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SPIROMETRY - MANUAL OF OPERATIONS

CARDIOVASCULAR HEALTH STUDY - CHS

Pulmonary Function Reading Center

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Tucson, AZ 85724
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Instrument and Software

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- *Manual Version 2.0*
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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.

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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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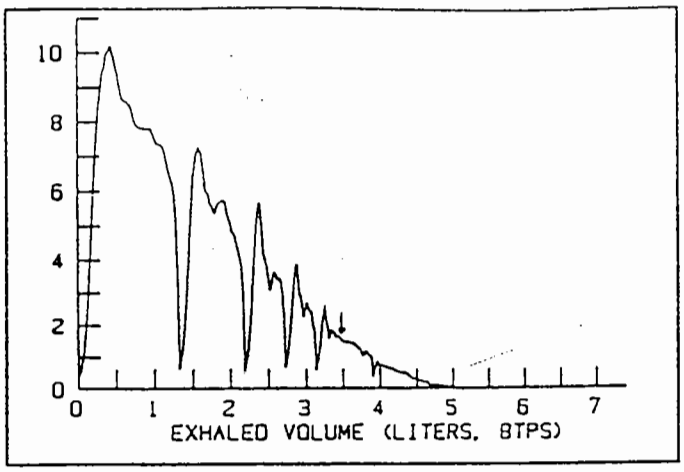

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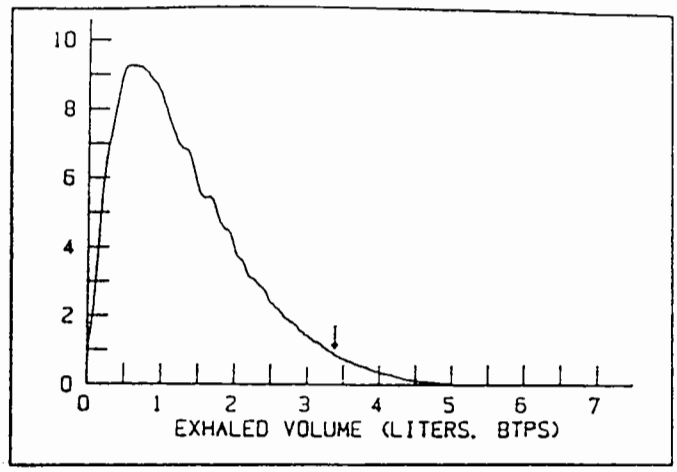
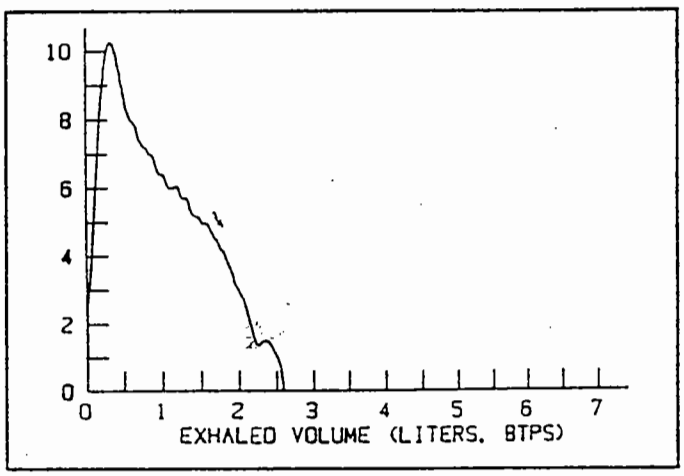
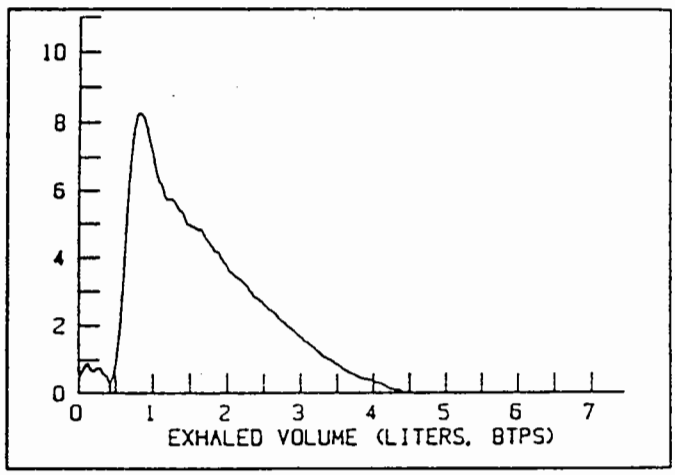


