for the exam, but will not be excluded from the exam if they have not fasted. There are no other exclusion criteria for the ultrasound examination.

B. Pre-Examination Procedures

1. Check that the VCR is on and that the VCR tape has been inserted and advanced by six digits since the previous exam. [Make sure [DISPLAY] on the control panel of the main unit is off.]

2. Code pertinent information into the identification portion of the ultrasound screen. [Press [CHAR] twice to move cursor into upper left portion of screen. Use keyboard on control panel to type in participant identification number and examiner number. Press [CHAR] once to move back to scale on screen.]

3. Assist the participant onto the exam table and into a supine position.

4. Ask the participant to fold up the gown top to expose the upper right quadrant of the abdomen. Drape the participant with two chucks to protect the gown top and pants.

5. Identify the participant's anatomical position and transducer plane (longitudinal or transverse) [and type abbreviations of these directions onto main screen. Identify position as necessary throughout exam.]

C. Examination Procedures

1. Ask the participant the screening questions for the examination. Specifications for the Ultrasound Data Collection Form are attached.

2. Place disposable glove on the hand that will operate the probe.
3. Apply acoustic gel to the participant’s upper right quadrant, and begin the scan. Survey the gallbladder area and identify the anatomical landmarks. Once the gallbladder is located, begin the VCR to record the examination.

4. Scan longitudinally through the gallbladder to demonstrate a thorough examination of the gallbladder neck and fundus as well as a clear and sharp posterior gallbladder wall. Scanning may be performed subcostal and/or intercostally, whichever procedure provides the best view of the gallbladder.

5. After the longitudinal scans are performed, stop the VCR tape, and change the transducer position annotation on the main screen. Start the VCR tape and begin scanning transversely through the gallbladder making clean sweeps from the fundus of the gallbladder to the neck.

6. When satisfactory wall definition is obtained in the transverse view, freeze the image and measure the thickness of the anterior gallbladder wall. This is a single measurement and may be obtained in either the supine or left lateral decubitus (LLD) positions.

7. When the supine screening is complete, stop the VCR tape, change the participant position annotations on the main screen. Ask the participant to turn onto the LLD position and start the VCR tape. Repeat steps 4 and 5.

8. If views of the gallbladder are unobtainable in the supine position, the sonographer may move directly to the LLD scanning position. Note the omitted position in the appropriate section of the Ultrasound Data Collection Form.

4.2.2. Ultrasonography Reading Center (URC)

A maximum of 30 examinations will be recorded on each VCR tape. If, during an examination, a condition requiring rapid review is noted, that examination will be the last to appear on the tape and that tape will be mailed that day to the URC. All VCR tapes whether rapid review or not will be express mailed to the URC. Data collection forms will be completed and sent to the Data Coordinating Center on the same monthly schedule as other data. A URC radiologist will read each examination sequentially and complete a similar Ultrasound Data Collection Form and return it to the coordinating center with the VCR tape. Following data entry, tapes that contain examination recordings that resulted in disagreements in gallbladder findings will be returned to the Ultrasound Reading Center for adjudication using the same radiologist’s form.

There are a few differences from the ultrasonography protocol of the NHANES.

1. Automated data collection. Hard copy forms are used in NHANES only when the computer system is (uncommonly) down.
2. A 5.0 MHZ probe as well as a 3.75 MHZ probe is used in NHANES. The 5.0 MHZ probe is used primarily to determine shadowing associated with wall irregularities and for better resolution in particularly thin persons. We have been advised by the NHANES 3 radiological consultant and the Accuson corporation that the 3.5 MHZ probe should be adequate for surveying the gallbladder. Nevertheless, if exam quality suffers, it may be necessary to purchase an additional probe.

3. The data collection form has been simplified from 16 possible categories to 9. This was done after examining the results of the first 7,000 NHANES examinations and merging or eliminating codes that were rare and for which disagreement was common. All significant codes that can be used for analysis still match NHANES codes.

4. For participants with gallstones, the radiologist is being asked to estimate the proportion of gallbladder volume that is being displaced by the gallstones. This measurement has been added because of the possible association of gallstone volume with risk of gallbladder cancer.

