



**MESA Lung II and MESA COPD
Pulmonary Function
Manual of Procedures**

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Prepared by the MESA Lung Pulmonary Function Reading Center

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1. BACKGROUND

1.1 The MESA Lung Study II

The MESA Lung Study II is measuring spirometry among over 3,000 MESA participants who previously enrolled into the MESA Lung Study in MESA Exam 3 or 4, plus “new recruits” in the MESA Air Pollution Study. The MESA Lung Study II is examining the interdependence of the heart and lungs with particular respect to heart failure with preserved ejection, in addition to vascular risk factors for progression of subclinical lung disease. Spirometry is measured in the MESA Lung Study II to define obstructive and restrictive lung disease in MESA Exam 5 and to measure decline in lung function since the first MESA Lung spirometry measurement in MESA Exam 3 or 4.

1.2 The MESA COPD Study

The MESA COPD Study is a case-control study of 200 MESA participants at four Field Centers with the aims to characterize abnormalities in pulmonary blood flow in COPD using magnetic resonance imaging (MRI) with gadolinium and analyses of cells in the blood. Eligible MESA participants are those who are under age 80 years, have smoked 10 or more packyears, do not have clinical cardiovascular disease and are able to undergo MRI with gadolinium (i.e., they are eligible for MESA COPD based on the MESA COPD Selection Form *and* eligible for the MRI with gadolinium based upon the MRI Exclusion Form and have eGFR > 45). Spirometry is also used in the MESA COPD Study in order to define cases of chronic obstructive pulmonary disease (COPD) and controls.

1.3 Combined Protocol for the MESA Lung Study II and the MESA COPD Study

Both the MESA Lung Study II and the MESA COPD Study will perform spirometry following a uniform, standardized protocol that is designed to be well-integrated into MESA Exam 5. We therefore have one Manual of Procedures for spirometry for both the MESA Lung Study II and the MESA COPD Study. Both studies include a lung CT scan, which is required for enrollment in the MESA COPD Study but not for the MESA Lung Study. The details of the lung CT scan (which is the same for MESA Lung and MESA COPD) are included in the MESA CT Manual of Operations. In addition, the MESA COPD Study involves a six minute walk test (6MWT), an additional tube of blood, and the MRI with gadolinium. The details of the MESA COPD MRI scan are described in the MESA COPD MRI Manual of Operations. The additional procedures are summarized in the table on the following page.

Procedure	MESA Lung Study II (n=~3,050, all FC)	MESA COPD (n=200; Col, JHU, NWU, UCLA only)
Spirometry		
Pre-bronchodilator	X	X†
Post-bronchodilator	if airflow obstruction	X†
Lung CT scan	X	X†
Selection form/questionnaire		X†
Six Minute Walk Test		X
Blood, 10 ml		X
MRI with gadolinium*		X†

* The MRI examination in the MESA COPD Study is identical to the MESA Exam 5 MRI from the participant's point-of-view except that it requires a regular intravenous line in the arm (20 gauge needle) instead of the butterfly intravenous line in the hand (25 gauge needle). The usual measures of the left ventricle are included in the MESA COPD protocol, so MESA and the participant will get the usual MESA report of left ventricular mass and function.

† The **required** procedures for the MESA COPD Study are: post-bronchodilator spirometry, the lung CT scan, the selection form and the MRI with gadolinium.

1.4 Spirometry

Spirometry is the simplest, most precise, and least expensive test for the assessment of pulmonary function. Low lung function is a major independent predictor of morbidity and mortality from cardiovascular, pulmonary and all causes.

The important spirometry measurements are the forced vital capacity (FVC), which is greatest volume of air exhaled from a maximal inspiration to a complete exhalation; the forced expiration volume in one second (FEV₁), which is the volume of air exhaled in the first second of the FVC maneuver; and the ratio between these two values: FEV₁/FVC. A low FVC defines restrictive lung disease whereas a low FEV₁/FVC ratio defines obstructive lung disease. These measurements were made in MESA Exam 3/4. In MESA Lung II, we shall repeat these measurements and also measure slow vital capacity (SVC), another measure of lung volume. Maximal inspiratory pressure (MIP) will not be measured again.

