

Jackson Heart Study Protocol
Manual 8
Pulmonary Function Assessment
Visit 1

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FOREWORD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the JHS Study. Manuals 2 and 10 describe the operation of the Cohort Procedures, Family Study, and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 9. The Data Management System is described in Manual 11.

JHS Study Protocols and Manuals of Operation

<u>MANUAL</u>	<u>TITLE</u>
1	General Description and Study Management
2	Cohort Component Procedures
3	Family Study
4	Blood Pressure
5	Electrocardiography
6	Echocardiography
7	Ultrasound Assessment
8	Pulmonary Function Assessment
9	Specimen Collection and Processing
10	Morbidity and Mortality Classification Manual
11	Data Management System

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1.0 FORWARD AND CONTACT INFORMATION

This manual serves three purposes:

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

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2.0 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 CHS baseline exam (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 sub clinical cardiovascular disease (CVD) and overt clinical CVD and lung disease (4).

Spirometry, and ambulatory monitoring of peak flows were measured during CHS exam 6 for both the original cohort and the new African American participants. Spirometry reference values were reported from the healthy subset of the elderly black participants. Spirometry (measuring the FEV₁ but not the FVC) will again be repeated during CHS year 9 to determine change in FEV₁, and as a disease outcome measure. In addition, a six minute walk with pulse oximetry will be performed.

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.

3.0 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.

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 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 at these conditions.

CALIBRATION SYRINGE is a large 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.

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 is displayed on the incentive screen as the maneuver "Duration," and should be at least 3 seconds.

FEV1 is the most important spirometry variable, short for Forced Expiratory Volume in one second. It is convenient to think of it as the volume exhaled 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.

FEV3 is the volume exhaled after 3 seconds. It is always larger than the FEV1 but smaller than the FVC.

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

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

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

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

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

PEF stands for Peak Expiratory Flow, the highest flow measured during the FVC maneuver. It is a good index of effort used at the onset of the maneuver.

PF is short for Pulmonary Function (lung tests).

PRED is short for the predicted value of a PF parameter. It is determined from a 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 morbid obesity are some of many causes. The FVC is reduced while the FEV1/FVC ratio is normal or increased.

4.0 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)

PH₂O = water vapor pressure (17-30 mmHg)

Factor to convert inches to centimeters: Inches x 2.54

To convert degrees F to Centigrade: $(5/9) \times (\text{degF} - 32)$

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)

The above equations are from the healthy CHS participants during their baseline exam (3) and are valid for ages 65-85

Reference equations derived from the NHANES III spirometry in healthy subjects will be used as well.

5.0 METHODS SUMMARY

5.1 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
- Add comments
- Print and store the results

Clean Equipment at the end of the day

- Clean breathing hoses
- Rinse and dry hoses overnight

5.2 Weekly Procedures

Monday mornings

- Run leak and volume cal checks

- Perform a biologic control test

Friday afternoons

- Send data to Salt Lake City, Ut via e-mail attachments to LDRJENS@IHC.COM
- Remove front plate of spirometer, clean with damp cloth and allow to air dry

6.0 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 an optical shaft encoder 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 PFRC in Salt Lake City, UT.

6.1 Main Menu

The MAIN MENU is automatically displayed when the OMI software is run from the main windows desktop. Moving from one function to another is performed by going back to the MAIN MENU first.

You usually move forward within a program by clicking the mouse when the mouse pointer is over the desired option or hitting the spacebar. If you obtain a program or screen by mistake, you can usually get back to the MAIN MENU by clicking on the "CANCEL" or "EXIT" button.

From the MAIN screen enter your 3-digit JHS code. Please use your code each time you login and make sure everyone who uses the system uses their own code as well.

Select the desired option from the MAIN MENU by placing the mouse cursor over the option and clicking the left button of the mouse.

Refer to the OMI Spirometry Software Manual for additional information.