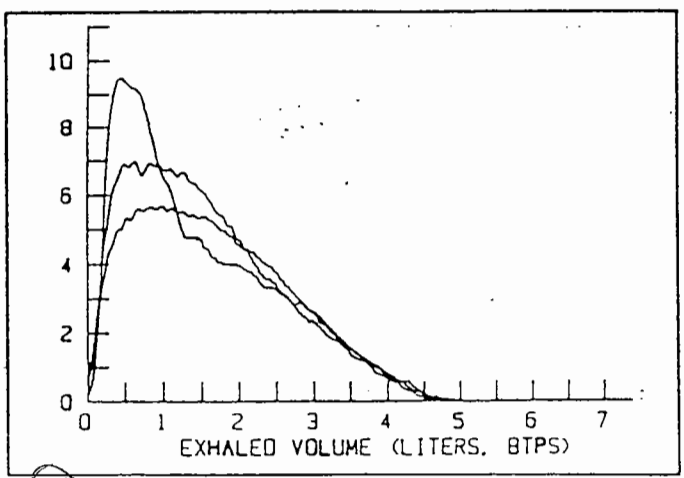
GOOD MANEUVER



BLOW OUT LONGER



START FASTER



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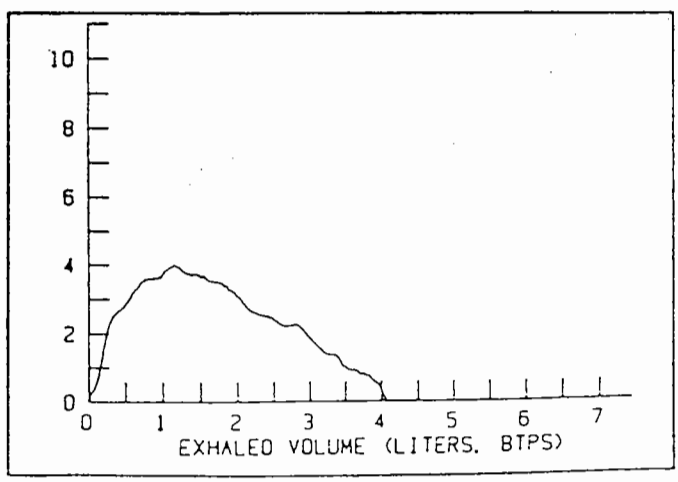
BLOW OUT HARDER



BLAST OUT HARDER

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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.

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DEFINITIONS

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

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

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

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

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

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

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

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

EV (see Back Extrapolation)

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

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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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.

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

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

:F stands for Peak Expiratory Flow Rate, ɐ 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. ɐxpensive $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

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

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

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).

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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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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 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.

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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

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.

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FVC Test Steps

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 d[redacted], 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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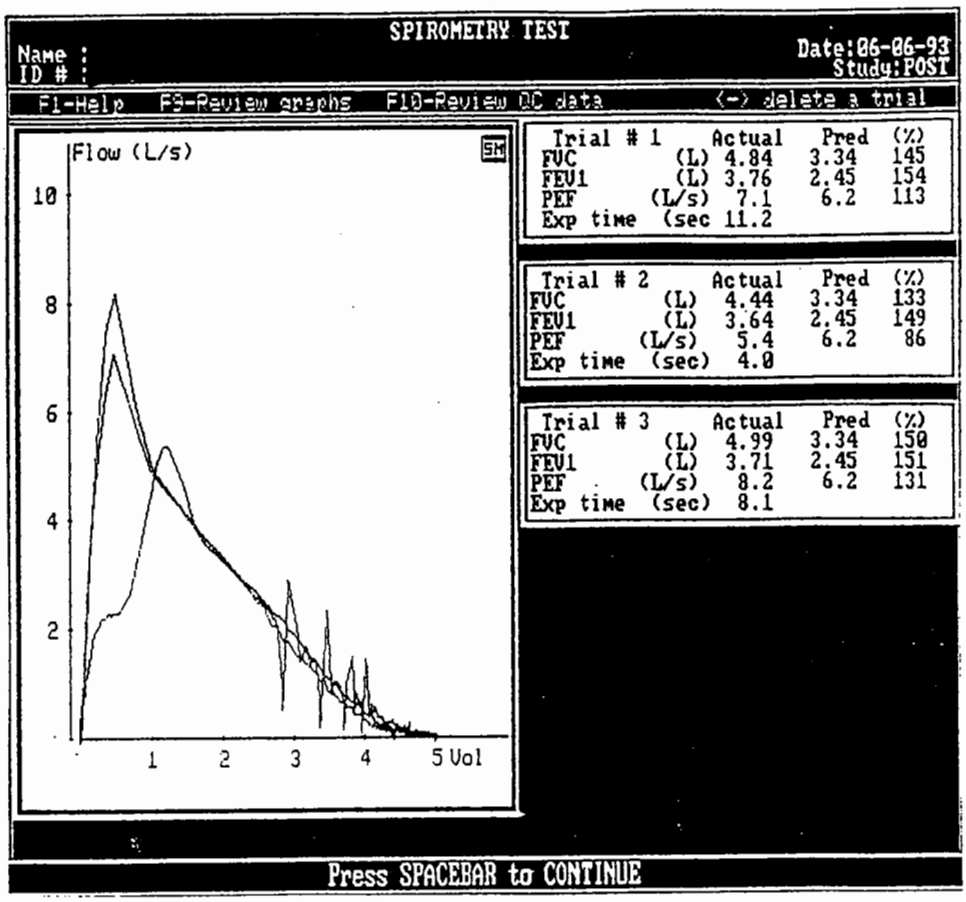
Review the Results

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.