4.2.3. Interview data

Many risk factors pertinent to gallstones are being asked. A small amount of additional information would also be helpful:

1. History of weight fluctuation - this may also be important for the cardiovascular component
2. On a daily basis, when does the participant usually first and last eat a meal or snack?, - for overnight fasting period
3. For women, in what year was her last child born? Did she breast feed that child and for how long? - gallstones are associated with recent pregnancy; metabolic effect of breast feeding, particularly increased energy usage and hormonal effects
4. History of gallbladder surgery - if ask here, may not need to obtain at ultrasonography
5. Current non-steroidal anti-inflammatory drug usage, besides aspirin - antinucleating effect in the gallbladder

4.2.4. Report of findings to participants

1. At the examination, the ultrasonographer may, if asked, tell the participant the gallbladder findings. It must be made clear that the diagnosis is not definitive and that the participant will receive a letter with all their results.
2. The letter to participants should state that the gallbladder was not seen, gallstones were seen, or the gallbladder had no stones. Interpretation would indicate that an absent gallbladder usually means the participant had gallbladder surgery and that gallstones usually do not require treatment unless they cause severe symptoms or complications. However, consideration of treatment must be made on an individual basis. In addition, conditions that require clinical follow-up, such as suspicious wall thickening suggestive of cancer, need to be noted, although not specified. The participant should be urged to have a follow-up evaluation. A physician referral form with the specific presumptive diagnoses can be completed and sent in accordance with the Strong Heart Study protocol.

4.3 Quality Control

4.3.1. Training

The gallbladder is a relatively easy organ to visualize by ultrasonography in a person who is not acutely ill. Nevertheless, training in the protocol is necessary even for an experienced ultrasonographer. Knowledge of hepatobiliary anatomy is necessary to identify landmarks and the gallbladder. Recognition of normal and abnormal findings in the gallbladder is critical, particularly wall irregularities and shadowing. Training requires demonstration of knowledge in these areas; it should be accomplished by short lectures on hepatobiliary anatomy and ultrasound principles, observation of gallbladder ultrasonography, and supervised gallbladder examinations. Training may be accomplished in a day for someone familiar with the equipment and ultrasound procedures.

4.3.2. Examination Sites

At the field clinics, the sonographers should have adequate opportunity to become comfortable with using the ultrasound equipment and VCR, filling out examination forms, and incorporating the ultrasonography into the necessary time constraints. Prior to formal data collection, approximately 20 ultrasounds should be performed at each site, recorded, and read at the URC. At least one and possibly two field visits for further training and to iron out problems with the examination may be necessary during the first year of examinations. Diagnostic agreement between the ultrasonographer and the URC and the radiologist's evaluations of the quality of the examination will guide the need for further training. It is expected that a kappa statistic of at least 0.8 will be maintained at each site between the readings of the ultrasonographer and radiologist.

4.4 Analysis

Analysis of the results of ultrasonography will be directed by the NIDDK program officer in accordance with the analysis and publications guidelines of the Strong Heart Study Manual of Operations. It is anticipated that manuscripts will be prepared in several areas:
1. Prevalence of gallstone disease among the 3 centers.
2. Risk factors for gallstone disease (could be several manuscripts).
3. Comparison of gallstone disease prevalence among the 3 centers with NHANES prevalence for Mexican-Americans, and non-Hispanic whites, and blacks.
4. Gallstone disease as a risk factor for coronary artery disease.
6. If adequate follow-up occurs, association of gallstone disease with all cause mortality, heart disease morbidity and mortality, and site specific cancer mortality.
THE STRONG HEART STUDY II

Ultrasonographer Data Form

Strong Heart Study ID Number

Social Security Number

Date of Examination (mo/day/yr)

1. Ultrasonographer ID Number

2. Videocassette Number

3. Tape sequence Number

4. Have you ever been told that you had gallstones?
   1=Yes  2=No  9=Unknown

5. Have you ever had gallbladder surgery?
   1=Yes  2=No  9=Unknown

6. Including your last meal and any snacks, at what time did you last have anything to eat?
   Military Time:

   Day:  1 = Today  2 = Yesterday

7. Time now (please use military time) (hh:mm)

8. Presence of surgical scar
   a. Right upper quadrant  1=Yes  2=No
   b. Epigastrium or periumbilical area  1=Yes  2=No
   c. Laparoscopic scars  1=Yes  2=No
Ultrasonographic Findings

