FRAMINGHAM HEART STUDY

OFFSPRING CYCLE 7

CLINIC PROTOCOL MANUAL

START DATE: 9/14/1998

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1 x 10 ml red serum	
1 x 10 ml light blue citrate	
1 x 5 ml EDTA	
4 x 10 ml ACD	

   a. Cholesterol, HDL Cholesterol, Triglyceride, Glucose
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Phlebotomy

Fasting	2 hr post Glucose (1gm/kg body wt) load
5 x 10 ml lavender EDTA	1 x 5 ml lavender
1 x 10 ml red serum	
1 x 10 ml light blue citrate	
1 x 5 ml EDTA	
4 x 10 ml ACD	

1. Fasting lavender tubes
   a. 1 lavender tube for Cholesterol, HDL-Cholesterol, Triglyceride, Glucose at Heart Study
   b. 2 lavender tubes plasma aliquotted and store at 4 degrees, then to Schaefer for other lipids
   c. 1 lavender tube plasma then freeze in 2 large cryos, freeze - 80 for pickup to Sehlub for homocystine, vitamin B12, B6, folate
   d. 1 lavender tube for approximately 0.5 ml aliquots in 1 ml cryo tubes, freeze - 80 for later Heart Study use
      1 aliquot to Nathan (MGH) for insulin fasting and post challenge
   e. From first 4 lavender tubes - buffy coat in glycerol freeze at - 80 for Ordovas
   f. 5 ml EDTA for HbA1C store at 4 degrees for regular delivery to Tufts and subsequent cross town courier Tufts to Nathan at MGH

2. Light blue citrate
   a. 4 aliquots for Heart Study fibrinogen, PAI, other tests

3. Large serum tube
   a. Take serum aliquot and freeze in 2 large cryo tubes
      freeze at - 80 for Heart Study (label serum)
      freeze at - 80 small cryo for Booth (Tufts)
   b. 1 aliquot for creatinine at Heart Study

4. 4 Yellow ACD tubes
   a. 2 for shipment to Gusella at MGH
   b. 2 for shipment to Ordovas at Tufts

5. Post load lavender tube - 5 ml
   a. Freeze - 80 for later insulin by Nathan (label post load plasma)

6. Urine spot
   a. Later microalbuminuria

Equipment For Exam Procedures

1. Scale to measure body weight in lbs.: Detecto
   Worcester Scale Co., Inc.
   228 Brooks Street
   Worcester, MA
   508-853-2886
   g440

2. Weight to calibrate scale: 50 lbs.
   Worcester Scale Co., Inc. (See above) g440

3. Vertical mounted metal ruler: Stadiometer g441

4. Marquette MacVu (electrocardiogram cart)
   Marquette Electronics
   100 Marquette Drive
   800-552-3249
   Jupiter, FL 33468-9100
   800-559-7072 (tech support)
   800-558-5544 (Jill Lopez, Sales Rep)
   EKG g356-g391

5. Microcomputer Augmented Cardiograph (MacPc) (cardiogram computer)
   Marquette Electronics (See above)
   EKG g356-g391

6. Power module for MacPc: Part #9518-001
   Marquette Electronics (See above)
   EKG g356-g391

7. Standard mercury column sphygmomanometer: Wall-mounted Baumanometer (E98169)
   W.A. Baum Co., Inc.
   620 Oak Street
   Copiague, NY 11726
   516-226-3940

8. Portable standard mercury column sphygmomanometer: Baumanometer, 300 model; Catalogue #0661-0320
   W.A. Baum Co., Inc. (See above)

   g271, g272
   g354, g355
   g450, g451

9. Blood pressure cuffs in three sizes: large, regular, and pediatric.

10. Litman stethoscope tubing and earpieces with bell: Classic II

(5)

11. Gulick retractable tape measure
    Novell Products
    3266 Yale Bridge Road
    Rockton, IL 61072
    815-624-4888
    815-555-1212
    800-323-5143

g444 - g446

12. Tailor's plastic tape measure

13. Ross Knee Height Caliper: Model #50452 g443
    Ross Laboratories
    Columbus, OH 43216

14. Body Composition Analyzer: Model #BIA-101
    RJL Systems
    9930 Whittier
    Detroit, MI 48224
    800-528-4513
    313-790-0200

g453 - g459

15. 8 Megahertz Doppler Pen Probe
    Parks Medical Electronics, Inc.
    19460 S.W. Shaw
    Aloha, Oregon 97007
    503-649-7007
    800-547-6427

16. Ultrasonic Doppler Flow Detector: Model 811-B (with power cord 91-2305)
    Parks Medical Electronics, Inc. (See above)

Ankle-Arm Doppler data set

17. For Pulmonary Function Test (PFT), please see:
    <u>Manual of Operations: Pulmonary Function Assessment</u>
    Paul Enright, MD
    Peter Boyle & Pam Boyer-Pfersdorf
    University of Arizona
    Respiratory Sciences Room 2342
    1501 N. Campbell Avenue
    Tuscon, AZ 85724
    602-626-6415
    fax: 602-626-6970

see PFT data set

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18. Spirometer: Collins Eagle II, Model #006038
Warren E. Collins, Inc.
220 Wood Road
Braintree, MA 02184
617-843-0610
800-225-5157

19. 3 Liter calibration syringe Model #021156

20. 1 Liter precision syringe: Vitalograph, Catalogue #20-408
Made in England

see PFT data set

NOTE: Items 18, 19, and 20 are used for the Pulmonary Function Test. Please see operations manual.

(7)

Equipment Calibration Time Table

Activity	Daily	Weekly	Monthly	Yearly
Detecto Scale				
Zero Reading	X			
50# Weight		X		
Professionally Calibrated				X
Manometer				
Zero Reading	X			
Check Inflation System			X	
Spirometer				
Leak Check	X			
Volume Calib. Check	X			
Change Hose	X			
Linearity Check		X		
Control Test		X		
Clean & Disinfect		X		
Stadiometer				
Check Level			X	
Tape Measure				
Against Stadiometer			X	
Urine Dip Sticks				
Positive Test			X	

NOTE: Most Weekly calibrations are performed on Monday.
Most Monthly calibrations are perfomed on the first Monday of the month.

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Guidelines For Coding Accuracy

To insure maximum accuracy and legibility for persons performing data entry, please adhere to the following guidelines:

1. Use a red or blue pen, or any other pen which will stand out from the page (pencil or black ball-point pens are unacceptable).

2. Make sure all numerals are unmistakably clear.

3. Do not leave any blanks on exam form. If measurements are not taken, please enter **9**s in blanks, and document the reason. Your comments are helpful at any point of the exam where data is not recorded in the standard manner.

4. If you make an error, please cross it out entirely, write the correct information *in the margin*, and *initial the change*. **Do not superimpose numerals one on top of the other**.

5. Make sure both sides of the examination form are completed.

(9)

Procedure To Determine Maximal Inflation Level

g271, g272, g354, g355, g450, g451

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.

2. Palpate the radial pulse.

3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10 mmHg increments.

4. Deflate the cuff quickly and completely.

5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

(10)

Technician's Seated Blood Pressure

9450, 9451

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M

2. One standard mercury column sphygmomanometer: Baumanometer

3. BP cuffs in three sizes

   Large adult cuff
   Regular adult cuff
   Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to above the point of the shoulder.

2. Determine correct cuff size using guidelines inside the cuff.

3. Palpate the brachial artery.

4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.

5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.

6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.

7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured.

2. All readings are made to the nearest even digit.

(11)

9450, 9451

3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).

4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.

5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

D. Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.

2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).

3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.

5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).

6. Deflate the cuff fully by opening the thumb valve.

7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

(12)

Ankle-Arm Doppler Blood Pressure Measurement

see ankle-arm blood pressure data set

PURPOSE

The ratio of the ankle blood pressure to the arm blood pressure provides a measure of lower extremity arterial disease (circulation problems).

A. Equipment:

1. 8 megahertz Doppler pen probe
2. Ultrasonic Doppler Flow Detector
3. Doppler conducting jelly
4. Standard mercury column sphygmomanometer: Wall-mounted Baumanometer
5. Calibrated V-Lok BP cuffs in three sizes:

   2 large adult cuffs
   2 pediatric cuffs
   4 regular adult cuffs

6. Washcloths to remove conducting jelly

B. Exclusions:

1. Persons with venous stasis ulceration or other pathology that precludes placing a BP cuff around the ankle (e.g. open wounds).
2. Persons with rigid arteries such that an occlusion pressure cannot be reached.
3. Persons with bilateral amputations of legs.
4. Subjects who fit any of the above categories are recorded as missing data.
5. If a subject has undergone a mastectomy, blood pressure measurement will be excluded in that extremity only, and recorded as missing data.

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see ankle-arm blood pressure data set

C. Set-up Procedure:

1. Ask participant to remove shoes and stockings so that the ankles are bare to mid-calf.

2. Lay participant supine on the examining table.

3. Keep participant supine for at least five minutes before measuring BP.

4. Place four BP cuffs on the participant (be sure to check for appropriate cuff size):

    a. Right arm
    b. Left arm
    c. Right ankle
    d. Left ankle

5. Apply ankle cuffs with midpoint of bladder over posterior tibial artery, with lower end of bladder approximately 3 cm above medial malleolus.

D. General Guide to Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after cuff has completely deflated.

2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth, continuous rate to the maximal inflation level (30 mmHg above systolic pressure).

3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

4. By opening the thumb valve slightly, and maintaining a constant rate of deflation at approximately 2 mmHg per second, allow the cuff to deflate.

5. Listen through the entire range of deflation, past the systolic reading (the pressure where the first regular sound is heard), for 10 mmHg. **Two subsequent beats should be heard for any valid systolic blood pressure reading, but continue to listen as the cuff is deflated 10 mmHg below the level of the systolic pressure.**

6. Deflate the cuff fully by opening the thumb valve.

7. Neatly enter the systolic readings in the spaces provided on the form.

(14)

see ankle-arm blood pressure data set

E. Right and Left Arm Systolic Blood Pressure Measurement:

1. Attach right arm cuff tubing to manometer.

2. Apply ultrasound jelly over brachial artery.

3. Locate brachial artery using Doppler pen probe.

4. **Hold the Doppler probe *absolutely* still.** It can easily slip off the artery.

5. Measure the systolic blood pressure:

   a. Inflate cuff quickly to maximal inflation level (30 mmHg above systolic pressure).
   b. Deflate at 2 mmHg/second, to appearance of systolic pressure.
   c. Follow down for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
   d. Remove Doppler pen probe.
   e. Deflate cuff quickly and completely.

6. Neatly record systolic blood pressure.

7. Follow same procedure for left arm.

F. Right and Left Ankle Systolic Blood Pressure Measurement:

1. Connect right ankle cuff to the manometer.

2. Apply ultrasound jelly over posterior tibial artery.

3. Locate posterior tibial artery using Doppler pen probe.

4. **Hold the Doppler probe *absolutely* still.** It can easily slip off the artery.

5. Measure the systolic blood pressure:

   a. Inflate cuff quickly to maximal inflation level (30 mmHg above systolic pressure).
   b. Deflate at 2 mmHg/second to appearance of systolic pressure.
   c. Follow down for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
   d. Remove Doppler pen probe.
   e. Deflate cuff quickly and completely.

6. Neatly record ankle systolic blood pressure.

see ankle-arm blood pressure data set

7. Disconnect right ankle cuff from manometer. Connect left ankle cuff to manometer and repeat procedure.

NOTE: If the posterior tibial pulse cannot be found with palpation or Doppler pen probe, use the dorsalis pedis artery for the measurement. Have another examiner verify the absent posterior tibial pulse.

G. Repeat of Ankle and Arm Blood Pressure Measurements:

1. Repeat the sequence of measures in reverse order:

   a. Left ankle
   b. Right ankle
   c. Left arm
   d. Right arm

NOTE: If initial and repeat blood pressures measured at any one site (Right arm, Left arm, Right ankle or Left ankle) differ by more than 10 mmHg, please take a third measurement at that site.

H. Completion:

1. Review form for completeness and legibility.

2. Remove cuffs and conducting jelly.

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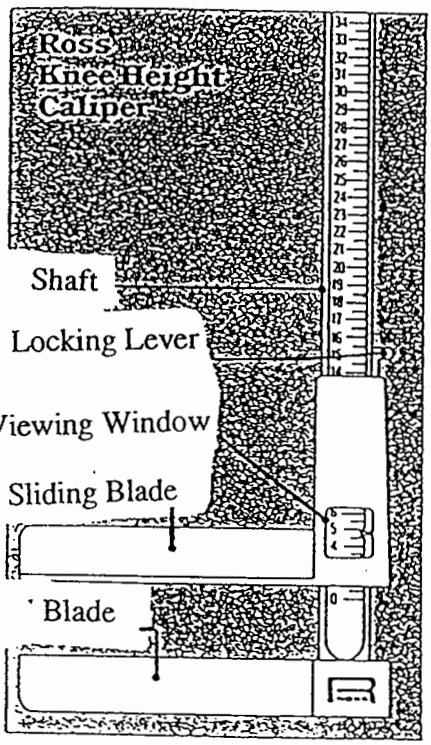
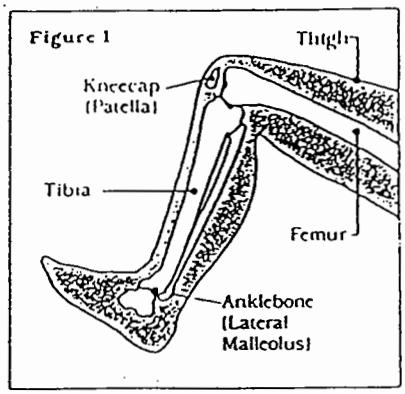
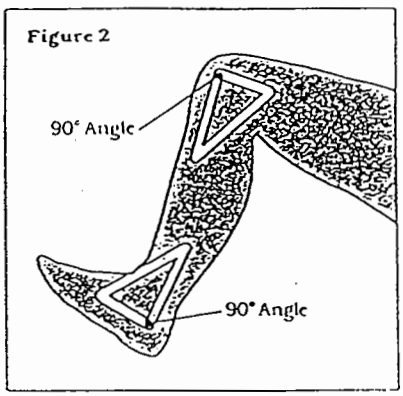
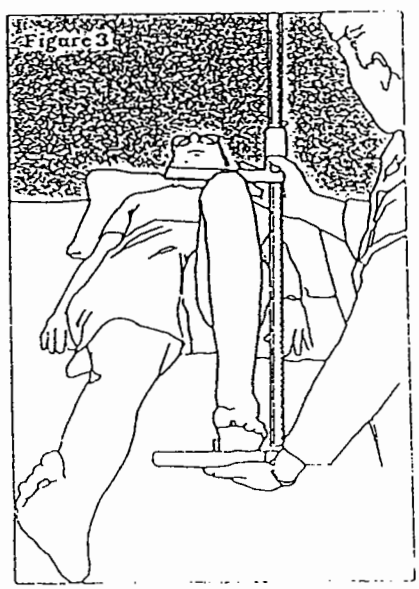
Heel to Knee Measurement 9443

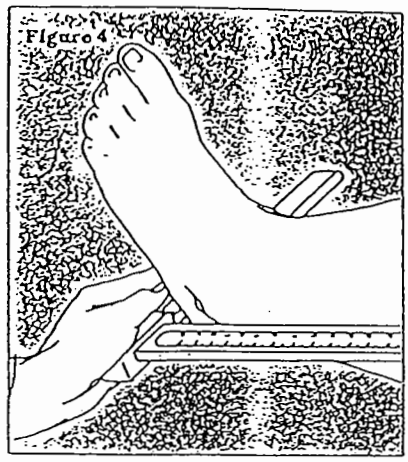


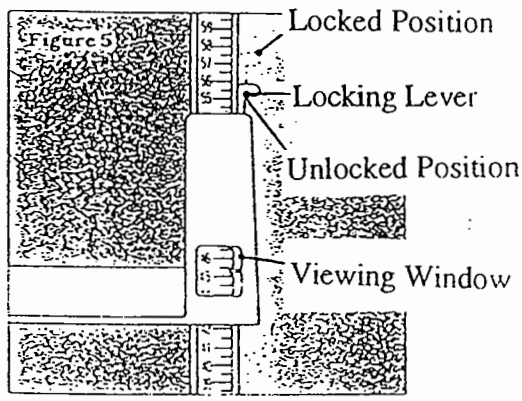


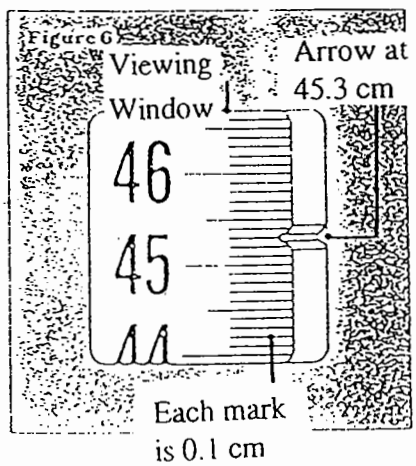




Note: Figure 3 is done in the seated position.







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Heel To Knee Measurement 9443

PURPOSE

As people age, they will often shrink in height. Generally, this shrinkage is due to the spaces between the bones in the spine shrinking. The lower leg consists of two bones which go from the heel to the knee - this does not change over time. By measuring this heel to knee distance and using a factor based on age, we are better able to compare people of different ages and different amounts of spinal shrinkage.

METHOD

1. With subject seated, bend both left knee and left ankle to a 90 degree angle (figure 1 on following page). Check the angles by using the triangle (figure 2).