6.1.1 Select/Add Patient

Used to enter the name, ID number, age, height, etc for a new participant. The name of the "current participant" is then shown on the top colored bar of the program.

6.1.2 Perform an FVC Test

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

6.1.3 Print the Report

Prints a report for the participant and his/her physician and a tabular report for the participant's on-site JHS chart.

6.1.4 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.

6.2 Participant Information (Select/Add Patient)

Enter or verify the information requested in each box. End each entry by pressing the ENTER key. All items listed below must be entered in order to calculate predicted values.

- Name Enter the participant's First name Last name Use all capital letters.
- ID # Enter the participant's JHS 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 birth date.
- 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%.

- Baro The average barometric pressure at your location (Barometric pressure should be entered in mmHg and is typically between 680 and 760 mmHg). It should NOT be changed during a session, however, if a large storm or weather changes occur during the day a second entry should be made.
- Temp The spirometer temperature is measured by an internal sensor and displayed here. Verify that it reads within 3 degC of an independent thermometer mounted close to the spirometer. Make sure the thermometer is not mounted close to any equipment that is warm or blows warm air. We want to obtain a "Room Temperature" as accurate as possible.

If the readings differ by more than 3 degC, call the PFRC. 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.

6.2.1 Help

Some entries are verified to make sure they are within a reasonable range. If your entry is rejected, a small window will pop-up indicating the error and how to correct it and explains the entry expected.

6.2.2 Editing

If a mistake was made when entering information, use the mouse to move the cursor to the error. Then begin typing the information. Press ENTER to complete the line. The entry screen is shown below:

Figure 1. Entry Screen

7.0 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. Of course JHS participants are of either gender.

7.1 Preparation

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 fast and how much air he can exhale. 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, and then **BLAST** out as hard and fast as possible.

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 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.

7.2 FVC Test Steps

From the MAIN MENU, select **Forced Vital Capacity**. Before the test is performed, the "Pre-Test screen" appears where the operator can enter the hose ID and change the type of test or the operator initials. A database grid showing a summary of the previous test session results is also shown. After making any changes or entries on this screen, the operator chooses to "Proceed with Testing".

The negator is usually engaged with the open circuit method forcing the spirometer piston to returned to zero volume. If the computer detects that the volume in the spirometer is greater than zero, then a message will be displayed to either "attach the negator or return the spirometer piston to zero volume." Operator should assure that spirometer reading is zero or return to main screen and follow instructions to "Zero Volume."

Step 1 The FVC Incentive screen will then be displayed. A window will prompt Start Test? When ready, the operator clicks OK. A "Wait, Checking Spirometer" message will appear/flash in red on the screen. Wait until the message disappears.

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 for at least 6 seconds"

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.

Once a maneuver is completed, depending on the options selected in the "OMI98Setup" menu, the parameters are calculated and the various quality checks are applied. A results screen is then displayed on a table that lists: Trial Number, FVC, FEV1, PEF, Corresponding differences from the largest observed values (expressed in milliliters and as a percentage), and a 6-item acceptability code. All of the flow-volume curves are also displayed (superimposed on top of each other or offset (optional) along with the table of values and quality codes. The last maneuver is highlighted from the other flow-volume curves in blue and the best curve is displayed in lime (green). All of the remaining curves are displayed in black. Any deleted or unusable curves (cough or large extrapolated volume) are displayed in red. Analyze the flow-volume curve produced by this maneuver.

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. The quality assessments are conducted and corresponding messages displayed for the operator to consider when coaching the client on any additional maneuvers. The quality assessment information should be used by the operator to judge whether a curve should be accepted or rejected. Curves previously obtained during the current session may also be reassessed based on better curves being achieved after them. Clicking on the quality code box, a popup window is displayed allowing the user to override any acceptability code or delete the curve. This same popup window also provides a legend of the acceptability codes. The reproducibility criteria, selected using the "OMI98Setup" program, is

applied and a message as to whether the test is reproducible is displayed. The operator now chooses to proceed to perform another maneuver ("Do More Tests"), or proceed to test completion procedures ("Done").