Participants with airflow obstruction in MESA Lung II and all participants in the MESA COPD Study will receive a bronchodilator, after which "post-bronchodilator" spirometry will be performed. The bronchodilator is very helpful in differentiating the two main types of obstructive lung disease. Asthma is characterized by airflow obstruction which is intermittent and which is generally reversible with a bronchodilator; chronic obstructive pulmonary disease (COPD), is characterized by airflow obstruction which is chronic and does not fully reverse with a bronchodilator.

Two professional societies publish widely recognized spirometry guidelines: the American Thoracic Society (ATS) and the European Thoracic Society (ERS), and a combined ATS + ERS

spirometry guideline was published in 2005. The authors of this manual were members of the spirometry guidelines committee. The instruments and methods in this manual conform to these guidelines and exceed their accuracy and repeatability recommendations.

The spirometers, software, and quality assurance program are the same as in the original MESA Lung Study, the 4th National Health and Nutrition Examination (NHANES IV), and the Hispanic Community Health Study (HCHS)/SOL. This standardization of methods makes the results of these large government-funded studies directly comparable.

Spirometry results are very dependent on an adequate effort by the participant performing the test. The participant must completely inhale and forcefully exhale throughout the entire expiratory maneuver. If the participant does not produce an adequate effort, the results are not valid. It is therefore essential that you explain, demonstrate, and evaluate each maneuver to coach the best possible effort from the participant.

Although the OMI software provides technical feedback to the technician, the technician still must instruct and demonstrate the test procedures to the participant. In addition, the technician must observe the results (flow-volume curves, volume-time curves, test values, and computer quality assessments) to determine the best coaching instructions to provide to the participants. This requires that the technician be familiar with what constitutes a valid test including unacceptable maneuvers as well as provide appropriate coaching instruction. There is no substitute for a well-motivated and well-trained technician.

The testing room is quiet and private, without distractions. No other tests are conducted in the room during spirometry testing. The ambient temperature in the testing room is maintained between 65-78°F. Ask for air conditioning if the room becomes uncomfortable due to high humidity or high temperatures.

2. EQUIPMENT AND SUPPLIES

- SensorMedics model 1022 dry-rolling seal volume spirometer is fitted by OMI with a digital volume encoder, temperature sensor, and RS232 serial computer interface (you should have from Exam 3/4).
- OMI spirometry software (version 5.05.11) is installed on a notebook computer with Windows XP. (you should have from Exam 3/4 but we're checking if new computers are necessary)
- Calibration syringe, 3.00 liters, Han Rudolph model # 5530 (you should have from Exam 3/4).
- Spirometer hoses, 3 feet long
- Disposable mouthpieces, nose clips
- Albuterol metered-dose inhalers (MDIs) and spacers

Note: Although this spirometry system is much larger than spirometers commonly used for clinical practice (office spirometers), it is more accurate. The volume accuracy of this system is better than 1.5 percent, which exceeds the ATS-ERS recommendation (accuracy within 3.5%).

2.1. Advantages of the Sensor Medics Zero Return Spring

- The spirometer's piston is returned to the zero position at the end of each maneuver by the zero return spring, reducing the time required to test a participant.
- Any leak in the spirometer or between the participant and his/her mouthpiece is easily detected because of the obvious loss in volume as a result of the positive pressure (0.4 cmH₂O) generated by the return spring
- There is a clear indication when the participant comes off the mouthpiece.
- The spirometer is always stored with minimal volume in the spirometer, which eliminates the development of a "blip" due to seal memory within the measuring volume.

2.2. Initial Equipment Setup

1. Set up the equipment and connect cables on a solid desk or table. Make sure that the rod on the rolling barrel (at back of unit) can slide backwards without hitting a wall or other object.
2. Connect the power cords to a grounded electrical socket.
3. Turn on the spirometer.
4. Power up the laptop computer.
5. Use the OMI Setup Program (desktop icon).
 - Double click on “OMISetup” windows icon.
 - The initial password to enter the setup program is ‘omisetup’
 - There are three screens showing user, spirometer and other information. Details are given in the appendix.

Setup Screen 1.

Hit F1 Key for Help

Registration Number: 12345

Register To: John Q. Public

Address: 1095 Willowdale Road
Anywhere, Texas 445566

Location: Medical Department

Spirometer Make: SensorMedics

Spirometer Model: 922

Spirometer Serial Number: 23459876

Computer ID: 3456098

Allow maintenance mode with system password

Change System Password

Proceed to Next Screen **Cancel**

Setup Screen 2. Please don't change the settings on this screen, which have been standardized for this study.