9. Portal vein at liver hilum on transverse scan?
   1=Yes   2=No   9=Unable to observe

10. Liver margin on longitudinal scan?
    1=Yes   2=No   9=Unable to observe

11. Intrahepatic right portal vein on longitudinal scan?
    1=Yes   2=No   9=Unable to observe

12. Anterior gallbladder wall thickness in mm (on longitudinal scan)
    If unable to observe, fill in 99.

13. Can gallbladder be observed?
    1=Yes   2=No (Skip to Question 20)

14. Were gallstones found?
    1=Yes (Echogenic clumps with shadowing in 2 views)
    2=No (Gallbladder visible, no echo clumps)
    3=No conclusion (Gallbladder clumps that shadow on only one view)

15. If "YES," how many gallstones were there?
    1=Single   2=Multiple

16. Measurement of largest echo clump (in mm)
    Fill in 0 if no clump was found, 99 if unable to observe.

17. Was gallbladder wall calcified? (Dense shadowing from gallbladder wall, exclusive of
gallstones)
    1=Yes   2=No
    If "Yes," attach still image and send with video tape.

18. Were cholesterol polyps found?
    (Echogenic clumps attached to gallbladder wall without shadowing that do not move)
    1=Yes   2=No

19. Was gallbladder sludge observed?
    (Echogenic clumps without shadowing that move)
    1=Yes   2=No
20. Were any other abnormal findings identified?
   1=Normal      2=Abnormal
   If "Abnormal," describe: _______________________________________________________

21. Results of Examination:
   1=Test done      2=Test incomplete      3=Test not done

22. Reasons Test Incomplete or Not Done
   1=Ultrasound malfunction
   2=VCR malfunction
   3=Insufficient time
   4=Examinee refused or uncooperative
   5=Examinee medically excluded by staff for safety
   6=Examinee unable to physically cooperate
   7=Positive history of gallbladder surgery and visible right upper quadrant scar

23. Comments?
   1=Yes      2=No
   If "Yes," Comments: _______________________________________________________

__________________________________________________________________________
THE STRONG HEART STUDY II
The George Washington University Medical Center
Gallbladder Ultrasonography - Radiologist's Form

Strong Heart Study ID Number

Last Name

Date of Examination (mo/day/yr)

1. Date of reading (mo/day/yr)

2. 1=First reading  2=Adjudication

3. Radiologist ID number:  1=Dr. Hill  2=Others

   Initial:

4. Videocassette Number

5. Tape sequence Number

Findings of gallbladder

6. Adequacy of examination?
   1=Adequate  2=Below standard  3=Inadequate

7. Can gallbladder be observed?
   1=Yes  2=No (Skip to Question 16)

8. Were gallstones found?
   1=Yes
   2=No (Gallbladder visible, no echo clumps)
   3=No conclusion (gallbladder clumps that shadow on only one view)

9. If "YES," how many gallstones were there?
   1=Single  2=Multiple

10. Percentage of gallbladder filled with gallstones
    1 = No gallstones  4 = > 50 %, but not filled
    2 = <25 %  5 = Filled
    3 = 25-50 %
11. Was gallbladder wall calcified? (Dense shadowing from gallbladder wall, exclusive of gallstones)  
1=Yes  2=No

12. Were cholesterol polyps found?  
(Echogenic clumps attached to gallbladder wall without shadowing that do not move)  
1=Yes  2=No

13. Was gallbladder sludge observed?  
(Echogenic clumps without shadowing that move)  
1=Yes  2=No

14. Other gallbladder abnormality

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>a. Gallbladder wall thickened (&gt;3 mm)</td>
<td>1=Yes 2=No</td>
</tr>
<tr>
<td>b. Contracted gallbladder</td>
<td>1=Yes 2=No</td>
</tr>
<tr>
<td>c. Compatible with chronic cholecystitis. However, underlying gallbladder cancer can not be excluded.</td>
<td>1=Yes 2=No</td>
</tr>
<tr>
<td>d. True polyp</td>
<td>1=Yes 2=No</td>
</tr>
</tbody>
</table>