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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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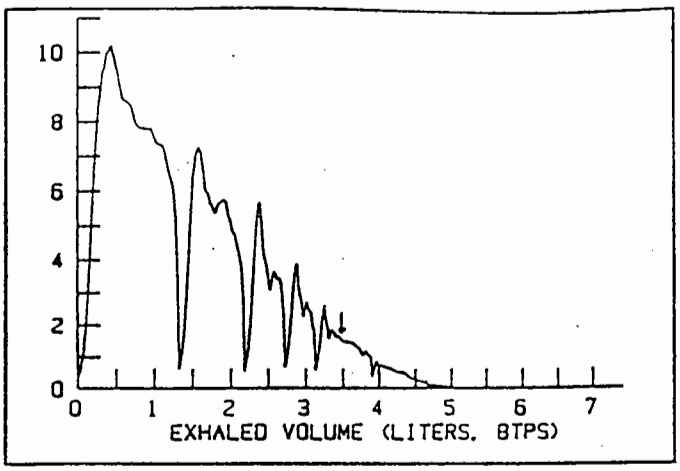
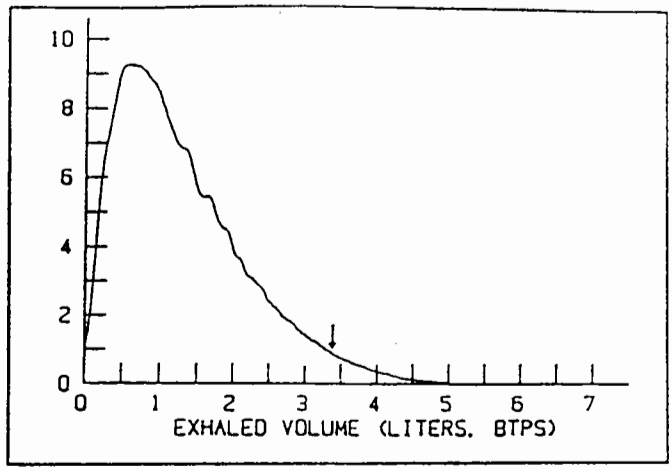
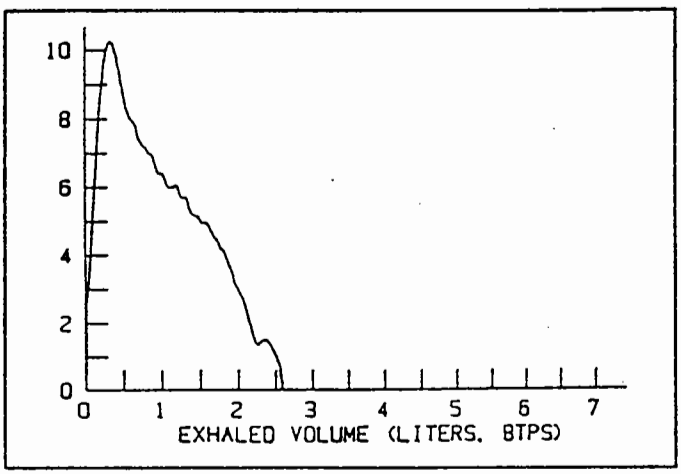