7.3 Review the Results

After the participant has performed three apparently good FVC maneuvers, review the results. From the menu bar "Preform/Review Tests" select "Review Test". The "Review Test" menu item is used to review the results of a client's data collected in previous test sessions. The screen displayed is essentially the same screen displayed at the completion of each maneuver during test performance. This menu item also is used to edit the acceptability of individual maneuvers performed by a client. "Review Test" is when a maneuver which was rejected should have been included in the report. For example, if a maneuver was terminated prematurely and the FEV1 from that maneuver was valid, it may be appropriate to include this unacceptable maneuver in the report. Similarly, this menu item can be used to change a maneuver/s rating from "acceptable" to "unacceptable" e.g., in the case of a variable effort. If this editing is performed after a testing session, a record of the operator who made the last change is saved in the client information results file -- see Acceptability Screen for additional details.

The "best" maneuver is the one with the highest sum of FVC + FEV1.

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.

7.3.1 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.

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.

7.3.2 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.

7.3.3 Acceptability Messages

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

<u>QC</u>	<u>Message</u>	<u>Criterion</u>
S	Start faster	BEV > 5% FVC
P	BLAST out harder	PEFT >120 msec
C	Avoid coughing	>50% drop

T	Blow out longer	FET < 3 sec
A	Blow out more air	Abrupt termination

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 > 0.20 L
f	Blow out faster	dFEV1 > 0.20 L
h	Blow out harder	dPEF > 2 L/s

Notes: QC = error code displayed in the Review QC window - F10 key.

BEV = back extrapolated volume

dPEF, dFVC, dFEV1 = the difference between the current maneuver's value and the highest value from any other acceptable maneuver from the testing session

7.3.4 Maximum Number of Maneuvers

Don't exhaust the participant by asking them to perform more than **FIVE** FVC maneuvers. If you haven't obtained 3 acceptable maneuvers by the time you have done five maneuvers, it is unlikely that you will. Only make 2 additional attempts if you and/or the subject clearly made a mistake such as a "false start". Make a note of the reason why the participant could not perform the maneuvers in the Comment Screen later.

The following figures show examples of flow-volume curves from acceptable and unacceptable maneuvers.

Figure 2. Flow-Volume Curves (#1)

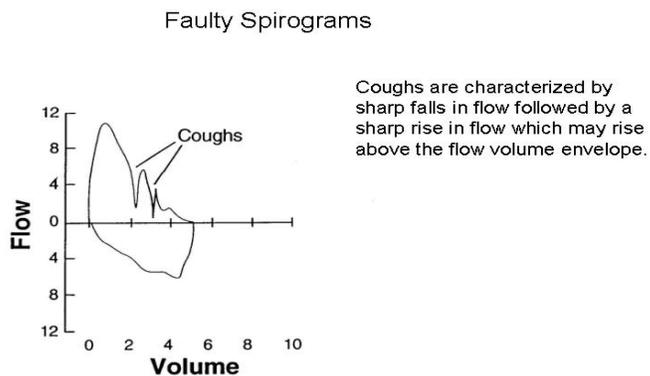


Figure 3. Flow-Volume Curves (#2)