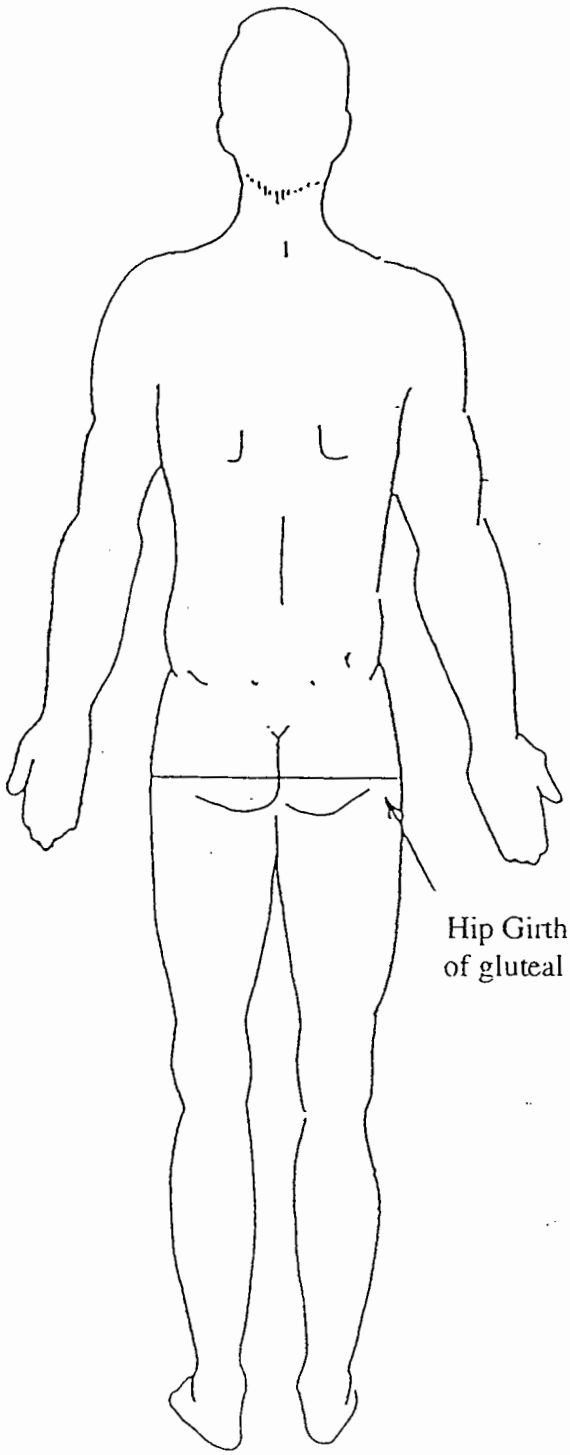
2. Open the caliper and place the fixed blade under the heel. The inside of the ankle and lower leg should be against the vertical bar of the caliper. Press the sliding blade down against the thigh about 2 inches behind the kneecap (patella) (figure 3). The shaft of the caliper should be in line with the large bone in the lower leg (tibia) and be over the ankle-bone (lateral malleolus) (figure 4).

3. To hold the measurement, push the locking lever away from the blades (figure 5). Read the measurement through the viewing window to the nearest 0.1 centimeter (figure 6).

4. Release the locking lever by pushing it toward the caliper blades.

(18)

Hip Girth 9446



Hip Girth (at maximum protrusion of gluteal muscles).

(19)

Hip Girth (Circumference) 9446

1. Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, head facing straight ahead.

2. Apply anthropometric tape at the level of the maximal protrusion of the gluteal muscles, underneath the gown but over the underwear (see figure on following page).

3. Apply tape snugly but not tightly.

4. Make sure the tape is horizontal and not twisted, checking from both the front and back.

5. Record measurement **to the nearest 1/4 inch, rounding down.**

(20)

Waist Girth (Circumference) 9445

1. Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, head facing straight ahead.

2. Apply anthropometric tape at the level of the umbilicus, underneath the gown (see figure on following page).

3. Apply tape snugly but not tightly.

4. Make sure the tape is horizontal and not twisted, checking from both the front and back.

5. Record measurement **to the nearest 1/4 inch, rounding down.**

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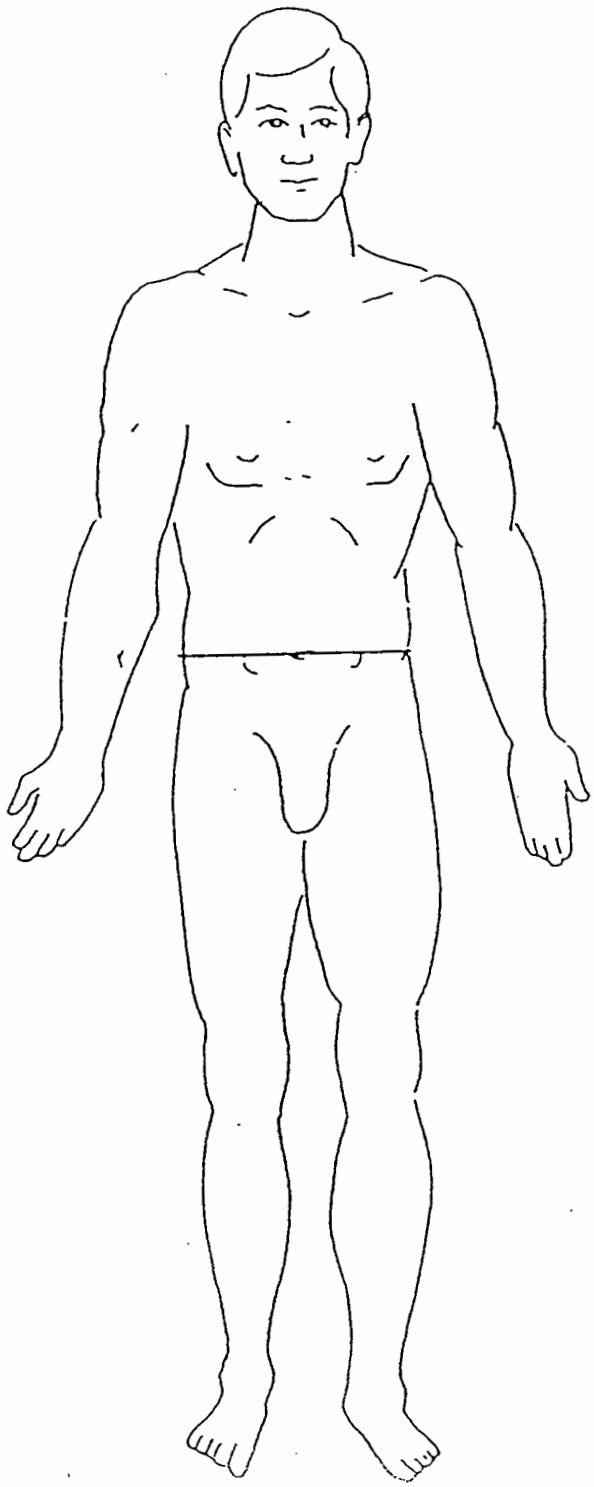
Waist Girth 9445



Waist Girth at level of umbilicus.

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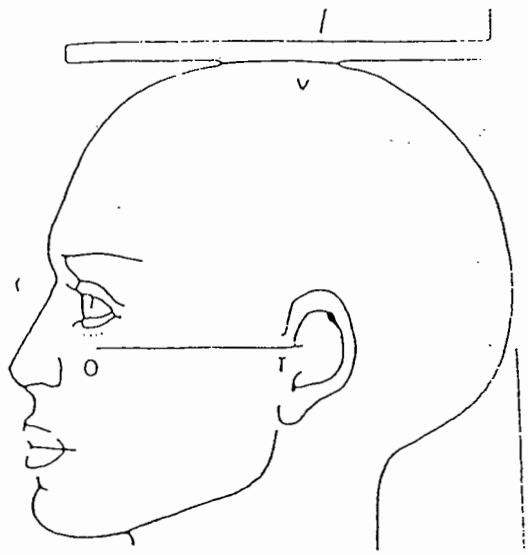
Neck Girth 9444



ORBITALE: Lower margin of eye socket
TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE: Orbitale-tragion horizontal line

Measurement of minimal neck circumference.

(23)

Neck Girth (Circumference) 9444

1. Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, head positioned in the Frankfort horizontal plane. (See figure 1, next page).

2. Standing to face the left side of the participant, identify the thyroid cartilage by gentle palpitation of the neck. Gently place your left index and second fingers on the front of the neck and ask the subject to swallow to help find the correct spot. You should feel a slight depression.

3. Place the superior border of the anthropometric tape just inferior to the laryngeal prominence.

4. Apply the tape snugly, but not tightly, perpendicular to the long axis of the neck, which is not necessarily in the horizontal plane. (See figure 2, next page) at approximately a 90 degree angle.

5. Record the neck circumference to the nearest 1/4 inch, rounding down.

6. The pressure on the tape should be the minimum required to maintain skin contact, and the measurement should be completed in less than 5 seconds, to avoid subject discomfort.

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Standing Height Measurement 9441

1. Participant should be barefoot or wearing thin socks so positioning of the body can be seen. Ask participant to stand erect with his/her back to vertical mounted metal ruler (stadiometer).

2. Heels should be together and against the vertical ruler, both feet flat on the floor, with weight distributed evenly across both feet. Check to make sure both feet are back against the wall.

3. Participant faces straight ahead with his/her head positioned in the Frankfort horizontal plane (see next page). The lower margin of the bony orbit (the socket containing the eye) should be on the same horizontal plane as the most forward point in the supratragal notch (the notch just above the anterior cartilaginous projections of the external ear).

4. Ask participant to let arms hang freely by the sides of the trunk, palms facing the thighs. Ask participant to inhale deeply and maintain a fully erect position.

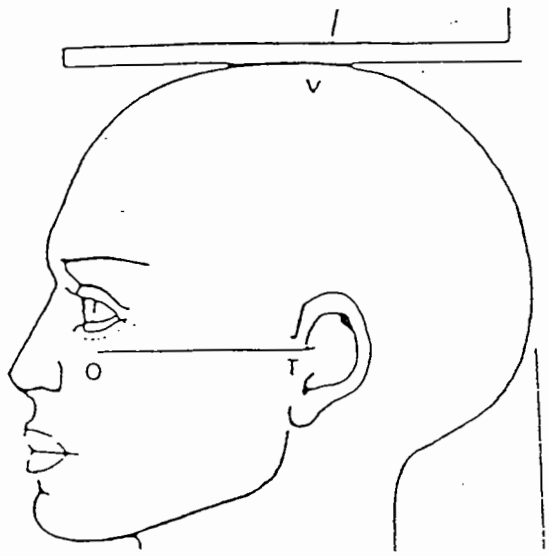
5. Bring the carpenter square down snugly (but not tightly) on top of participant's head. Use an extension board for proper measurement of severely kyphotic subjects.

6. Record measurement to the **nearest 1/4 inch, rounding down.**

(25)

Standing Height Measurement

FRANFORT PLANE FOR MEASURING BODY HEIGHT



ORBITALE: Lower margin of eye socket
TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANFORT PLANE: Orbitale-tragion horizontal line

Weight Measurement 9440

1. Ask participant to wear FHS gown for measurement if he/she brought a heavy gown from home. The participant should remove slippers or shoes.

2. Prior to asking participant to step onto the scale, lift the counter poise and position it at zero.

3. Ask the participant to step onto the scale, facing measurement beam.

4. Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet, and participant should not touch or support him/herself.

5. With the participant standing still in the proper position, lift the counterweight (larger weight), and slide it to the right until the beam approaches balance.

6. Adjust the top poise until the beam is evenly balanced.

7. Have the participant step off the scale. The technician should stand directly in front of the scale and read the weight with eyes level to the point of measurement.

8. Record the weight to the nearest pound; **round up if ≥ 0.5, round down if < 0.5.**

9. Calibrate the scale daily.

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ECG Lead Placement

g 356 - g 391

Before electrodes are placed on the participant, ask if he/she is known to be allergic to alcohol swabs. If yes, prepare the areas of electrode placement by rubbing with water and drying with a washcloth. If allergies are denied, prepare the areas by wiping with an alcohol swab and drying with a washcloth.

NOTE: Place the electrodes on the participant and hook up the leads before entering the data in the ECG machine. This will allow ample time for the participant to relax and the machine interference to smooth out.

1. **V1:** The first intercostal space is palpated just below the clavicle. Count down and identify the 4th intercostal space just below the fourth rib. **Point V1** is just to the right of the sternum in the ***fourth*** intercostal space. Make a small line with a marking pencil here to show where the ECG lead should be placed.

2. **V2:** Should be at the same level as **Point V1** and immediately to the left of the sternum. Make a small line with a marking pencil to show where the ECG lead should be placed.

3. To locate the horizontal reference level for electrodes **(Point E)**, starting from **V2**, locate the **fifth** intercostal space. Move your finger in the **5th** intercostal space laterally to where the midclavicular (center of the chest where you feel a bend in the clavicle) line intersects the **fifth** intercostal space. Make a horizontal line at this point.

   Mark the exact transverse (horizontal) level at this spot with the midsternal line. It should be about one inch (1") below **V1** and **V2** placements.

4. **V6:** Move the participant's elbow laterally away from the body. Mark the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of **E**. This is the exact location of **V6**. (***NOTE:*** It is a common mistake to locate the midaxillary line too far anteriorly, toward the **V5** location).

5. **V4:** Place the # arm of the Heart Square firmly across the lower sternum at the level of **Point E** (as you face the participant, the writing on the Heart Square will appear upside down and backwards). Adjust the **E** and **V6** arms of the Heart Square so they are both perpendicular to the long axis of the thoracic spine at the level of the **E** position. The **E** arm should be exactly horizontal. If the participant is lying flat, the **V6** arm should be exactly vertical.

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9356-9391

Slide the **V6** arm so the **0** point (the *arrow* labeled **V6**) is at the marked location for **V6**. Double check that the **E** arm is still in the correct spot. Record the **E** measurement on the ECG log sheet. Record the measurement to the nearest **0.5** cm (e.g. 16). Log the reading where the two sections of the Heart Square meet (e.g. 12) under **V6** on the log sheet (see Heart Square diagram for reference).

V4: On the **V6** arm (the slide), find the number corresponding to the **E** measurement. Following the corresponding 45 degree line to the surface (e.g. 16) and mark the location. Place electrodes on ***TOP*** of the breast.

The participant may now lower the left arm in a more comfortable position.

6. **V3:** Exactly halfway between **V2** and **V4**.

7. **V5:** Exactly halfway between **V4** and **V6**.

8. Attach limb leads in the following order: right leg, left leg, right arm, left arm. This will avoid lead reversal.

9. If ECG needs to be run at **5 mmHg** because of high voltage (if the standard **10 mmHg** is beyond the lines of the ECG paper), highlight (yellow or orange highlighter) the **5 mmHg** on the bottom of the printed ECG. On the top margin of the tracing write " *1/2 **STANDARD***" using a bold magic marker.

10. After each use, wash the Heart Square gently with soap and water (1 part detergent to at least 20 parts water, approximately 3 drops of detergent to one cup of water) and gently wipe dry with a soft cloth.

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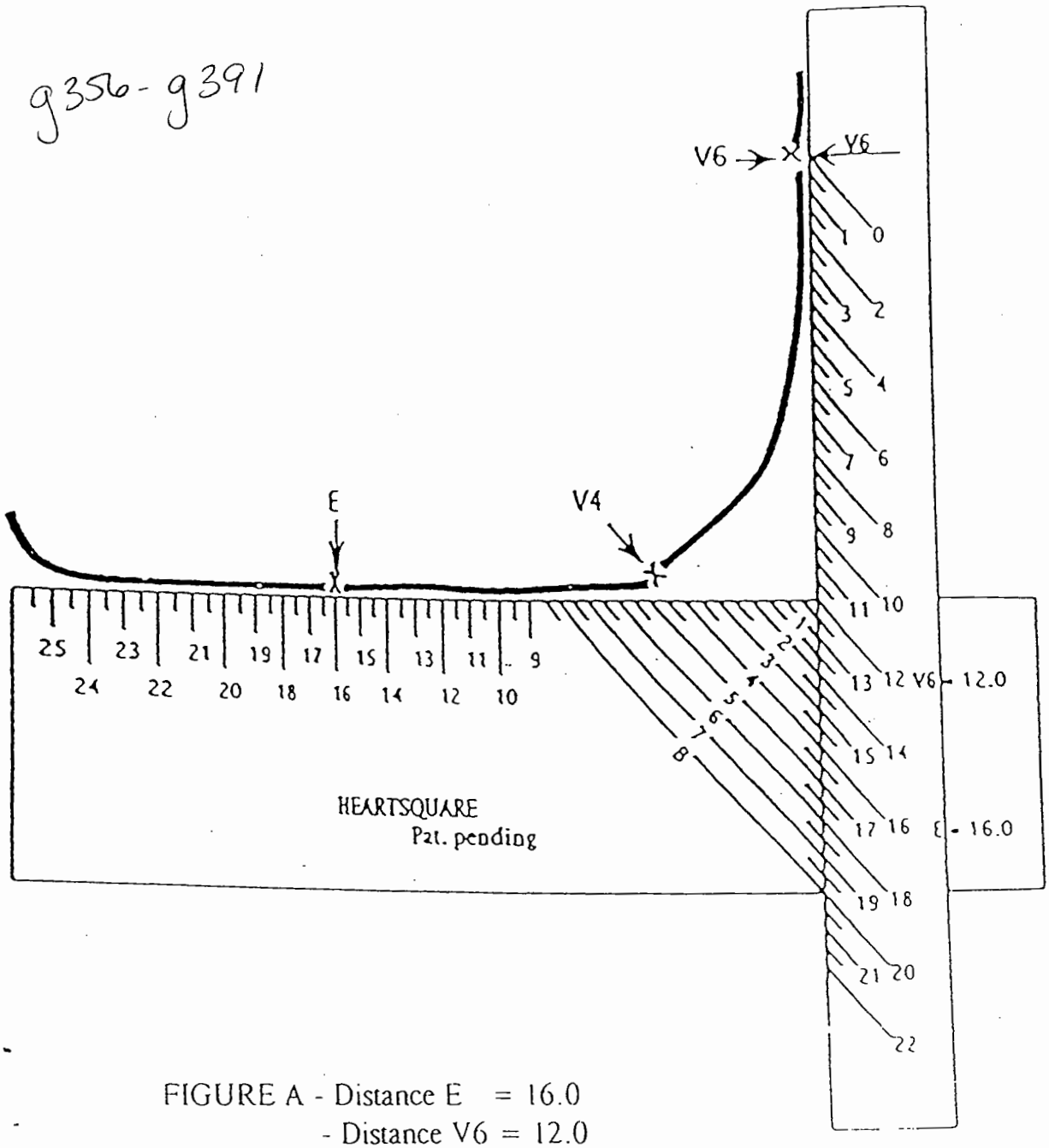

FIGURE A - Distance E = 16.0
- Distance V6 = 12.0

Follow 45° line from 16.0 at V6 arm
to locate V4.