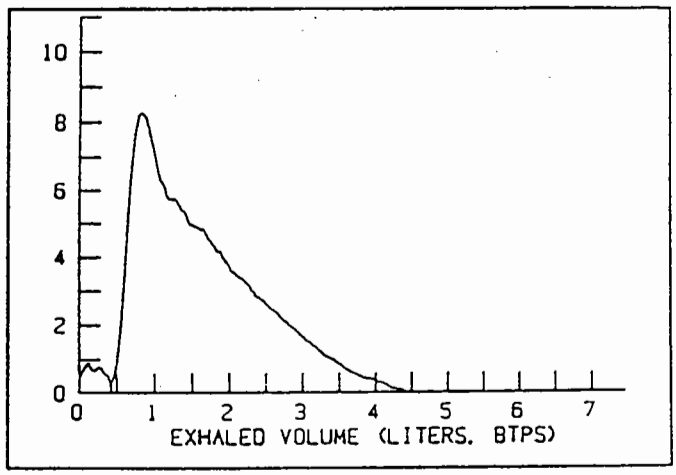
AVOID COUGHING



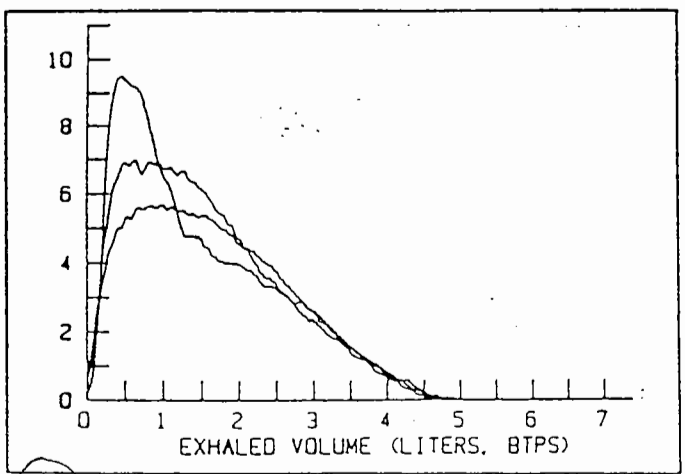
GOOD MANEUVER



BLOW OUT LONGER



START FASTER



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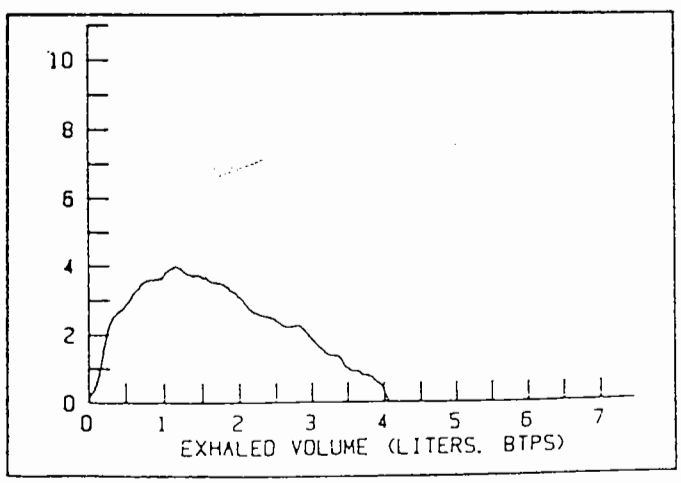
BLOW OUT HARDER



BLAST OUT HARDER

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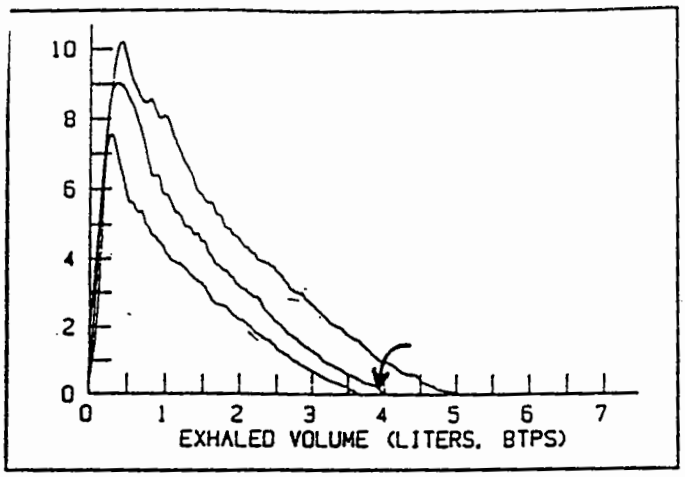