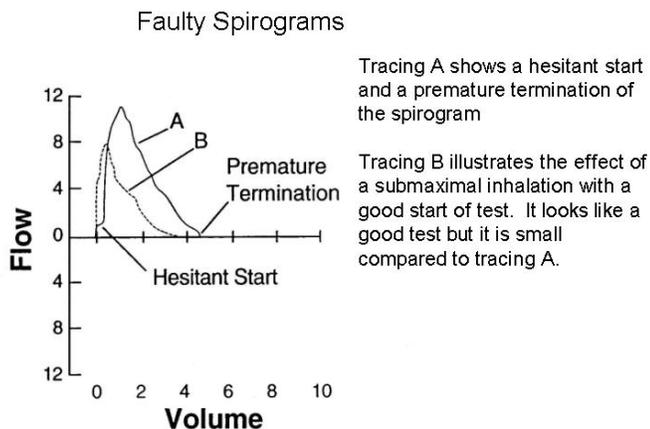
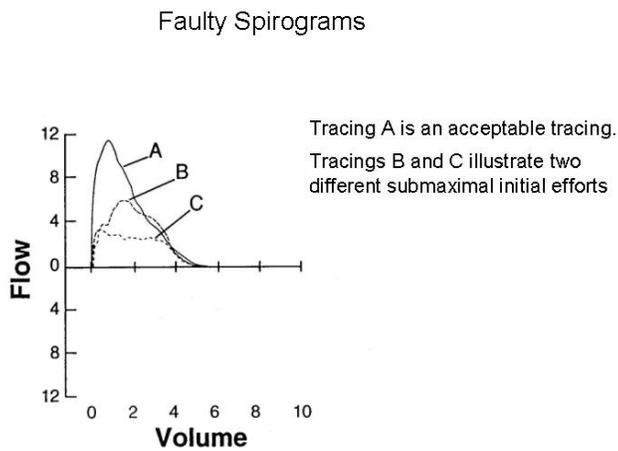


Figure 4. Flow-Volume Curves (#3)



7.4 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.

7.5 Print Current Test

Get the printer ready to print the report. In general, the printer will be connected to the computer and should not require any assistance. Keep an “eye” out for a toner cartridge that is failing and replace as needed. You can always return to a patient’s data and re-print the report.

The “Print Current Test” menu item allows the operator to immediately print the results for the current client, without going to the “Print Report” menu.

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 report will then be printed to place in the participant's JHS file. We do not plan to give a full-page spirometry report to the participant this year.

7.6 Printing Reports

The "Print Report" main menu item is used to print all tests results. The "Print Current Test" menu item under "Perform/Review Test" is used, while client information and results are still current in the computer. The right mouse button can also be clicked to display a pop-up menu with the "Print Current Test" menu item. The "Print Report" menu items are most useful for printing results for a group of clients or a group of tests conducted on an individual client. The details of each of the "Print Report" sub-menus are described below.

8.0 LEAK AND CALIBRATION CHECKS

8.1 Leak Test

This option is a submenu item under the main "Calibration" menu. The leak test screen is shown on the right. A leak test is performed by checking that the negator (return spring) is engaged and then adding approximately 3 liters of air into the spirometer with a calibrating syringe (or pulling the piston back, adding volume and placing a stopper in the hose.) Click on "Start Timing" The computer will then monitor the spirometer volume for 60 seconds and determine if the volume is maintained. (no excessive leak within user-selectable acceptable limits, default 76 milliliters.) A progress bar shows the time left until completion of the leak test. The results of the leak test are written to a calibration/leak test log file, including the date and time of the test, by clicking on the "save" button. Because of the possibility of a leak in the hose, the hose identification number should be entered and is saved in the calibration log file. A warning is displayed if a leak larger than the "Leak Tolerance" is observed.

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. Pull the spirometer guide bar back halfway and insert a rubber stopper into the metal breathing tube connector at the front of the spirometer.
2. Start the leak test again.

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 rolling seal or the front plate is leaking.

3. First remove the front plate and re-grease the large O-ring with a light grease (petroleum jelly or equivalent) and retighten the plate. Rerun the leak tests.

If this does not remove the leak, the rolling seal is probably at fault and you need call OMI at (800) 869-6783 for technical assistance. You can also phone the PFRC at (801) 408-3146, or (801) 408-3142.