OMI Spirometry Configuration Setup Screen 2

Barometric Pressure: 760 mmHg

Leak Volume: 30 ml Request BP on Startup

Repeatability Criteria: 150 ml

PEF Repeatability Percent: 20 %

Plateau Volume: 30 ml

Plateau Time: 1 seconds

Time Check Percent Allowed: 02.0 %

Extrapolated Volume Criteria: 150 ml

MVV Test Time: 12 seconds

Communications Port: 1

Test Start Method: Auto

Save Tidal Volume with SVC Curve

Starting Session Number: 50

Allow temporary change of database path

Report Header:

Hispanic Community Health Study
Miami, Chicago, San Diego, New York City

Limit data to selected company

Next Screen Main Screen Cancel

Nomograms

	Scale Factor
Caucasian: Hankinson(C)-1996	1.00
Black: Hankinson(B)-1996	1.00
Asian: Caucasian	0.88
Hispanic: Hankinson(H)-1996	1.00
Other 1 (D): Caucasian	1.00
Other 2 (E): Caucasian	1.00

MESA Interpretation Algorithm

Computer Automated Interpretation [? Help](#)

Select Link File: s:\OMI\Spirometry_2003\OMISource.udl

Edit Link Create Link File Create Database

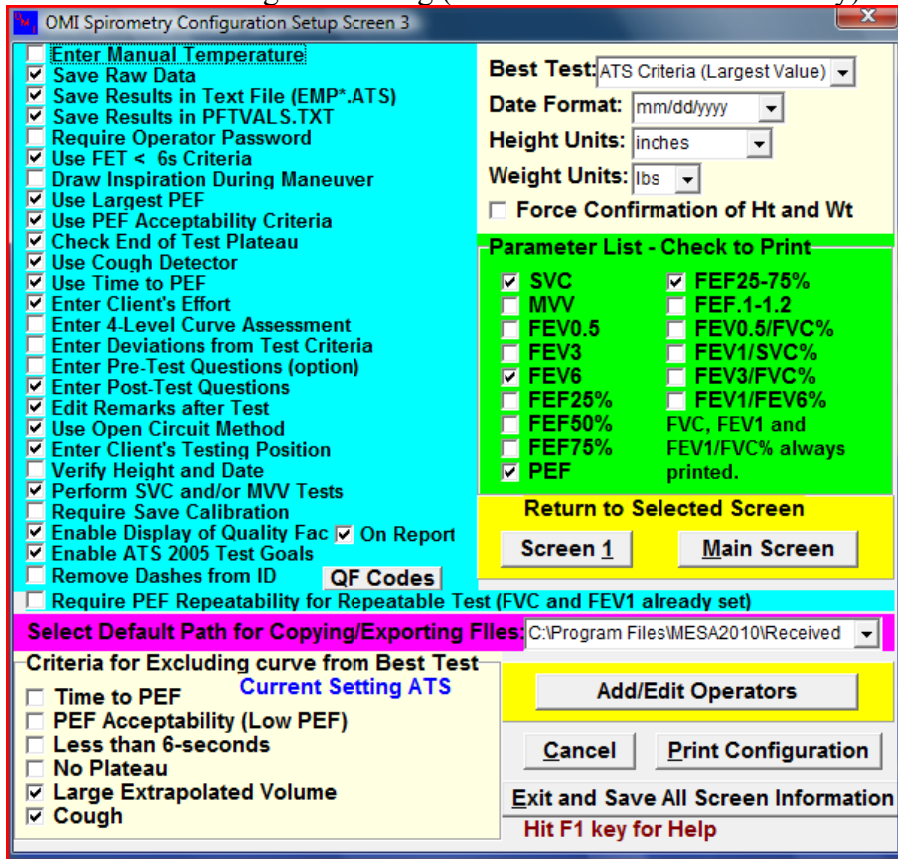
Report Options

- Detailed Session Report
- Overview of Session Report
- Volume/Time and Flow/Volume Graphs
- Large Flow/Volume Graphs
- Large Volume/Time Graphs
- Overlap Curves on Graphs
- Include Baseline Comparison
- Black and White Printer Only
- Disable Box (yellow) on values below LLN

TrendGram Options

Absolute %Pred %Deviation

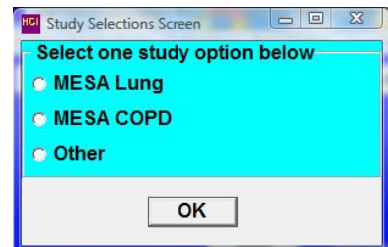
Setup Screen 3. Do not change the setting (also standardized for this study):



2.3. Daily Leak and Calibration Checks

Perform a leak and calibration check before each day of testing.