MAC-PC Entries: E = 160 ("height")
V6 = 120 ("weight")

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Bioelectrical Impedance Assessment (BIA)

9453-9459

PURPOSE

For the participant: Bioelectrical Impedance Assessment (BIA) is a method for determining the amount of lean and fat tissue in the body. These measurements will be used to investigate health risks associated with obesity.

For the medical technician: Electrodes placed on the body are attached to the BIA machine. A very slight charge is run through the body (one cannot feel this). Fat and lean tissue conduct the charge differently and give us resistance and reactance values which are then used to calculate the percentages of lean and fat in the body.

A. For best results:

1. Use electrodes only once.

2. Legs should be far enough apart that thighs do not touch each other. If participant is obese, it may be necessary to use a towel to separate thighs.

3. Hands and arms should be far enough apart that they do not touch the torso.

4. No body part should be in contact with any **external** metal (although jewelry and pins in bones will not affect the results).

5. The subject's skin should be clean, dry and warm (not hot or cold) to the touch.

    a. If skin is oily, clean with an alcohol swab before attaching the electrodes.
    b. If skin is extremely dry, apply a small amount of ECG or conductive paste before attaching the electrodes.

6. Prior to attachment, cut the electrodes in half, bisecting the foil tab.

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B. Electrode placement: 9453-9459

1. Bioelectrical Impedance Assessment (BIA) measurements will be made with the electrode halves in order to allow estimation of total body composition. The sites are:

    a. Wrist/metacarpal prominence (MCP) and ankle/metatarsal prominence (MTP).

2. Each pair of electrode halves should face each other on the cut side and be parallel. The tab side of the electrode should face toward the BIA machine.

3. Three measures are made at each site, without moving the electrodes between measurements.

C. To read the Impedance Data:

1. Turn on power switch.

2. Place the x1/x10 switch in the x1 position.

3. Place the Resistance/Reactance switch in the Resistance position. Record the Resistance value which appears on the Impedance meter.

4. Place the Resistance/Reactance switch in the Reactance position. Record the Reactance value which appears on the Impedance meter.

5. **Immediately** after taking the Resistance and Reactance values, turn off the power switch to conserve the system's batteries.

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Mini-Mental State Exam 9478-9502

A. Background and Rationale:

Cognitive function may decline as a result of certain risk factors (e.g. hypertension, elevated cholesterol, cardiac arrhythmias). This in turn could adversely impact the physical functioning and quality of life of older adults. Dementia is a major illness and cause of disability among the elderly. Cerebrovascular disease or multi infarct dementia is the second leading cause of dementing illness among Caucasians, preceded only by Senile Dementia of the Alzheimer's Type (SDAT).

The Mini-Mental State Exam (MMSE) is a widely used test of cognitive function among the elderly; it includes tests of orientation, registration, attention, calculation, recall, language and visuo-spatial skills.

B. Definitions:

1. Alert Level: Participant scoring 23 or less on the MMSE may have a cognitive impairment and will be referred for further evaluation. Referral forms may be obtained from the clinic. They should be filled out and sent to Maureen Valentino, Research Assistant.

2. Mini-Mental State Exam Scoring: The MMSE will be computer scored.

C. Methods:

1. The MMSE asks questions to ascertain cognitive status. Responses are scored **correct** or **incorrect**.

2. If a response is ambiguous, the interviewer records the response in the margin so a decision can be made on its appropriateness.

3. When a participant is incapacitated by blindness, has a functional disability, is illiterate, or is otherwise unable to respond to all questions, the interviewer should specify the problem and questions involved (see "Examiner's Impression" later in the section).

D. Expanded Scoring Instructions for Mini-Mental Exam:

Important note: **0** is meant to represent whenever subjects demonstrate the inability to correctly answer a particular item. They refuse to listen to the question, they have not demonstrated that they can answer the question, they have only indicated they do not want to answer it. If subjects give no response it will

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not always be clear why, again, it has been demonstrated that they have not answered it.

> **1 - 5** = Correct response(s). Note that the scoring method for spelling WORLD backwards has been standardized. (Scoring is shown later in this section.)

Important note: Sometimes hearing impairments prevent subjects from correctly hearing test questions (for example, when asked to repeat three items, *apple, table, penny,* they may repeat *April, tablet, pencil* -- these alternate responses should be accepted both under the repetition and recall conditions). In the case of repeating *no ifs, ands, or buts,* some judgment must be made on the part of the examiner as to whether the participant could hear the "*s*" or not.

> **6** = When a test item is administered and no response is given, regardless of why (such as when a person is too severely demented, or refuses to respond to that single item (but does respond to other items on the test -- right or wrong).

Important note: The single exception to scoring **6** for no response is if a subject is in a coma (this circumstance would be encountered in a nursing home visit, not in a clinic visit). In this instance, administer the first item (to establish no response -- give a **0** to the first item if there is no response). (This exception is made to conform with the stroke protocol.)

> **9** = When test item was not administered (if subject refuses entire test, then all items were not administered and should be scored **9**).

Important note: Sometimes a participant might produce a response that is not a word (i.e. a neologism) but has been responding with intelligible responses on previous items (right or wrong). In this case the items should be scored **0**. The key to differentiating a **0** or a **9** is consistency within test. If a person has a speech abnormality, such as aphasia or dysarthria, across all items, most (or many) responses will be unintelligible. If a person is, for example, demented, he/she may produce a flow of intelligible responses with occasional unintelligible responses. Remember, a **9** must represent situations in which the EXAMINER is not sure whether (1) the participant responded correctly (because of slurred speech, severe stuttering, etc.), or (2) if the participant has some other factor that prevents test item administration (such as an inability to administer *copy this figure* test item to a right-handed person who has right-handed paralysis, or to someone who has a visual impairment or inability to hear).

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Scoring Entire Test:

Add up all correct responses. The total score must be less than or equal to **30** (give **6** or **9** scores a value of **0**). EXCEPT:

Score	
99	If ALL items are scored **9**
66	If ALL items are scored **6**
99	If MOST items are scored **6** and or **9** and it is unclear whether the participant was able to answer questions.

Scoring for Administered Individual Items: (applies only if a test item is administered)

Score **0** for the following reasons:

1. Incorrect response
2. *I don't know*
3. Unintelligible response in context of other intelligible responses (see scoring of **9** as well).
4. No response, but participants attempted to respond (i.e. they are demonstrating that they heard the question and are making an attempt to respond to it).

Examiner's Impression:

The examiner's impression for Cohort Cycle 25 will include the following:

NO	YES	MAYBE	UNKNOWN	
0	1	2	9	Illiteracy or low education
0	1	2	9	Not fluent in English
0	1	2	9	Poor eyesight
0	1	2	9	Poor hearing
0	1	2	9	Depression/possible depression
0	1	2	9	Aphasia
0	1	2	9	Coma
0	1	2	9	Parkinsonism/other neurologic disorder
0	1	2	9	Other

E. Questions: Scripts and Procedures for Each Question:

Introductory Script: *I would like to ask you a few questions dealing with concentration and memory. Some questions may seem easy and others may be a bit more difficult.*

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Read each question on the form.
Record the response on the form.

1. *What is the date today?* (**3** = correct score for month, day and year)

    a. Ask for the date. Then ask specifically for parts omitted (e.g. *Can you also tell me what month, year it is?*)
    b. If participant supplies part or all of the date (e.g. month and day, or month, day, and year), record as appropriate and do not ask those questions again.

2. *What is the season?*

    Since distinctions between seasons can be difficult during certain months, one week leeway is allowed on either side of the actual date.

Month	Correct Response
January	Winter
February	Winter
March	Winter or Spring
April	Spring
May	Spring
June	Spring or Summer
July	Summer
August	Summer
September	Summer or Fall
October	Fall
November	Fall
December	Fall or Winter

3. *What day of the week is it?*

4. *What town, county, and state are we in?*

    a. Ask the participant what town, county, and state we are in. Then ask specifically for parts omitted (e.g. *Can you also tell me what county this is?*)

5. *What is the name of this place?*

    a. Ask the participant where they are. Any appropriate answer is okay. On home visits, the examiner can ask, *What is the address of this place?*

6. *What floor of the building are we on?*

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7. *I am going to name 3 objects. After I have said them I want you to repeat them back to me. Remember what they are because I will ask you to name them again in a few minutes: Apple, Table, Penny.*

    a. Make sure participant is attentive when beginning the question.
    b. Read the list of objects slowly. DO NOT REPEAT ITEMS UNTIL AFTER THE FIRST TRIAL.
    c. If participant asks you to repeat the 3 items, respond, *Can you tell me the items I just mentioned?* or *Just do the best you can.*
    d. Participant should repeat the items in the same order.
    e. Read *Apple, Table, Penny.*
    f. Script: *Could you repeat the three items for me?*
    g. Record the score for the first trial.
    h. If, after scoring the first attempt, the participant has not learned the 3 objects, repeat the list of objects up to 6 times until he/she has learned them.
    i. If, items are repeated in correct order, score 3 points. If the participant does not repeat the items in the correct order, score as follows:

Score	Order of Items Given on Recall		
2	Table	Penny	Apple
2	Apple	Penny	Table
1	Penny	Apple	Table
1	Penny	Table	Apple
2	Apple	Penny	------
2	Apple	Table	------
2	Apple	------	Penny
2	Apple	------	Table
2	Table	Penny	------

8. *Now I am going to spell a word forward and I want you to spell it backwards. The word is WORLD. W-O-R-L-D. Please spell it in reverse order.* Write in letters _____ (letters are entered and scored later).

    a. Read the question slowly. Where *world* has hyphens between the letters, spell out the word.
    b. Repeat the spelling if necessary.
    c. Record the participant's response. Write in the letter as the participant has spelled the word.

9. *What are the 3 objects I asked you to remember a few moments ago?*

    a. Items may be repeated in any order.

10. *What is this called?* (Watch)

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11. *What is this called?* (Pencil)

    a. Show the wrist watch/pencil to the participant. NOTE: the pencil should be a standard sharpened wooden pencil with eraser.
    b. Correct responses include: watch, wristwatch, timepiece.
    c. Code **1** = correct for correct answer.

12. *Please repeat the following: No ifs, ands or buts.*

    a. Enunciate clearly -- include the "**S**" at the end of *ifs, ands, or buts*, (if you think the participant heard you but repeated it incorrectly, make a note of what was missed and score **0**).
    b. Allow only **one** attempt.
    c. Code **1** = correct when the participant correctly repeated the phrase.
    d. Code **0** = incorrect when the participant did not repeat the phrase exactly.

13. *Please read the following and do what it says.*

    a. Hand participant the card.
    b. The participant may read the sentence out loud. The task to be coded is the participant's ability to follow instructions by closing his/her eyes. It is not necessary for the sentence to be read out loud if the participant performs the function properly.
    c. Code **1** = correct when the participant closes his/her eyes.
    d. Code **0** = incorrect when the participant did not close his/her eyes.

14. *Please write a sentence.*

    a. Script: *Write any complete sentence on this piece of paper for me.*
    b. Repeat the instructions to participant if necessary.
    c. Code **1** = correct if the participant wrote a complete sentence as directed.
    d. Written commands, such as *sit down*, where the subject is implied, are considered correct responses.
    e. Spelling and/or punctuation errors are not counted as errors.
    f. Code **0** = incorrect when the participant did not write a complete sentence as directed.
    g. Code **0** = if the participant is cognitively able to dictate a sentence but is physically unable to write it. In this case the examiner should write the dictated sentence and make a note that it was dictated.

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15. *Please copy this drawing.*

    a. Script: *Here is a drawing. Please copy the drawing on the same piece of paper.*
    b. If the participant asks if the figures should be drawn separately or together the examiner should respond, *Draw the figures as you see them.*
    c. To be correct, each pentagon must have 5 sides, 5 sides that point outward. The two figures must be overlapping.
    d. The overlap figures must have 4 sides.
    e. Code "**0**" = incorrect when the participant's figure did not match.

16. *Take this piece of paper in your right hand, fold it in half with both hands, and put it in your lap.*

    a. Read the full statement **BEFORE** handing the paper to the participant.
    b. **DO NOT** direct the paper to participant's right side. Hold the paper in front and have the participant reach out to take it. Observe which hand is used.
    c. **DO NOT** repeat instructions or coach participant. Only repeat if the examiner felt it was not heard or if instructions were not given clearly (just repeat the directions in full as they were the first time).
    d. Score: **1** for <u>each</u> correctly performed act (code **6** if low vision).

9478-9502

PLEASE CLOSE YOUR EYES

(40)

Sociodemographics and Subjective Health 9504-9515

A. Sociodemographics

1. *Where do you live?*

   Coding
   0 = Private residence
   1 = Nursing home
   2 = Other institution, such as: home self-care retirement village
   9 = Unknown

2. *Does anyone live with you?* (NOTE: Code nursing home resident as NO to these questions.)

   Coding
   0 = No
   1 = Yes
   9 = Unknown

   NOTE: If the answer to the above question was **0** or **9** you may skip the following section. If the answer was yes, the examiner needs to determine who lives in the same household. It is important to ask whether others lives in the same household for < 3 months per year or > 3 months per year. The list is:

   Spouse
   Significant other
   Children
   Friends
   Relatives
   Pets

   Coding
   0 = No
   1 = Yes, less than 3 months per year
   2 = Yes, more than 3 months per year
   9 = Unknown

9504-9515

3. *In general, how is your health now?*

Coding
1 = Excellent
2 = Good
3 = Fair
4 = Poor
9 = Unknown

4. *Compare your health to most people your own age:*

Coding
1 = Better
2 = About the same
3 = Worse than most people your own age
9 = Unknown

5. *Are you employed now?*

Coding
0 = No
1 = Yes, full time
2 = Yes, part time
9 = Unknown

NOTE: The following two questions MAY NOT be answered by a proxy.

Activities of Daily Living: Self Reported Performance

9517 - 9546

A. Background and Rationale:

This section is designed to assess the following spectrum of physical functioning. This section assesses:

a. General level of physical functioning and mobility
b. Ability to carry out instrumental activities of daily living
c. Ability to carry out activities of daily living
d. Framingham Disability Index

B. Activities:

Ask the participant, *During the course of a normal day, can you do the following activities independently or do you need human assistance or the use of a device?*

The answers will be coded by the examiner as:

0 = No help needed, independent
1 = Uses device, independent
2 = Human assistance needed, minimally dependent
3 = Dependent
4 = Does not do during a normal day
9 = Unknown

The activities include:

1. Getting dressed and undressed
   - Picking out clothes, dress oneself including buttoning, fastening, etc.
2. Bathing
   - Getting water, soap, towel and other necessary items and wash oneself
   - Includes getting in and out of shower or tub
3. Eating foods and drinking liquids
   - Able to eat from a dish and drink from a cup
4. Getting in and out of a chair
   - Arising from a sitting position to a standing position and back
5. Using the toilet
   - Using the bathroom facilities and handling clothing

9517-9546

6. Bladder continence
   - Bladder and bowel continence: complete and voluntary control; use of a medication is **NOT** considered a device.
   - Coding: as above but **5** = uses commercial external product to maintain continence, e.g. Depends.
   - If the participant is on medication for incontinence, code **0** = independent.
7. Walking on a level surface about 50 yards (150 ft).
8. Walking up and down one flight of stairs
   - Can climb front steps of 5 Thurber Street
9. Using a telephone
   - Able to dial a phone number: ex. 935-3400. (The participant does not need to be observed doing this task).
10. Preparing and taking own medications
    - Is able to measure out and take medications without being dependent on another person.
    - Coding: as above but **8** = takes no meds.
    - Medications include prescriptions and aspirin taken on a regular basis. PRN pain medications and over-the-counter are not considered.

C. *Are you in bed or in a chair for most or all of the day (on the average)?* (This question refers to lifestyle, not health.)

Score
0 = No
1 = Yes
9 = Unknown or not sure

Do you need a special aid (wheelchair, cane, walker) to get around?

If the answer to the above question is **YES**, code which equipment is used:

a. Cane or walking stick
b. Wheelchair
c. Walker
d. Other (write in)

Score
0 = No
1 = Yes
2 = Yes, sometimes
9 = Unknown

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9517-9546

D. Use of Nursing and Community Services:

Coding for the following questions is:

0 = No
1 = Yes
9 = Unknown

Ask the participant, *Have you been admitted to a nursing home (or skilled facility) in the past two years?*

Ask which services were used and how often.

1. Home health aides
2. Homemaker visits
3. Visiting nurses
4. Rehabilitation services (such as physical therapy, occupational therapy, speech therapy)
5. Cardiac rehabilitation
6. Meals on wheels
7. Community day programs

Score

1 = < 1 per month
2 = 1-5 times per month
3 = 6-15 times per month
4 = 16-30 times per month
9 = unknown

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Rosow-Breslau Questions

9547-9550

The method of assessing physical functioning is self-report. The questions assess the degree of difficulty that a person has performing a specific activity. This form has several important purposes:

1. These data will enable us to assess the level of independence and function in the study population.
2. It is hypothesized that impairments of physical function may be a risk factor for cardiovascular end points and progression of disease.
3. It will measure loss of physical functioning as a consequence of cardiovascular disease.