Figure 17. TAKE A DEEPER BREATH

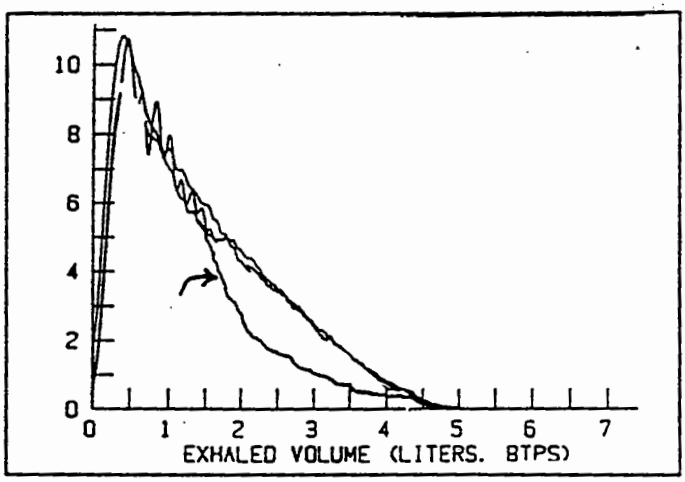

Figure 18. BLOW OUT FASTER

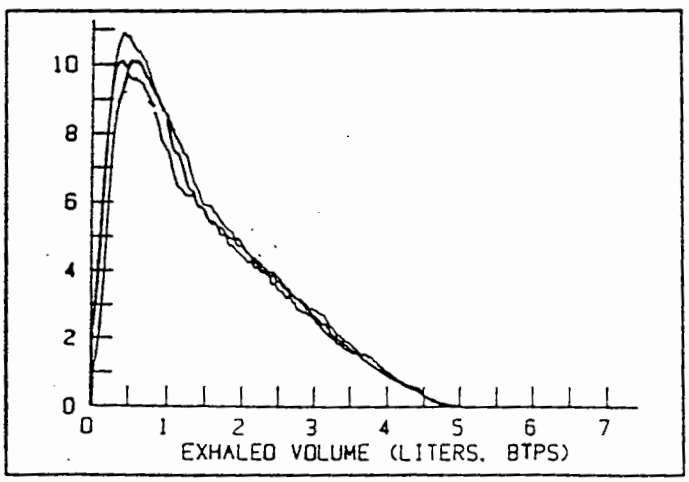

Figure 19. THREE GOOD MANEUVERS

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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

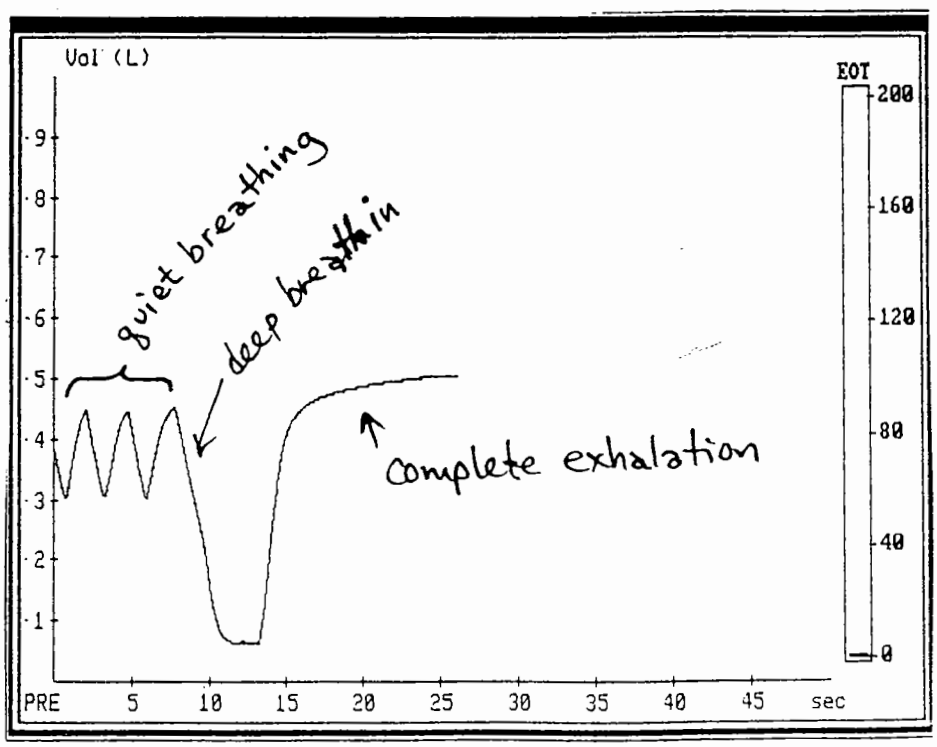
1. Ask the participant to hold the spirometer hose. Grasp the top of the spirometer's bell by the black knob and lift it to its midposition.

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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(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.

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Sample report printed for the participant:

Cardiovascular Health Study
Pulmonary Function Report

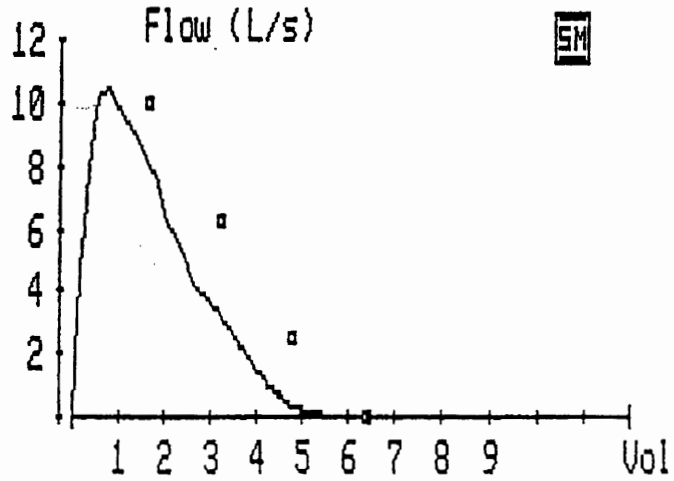
Patient : [redacted]
ID Number: [redacted]
Date : [redacted]
Clinic : ARIZONA
Predicted: Knudson 83