8.2 Volume Calibration Check

"Calibration Check" can be accessed using the "Perform Cal Check" button on the main screen or in the "Calibration" menu. A calibration check should be performed daily, using a 3-liter calibrating syringe. (NOTE: When injecting air from the syringe, do not "Slam" the syringe at the end of the injection by pushing the air out too vigorously as this may cause erroneous calibrations.) Check that the "Current Volume" is zero before adding any air into the spirometer. Fill the calibrating syringe and connect it to the spirometer hose. Click on "OK" or type any key, inject the full 3-liters from the syringe

into the spirometer, and then pull back on the syringe. The computer determines the volume injected. The operator then verifies the calibrating syringe's volume and the computer compares this volume with the volume measured by the spirometer. If a chart drive is available, the operator can enter and "Save" the chart drive reading as well. The American Thoracic Society recommends an acceptable limit of + 3 percent of the syringe volume. The computer displays the difference between the syringe and spirometer-determined volume in both absolute volume and as a percentage. As with the leak test results, the calibration test results are written to the calibration database file as "Save" is clicked. A warning is displayed if there is a failure in the calibration check.

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 PFRC 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 PFRC to discuss this.

8.2.1 Print Calibration

This option, under the "Calibration" menu, will print the calibration results to the printer using all dates or a selected date range. This report includes leak, volume calibration check, linearity and time check results.

8.3 Linearity Check

This option, under the "Calibration" menu, allows the operator to conduct a linearity check of the spirometry system. Linearity checks are usually performed quarterly. The definition of Linearity is: of or pertaining to a straight line. The SensorMedics 922 measures volume using a digital encoder or a potentiometer. If this volume is displayed on the chart recorder graph paper 1 liter is equal to 10mm, therefore 2 liters equals 20mm and 3 liters equals 30mm, etc. If graphed, these volumes would be a straight line graph. The significance of the linearity check is to show that the spirometer is in calibration along its entire volume range, This means if a person blows into the spirometer his or her volume will be measured accurately across the entire graph. Daily calibration checks the range from 0 to 3 liters. The OMIS98 linearity calibration checks the volume from approximately 2.5 to 5.5 liters or across the middle portion of the spirometer volume measurement. This measures the linearity over the most significant portion of the volume most people can expire. Linearity calibration can be performed using any volume intervals. (However, when using initial volumes other than 2 to 2.5 liters, a red line will appear indicating the initial volume, but the blue line on the screen will not disappear.)

NOTE: This procedure is most easily performed with two people. One to pull the spirometer piston back to the desired initial volume and hold it until the other connects the syringe to the spirometer tubing. The 3 liter syringe volume is then injected and withdrawn from the spirometer. If only one person is available to perform this procedure, the negator (return spring) may be disengaged so when the spirometer piston is pulled back it will remain at the selected volume while the syringe is attached to the spirometer. If the negator is disengaged, remember to re-engage it before testing.

On the first screen after checking that the "Current Volume" is zero, click "OK." Fill the spirometer with approximately 2 to 2.5 liters of air by pulling the spirometer piston back from the rear of the spirometer (or by using a one-way valve and a calibrating syringe.) When the correct volume of air is added the blue

line on the left of the screen will disappear. Maintain this volume of air in the spirometer by holding the piston rod (or disengaging the negator). Attach a full syringe of air to the spirometer hose. Following the instructions on the computer screen, inject and then withdraw the 3-liter syringe volume. The computer will determine the volume injected and compare this volume with the volume measured by the spirometer. The linear calibration test results are written to the calibration database file as "Save" is clicked. A warning is displayed if there is a failure in the calibration check

9.0 CLEANING THE SPIROMETER

9.1 Clean the Breathing Tubes

This should be done at the end of each day of testing. First wash them in warm soapy water, rinse, roughly dry, then soak them in the disinfectant solution for at least 30 minutes. Be sure to wear protective rubber gloves and eye protection when using the disinfectant since it causes a rash in some persons. Rinse thoroughly and hang them to dry completely overnight before reusing. These procedures should be done in accordance with the established procedures in you institution.