Definitions:

This section contains definitions of the activities, symptoms, and diseases identified in the Assessment of Physical Functioning Form.

Activities:

1. Walking one half mile or four to six city blocks. Walk this distance without stopping for more than five minutes.
2. Walking around home, walk from room to room, or within one room within the participant's principal residence.

Questions:

Scoring
0 = No
1 = Yes, independent
2 = Does not do
9 = Unknown

Are you able to do heavy work around the house, like shovel snow or wash windows, walls, or floors without help? (Scrub floors, wash windows, rake leaves, mow lawn). *(Note:* Code **2** if person **does not** do this activity).

Are you able to walk half a mile without help? (Walk one half mile or 4-6 blocks without stopping for more than 5 minutes). *(Note:* Code **2** if person does not do this activity).

9547 - 9550

If you had to, could you do all the housekeeping yourself (like washing clothes and cleaning)?

If you had to, could you do all the cooking yourself?

If you had to, could you do all the grocery shopping yourself?

Do you drive?
Reason for not driving now:

Scoring for not driving:
1 = Health
2 = Other non-health reason
3 = Never licensed
8 = N/A, current driver
9 = Unknown

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Nagi Exam

g552 - g562

1. Show and explain the answer sheet *before* administering the test.

2. Ask each question individually. Start with, *For each item, tell me whether you have. . .*

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g552-g562

No difficulty

A little difficulty

Some difficulty

A lot of difficulty

Unable to do

Do not do on MD orders

(49)

Procedures For CES-D Interview 9587-9606

A. Rationale and Background:

The Center for Epidemiologic Studies Depression Scale (CES-D) was developed for use in epidemiologic research of depressive symptomatology in the general population. It was designed as a screening instrument to elicit symptoms associated with depression. It is intended to document the presence and severity of depressive symptoms but is not intended to make clinical diagnosis. It assesses the current state of the subject by focusing on symptomatology in the past week.

The scale is given at each exam. The scale is not given if the patient is: sedated, aphasic, non-English speaking, or uncooperative.

B. Procedure:

1. Each question is read to the participant who responds with one of four answers.

2. Response alternatives should be printed on paper which is placed in front of the participant for reference.

3. Each category of response should be explained to the participant prior to administering the scale.

4. If the participant is unable to read the response sheets, the interviewer should read each response as well as the question referring to their feelings in the past week.

5. Be sure the participant understands that the questions refer to his/her feelings only during the past week.

C. CES-D Scoring:

Responses are circled on the form. The score is the sum of 20 weighted responses and the final score is calculated by the computer. Score ranges from 0 to 60 by totaling all responses. Code **9** = *refused or do not know* is not included in the score. Values for each question range from **0** to **3**.

D. Methods:

The CES-D Questionnaire consists of 20 questions. Since it is a scale for depression, it must be completed using responses by the participant, not a proxy.

9587-9606

SCRIPT: *The questions below ask about your feelings. For each of the following statements please say if you felt that way during the past week.*

1. Hand the response sheet to the participant and explain the categories. The following definitions should be given:

   Code
   0 = Rarely or none of the time (< one full day)
   1 = Some or a little of the time (1 to 2 days in the past week)
   2 = Occasionally or moderate amount of time (3 to 4 days in the past week, or about 1/2 the time)
   3 = Most of the time (5 to 7 days in the past week)

   If participant answers *YES* to a given statement, repeat the above responses to get a correct answer.

2. Read each item as it is written on the form, prefacing each question with the statement *During the past week*, then continuing with the response categories. For example:

   SCRIPT: *During the past week I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time, occasionally or moderate amount of time, or most or all of the time?*

3. Discontinue reading the responses when the participant provides a response before you are finished. On the next item, however, again begin to read the entire set of responses.

4. When a participant asks for an interpretation of a particular response, reread the definitions to him/her.

5. Code **9** = *Refused* or *Do not know* is used when:

   a. The question was asked, but the participant chooses not to answer. For example, response was *I would rather not say,* or *Go on to the next question.*
   b. The question was asked, but the participant does not know, does not remember, or does not understand the form.

6. Check the response on the form.

7. When the participant refuses to respond to the statement, check **9** = refused or do not know.

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9587-9606

8. When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement. For example:

   Participant: *What do you mean by bothered?*

   Interviewer: *I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time, occasionally or moderate amount of time, or most or all of the time during the past week?*

9. When the participant still asks about the meaning or says he/she does not understand, check **9** = refused or do not know. Do not try to interpret the statement for the participant.

NOTE:
Do not ask why the participant appears depressed. However, if that information is volunteered, briefly document the reason.

Do not score positive for *restless sleep* if the participant wakes to go to the bathroom and is able to get back to sleep easily.

This is a self-reported questionnaire and answers should be accepted as given.

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g587-g606

0 = Rarely or none of the time
(less than 1 day)

1 = Some or a little of the time
(1 - 2 days)

2 = Occasionally or moderate amount of time
(3 - 4 days)

3 = Most or all of the time
(5 - 7 days)

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Guidelines for Review of Willet Food Frequency Questionnaire

see Willet Food Questionnaire data set

The purpose of the Willet Food Frequency Questionnaire is to obtain information about what the participant usually eats and drinks. The questions review specific foods and portion sizes, to find out how often, on average, the specified amount was eaten or drunk during the past year. The Willet Food Frequency Form is completed prior to the participant's clinic visit.

Special arrangements may be made if the participant is illiterate, has problems in reading, cannot read English, or is unable to answer the questions accurately due to physical or cognitive disabilities. This may be evident for example, the answer sheet has all circles filled out in the first column or is not filled out at all.

1. Check that there are no staples, rips, tears, or writing other than where indicated. If so, the form must be redone.

2. Make sure that the form is completed with a #2 pencil.

3. Check that circles are filled in completely - no Xs, checkmarks, etc.

4. Check that a response has been filled in for every line. If never used, fill in that circle.

5. Check that there is only one response for every line.

6. For vitamins, make sure the brand, the dose and how long taken is written in the spaces provided.

7. Make sure that all extra foods are written in the numbered spaces (up to 4 items) with complete information.

8. Make sure that what is written in the extra foods section is not something that is already in another part of the questionnaire.

9. Make sure to check for completeness of I.D. number.

10. Make sure to stamp the date on top when the participant brings in the form.

11. Make sure the exam number is on the form. This is most important when you are at the beginning/end of a cycle where there is overlap.

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Procedures for Raynaud's Interview

g608 - g623

A. Rationale and Background:

The Raynaud's questionnaire was designed by Dr. H. Maricq as a tool to ascertain cases of prevalent Raynaud's phenomenon in community based samples. This tool has been well validated. It utilizes a questionnaire and photographs, and must be administered by a trained interviewer.

The questionnaire should be administered to all cooperative participants who are able to understand English. This questionnaire should not be administered to blind subjects.

B. Procedure:

Each question and the possible responses are read aloud to the participant. The interviewer then circles the subject's response. ***Past,*** should only be recorded for subjects not having any symptoms for over a year. If the subject answers No or Don't Know for **both** question #1 and #2A, the interviewer should stop administering the questionnaire and proceed to the next set of Framingham questions.

After answering questions 1 and 2, the participant is shown a color chart and asked to identify the color corresponding to the palest his or her fingers ever become. The interviewer proceeds to question 4 only if the participant chooses box #1 or #2, otherwise the Raynaud's questionnaire is ended and the interviewer should proceed with the next set of Framingham questions.

For participant's choosing box #1 or #2, the interviewer then shows each participant a series of photographs, and scores the subject's response for **each** photograph.

Questions #6 to #10 are not part of the validated questionnaire but are essential to further characterize the disorder. For questions #6, #7, #9, and #10 the participant's answer is circled, and for #8 the interviewer should record the frequency ot attacks in the last 12 months in the spaces provided. If, for example, the subject responds "2 times a month," the interviewer should multiply this answer by 12 and record 24 in the spaces provided.

9608 - 9623

Raynaud's Questionnaire

1. *Are your fingers usually sensitive to cold, now or in the past?* (If asked to define "unusually", say: *Are they more sensitive to cold than most other people?*)

   Coding
   1 = Yes
   2 = No
   3 = Don't know
   4 = Past

2. *Do your fingers sometimes show unusual color changes?* (If asked to define "unusual" say: *Do they become white?*)

   Coding
   1 = Yes (Answer questions 2a, 2b, and 2c)
   2 = No
   3 = Don't know
   4 = Past (Answer questions 2a, 2b, and 2c)

   a. *Do they become white?*

      Coding
      1 = Yes
      2 = No
      3 = Don't know
      4 = Past

   b. *Do they become red?*

      Coding
      1 = Yes
      2 = No
      3 = Don't know
      4 = Past

   c. *Do they become blue?*

      Coding
      1 = Yes
      2 = No
      3 = Don't know
      4 = Past

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If answered No or Don't know to BOTH question #1 and question #2 then END otherwise go to question #3.

Show Color Scale

3. *What's the palest your fingers ever get?* (If hesitating between box #1 and #2, ask *Do they become completely bloodless?,* if answer Yes score = **1**, if answer No score = **2**)

Coding
1 = Box #1 (Go to question 4)
2 = Box #2 (Go to question 4)
3 = Other (Go to END)

Show Hand Photograph A

4. *Do your hands ever look like this picture? We want to know whether your fingertips or whole fingers are clearly more white than the rest of your hand. We don't need an exact match.* (If there is any doubt whether there is true blanching ask whether the fingertips or fingers become completely bloodless.)

Coding
1 = Yes
2 = No
3 = Don't know

Show page with 4 hand photographs labeled 1,2,3,4

5. *Now let me show you a few more pictures. Do your hands ever look like any of these 4 pictures?*

Photo 1 Coding
1 = Yes
2 = No
3 = Don't know

Photo 2 Coding
1 = Yes
2 = No
3 = Don't know

Photo 3 Coding
1 = Yes
2 = No
3 = Don't know

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Photo 4 Coding
1 = Yes
2 = No
3 = Don't know

If answered yes to question #4 or any part of question #5 then ask questions #6 to #10, otherwise END.

6. *How old were you when your fingers first became sensitive to cold or showed unusual color changes?*

Coding
1 = Younger than 20
2 = 20-29
3 = 30-39
4 = 40-49
5 = 50 or over
6 = Don't know

7. *When is the last time your fingers were sensitive to cold or showed unusual color changes?*

Coding
1 = Less than 1 year ago
2 = 1-4 years ago
3 = Over 4 years ago

8. *In the last 12 months, how many times were your fingers sensitive to cold or showed unusual color changes?*

9. *In the last 12 months have your fingers become white when you were not in the cold, that is at normal temperature?* (If asked to define "normal temperature", say: *for example, in the summer.*)

Coding
1 = Yes
2 = No

10. *In the last 12 months did you limit your activities because your fingers were sensitive to cold or showed unusual color changes?*

Coding
1 = Yes
2 = No

(5)

SPIROMETRY - MANUAL OF OPERATIONS

see PFT data set

CARDIOVASCULAR HEALTH STUDY - CHS

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- *Software Version 42.710.04*
- *June 8, 1993*
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TABLE OF CONTENTS see PFT data set

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see PFT dataset

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.

BACKGROUND

Spirometry is the simplest, most effective test for assessment of lung function (1). That is why it has been included in many cardiovascular epidemiology studies, including the Tecumseh, Framingham, CARDIA, ARIC, and Honolulu Heart studies (6-10). Spirometry and maximal respiratory pressures (MIP & MEP) were measured during the baseline exam of the CHS (2); and reference values for the 65-85 year-old age group were thereby established from the healthy CHS participants (3-4). The FEV1, FVC, and MIP were found to be associated with cardio-pulmonary symptoms, anthropometric measures, past exposures, and subclinical cardiovascular disease (CVD) and overt clinical CVD and lung disease (4). Spirometry, ambulatory monitoring of peak flows, and sleep disordered breathing (pulse oximetry) are to be measured during follow-up year 6 and 10 exams.

Spirometry records the relationship between airflow (FEV1) and the exhaled volume of air during a breathing maneuver called the FVC maneuver (forced vital capacity maneuver). The most common lung diseases reduce forced expiratory flows. Such "obstructive" lung diseases include asthma, bronchitis, and emphysema. The ratio of FEV1/FVC is very sensitive for detecting mild airways obstruction, such as that due to mild airway inflammation secondary to exposure to cigarette smoke, asthma triggers, and mild pulmonary congestion due to CVD.

DEFINITIONS see PFT data set

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.

FEV1 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.

FEV1/FVC RATIO is the most sensitive and specific index of airways obstruction measured by a spirometer. It is normally above 70%.

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See PFT data set

LOPPY DISKS are removable, rather slow, omputer storage media. The personal omputer's floppy disk (drive A:) uses high ensity (HD) 3 1/2 inch floppy disks which an each store up to 1.44 million haracters (Mbytes).

LOW-VOLUME CURVE is the graph btained from a forced exhalation ıaneuver plotted with flow on the vertical xis and volume on the horizontal axis. /hen compared with the traditional ɔirogram, it has the advantage of allowing ɜsy recognition of unacceptable or poorly ɨproducible maneuvers and disease ɜtterns.

VC is the Forced Vital Capacity, the ɔlume of air exhaled during the maneuver ɜmed after it. The subject takes as deep breath as possible and then quickly ɕhales as much air as possible. The FVC reduced with restrictive disorders.

4*RD DISK* is the personal computer's st, mass storage device (drive C:) which ores millions of characters.

3*STRUCTION* is a decrease in maximal flow rates caused by airway narrowing. ıe FEV1/FVC ratio and the FEV1 are both ɨcreased.

F stands for Peak Expiratory Flow Rate, e highest flow measured during the FVC ɜneuver. It is a good index of effort used the onset of the maneuver. It can be en on a flow-volume curve but not on a ıditional volume-time spirogram. ɨxpensive $10 hand-held instruments can ɨo measure PEF with better than 10% curacy. These peak flow meters will be ed to assess the lability of airways struction in a subset of the CHS pulation.

PF is short for Pulmonary Function (lung tests).

PRED is short for the predicted value of a PF parameter. It is determined from the regression equation from a large population study of supposedly normal people.

RAM is very fast computer memory which "goes away" when the power is turned off. Results are copied from RAM to a disk for permanent storage. The personal computer has at least 640K of RAM memory.

RESTRICTION is a decrease in lung volumes. Scarring of lung tissue (fibrosis), severe heart failure (CHF), pneumonia, and simple obesity are some of many causes. The FVC is reduced while the FEV1/FVC ratio is normal or increased.

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Equations see PFT data set

BTPS Correction Factor (ATPS to BTPS):

$$[(273 + 37)/(273 + T)] \times [(PB - PH_2O)/(PB - 47)]$$

T = spirometer temperature (20-30 deg C)
at the end of each maneuver
PB = barometric pressure
(625-760 mmHg)
PH_2O = water vapor pressure
(17-30 mmHg)

Factor to convert inches to centimeters:
Inches x 2.54

To convert degrees F to Centigrade:

(5/9) x (degF - 32)

Prediction equations for healthy elderly women and men

	Equation	LLN
MEN		
FVC	.0567 Ht -.0206 Age -4.37	-1.12
FEV1	.0378 Ht -.0271 Age -1.73	- .84
FEV1/FVC%	-.294 Age +93.8	-11.7
WOMEN		
FVC	.0365 Ht -.0330 Age -0.70	- .64
FEV1	.0281 Ht -.0325 Age -0.09	- .48
FEV1/FVC%	-.242 Age +92.3	- 9.3

volumes in liters, BTPS
Ratio = FEV1/FVC x 100%
Ht = height in cm
LLN = lower limit of the normal range (fifth percentile)
Equations are from the healthy CHS participants
during their baseline exam (3) and are valid for ages 65-85

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METHODS SUMMARY see PFT data set

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 and neck size
- Print and store the results
- Instruct for PEF or sleep oximetry

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

Weekly Procedures

Monday mornings
- Refill with distilled water
- Run leak and volume cal checks
- Perform a biologic control test

Friday afternoons
- Remove spirometer shell
- Clean bell & internal hose
- Rinse and dry the bell overnight

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DESCRIPTION OF THE PF WORKSTATION

see PFT data set

A dry-sealed 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 transmitted to the PF Reading Center

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.

FVC - Forced Vital Capacity
Guides performance of FVC maneuvers. Flow-volume curves are displayed on the screen for quality control.

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.

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see PFT data set

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 for details).

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.

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: A for Asian, B for Black, C for Caucasian, H for Hispanic, I for American Indian, or O for other.

Note: When based on standing height, 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 the participant's neck circumference in centimeters. This should be measured using a cloth measuring tape. 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.

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FORCED VITAL CAPACITY TESTING see PFT data set

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 elevated.

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 see PFT data set

Step 1 From the MAIN MENU, select **FVL**. The FVC Incentive screen will then be displayed.

Step 2 Tell him 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 spirograms, 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.