Height: [redacted]
Weight: [redacted]
Age: [redacted] BP: 760 Temp: 23

Sex: M
BMI: 20.
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:

Cardiovascular Health Study
Pulmonary Function Report

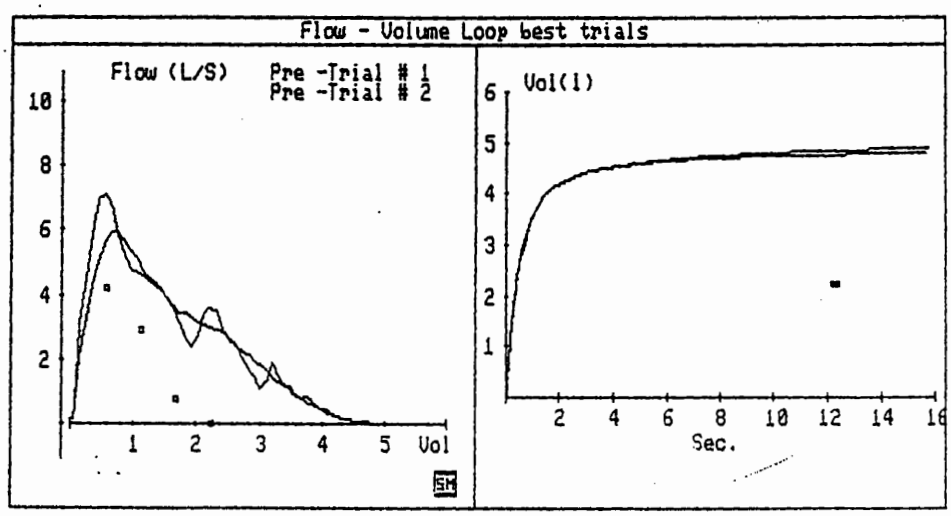
Patient : [redacted]
ID Number: [redacted]
Date : [redacted]
Clinic : ARIZONA
Predicted: Knudson 83

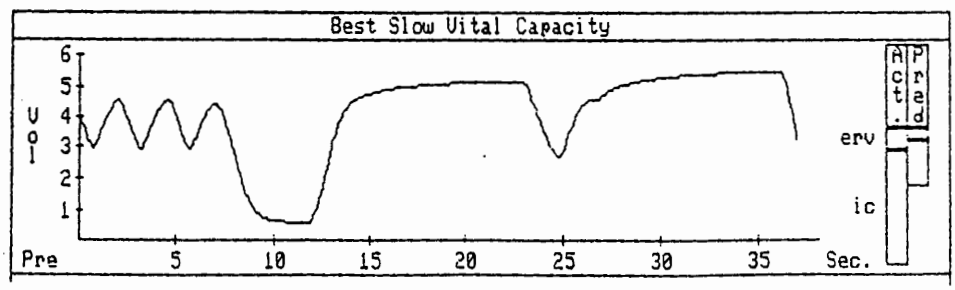
Height: [redacted]
Weight: [redacted]
Age: [redacted] BP: 760 Temp: 22

Sex: M
BMI: 27.3
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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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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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.

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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

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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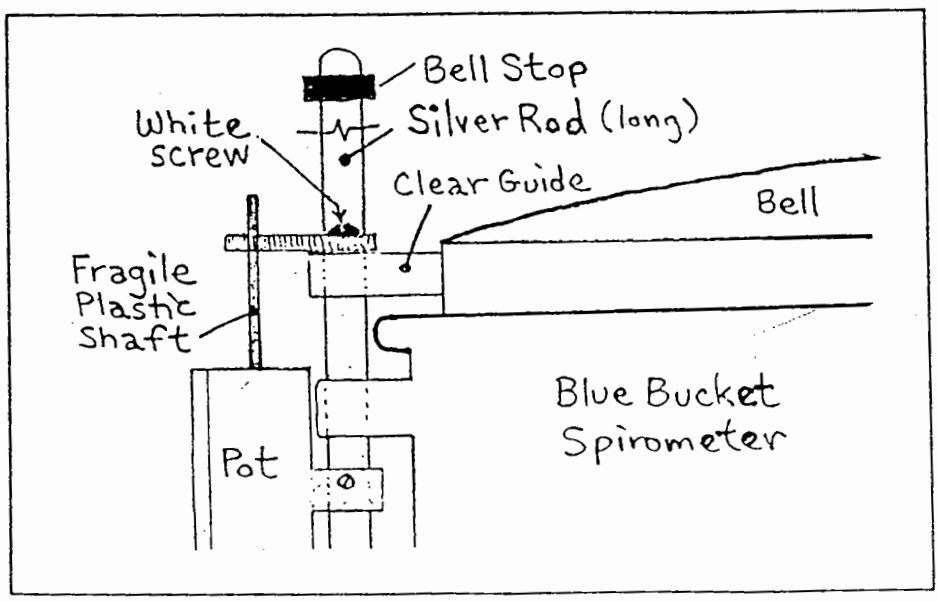
Calibration Syringe Care