9.2 Clean the Spirometer

This should be done every Friday afternoon following these steps:

1. Disposable gloves should be worn when cleaning. Eye protection should also be worn when handling the dilute bleach solution. The disinfectant used will be a standard commercial liquid bleach (5.25% sodium hypochlorite) diluted 1:10 with water (1 part bleach to 9 parts water).
2. Unplug the power cord and remove any electrical connections to external devices. Detach the breathing tube.
3. Clean external surface with a mild detergent and warm water; rinse and wipe dry with a soft cloth.
4. Disconnect the auto-return negator. Remove the front plate of the spirometer by loosening the thumb screws on the front. Carefully reach inside the spirometer and push the piston back to its maximum position.
5. Wash the front plate with a small amount of mild detergent on a wet cloth. Then rinse the front plate and wipe dry with a clean cloth.
6. Carefully clean the inside of the with a damp cloth that has been dipped in a 10% bleach solution and squeezed dry. Wipe the inside walls of the spirometer using a light touch. **Warning: do not get water or bleach solution in the joint of the rolling seal. Wipe again with a cloth moistened with clean water (squeeze dry each time) to remove the bleach solution and dry with a dry soft cloth.**
7. Allow the front plate and spirometer to air dry for the weekend.
8. Once the cylinder is dry, lubricate the cylinder with a small amount of starch-base powder (SensorMedics, Part No. 768541). Apply sparingly using a gloved hand. Remove excess with a small vacuum. **Warning: do not use talc-based powders. Inhalation of talc may cause lung injury.**
9. Replace the front plate. You should place a small amount of silicone based lubricant on the O-ring before, reposition the plate and tighten the thumb screws gradually in a clockwise fashion a little at a time until they are "firm"

9.3 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.

10.0 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 10 PF tests performed will be observed by a certified PF technician and then examined by the PFRC 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 PFRC. Copies of sub optimal 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 the exam year. Complete calibration, leak, and complete PF testing of at least three participants by each PF certified technician will be observed. Copies of sub optimal 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.

11.0 QUALITY CONTROL

11.1 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

11.2 Feasibility of QC Procedures

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

11.3 Implementation of QC Procedures

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

1. Daily spirometer leak and calibration checks using a 3.000 liter syringe as the "gold standard" check the **equipment** accuracy.
2. Eight computerized checks of FVC maneuver acceptability and reproducibility check **every maneuver** immediately after it is performed.
3. The PF technician is trained to recognize the patterns of unacceptable maneuvers, **watching the participant** during the performance, and reviewing the colorfully displayed flow-volume curves on the computer monitor.
4. The results of the leak and calibration checks and the FVC maneuvers are stored and sent to the PFRC 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 PFRC (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 PFRC 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.

12.0 QC ANALYSIS AND REPORTING

Each week the Field Center will backup all PF data for participants tested during the previous week and the calibration result files. These backup files will be e-mailed to the PFRC. The e-mail address is LDRJENS1@IHC.COM. This is Dr. Jensen's address.

At the PFRC, the result files are read by the PF QC workstation. The PF QC workstation displays the FVC maneuvers from a test session as differently colored flow-volume curves superimposed at the onset of each maneuver.

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 flow (PEF), FEV1 and volume (FVC). A flow grade of A is entered if at least 3 maneuvers demonstrate sharp peak flows and if the best two have very reproducible PEFs. A FEV1 grade is given when the difference between the two best test is less than 100 ml, and a grade of A is given to FVC (volume score) when the difference between the two best FVCs is less than 100 ml.

After over reading 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, over read PF results are generated and sent by mail to the 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.

12.1 Weekly Biologic Control

Perform a normal FVC test. Use the same technician and the same ID number for all tests. It should be 999xxx where xxx is the technician's 3 digit ID code. Perform FVC maneuvers as if testing a participant. Store the results and then review the trends. Ensure that your current FEV1 is within %5 of the mean of your previous values.

13.0 ANNUAL INSTRUMENT CHECKS

Prior to the onset of each exam year, the following items will be checked by the PFRC 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.