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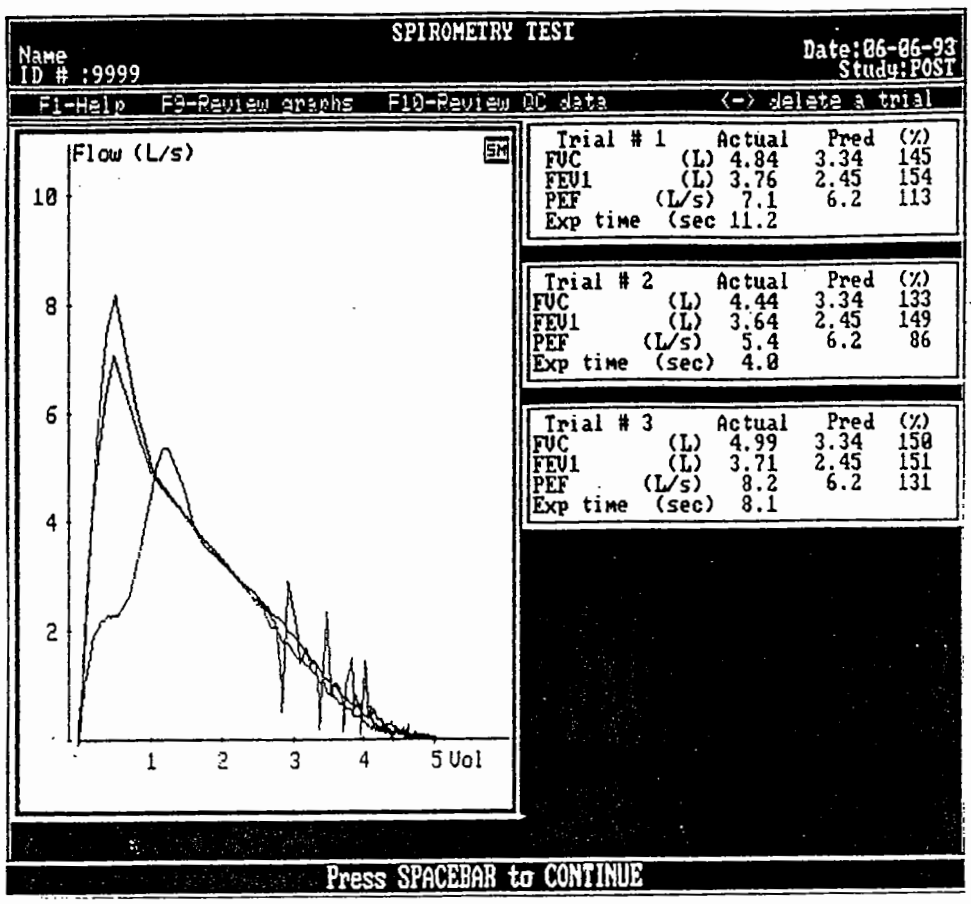
Review the Results see PFT data set

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.



see PFT data set

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:

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

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	Deeper breath	dFVC > 5% and 200 mL
f	Blow out faster	dFEV1 > 5% and 150 mL
h	Blow out harder	dPEFR > 15% and 1 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.

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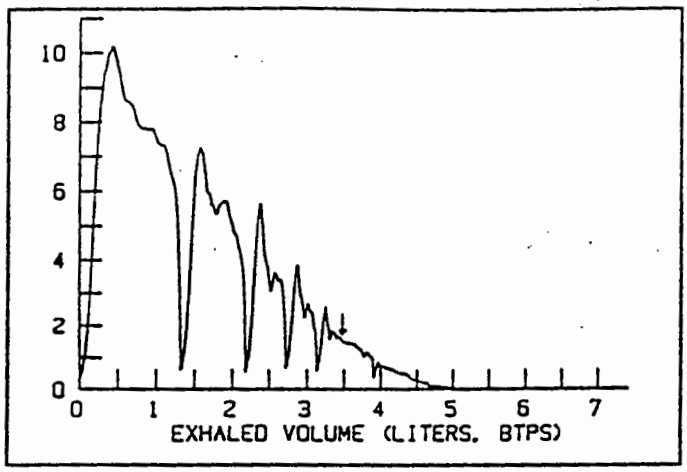
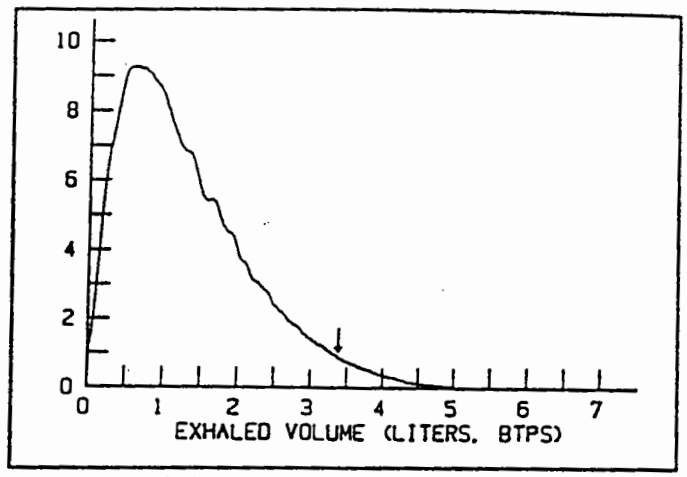
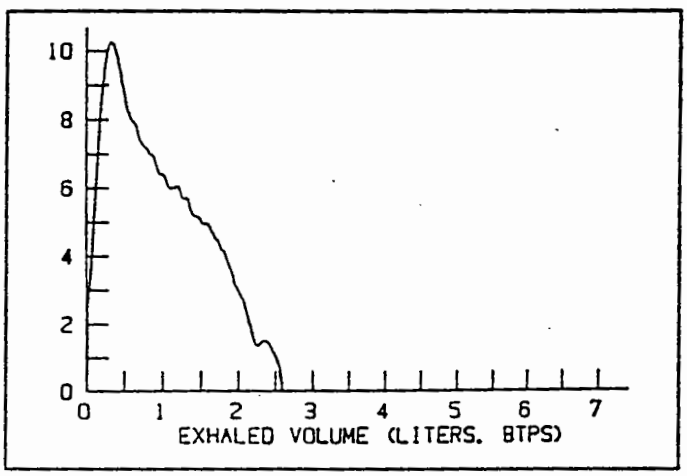
see PFT data set



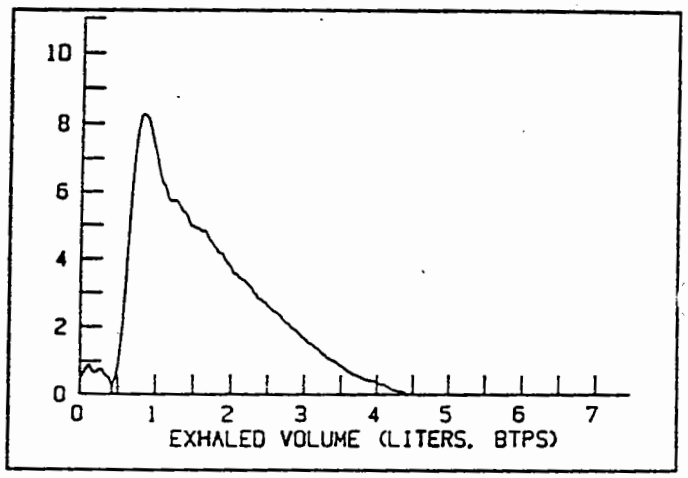
AVOID COUGHING



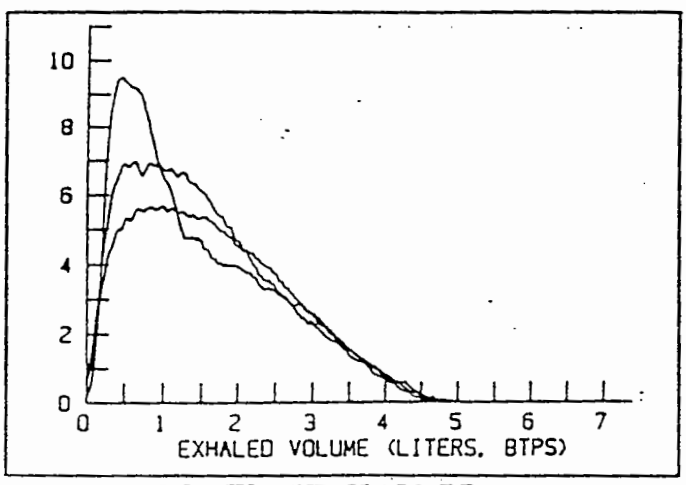
GOOD MANEUVER



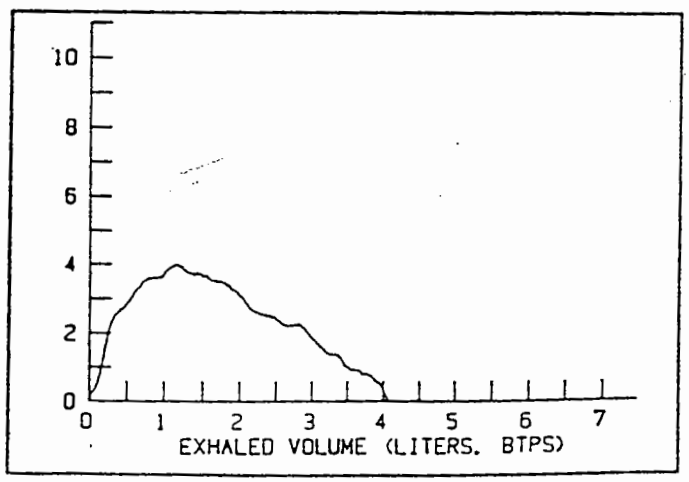
BLOW OUT LONGER



START FASTER



BLOW OUT HARDER



BLAST OUT HARDER

(22)

see PFT data set

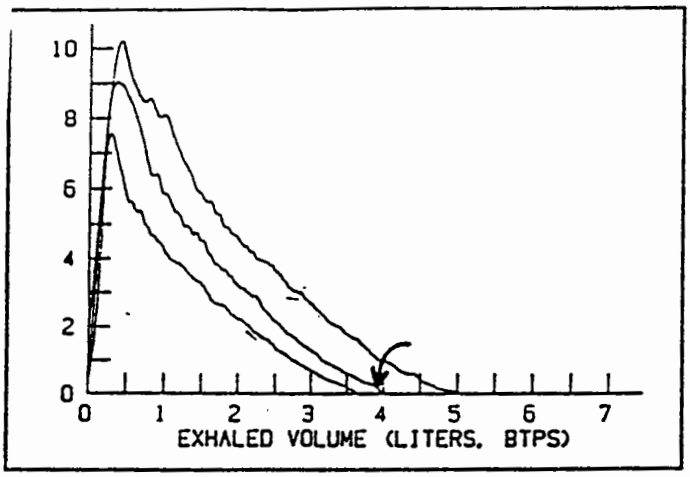


Figure 17. TAKE A DEEPER BREATH

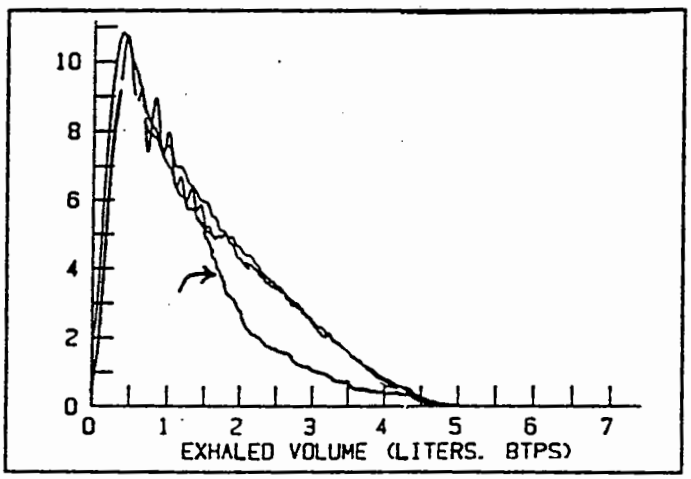


Figure 18. BLOW OUT FASTER

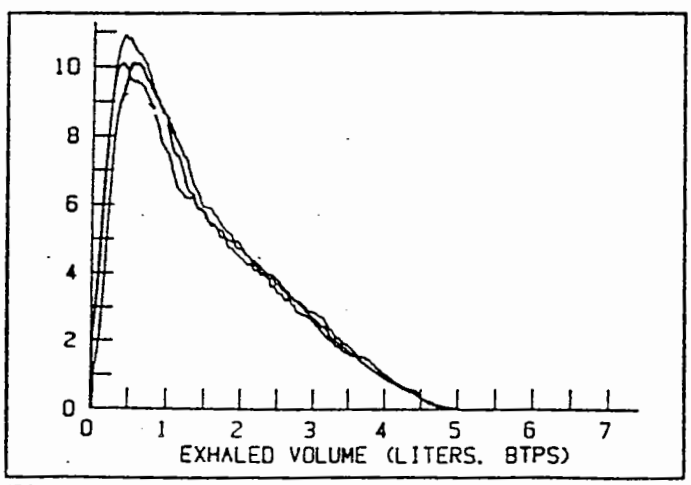


Figure 19. THREE GOOD MANEUVERS

see PFT data set

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.

SVC Maneuver Steps

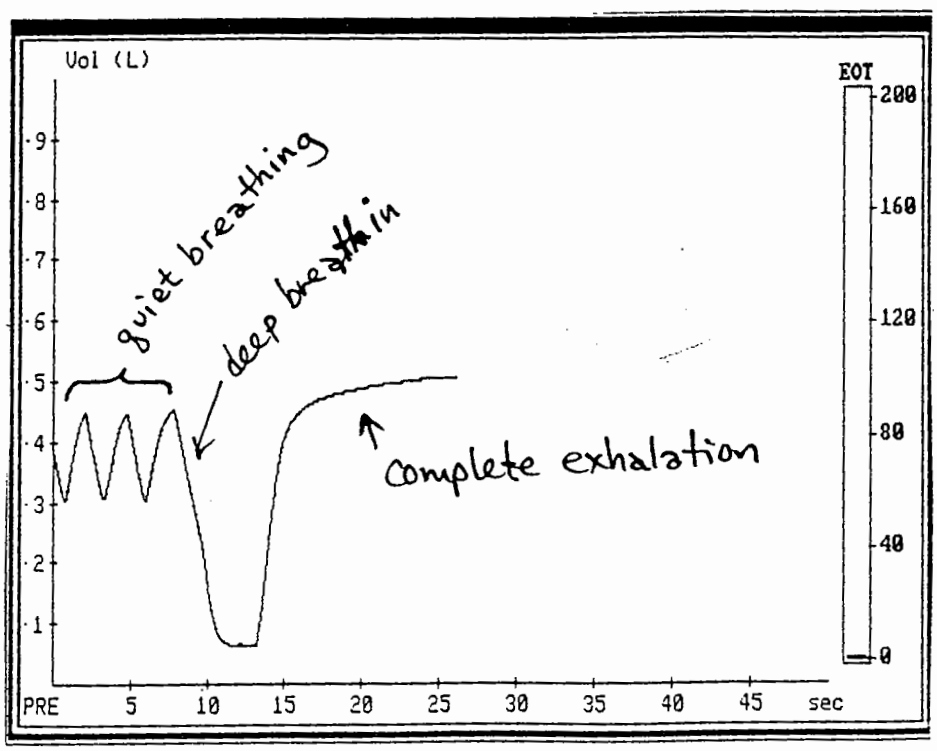
1. Ask the participant to hold the spirometer hose. Grasp the top of the spirometer's bell by the black knob and lift it to its midposition.

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.

Sample SVC tracing:



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see PFT data set

(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).

Press the spacebar to end the test BEFORE the participant takes the mouthpiece out of his mouth.

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 -- The SVC/SVCmax ratio should be above 95%.

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

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 ppages).

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: see PFT data set

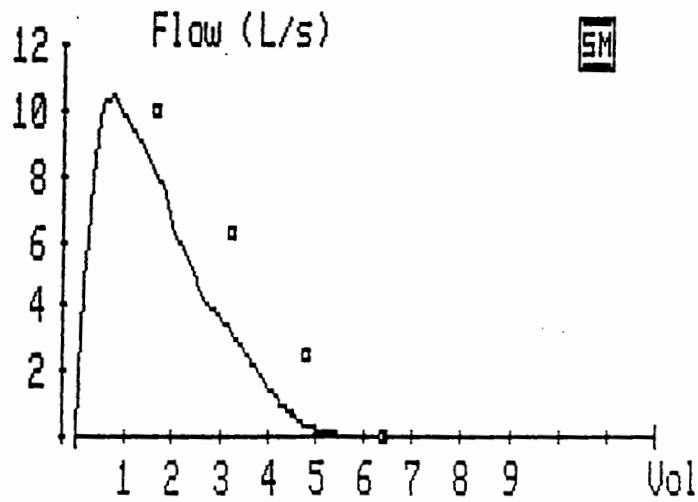
Cardiovascular Health Study
Pulmonary Function Report

Patient : Martin McInroe
ID Number: 1233
Date : 06-11-93
Clinic : ARIZONA
Predicted: Knudson 83

Height: 77.0(in) - 196 (cm) Sex: M
Weight: 170 (lb) - 77 (kg) BMI: 20.
Age: 45 BP: 760 Temp: 23 ATPS: .91

		Actual	%Pred	Pred
FVC	(L)	5.44	85	6.38
FEV1	(L)	4.16	80	5.18
PEF	(L/s)	10.5	97	10.8
FEV1/FVC	(%)	76.5	94	81.1

Comments :
Good test



Computer Impression:

SPIROMETRY is within NORMAL limits.