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

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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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ıplementation of QC Procedures. There 'e five separate levels of quality control ıplemented for spirometry testing which ddress 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.

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

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

5. Results from all of the above are taken into account during the **analysis** of the data by the PF Reading Center (3,24). The calibration factors, PF tech's impression of participant and maneuver quality, and the QC supervisor's impression of test session quality are all integrated to obtain the final FEV1 and FVC results reported to the Data Coordinating Center.

6. **Replicate testing** will be performed on a total of 30 participants scattered throughout the recruitment period. Choice of the participants will be by the Field Center staff, usually a participant who did not complete an exam and must return on another day to finish it. Spirometry should then be performed again by a different PF technician. The PF reading center will then examine the two sets of results for reproducibility.

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

Weekly Biologic Control

Type GET from the MAIN MENU. Use the same technician and the same ID number for all tests. It should be 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

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.

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ANNUAL INSTRUMENT CHECKS

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

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

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

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

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

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

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PEAK FLOW MONITORING

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.

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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

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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200 L/m baseline PEF DIARY

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

Name [redacted]

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 [redacted]

Date [redacted]

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

Write in the value if off the chart:

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APPENDICES

EQUIPMENT AND SUPPLIES

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

PF Workstation Major Components

1. WE Collins "Survey" spirometer, with potentiometer and temperature sensor
2. IBM PS/2 model 30-286 personal computer, with 20 Mbyte HD, MS DOS 6.0
3. 8 channel 12 bit A-D Converter XT Interface Card (internal)
4. Internal 14.2 MPS modem (added June 1993)
5. Cannon BJ-10ex bubble-jet printer (added June 1993)
6. IBM model 8512 color monitor
7. Hans Rudolph 3.00 L calibration syringe

Spirometry Supplies

The maintenance and supplies kit includes:

- Mouthpieces, 1 3/8 dia cardboard (qty 1000)
- Sanitary storage box for mouthpieces
- Noseclips (qty 10)
- Chart Pens and paper for Collins Survey
- Chart paper labels
- Breathing hoses, 36" long (qty 20)
- Blue internal spirometer tubes (qty 4)
- Diskette Holder and 10 Diskettes, 3.5 inch
- Power strip with 6 surge protected outlets
- Denture cups (qty 50)

The tool kit includes:

- Electronic stopwatch
- Rubber stoppers, size #6 and #7 (qty 2)
- Adhesive to repair leaks
- Allen wrench, Small screwdriver

Other supplies to be purchased locally:

- Detergent and cleaning bucket
- Disinfectant solution (Cidex, Metracide, etc)
- White vinegar, Distilled water
- Alcohol wipes, Cleaning cloths, Q-tips
- Water pitcher, 1 quart size

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PROGRAM FILES

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

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

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

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

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RESULT FILES

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

Filename	Description of contents (type)
FILE	Participant directory (A)
DATAxxxx.BST	3 best FVC maneuvers + 8 parameters (G)
DATAxxxx.LOP	1 best FVC maneuver (G)
DATAxxxx.MIP	5 best MIP maneuvers (G)
DATAxxxx.MEP	5 best MEP maneuvers (G)
DATAxxxx.TXT	Comments and other free text (A)

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

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

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

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

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

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

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QC FILES

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

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

PRE.BAS
COM.DOC
PTA.DOC

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

CUSTOM CONFIGURATION

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

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COMPUTER INTERPRETATION

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

Interpretation:	Criteria
Normal spirometry:	FEV1/FVC ratio $\geq$70% and FEV1$\geq$80% pred and FVC $\geq$80% pred
Borderline obstruction:	FEV1/FVC ratio < 70% but FEV1$\geq$80% pred.
Mild obstruction:	FEV1/FVC ratio < 70% and FEV1 60% to 79% pred.
Moderate obstruction:	FEV1/FVC ratio < 70% and FEV1 of 41% to 59% pred.
Severe obstruction:	FEV1/FVC ratio < 70% and FEV1 < 40% pred.
Reduced vital capacity:	FVC < 80% pred, in addition to obstruction.
Mild restriction:	FVC 60% to 79% pred, with FEV1/FVC ratio $\geq$ 70%
Moderate restriction:	FVC 51% to 59% pred, with FEV1/FVC ratio $\geq$ 70%
Severe restriction:	FVC 50% or less than pred with FEV1/FVC ratio $\geq$ 70%

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

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MAINTENANCE

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

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

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

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

Channel 2 is Flow (obtained by differentiating the volume signal using an analog circuit on the A/D interface card). It should be about 2000 with no spirometer motion. It should flicker to higher or lower values when the spirometer bell is moved.