14.0 REFERENCES

Please call the PFRC for a copy of any of these references.

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15.0 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. OMI dry rolling seal spirometer
 - optical shaft encoder, temperature sensors,
 - serial data cable
2. 3.00 L calibration syringe
3. Personal computer, Windows OS
 - OMI S98 Spirometry Software
 - At least a 1GB Hard Disk
4. Inkjet printer
 - parallel cable, power strip
5. Color monitor with cables

Spirometry Supplies

- Mouthpieces, 1 & 3/8 inch cardboard (regular size), qty 500
- Small mouthpieces, 1 inch (optional size), qty 100
- Sanitary clear plastic storage box for mouthpieces
- Noseclips (qty 10)
- Breathing hoses, 36" long (qty 10)
- Denture cups (qty 30)

The tool kit includes

- Small screwdriver

Other supplies to be purchased locally

- Standard size copier paper for the printer
- Detergent and cleaning bucket
- Disinfectant solution (5% bleach mixed 1:10 with water)
- White vinegar, Distilled water
- Alcohol wipes, Cleaning cloths, Q-tips
- Water pitcher, 1 quart size
- Spare inkjet cartridges

16.0 COMPUTER INTERPRETATION

The Printer Workstation will compare the observed values to those predicted by the JHS 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 $\geq 70\%$

APPENDICES

Appendix 1 OMIS98 Spirometry Troubleshooting Guide

PROBLEM	POSSIBLE SOLUTION
OMIS98 Setup Program asks for password.	The default system password is omisetup - all lower case letters, all one word. It is suggested that you do not change this password.
Cannot enter OMIS98 Spirometry Program because it asks for a password.	Screen 3 of the OMIS98 Setup Program sets option for use of password or no password. . If you do not want to use password uncheck the option. If you choose to use passwords set up passwords on this screen. Exit and save data after making choice.
When performing calibration get Waiting Interface slow to respond window.	Computer is not able to read interface. 1.)Check all connections to make sure they are correctly installed and are firmly connected. (See hardware installation diagram.) 2.)Is the green light on the interface lighted? (If not, is the power cord plugged into a power source?) 3.)Is the Communications Port selected in the OMIS98 Setup Program menu the correct port that the serial cable is plugged into? (Screen 2 in OMIS98 Setup Program)
Volume zero must be established, position spirometer to zero or attach negator message.	Check to make sure that spirometer piston is pushed all the way in and pen is reading zero. On main OMIS98 Spirometry screen select the Setup menu. Select Zero Spirometer Click on OK to reset zero.
Warning: Ambient temperature:___, Spirometer temperature:___ . These should be within 3 degrees message.	This alerts you that the temperature where your spirometer is located has changed from the range preset to represent your normal ambient temperature. You may reset the ambient temperature or the preset limit of variation using the Setup menu on the main OMIS98 Spirometry screen. Select Enter Ambient temperature or Enter Temperature Limit selections.
Leak Check failure	<ol style="list-style-type: none"> 1) Check connections: between syringe and spirometer tubing; between spirometer tubing and spirometer. 2) Change to a different spirometer tube. 3) Remove spirometer tube and perform leak check by manually adding air to spirometer and sealing at snout plate using a rubber stopper. 4) Check snout plate where spirometer tube is attached to see that all screws are finger-tight plus another 1/4 to turn. 5) Remove snout plate and check o-ring. Lightly lubricate o-ring and replace. Rotate snout plate one-third turn.