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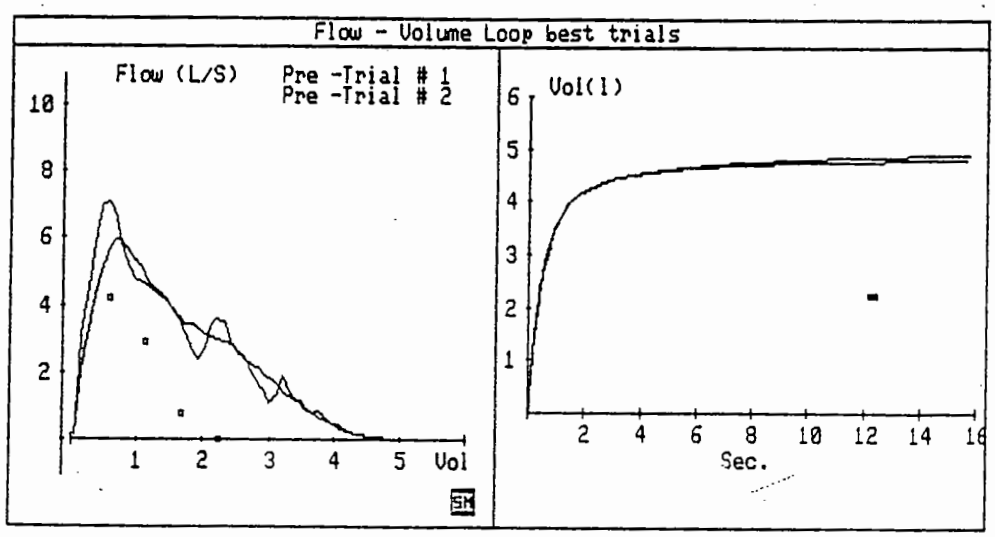
Sample tabular report for the CHS chart: see PFT data set

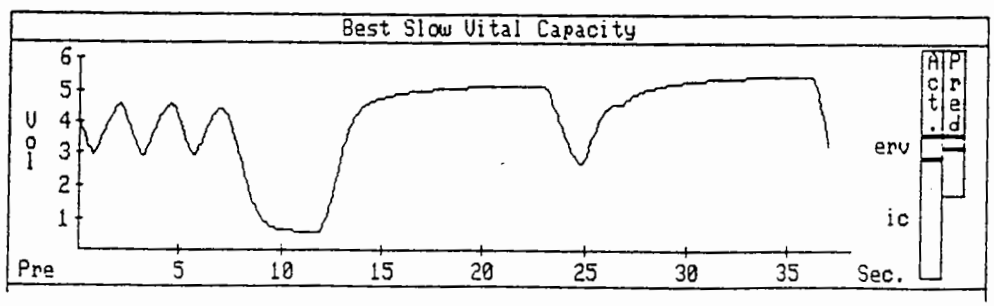
Cardiovascular Health Study
Pulmonary Function Report

Patient : James Garner
ID Number: 12376
Date : 06-11-93
Clinic : ARIZONA
Predicted: Knudson 83

Height: 70.0(in) - 178 (cm) Sex: M
Weight: 190 (lb) - 86 (kg) BMI: 27.3
Age: 54 BP: 760 Temp: 22 ATPS: .918

Pre-dilator		Pred.	Selected	Trial 1 Actual	(%)	Trial 2 Actual	(%)	Trial 3 Actual	(%)
FVC	(L)	4.62	5.60	5.33	115	5.60	121	5.27	114
FEV1	(L)	3.73	4.09	3.99	107	4.09	110	3.83	103
FEV1/FVC	(%)	80.9	73.1	74.9	93	73.0	90	72.7	90
PEF	(L/s)	8.8	11.8	11.7	132	11.8	134	12.5	142
Exp time	(sec)		12.0	11.9		12.0		14.1	
PEFT	(sec)		0.060	0.060		0.060		0.050	
BEV	(mL)		91	92		91		60	
SEQ#		6	2	1	17	2	35	3	52
QC code			32			32			





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see PFT data set

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. First check the spirometer's **water level.** Water should always be visible through the round window.

Note: If the water level is not visible, add distilled water as follows: grasp the black knob at the top of the bell, raise the bell several inches, and pour water against the side of the bell to prevent spillage.

2. Attach a breathing hose. Raise the spirometer bell by the black knob to midposition (approximately 4 liters) and hold it as you cork the white mouthpiece adaptor with the #6 rubber stopper.

Don't lift the bell by the clear plastic guides.

3. Place the black kymograph drum gently on top of the spirometer bell (to provide a constant pressure within the spirometer).

4. Enter a test time of 1 minute.

The Leakage Rate displayed after one minute should be less than 40 cc/min.

If a Leak is Detected Determine whether the leak is in the breathing tube, the blue internal tube, or in the spirometer bell as follows:

1. Disconnect the breathing tube from the spirometer. Raise the bell halfway and insert a #7 solid stopper into the metal breathing tube connector at the front of the spirometer. Place the weight on top of the spirometer bell.

2. Select LEA again and enter a time of 1 minute. Start the leak test.

If the Leakage Rate is now less than 40 cc/min, then the breathing tube is 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, then the internal tube or the bell is leaking.

3. Reach underneath and inside the spirometer, and disconnect the internal tube from the topmost internal port. Raise the bell halfway and insert a #7 solid stopper into this topmost internal metal tube connector. Place the weight on top of the spirometer bell. Repeat Step 3.

If the Leakage Rate is now below 40 cc/min, then the internal tube is leaking - throw it away and replace it with a new one. If, however, the Leakage Rate is still above 40 cc/min, then the leak is in the spirometer bell. Replace it and check the new bell for leaks and recalibrate the system.

To locate a leak in the spirometer bell, remove the bell, turn it upside down, and fill it with about an inch of water (above the seam). Tip the bell at an angle and turn it, observing to see where water escapes. Repair it with silicone sealant.

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see PFT data set

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 Hans Rudolph 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. 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. (The Flow reading should be between -0.05 and +0.05 with the bell empty.)

If the volume calibration error is too high 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.

- A large flow number (beyond -20 or +20 liters/sec) may indicate a problem with the A/D interface. Call the PF Reading Center to discuss this.

ADJ If the volume error was greater than 5% 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.

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CLEANING THE SPIROMETER see PFT data set

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 when using the disinfectant since it causes a rash in some persons. Rinse thoroughly and hang them to dry completely overnight before reusing.

Clean the Spirometer every Friday afternoon. You will need a small screwdriver and one liter of distilled water.

1. Unplug the spirometer power cord and disconnect the cable leading from the base of the spirometer to the rear of the computer. Lift off the kymograph drum. Detach the white breathing tube.

2. There are two vertical guide rods located on either side of the spirometer. At the top of the guide rod holding the square red potentiometer (pot) is a **bell stop** which prevents the spirometer bell from being raised to a position which could damage the grey plastic shaft. Unscrew and remove the bell stop. **The grey plastic shaft is very fragile.** Do not twist it. Do not bend it except when it is fully extended.

3. Loosen, by 1/2 turn, the **white screw** at the top of the pot clamp.

4. At the top of the spirometer bell, across from the potentiometer clamping piece, is the **pen holder screw**. Remove this screw. Raise the spirometer bell up about six inches by the black knob, then gently slide the silver clamp away from the white screw and remove the bell.

5. Wash the inside and outside of the spirometer bell with **vinegar** and rinse with water. Vinegar will remove the fi that tends to build up on the bell. CAUTION: The plastic bell is very frag Don't squeeze it. Don't lay it on its sic

6. **Drain** the spirometer by tipping it sideways over a sink. Avoid getting ar water near the grey pot shaft.

7. Remove the **blue internal hose:** reac up under the spirometer and twist the e off the metal tubes. Clean it just like th white breathing tubes. Swab the inside the two stainless steel breathing tubes (the top and front of the bell housing) wit alcohol to disinfect them.

8. **Replace the bell:** Insert the clear plas guides over the rods, then slide the silver clamp under the white screw before lowering the bell. Insert and retighten th pen holder screw, making sure the clear pen holder doesn't rub against the tan wa of the spirometer. Tighten the white screw. CAUTION: Be sure to not secure the white screw too tightly, as this may cause the potentiometer rod to break (a $250 repair). Lift the bell and make sure that it moves freely from 0 to 8 liters.

Replace the bell stop. Position the bell stop so that the pen stops at the top line on the paper chart (8.0 liter mark) when the spirometer is filled with air.

9. Attach a clean blue internal hose securely. Reattach the cable to the computer. Wait until ready to operate the spirometer again, then refill it with one liter of **distilled** water and attach a clean breathing tube.

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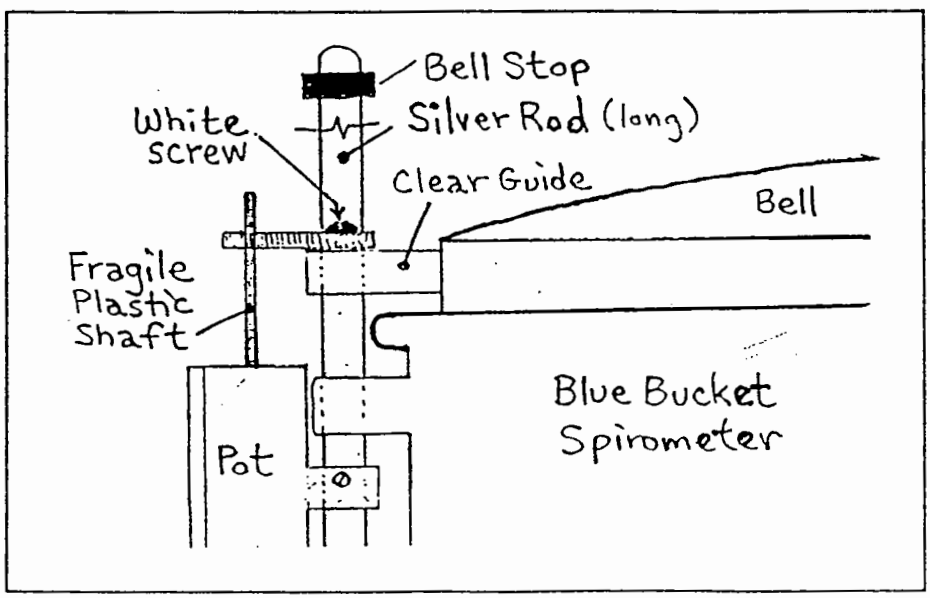
Calibration Syringe Care

See PFT data set

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.



Cleaning the Spirometer

see PFT data set

TECH CERTIFICATION

The certification examination includes 50 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 75 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 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.

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. Personal computer systems, such as the S&M Instruments system used by the CHS, have 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.

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see PFT data set

ıplementation of QC Procedures. There 'e five separate levels of quality control ıplemented for spirometry testing which ıdress the five factors known to influence ıe results:

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

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

ı. 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.

ı. 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 999xxxc 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.

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QC ANALYSIS AND REPORTING see PFT data set

Each week the PF Reading Center will establish a modem connection with each Field Center and download all PF data for participants tested during the previous week and the calibration result files.

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.

ANNUAL INSTRUMENT CHECKS

see PFT data set

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.

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PEAK FLOW MONITORING see PFT data set

Background. Peak expiratory flow (PEF) occurs during the first tenth of a second of the FVC maneuver. PEF is a quick and easy-to-obtain index of airway patency because 1) unlike the entire FVC maneuver, the patient doesn't need to exhale for more than a second, and 2) unlike a spirometer, instruments to measure PEF are small and cost only about $20. The portability and low cost of peak flow meters make it possible to give trained patients a PEF meter to take home so that a measure of the degree of airflow obstruction can be obtained in their own environment 1-4 times a day for a week or two (31-33). This is called ambulatory monitoring or home monitoring.

Although the PEF is less accurate and less reproducible than the FEV1 as an index of airways obstruction, the FEV1 has a temporal disadvantage: since it currently can only be measured during an office visit, it provides only a single "snapshot" of airways obstruction. Airway smooth muscle tone, however, varies from hour-to-hour and day-to-day in healthy persons and an increase in this variation is a primary characteristic of asthma (and persons with less severe airways hyper-responsiveness). Ambulatory monitoring of PEF allows measurement of this variability or "lability."

The usual diurnal variation of PEF is for the smallest value to occur during the early morning hours, the so-called "morning dip," while the largest value occurs during midday or late afternoon. The difference between the minimum PEF value and the maximum PEF value during the day (max-min) is the amplitude. In order to correct for differences in body size, a "lability index" is calculated by dividing the amplitude by the mean PEF and expressing the result as a percent. Healthy persons have a mean lability index of about 5% while at the other end of the spectrum, patients with a diagnosis of asthma often have more than 30% lability within a day. The generally accepted cutoff between normal and asthma for adults is 20% lability (34-36).

Daily measurement of PEF for a week or two increases the likelihood that provocative exposures will naturally occur, therefore, the sensitivity of the test improves over measurement for a single day. Monitoring for several days necessitates a diary in which the study participant writes the date, time, and PEF.

Instruments. Several PEF meters are now available. The Mini-Wright model has traditionally been selected for epidemiologic studies, but the new Personal Best model is more compact, more rugged, easier to read the results, more hygienic, and just as accurate. The NHLBI recently published accuracy standards for PEF meters and recommendations for their use (37). The Personal Best is typically accurate to within 5% of the "gold standard" PEF from ATS waveform #24. This accuracy is usually maintained for many months of use (38). In order to reduce expense, after each use, PEF meters will be cleaned and accuracy verified at the PF Reading Center. They will then be shipped back to the Field Centers and reused by several study participants before they are discarded, lost, or broken.

see PFT data set

PEF Training. Study technicians must train participants how to properly perform PEF ambulatory monitoring during the clinic visit. Training will proceed as follows:

1. Show the participant the PEF meter and its parts. Explain that we would like him to take it home to measure his lung function himself for a week in order to see how daily exposures to dusts, fumes, and smoke affect his lungs. (The participant is referred to as a male for easy reading here.) Ask him if he is willing to do so. If he is reluctant, show how easy it is and explain that he need not return to the clinic, but merely mail the PEF meter and diary back to the study in a week, in a prepaid envelope.

2. Demonstrate the correct PEF maneuver (just like the FVC maneuver only you can quit after a second). Show how to read the results and reset the needle back to zero. Tell him to repeat the maneuver 3 times and mark the highest reading on his diary sheet.

3. Review a sample diary which has been filled out completely and correctly. Describe the ideal times of day to perform the test: as soon as getting out of bed (early AM), and at dinner time from 5-6 PM. Tell him that the best place to keep the PEF meter is next to the bathroom sink where he will be reminded to use it, perhaps when he brushes (or inserts!) his teeth.

4. Ask him to try the maneuver himself. Watch him do so. Correct any errors. Ask him to repeat the PEF maneuver 2 more times while you watch. Select the correct diary form (mean 200, 300, 400, 500, or 600 L/min) according to his largest current value. Show him how to mark that value in the diary by blackening the circle next to the highest PEF value. Compare the PEF with that obtained using the spirometer. *Write his name, ID number, the PEF serial number, today's date, and the days of the week on his diary yourself.*

Binary code the participant's ID number by filling in the appropriate 1,2,4,8 circles below each ID digit (as in the sample diary). For example, if the digit is 5, blacken the 1 and the 4 circles (1 + 4 = 5).

5. Ask the participant if he thinks that these tests will be easy to do, or if travel during the next week will interfere or if he currently has a cold or bronchitis (if so, postpone the start of testing).

Remind him not to *estimate* results if he forgets to perform the test - just leave that time or day blank. Ask if he has any questions about the procedure. Place the PEF meter, instruction sheet and the diary (folded in half) in the postage-paid return envelope.

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INSTRUCTIONS FOR PEAK FLOW see PFT data set

Keep the PEF meter next to the bathroom sink (where you will be reminded to use it).

Perform the test 1) as soon as getting out of bed (early AM) and at dinner time from 4-6 PM. If you take breathing medications, do the test before taking the medicine.

Each time perform the following 6 steps:

1. Stand for the test, if possible. Remove the grey cover and fold the handle.

2. Return the red arrow to the zero position (close to the mouthpiece).

3. Take as deep a breath as you possibly can, hold the meter horizontal, then seal your lips around the mouthpiece, then BLAST out the air as fast as you can ... like a HUFF, for about one second.

4. Repeat step 3 twice more.

5. Note the position of the red arrow and carefully mark the value on your diary under the appropriate day and time of day.

At the end of the week of testing, please return the peak flow meter and your diary to us in the postage-paid envelope provided. If you missed some tests or some days of testing, please do not guess what your values were, just leave the spaces blank. If the peak flow meter becomes inoperative or if the readings are suddenly considerably lower than those previously obtained, please call us.

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see PFT data set

200 L/m baseline PEF DIARY

200	ID	1	2	3	4	5	6	7
○	1	●	○	●	○	●	○	●
●	2	○	●	●	○	○	●	●
○	4	○	○	○	●	●	●	●
○	8	○	○	○	○	○	○	○

Name FRANK KRAMER

Fill in the circles **completely** using a pencil or pen, as in the box to the right. →

Do not mark outside the circles.

PEF S/N	1234
Date:	8/12/93

PEF (L/m)	TUE C	TUE PM	WED AM	WED PM	THUR AM	THUR PM	FRI AM	FRI PM	SAT AM	SAT PM	SUN AM	SUN PM	MON AM	MON PM	TUE AM	TUE PM
—300	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—250	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	●	○	○	○	●
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	●	○	●	○	○	○	●	○	○	○	○	○	○	●	○	○
—200	○	●	○	○	●	●	○	○	○	●	●	○	○	○	●	○
—	○	○	○	●	○	○	○	●	○	○	○	○	●	○	○	○
—	○	○	○	○	○	○	○	○	●	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—150	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
—100	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○

Write in the value if off the chart:

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see PFT data set

REFERENCES

1. Enright PL and Hyatt RE. Office Spirometry: A Practical Guide to the Selection and Use of Spirometers. Lea & Febiger, Philadelphia, 1987.

2. Fried LP, Borhani NO, Enright P, et al. The Cardiovascular Health Study: Design and rationale. *Annals Epidemiol* 1991; 1:263-276.

3. Enright PL, Kronmal RA, Higgins M, Schenker M, Haponik EF. Spirometry reference values for women and men 65-85 years of age: Cardiovascular Health Study. Am Rev Respir Dis 1993; 147:125-133.

4. Enright PL, Kronmal RA, Schenker M, Haponik EF, Manolio T, Hyatt RE. Correlates of respiratory muscle strength, and maximal respiratory pressure reference values in the elderly. Am Rev Respir Dis 1993; 148:xxx

5. Higgins MW, Enright PL, Kronmal RA, Schenker MB, Anton-Culver H, Lyles M. Smoking and lung function in elderly men and women: The Cardiovascular Health Study. JAMA 1993; 21:2741-2748.