15. Certainty of gallbladder diagnoses:  
1=Certain  2=Uncertain

16. Comments?  
1=Yes  2=No

If “Yes,” Comments:

________________________________________________________________________

________________________________________________________________________

Confirmed By: _______________________________  
Signature

Strong Heart Study II  1/27/94  IV - 107  Radiologist’s Form
5. Foot Examination

**Background:** Amputation and ulceration of the foot and lower extremities are important problems in the management of diabetes. Diabetes damages peripheral nerves. The nerve damage leads to poor sensation, loss of muscle tone, and repeated and sometimes unrecognized trauma to the foot. The trauma can be evident as ulceration, infection or fractures of the small bones of the foot. Such fractures of the foot can cause deformities, and are known as "Charcot Joints".

It is clear that foot problems are often predictable in that they are highly correlated with loss of the ability to feel pressure, pain, vibration or to sense the position of the foot (proprioception). Thus, it is valuable to know whether patients have nerve damage. Such patients benefit from education about foot care, and they may need special footwear or therapy to prevent or delay foot and lower leg problems.

![Figure 1. The Semmes-Weinstein Pressure Filament](image1)

![Figure 2. The filament should be placed against the skin at a 90° angle. Apply pressure until the filament bends slightly, then ask the volunteer if they can feel the pressure.](image2)
The Semmes-Weinstein pressure filaments are a simple and reliable technique to detect the loss of pressure sensation in the foot. The Semmes-Weinstein pressure filaments is a simple, inexpensive device consisting of a plastic filament attached to a small handle.

Extensive studies of diabetic patients indicates that the loss of the ability to sense a pressure of 10 g on the great toe or 1st metatarsal head is highly correlated with ulceration. Ninety-five percent of norma individuals can detect the 10 g pressure.

Testing Pressure Sensation with the Semmes-Weinstein Filament:

1. Use the 10 g filament only.

2. The sites to be tested are indicated on the Diabetic Foot Screen Form. Examine the participant while he/she is in the supine position (lying down on their back)

3. Apply the Filament perpendicular to the skin's surface.

4. Apply sufficient force to cause the filament to bend. Keep it against the skin for about 1\(\frac{1}{2}\) seconds.

5. Randomize the selection of test sites and time between successive tests to reduce the potential for patient guessing.

6. Do not allow the filament to slide across the skin or make the repetitive contact at the test site.

7. Ask the patient to respond "yes" when the filament is felt and record the response on the Diabetic Foot Screen Form.

8. If the patient has a foot ulcer, apply the filament along the perimeter of the ulcer and NOT on an ulcer site, callous or necrotic scar.

9. Do not test parts of the foot that are covered by heavy bunions or callouses.

10. Express the foot exam results as a fraction such as "7/9." This means that 9 sites were tested and seven of them were felt.

*Strong Heart Study II 10/01/93*
THE STRONG HEART STUDY II

Diabetic Foot Screen

ID Number

Name (First, Last) ___________________________ IHS Chart Number ___________________________

1. Is there a foot ulcer or a history of foot ulcer? (1=Yes 2=No) ___________________________

2. Are the nails thick, too long or overgrown? (1=Yes 2=No) ___________________________

3. Is either foot numb? (1=Yes 2=No) ___________________________

4. Label: Sensory level with a "+" if the participant can feel the 10 gram filament and ",-" if he/she cannot feel the 10 g filament. Test each site only once. Testing may not be accurate in areas where thick callous or bunion is present.

   1=Positive 2=Negative

   a. Right top ___________________________

   b. Right large toe ___________________________

   c. Right middle toe ___________________________

   d. Right small toe ___________________________

   e. Right sole front ___________________________

   f. Right sole right ___________________________

   g. Right sole left ___________________________

   h. Right sole back right ___________________________

   i. Right sole back left ___________________________

   j. Right heel ___________________________

5. If the right foot has been amputated, conduct the exam on the left foot and make a note here: ___________________________ (approx date of amputation).

6. RESULTS:

   Number of correct answers ___________________________

   Number of sites tested ___________________________

7. Examined by: ___________________________

8. Date examined mo __ day ___ yr ______