	6)Check the screws around the middle of the spirometer that they are not loose or overly tightened.
Calibration failure	<ol style="list-style-type: none"> 1. Check that beginning volume is zero. 2. Be sure that you are injecting the full syringe volume and that you do not slam the syringe at the end of calibration.
Predicted and % Predicted values do not appear on report.	<ol style="list-style-type: none"> 1) Were predicted tables chosen in the OMIS98 Setup Program? Before using program, you must choose Caucasian predicted table and/or predicted or scale factor for other races. 2) Did you enter all of the following parameters correctly: Race, Age, Sex, Height? 3) Does the age exceed the limits of the predicted tables? (Too young or too old)
Observed values do not appear on report but predicted values are there.	<p>None of the client curves performed were acceptable curves. At least one of the curves MUST be acceptable for the values to be saved.</p> <ol style="list-style-type: none"> 1) Repeat test after re-instructing the client. Or 2) Override a unacceptable curve if in your opinion it is the best the client can do. To override an unacceptable curve see 7.04 Acceptability Screen Codes.
Entered wrong Social Security Number or ID	This number CANNOT be changed. Double check this number before entering and testing. Test values can be manually entered using the OMIS98 Utility program but the graphs cannot be transferred to the manually entered test results.
Entered wrong client information other than ID. (Wrong age, height, weight, race, gender, etc.)	These can be corrected on the Client Information Screen. Entering the correct information will correct on any future tests but will not correct tests already completed. To correct previously completed tests you must Edit Session Summary Data in the OMIS98 Utility Program.
Program already running! Check icon bar message.	<ol style="list-style-type: none"> 1) Close program using x in upper right of screen. Check icon bar to see if program running. Open from icon bar if it is present there. 2) If problem continues, reboot computer.
Printer problem	<ol style="list-style-type: none"> 1) Check printer is on. 2. Check printer cartridge or ink. Check paper supply and path. 2) Check printer setup in Windows program.

Appendix 2 Barometric Pressure Values

Note: If as an alternative, you choose to obtain and enter barometric pressure directly, make certain that it is not corrected to sea level, which is the way that the weather service normally reports it.				
Elevation (feet)	Pressure (mmHG)		Elevation (feet)	Pressure (mmHG)
-1000	790		7200	582
-800	784		7400	577
-600	778		7600	573
-400	772		7800	568
-200	766		8000	564
0	760		8200	560
200	754		8400	556
400	749		8600	551
600	743		8800	547
800	738		9000	543
1000	733		9200	539
1200	727		9400	535
1400	722		9600	531
1600	717		9800	527
1800	711		10000	523
2000	706		10200	519
2200	701		10400	515
2400	696		10600	511
2600	691		10800	507
2800	686		11000	503
3000	681		11200	499
3200	676		11400	495
3400	671		11600	491
3600	666		11800	487
4000	656		12000	483
4200	651		12200	479
4400	647		12400	475
4600	642		12600	471
4800	637		12800	467
5000	632		13000	463
5200	628		13200	459
5400	623		13400	455
5600	618		13600	452
5800	613		13800	449
6000	609		14000	446
6200	604		14200	443
6400	600		14400	440
6600	595		14600	437
6800	591		14800	435
7000	586			

Appendix 3 Quality Check Messages

After test completion the screen will appear. On this screen the operator indicates client effort, testing position, reactions, and adds any comments he/she would like to make.

Extrapolated volume too large

Either 5% of FVC or 150 (100 milliliters optional) milliliters, whichever is greater. Since a curve with a large extrapolated volume cannot be used, the operator is notified immediately during the testing procedure if the extrapolated volume is excessive. Since FVC must be used to calculate excessive extrapolated volume, the largest FVC previously observed for this client is used. This immediate check is not possible for the first maneuver performed by the client.

Plateau not detected

If a plateau is not detected during the FVC maneuver, then the plateau not detected message is displayed.

FET Less < 6 s

If the forced expiratory time of the test is less than six seconds and the user has selected this option, then the message is displayed.

Low Peak Flow

A low peak flow message appears if a maneuver with a low peak flow is detected.

Cough

If the client has coughed during the first second of exhalation, then the Cough message is displayed.

Time-to-PEF

The time required to reach PEF is measured and a message displayed if it exceeds the cutoff value established in **OMI98Setup** program.