6. Higgins MW, Keller JB. Predictors of mortality in the adult population of Tecumseh: Respiratory symptoms, chronic respiratory disease and ventilatory lung function. Arch Environ Health 1970; 21:418-424.

7. Beaty TH, Cohen BH, Newill CA, Menkes HA, Diamond EL, Chen CJ. Impaired pulmonary function as a risk factor for mortality. Am J Epidemiol 1982; 116:102-113.

8. Tockman MS, Khoury MJ, Cohen BH. The epidemiology of COPD in Chronic Obstructive Pulmonary Disease, 2nd ed. Petty TL, Ed. Marcel Dekker, New York 1985; pp. 43-92.

9.

10.

11. Sorlie P, Lakatos E, Kannel WB, Celli B. Influence of cigarette smoking on lung function at baseline and at follow-up in 14 years: The Framingham Study. J Chron Dis 1987; 40:849-856.

12. Discher DP, Massey F, Hallett WY. Quality evaluation and control methods in computer assisted screening. Arch Environ Health 1969; 19:323-333.

13. Townsend MC, DuChene AG, Fallat RJ. The effects of underrecorded forced expirations on spirometric lung function indices. Am Rev Respir Dis 1982; 126:734-737.

14. Townsend MC, Morgan J, Durkin D, DuChene AG, Lamb S. Quality control aspects of pulmonary function testing in the Multiple Risk Factor Intervention Trial. Control Clin Trials 1986; 7:179S-192S.

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see PFT data set

15. Gardner RM, Crapo RO, Billings JW, Shigeoka JW, Hankinson JC. Spirometry - what paper speed? Chest 1983; 84:161.

16. Dales RE, Hanley JA, Ernst P, Becklake MR. Computer modelling of measurement error in longitudinal lung function data. J Chron Dis 1987; 40:769-773.

17. Townsend M. The effects of leaks in spirometers on measurements on pulmonary function. The implications for epidemiologic studies. J Occupational Med 1984; 26:835-841.

18. Burrows B, Lebowitz MD, Camilli AE, Knudson RJ. Longitudinal changes in FEV1 in adults. Methodologic considerations and findings in healthy nonsmokers. Am Rev Respir Dis 1986; 133:974-980.

19. Ferris BG. Epidemiology Standardization Project. III. Recommended standardized procedures for pulmonary function testing. Am Rev Respir Dis 1978; 118:55-88.

20. Gardner RM, Hankinson JL, Clausen JL, Crapo RO, Johnson RL, Epler GR. Standardization of spirometry -- 1987 update. Official statement of the American Thoracic Society. Am Rev Respir Dis 1987; 136:1285-1298.

21. Nelson SB, Gardner RM, Crapo RO: Performance evaluation of contemporary spirometers. Chest 1990; 97:288-297.

22. Vollmer WM, Johnson LR, McCamant LE, Buist AS. Methodologic issues in the analysis of lung function data. J Chron Dis 1987;40:1013-1023.

23. Ostler DV, Gardner RM, Crapo RO. A computer system for analysis and transmission of spirometry waveforms using volume sampling. Computers Biomed Res 1984; 17:229-240.

24. Enright PL, Johnson LR, Connett JE, Voelker H, Buist AS. Spirometry in the Lung Health Study: 1. Methods and Quality Control. *Am Rev Respir Dis* 1991; 143:1215-1223.

25. Hankinson JL, Viola JO, Ebeling T, Knutti E, Pappas G. NHANES III Spirometry Instrumentation and Quality Control. NIOSH Division of Respiratory Disease Studies. May 1988, Draft #304-291-4755.

26. Hankinson JL, Bang KM: Acceptability and reproducibility criteria of the American Thoracic Society as observed in a sample of the general population. Am Rev Respir Dis 1991; 143:516-521.

27. Hankinson JL, Castellan RM, Kinsley BS, Keimig DG. Effect of spirometer temperature on measurement of FEV1 shift changes. J Occupat Med 1986; 28:1222-1225.

28. Krowka MJ, Enright PL, Rodarte JR, Hyatt RE. Effect of effort on measurement of FEV1. Am Rev Respir Dis 1987; 136:829-833.

(91)

see PFT data set

29. American Thoracic Society official Statement: Lung function testing: Selection of reference values and interpretative strategies. Am Rev Respir Dis 1991; 144:1202-1218.

30.

31. Woolcock AJ. Epidemiologic methods for measuring prevalence of asthma. Chest 1987; 91:89S-92S.

32. Sheffer AL (chairman) for the International Asthma Management Project. International consensus report on diagnosis and treatment of asthma. DHHS NIH publication 92-3091 and Eur Respir J 1992; 5:601-641.

33. Lebowitz MD. The use of peak expiratory flow rate measurements in respiratory disease. Ped. Pulmonol. 1991; 11: 166-74.

34. Lebowitz MD, Krzyzanowski M, Quackenboss JJ. Diurnal variation of PEF and its use in epidemiological studies. In press, 1992.

35. Quackenboss JJ, Lebowitz MD, Krzyzanowski M. The normal range of diurnal changes in peak expiratory flow rates: relationship to symptoms and respiratory disease. Am Rev Respir Dis 1991; 143:323-330.

36. Higgins BG, Britton JR, Chinn S, et al. The distribution of peak expiratory flow variability in a population sample. Am Rev Respir Dis 1989; 140:1368-1372.

37. Cherniack RM, Hurd SS for the NAEP and NHLBI. Statement on technical standards for peak flow meters, 1991.

38. Venables KM, Burge PS, Davison AG, Newman Taylor AJ. Peak flow records in surveys: reproducibility of observers reports. Thorax 1984; 39:828-832.

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Appendix B: Exam Referral Forms

Neurology Clinic Referral Form

No Data Set, Internal Tracking Sheet

ID#:_____ Name:_____

Date:____/____/____ Person Making Referral:_____

Source of Referral:_____

1 = Hospital Admission
2 = Biennial Exam
3 = Offspring Exam
4 = Family
5 = Medical Records
6 = Other (Please specify)
7 = Review

Reason for Referral:_____

_____

Reason for Hospitalization (if applicable):_____

_____

Living Situation (if applicable): _____

1 = Own Home
2 = Elderly House
3 = Hospital
4 =Relative's Home
5 = Nursing Home
6 = Other

DISPOSITION (OFFICE USE)

Date Opened: ____/____/____
Date Closed: ____/____/____

1. To be scheduled for Neuro Clinic
2. Seen in Neuro Clinic: ____/____/____
3. Medical Records to be Obtained
4. Medical Records Complete: ____/____/____
5. Review Status:_____
   1 = Reviewed
   2 = Awaiting review
   3 = No review to be done
6. Enrolled Case in Stroke Study:_____
   1 = No
   2 = Yes
   Date:____/____/____
7. Reasons Not Seen:_____
   1 = N/A
   2 = Refused
   3 = Deceased
   4 = Out of state
8. Previously Seen:_____
   1 = Stroke
   2 = Dementia

Stroke Tracking Referral Form
The Framingham Study

No data, Internal Tracking Sheet

* Please complete the upper portion of this form if you identify a new neurological event.

ID#:_____ Name:_____

Date Opened: ____/____/____

Date of Event: ____/____/____ Date Type:____ (0=Exact, 1=Approximate)

Source of Referral:_____

1 = Hospital Admission
2 = Biennial Exam
3 = Offspring Exam
4 = Family
5 = Medical Records
6 = Review
7 = Other (Please specify)

Initials:_____

Reason for Referral:_____

Reason for Hospitalization:_____ (1=Neurology, 2=Other, 8=NA)

Comments:_____

_____

_____

DISPOSITION (FOR TRACKING PERSONNEL TO COMPLETE)

1. Dictation:_____ (0=Awaiting, 1=In)
2. To be Scheduled in Stroke Clinic:_____ (0=No, 1=Yes, 2=Pending)
3. Date Seen in Stroke Clinic:____/____/____
4. Reason Not Seen in Clinic:_____ (1=NA, 2=Refused, 3=Deceased, 4=Out of State)
5. Part of PSIP Follow-Up Protocol:_____ (0=No, 1=Yes, 9=Unknown)
6. Previously Seen:_____ (0=No, 1=Stroke, 2=Dementia, 3=Other)
7. Medical Records needed:_____ (0=No, 1=Yes)
8. Date:____/____/____
9. CT/MRI/MRA to be obtained:_____ (0=No, 1=Yes)
10. Date:____/____/____
11. Review Status:_____ (1=Awaiting Review, 2=Reviewed, 3=Need Info)
12. Date Reviewed:____/____/____
13. Status of Case:_____ (1=Open, 2=Closed)
14. Date:____/____/____
15. Diagnosis:_____
    (1=Stroke, 2=TIA, 3=? TIA, 4=Parkinson's, 5=No CVA, 6=Other Neuro, 7=Migraine, 10=?Stroke, 20=Recurrent TIA, 9=Unknown)

Record Of Telephone Encounter

(to be filed in chart)

No Data, Internal Tracking Sheet

Participant's ID#: _____ Participant's Name: _____

Date of Incident: ____/____/____

Person Contacted:_____

_____

Regarding:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Contact Made By:_____

_____

_____

Record Of In-Clinic Medical Encounter

(to be filed in chart)

No Data, Internal Tracking Sheet

Participant's ID#: _____ Participant's Name:_____

Date of Incident: ____/____/____

Description of Incident:

_____

_____

_____

_____

_____

_____

_____

_____

Physician:_____

Follow-Up (if any)

Date of Follow-Up: ____/____/___

_____

_____

_____

_____

_____

_____

_____

Physician/Staff:_____

Glucose Challenge Incident Log

No Data, Internal Tracking Sheet

Date	ID#	Comments
___/___/___		
___/___/___		
___/___/___		
___/___/___		
___/___/___		
___/___/___		
___/___/___		
___/___/___		
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___/___/___		
___/___/___		
___/___/___		
___/___/___		

Appendix C: Technician Reproducibility Forms

Framingham Heart Study
Repeat Ankle Blood Pressure Observations

ankle-arm BP reproducibility
QC Purposes only

ID TYPE/ID: _____ PARTICIPANT'S NAME: _____

DATE: _____

TECHNICIAN: _____ (1 = First Technician, 2 = Second Technician)

TECHNICIAN ID: _____

Every technician should, with a second technician, repeat arm and ankle systolic pressures with the Doppler. Each technician should separately (and out of the other's view), record her or his measurement. If the difference in measurement on any given measurement is greater than 10 mmHg, or if the average of the readings for each technician differ by more than 3 mmHg, the measurement should be redone.

_____	Initial Cuff Size Selected - Arm
_____	Initial Cuff Size Selected - Leg
_____	Right Maximal Inflation Level - Arm
_____	Right Maximal Inflation Level - Leg
_____	First SBP - Right Arm
_____	First SBP - Left Arm
_____	First SBP - Right Leg
_____	First SBP - Left Leg
_____	Second SBP - Left Leg
_____	Second SBP - Right Leg
_____	Second SBP - Left Arm
_____	Second SBP - Right Arm
_____	Repeat SBP - Right Arm
_____	Repeat SBP - Left Arm
_____	Repeat SBP - Right Leg
_____	Repeat SBP - Left Leg

Cuff Size:
1 = Regular
2 = Pedi
3 = Large
4 = Thigh

Consistently different blood pressure measurements (> 10 mmHg) should be brought to the attention of Dr. Joanne Murabito.

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Framingham Heart Study
Repeat Standing Height/Weight Observations

height/weight reproducibility
QC purposes only

ID TYPE/ID: _____ PARTICIPANT'S NAME: _____

DATE: _____

TECHNICIAN: _____ (1 = First Technician, 2 = Second Technician)

TECHNICIAN ID: _____

Every technician should, with a second technician, measure one set of height/weight measurements on a monthly basis. Each technician should separately (and out of the other's view) record her or his measurement. If the difference in measurement on any given weight is greater than 0.5 pounds (or the average of 1 pound), or the height is more than 1/4 inch, the measurement should be redone.

_____ Weight Measurement

_____ Height Measurement

_____ Repeat Weight Measurement

_____ Repeat Height Measurement

Consistently different anthropometric measurements (> 0.5 lb. or 1/2 in.) should be brought to the attention of Dr. Joanne Murabito.

Framingham Heart Study
Repeat Anthropometric Measurements

girth measurement reproducibility QC purposes only

ID TYPE/ID: _____ PARTICIPANT'S NAME: _____

DATE: _____

TECHNICIAN: _____ (1 = First Technician, 2 = Second Technician)

TECHNICIAN ID: _____

Every technician should, with a second technician, repeat anthropometric measurements. Each technician should separately (and out of the other's view), record her or his measurement. Repeat measurements should be taken if the neck is more than 1/4" different, or if the waist , hip, and thigh girths are more than 1/2" different.

REGIONAL ANTHROPOMETRY

____ ____ • ____ ____ Neck Circumference (inches, to next lower 1/4 inch)

____ ____ • ____ ____ Waist Girth (inches, to next lower 1/4 inch)

____ ____ • ____ ____ Hip Girth (inches, to next lower 1/4 inch)

SAME TECHNICIAN REPEAT REGIONAL ANTHROPOMETRY

____ ____ • ____ ____ Neck Circumference (inches, to next lower 1/4 inch)

____ ____ • ____ ____ Waist Girth (inches, to next lower 1/4 inch)

____ ____ • ____ ____ Hip Girth (inches, to next lower 1/4 inch)

Consistently different measurements should be brought to the attention of Dr. Joanne Murabito.

Framingham Heart Study
Repeat Technician's Blood Pressure Observation

blood pressure reproducibility
QC purposes only

ID TYPE/ID: _____ PARTICIPANT'S NAME: _____

DATE: _____

TECHNICIAN: _____ (1 = First Technician, 2 = Second Technician)

TECHNICIAN ID: _____

Every technician should separately (and out of the other's view) record his or her measurements. If the measurements on any given measurement is greater than 4 mmHg, or if the average of the readings for each technician differ by more than 3 mmHg, the measurement should be redone.

_____	Initial Cuff Size Selected	**Cuff Size:**
_____	Palpated Systolic Pressure	**1 = Regular**
_____	SBP	**2 = Pedi**
_____	DBP	**3 = Large**
_____	Repeat SBP	**4 = Thigh**
_____	Repeat DBP	

Consistently different blood pressure measurements (> 4 mmHg) should be brought to the attention of Dr. Joanne Murabito.

Technician Certification Check List

No Data, Internal use only

Tech #	Procedure	Date of Certification or Recertification	Certifier
_____	Arm/Ankle Pressures	____/____/____	_____
_____	Arm/Ankle Pressures	____/____/____	_____
_____	Arm/Ankle Pressures	____/____/____	_____
_____	Blood Pressure (Sitting)	____/____/____	_____
_____	Blood Pressure (Sitting)	____/____/____	_____
_____	Blood Pressure (Sitting)	____/____/____	_____
_____	Blood Pressure (Sitting)	____/____/____	_____
_____	Blood Pressure (Sitting)	____/____/____	_____
_____	Girth Measurements	____/____/____	_____
_____	Girth Measurements	____/____/____	_____
_____	Girth Measurements	____/____/____	_____
_____	Girth Measurements	____/____/____	_____
_____	Interview/Questions	____/____/____	_____
_____	Interview/Questions	____/____/____	_____
_____	Interview/Questions	____/____/____	_____
_____	Interview/Questions	____/____/____	_____
_____	Interview/Questions (Home/Nursing Homes)	____/____/____	_____
_____	Spirometry	____/____/____	_____
_____	Spirometry	____/____/____	_____
_____	Spirometry	____/____/____	_____
_____	Spirometry	____/____/____	_____
_____	12 - Lead ECG	____/____/____	_____
_____	12 - Lead ECG	____/____/____	_____
_____	12 - Lead ECG	____/____/____	_____
_____	12 - Lead ECG	____/____/____	_____
_____	12 - Lead ECG	____/____/____	_____
_____	Weight/Height	____/____/____	_____
_____	Weight/Height	____/____/____	_____
_____	Weight/Height	____/____/____	_____
_____	Weight/Height	____/____/____	_____

Appendix D: Supervisory Observation Forms

Supine Ankle-Arm Blood Pressure Examination Supervisor Check List

See ankle-arm blood pressure data set

Date:____/____/____ Technician #:_____ Supervisor:_____

Instructions: For each item, circle Y (yes) or N (no) to indicate whether the procedure is carried out correctly. Record any comments in the blank space between that item and the next.

Right Arm Systolic Blood Pressure Measurement:

Y N Applies appropriate size cuff to right arm.

Y N Attaches cuff tubing to manometer.

Y N Applies ultrasound jelly over brachial artery.

Y N Located brachial artery using Doppler probe.

Y N Stands next to the participant's arm.

Y N Measures the systolic blood pressure using the Doppler probe and standard manometer.

- Inflates cuff quickly to maximal inflation level.
- Deflates at 2mmHz/second to appearance of systolic pressure.
- Deflates cuff quickly and completely.

Y N Records right arm systolic blood pressure.

Left Arm Systolic Blood Pressure Measurement:

Y N Applies appropriate size cuff to left arm.

Y N Attaches cuff tubing to manometer.

Y N Applies ultrasound jelly over brachial artery.

Y N Located brachial artery using Doppler probe.

Y N Stands next to the participant's left arm.

Y N Measures the systolic blood pressure using the Doppler probe and standard manometer.

- Inflates cuff quickly to maximal inflation level.
- Deflates at 2mmHz/second to appearance of systolic pressure.
- Deflates cuff quickly and completely.

Y N Records left arm systolic blood pressure.

see ankle-arm blood pressure data set

Right Ankle Systolic Blood Pressure Measurement:

Y N Applies appropriate size cuff to right ankle.

Y N Attaches cuff tubing to manometer.

Y N Applies ultrasound jelly over brachial artery.

Y N Located posterior tibia using Doppler probe.

Y N Stands by the participant's right ankle.

Y N Measures the systolic blood pressure using the Doppler probe and standard manometer.