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

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

Channels 5-8 are not used and should all read 0.

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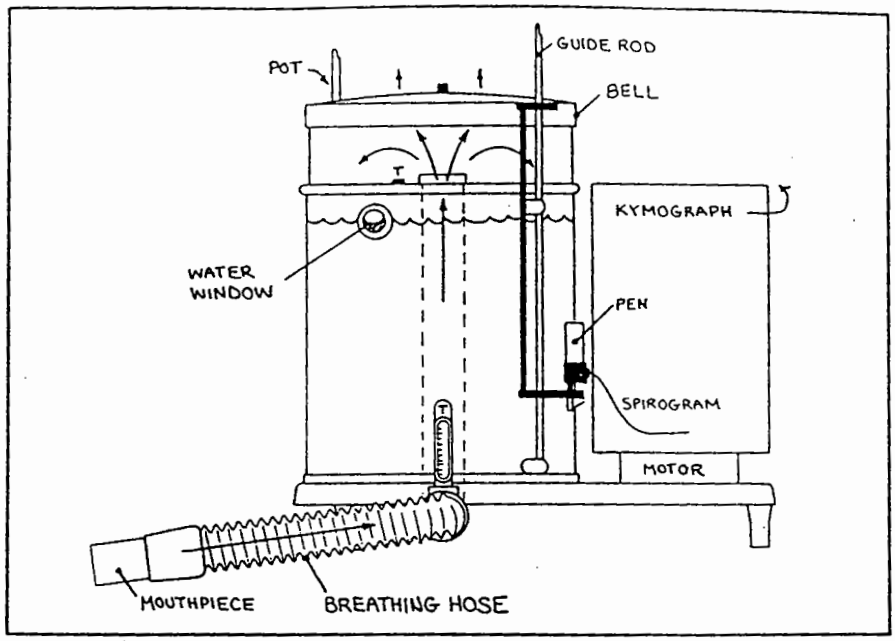
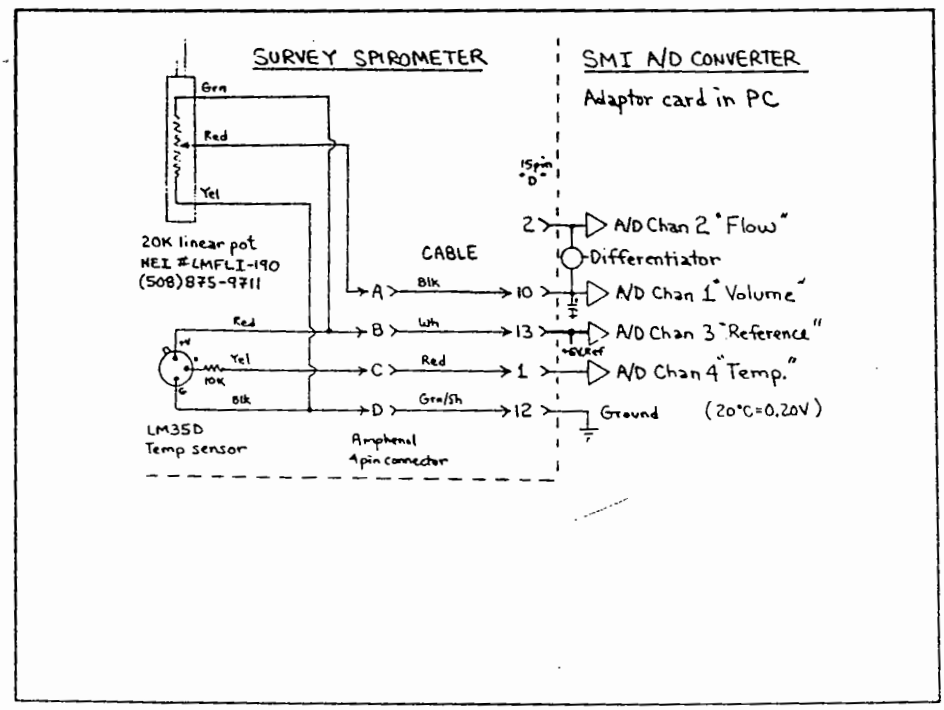


Collins Survey Spirometer.



Electronic Schematic Diagram

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