Inflates cuff quickly to maximal inflation level.
Deflates at 2mmHz/second to appearance of systolic pressure.
Deflates cuff quickly and completely.

Y N Records right ankle systolic blood pressure.

Left Ankle Systolic Blood Pressure Measurement:

Y N Applies appropriate size cuff to left ankle.

Y N Attaches cuff tubing to manometer.

Y N Applies ultrasound jelly over brachial artery.

Y N Located posterior tibia using Doppler probe.

Y N Stands by the participant's left ankle.

Y N Measures the systolic blood pressure using the Doppler probe and standard manometer.

Inflates cuff quickly to maximal inflation level.
Deflates at 2mmHz/second to appearance of systolic pressure.
Deflates cuff quickly and completely.

Y N Records left ankle systolic blood pressure.

Repeat of Ankle-Arm Measurements:

Y N Repeats the sequence of measurements in reverse order:

Left ankle
Right ankle
Left arm
Right arm

Completion:

Y N Reviews form for completeness.

Y N Removes cuffs and conducting jelly.

see ankle-arm blood pressure data set

Overall comments of supervisor:

Instructions to technician/corrective action:

_____

Signature, Supervisor

Girth Measurements QC Supervisor Check List

9444 - 9446

Date: ____/____/____ Technician #: _____ Supervisor:_____

Instructions: Check that each procedure is carried out correctly. Circle Y (yes) if correct. If incorrect, circle N (no) and provide an explanation in the space following the item or at the end of the section. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

Waist Circumference Measurements:

Y	N	Participant is standing erect and facing straight ahead, arms hanging loosely at sides and weight equally distributed on both feet.
Y	N	The tape is applied at the level of the umbilicus, underneath the underwear.
Y	N	The tape is neither too loose nor too tight and is horizontal.
Y	N	The measurement is recorded to the nearest 1/4 pound, rounding down.

Hip Circumference Measurements:

Y	N	Participant is standing erect and facing straight ahead, arms hanging loosely at sides and weight equally distributed on both feet.
Y	N	The tape is applied at the level of the maximal protrusion of the gluteal muscles, over the underwear.
Y	N	The tape is horizontal.
Y	N	The measurement is recorded to the nearest 1/4 pound, rounding down.

Neck Girth Circumference:

Y	N	The participant is standing erect, arms hanging loosely at sides, weight equally distributed on both feet, and head in Frankfort horizontal plane.
Y	N	Standing to face the left side of the participant, the thyroid cartilage is located by gentle palpitation of the neck. The participant is asked to swallow to identify the correct spot.
Y	N	The tape measure is placed just inferior to the laryngeal prominence.
Y	N	The tape is applied snugly, but not tightly, perpendicular to the long axis of the neck at approximately a 90% angle.
Y	N	The neck circumference is recorded to the nearest 1/4 inch, rounding down.

9444-9446

Overall comments of supervisor:

Instructions to technician/corrective action:

_____

Signature, Supervisor

Weight and Height Supervisor Check List

9440, 9441

Date:____/____/____ Technician #:_____ Supervisor:_____

Instructions: Check that each procedure is carried out correctly. Circle Y (yes) if correct. If incorrect, circle N (no) and provide an explanation in the space following the item or at the end of the section. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

Weight Measurements:

Y	N	Scale is positioned at zero.
Y	N	Participant is not wearing shoes.
Y	N	Participant's weight is equally distributed on both feet.
Y	N	Participant is not supporting himself or herself.
Y	N	Examiner's eyes are level with the point of measurement.
Y	N	The measurement is recorded, rounding down to the nearest pound.

Height Measurements:

Y	N	Participant is not wearing shoes.
Y	N	Participant is standing erect with his/her back to the stadiometer.
Y	N	Participant's heels are together and against the stadiometer.
Y	N	Participant faces straight ahead.
Y	N	Examiner's eyes are level with the point of measurement.
Y	N	The measurement is recorded to the nearest quarter inch, rounding down.

Overall comments of supervisor:

Instructions to technician/corrective action:

_____

Signature, Supervisor

Standard Blood Pressure Examination Supervisor Check List

9450, 9451

Date:____/____/____ Technician #:_____ Supervisor:_____

Instructions: For each item, circle Y (yes) or N (no) to indicate whether the procedure is carried out correctly. Record any comment in the blank space between that item and the next. For certain items, specific parts of the procedure which are important are listed separately.

The following items apply throughout the exam:

Y	N	Participant is kept warm, relaxed, and comfortable.
Y	N	Participant is discouraged from talking, except to voice discomfort or confusion about instructions.

Standard blood pressure examination:

Y	N	Technician greets and informs participant appropriately.
Y	N	Technician bares participant's arm to allow proper placement of cuff.
Y	N	Technician assesses participant's arm for correct cuff size.
Y	N	Technician palpates brachial artery.
Y	N	Technician wraps cuff center of bladder over brachial artery.
Y	N	Instructs participant on posture.
Y	N	Finds palpated systolic pressure using standard manometer.
Y	N	Calculates maximal inflation level, standard manometer.
Y	N	Waits at least 30 seconds before proceeding.
Y	N	Keeps work station free of excessive noise.
Y	N	Places stethoscope in ears, earpieces forward.
Y	N	Inflates rapidly to maximal inflation level.
Y	N	Places bell on brachial pulse.
Y	N	Deflates cuff 2 mmHg per second.
Y	N	Deflates cuff 10 mmHg below diastolic.
Y	N	Opens thumb valve or disconnects tubing.
Y	N	Records readings.

9450, 9451

Overall comments of supervisor:

Instructions to technician/corrective action:

_____

Signature
Blood Pressure Supervisor

12 - Lead ECG Supervisor Check List

9356 - 9391

Date:____/____/____ Technician #:_____ Supervisor:_____

Instructions: Please circle Y (yes) or N (no) to indicate if the technician correctly performed the specific maneuver.

Y	N	The participant's correct name and ID number are entered into the MAC.
Y	N	Participant's arms are resting comfortably on the bed alongside the body.
Y	N	Technician has established a rapport with the participant so the participant is at ease with the procedure.
Y	N	Electrode location V2 is located in the 4th intercostal space at the left sternal border.
Y	N	V1 is at the same level as V2 but at the right sternal border.
Y	N	The E point is located at the intersection of the 5th intercostal space and the mid-clavicular line.
Y	N	V6 is located in the mid-axilla at the same level as the E point. (The DAL-square should be firmly placed on the body and kept on a horizontal plant from the E point to the mid-axillary point.)
Y	N	The difference between the E-0 measurement and the 0-V6 measurement is calculated.
Y	N	The measurements (in the item directly above) are accurately recorded on the log sheet.
Y	N	The difference from the above calculation is located on the DAL-square and V4 is located on the chest .
Y	N	V3 is located midway between V2 and V4.
Y	N	V5 is located midway between V4 and V6.
Y	N	RL is located on the inside right ankle.
Y	N	LL is located on the inside left ankle.
Y	N	RA is located on the outside right wrist.
Y	N	LA is located on the outside left wrist.
Y	N	The electrode labels are checked before positioning to guard against lead misplacement.
Y	N	The paper ECG record is reviewed for quality and corrective action is taken if necessary.

9356-9391

Overall comments of supervisor:

Instructions to technician/corrective action:

_____

Signature, Supervisor

Interview Supervisor Check List

No Data, Internal use only

Date:____/____/____ Technician #:_____ Supervisor:_____

Using the scale key below, evaluate the interviewer's performance for each of the following procedures. Write any comments in the spaces provided.

Key:
- **N/A** Not applicable
- **1** Unsatisfactory (failed to meet standards)
- **2** Below expectations (did not meet some standards)
- **3** At expectation (met standards)
- **4** Above expectation (met all standards and in some instances exceeded them)
- **5** Outstanding (distinguished performance, consistently exceeded all standards)

N/A 1 2 3 4 5 Answers respondent's questions and concerns.
Comments:_____

N/A 1 2 3 4 5 Speaks slowly and distinctly, reading the questions at neutral/even pace.
Comments:_____

N/A 1 2 3 4 5 Maintains the focus of the interview but allows participant to express thoughts.
Comments:_____

N/A 1 2 3 4 5 Follows instructions/reads questions as they are written.
Comments:_____

N/A 1 2 3 4 5 Initiates (where needed) appropriate non-leading questions.
Comments:_____

N/A 1 2 3 4 5 Records/codes answers correctly (follows skip patterns as needed).
Comments:_____

N/A 1 2 3 4 5 Reviews forms.
Comments:_____

N/A 1 2 3 4 5 General overall rating.
Comments:_____

Signature of Reviewer:_____

SPIROMETRY QUALITY CONTROL SUPERVISOR CHECK LIST

PFT data set

Date:_____ Technician #:_____ Supervisor:_____

Instructions: Check that each procedure is carried out correctly. Circle **y** (*yes*) if correct. If incorrect, circle **n** (*no*) and provide an explanation in the space following the item or at the end of the section. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

Preparation:

y n Participant is asked if s/he has, within the past 3 months, had any major surgery, a heart attack, stroke, or aneurysm.

y n Participant's blood pressure is <210/120.

y n Participants name, ID #, age, sex, height, weight, and race are correctly entered on screen 1.

y n If the participant is a smoker or has a known medical condition, that is noted on the "comments" section of screen 2.

y n Neck measurement, standing or sitting, and tech ID are correctly entered

y n Data screen is closed and testing screen is opened.

y n A clean cardboard tube is inserted into the hose.

Testing Procedure:

y n The tech explains the procedure for testing, explaining to take as deep a breath as possible and blowing out as hard as possible, maintaining the exhale for 10-15 seconds or until told to stop. The tech demonstrates the correct technique.

y n The participant is advised to stop blowing if s/he feels lightheaded or dizzy, and to sit down.

y n Participant is made aware that 3 matches are needed, and that it often takes more than 3 trials to achieve that goal.

y n Participant faces spirometry machine with the back close to the chair.

y n When the participant is ready the examiner puts a noseclip on the subject.

y n Examiner forcefully says "Blast out" (or words to that effect) and encourages the participant to keep pushing until the EOT plateau has been reached and it has been a minimum of 10 seconds, or 15 seconds have elapsed.

y n Examiner carefully observes the participant's body language.

y n Tech is encouraging and acts as a good coach.

y n Tech presses the space bar to save the maneuver when appropriate.

PFT data set..

y	n	Tech presses the spacebar to get the results screen and as testing progresses she compares trials to see if the maneuvers are close matches.
y	n	If necessary, tech explains how to improve performance and again demonstrates the correct procedure.
y	n	Tech appropriately identifies when an adequate number of maneuvers have been performed (or when the participant is unable to continue).
y	n	Testing is stopped if participant cannot obtain 3 matches after 8 trials (unless s/he is willing to try another)
y	n	After testing is completed, screen is closed by pressing ESC button 2 times.
y	n	Participant is asked to remove white cardboard tube from the hose and dispose of it. Nose plug is put in a separate container to be washed later.
y	n	Participant is thanked for doing a good job/working so hard, etc.
y	n	If necessary, notes on the participant or test observations are entered in the comment after the participant has left the room.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor

2/97

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Appendix E: Problems/Corrective Action Log

Problems/Corrective Action Log

ECGs

9356 - 9391

Date	Problem	Date	Corrective Action

Problems/Corrective Action Log

Blood Pressures

g271, g272, g354, g355, g450, g451

Date	Problem	Date	Corrective Action

Problems/Corrective Action Log

Cognitive Function and Physical Activity Questionnaires

9504-9515, 9685-9693

Date	Problem	Date	Corrective Action

Problems/Corrective Action Log

Anthropometrics

9443 - 9449

Date	Problem	Date	Corrective Action

FRAMINGHAM HEART STUDY: OFFSPRING EXAM 7

TESTS: PURPOSE, RISKS, AND DISCOMFORTS

I. BRISK WALK TEST

see HKV data set

You may be asked to participate in a six minute walk test. We are conducting this test to learn about heart rate and blood pressure response to low levels of standardized exercise with the belief that in the future such information may be helpful in detecting silent heart disease.

For this test, you will walk on a treadmill for a total of six minutes: three minutes at an average pace and three minutes at a brisk walking pace. You will only be asked to participate if you are able to walk on a treadmill and are free of clinically apparent heart disease including congestive heart failure. In persons like you, who have no clinical evidence of heart disease, we believe the risks of this test are negligible. Although the level of exertion in this test is not high, there is a small chance that this degree of exertion could cause discomfort. A small percent of subjects report discomfort from the ECG leads or from frequent blood pressure measurements. Please remember that you are free to stop walking on the treadmill at any time during the test.

This is a relatively low degree of exertion and should not be regarded as a diagnostic test for heart disease. It is only a research test. If, however, you experience any abnormality that is of concern, we will report your test results to your personal physician.

II. BLOOD SAMPLE

g702 - g706

Fasting blood draw.
Part of the general physical exam includes obtaining a blood sample. You may experience some minor discomfort during the blood draw. A tourniquet will be applied tightly to your arm to make the vein more prominent. There is a minimal risk of bruising at the site of the needle stick.

Glucose Tolerance Test (GTT)
Some of the participants may be asked to drink 10 ounces of a glucose tolerance test beverage after the first blood sample draw. Potential adverse reactions include nausea, vomiting, abdominal bloating and headache. We will collect a second blood sample 2 hours after taking the glucose drink. The risks and discomforts are the same as described above.

III. LUNG FUNCTION TEST

PFT data set

The lung function test measures your lung capacity. The lung function test may cause minor coughing or lightheadedness at the time of the test, resulting from blowing forcefully into the tube. There are no known major risks from this test.

IV. BRACHIAL ARTERY VASCULAR REACTIVITY TEST

see brachial data set

The brachial artery ultrasound test is designed to look at the function of the blood vessel lining. This noninvasive test has been performed in thousands of research participants safely.

For this test you will be asked to do the following:

- Have an ultrasound picture taken of the artery located in your upper arm.
- Have a blood pressure cuff inflated on your lower right arm for 5 minutes.

  When the cuff is inflated, your arm may feel like it is going to sleep or numb.

- After the blood pressure cuff is released, we will take pictures of your artery for 2 ½ more minutes.

  When the cuff is released your arm may feel pins and needles, warm or cold.

- At a later date, we will make computer measurements of the amount that your artery expands after the cuff was released. The changes are very small, so we cannot tell you the results while we are doing the study.
- ***To get the best information it is very important that you not move when we are taking the ultrasound pictures.***

Why are we doing this test?

- We are doing the test to understand if the results relate to risk factors for heart disease and to understand if the results will help predict the development of heart disease and stroke.

THIS TEST IS ONLY USED FOR RESEARCH PURPOSES. WE WILL NOT BE SENDING THE RESULTS TO YOUR PHYSICIAN BECAUSE THE TEST'S CLINICAL SIGNIFICANCE IS YET TO BE DETERMINED.

THANK YOU FOR YOUR SUPPORT OF THE RESEARCH AT THE FRAMINGHAM STUDY.

If you have further questions about the Brachial Reactivity Test, please contact Dr. Emelia Benjamin by leaving a message at 508-935-3445 or 617-638-8968.

(Version 10/26/98 c: corel/mkh/fhsbavrtest.wpd) (revised 2-24-00)

9685-9693

OCCUPATION CODING SCHEME FOR OFFSPRING PHYSICAL ACTIVITY QUESTIONNAIRE

FIRST COLUMN SPECIFIES FULL OR PART TIME EMPLOYMENT; ASSUME FULL TIME UNLESS OTHERWISE NOTED. CODE THE FIRST COLUMN AS FOLLOWS:

0 = UNEMPLOYED, RETIRED OR HOMEMAKER
1 = FULL TIME EMPLOYMENT
2 = PART TIME EMPLOYMENT
9 = UNKNOWN

SECOND AND THIRD COLUMNS SPECIFY PRESENT OCCUPATION. CODE SECOND AND THIRD COLUMNS AS FOLLOWS:

99 = UNKNOWN
00 = UNEMPLOYED
01 = HOMEMAKER
02 = RETIRED
03 = SELF EMPLOYED BUSINESS OWNER
04 = M.D./DENTIST
05 = LAWYER/JUDGE
06 = PSYCHOLOGIST/SOCIAL WORKER/MENTAL HEALTH COUNSELOR
07 = SCIENTIST/RESEARCH
08 = ENGINEER/COMPUTER SCIENCE
09 = BANKER/ACCOUNTANT
10 = MANAGER/CONSULTANT (e.g. PRODUCTION MANAGER)
11 = ADMINISTRATIVE (e.g. PERSONNEL)
12 = EDUCATOR
13 = NURSE/MEDICAL PERSONNEL
14 = LABORATORY TECHNICIAN
15 = PHYSICAL/OCCUPATIONAL/SPEECH THERAPIST
16 = SECRETARY/CLERK/DATA ENTRY
17 = RETAIL/CASHIER
18 = SALES/MARKETING/INSURANCE
19 = REALTOR
20 = WRITER/EDITOR
21 = ARTIST/GRAPHIC DESIGNER/CRAFTSPERSON
22 = MUSICIAN
23 = POLICE/FIRE/SECURITY/MILITARY
24 = FACTORY/ASSEMBLY
25 = MECHANIC
26 = RESTAURANT/FOODWORKER
27 = SKILLED LABOR (e.g. PLUMBER, CARPENTER, PAINTER, HAIRDRESSER)
28 = GENERAL LABOR (e.g. CUSTODIAN, DELIVERY, MAILMAN, TRUCKDRIVER)
29 = HEAVY LABOR (e.g. CONSTRUCTION, LANDSCAPING)
30 = CLERGY (MINISTER, PRIEST, RABBI)
31 = SPORTS PRO/COACH/EXERCISE INSTRUCTOR
88 = OTHER

EXAMPLES: 000 = UNEMPLOYED
001 = HOMEMAKER
104 = FULLTIME M.D.
213 = PART TIME NURSE
220 = PART TIME WRITER