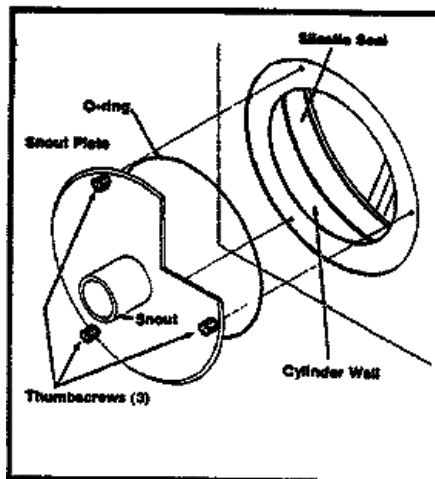
1. Double click "OMIWSP.exe" windows icon.
2. Select your study (MESA Lung, MESA COPD, or Other)
3. Enter your initials
4. Select "Calibration"
5. Select Leak Test from pull-down "Calibration" menu.
6. A leak test is performed by checking that the negator (return spring) is engaged and then adding 3 liters of air into the spirometer with a calibrating syringe.
7. Click on "Start Timing". The computer then monitors the spirometer volume for 60 seconds and determines if the volume is maintained. A progress bar shows the time left until completion of the leak test.
8. The result 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. A warning is displayed if a leak larger than the 20ml is observed.
9. Select "Perform Cal/Leak Check" button on the main screen or in the "Calibration" menu.
10. Check that the "Current Volume" is zero.
11. Fill the calibrating syringe and connect it securely to the spirometer hose.



12. 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. (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.)
13. The computer determines the volume injected. You then verify the calibrating syringe’s volume and the computer compares this volume with the volume measured by the spirometer. The computer displays the difference between the syringe and spirometer-determined volume in both absolute volume and as a % Error.
14. Detach the calibration syringe and store it near the spirometer.
15. View Calibrations: The “View Calibrations” menu item allows you to view all previous calibration results.

2.4. How to Clean the Spirometer

1. Clean the inside of the spirometer at the end of each day.
2. Wear gloves. Disassemble the spirometer for cleaning. Unplug the power cord. Remove the snout plate by rotating the three thumbscrews counterclockwise until the snout plate is free. It is not necessary to remove the blue adaptor from the snout for cleaning. Carefully reach inside the cylinder and slowly push back the piston.
3. Wipe the snout plate, O-ring and cylinder wall with a germicidal disposable cloth. Do not use alcohol, acetone, other volatile agents or abrasive cleaners on the rolling seal.
4. Allow the interior of the spirometer to dry thoroughly (perhaps overnight) before reattaching the snout plate.



5. Examine the O-ring for any irregularities. If damaged, replace it. Lubricate the O-ring lightly with stopcock grease. Fit the O-ring into the groove on the back of the snout plate.
6. Position the snout plate so that the three thumbscrews are aligned with the three holes on the spirometer housing. Tighten only “finger-tight”.

2.5. How to Clean the Hoses

The hoses and accessories will be cleaned and disinfected at regular intervals.

1. Tubing will be cleaned and disinfected daily using a solution of Detergezime and water according to the following protocol.
2. Add one ounce of Detergezime to every gallon of water (can be cold or warm but not hot) in the 5-gallon bucket.
3. Rinse hoses after use in this solution. Hoses that are not rinsed after use (i.e., saliva or mucous has dried) should be soaked in this solution for 10 minutes (IT'S ONLY NECESSARY TO SUBMERGE HOSES FOR 10 MINUTES IF THEY'VE DRIED (EG LEFT OVER THE WEEKEND WITHOUT CLEANING)).
4. Ideally, re-rinse hoses with water.
5. Hang hoses up to dry using clothes pegs.

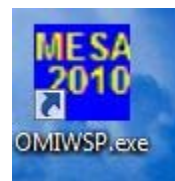
3. HOW TO TEST PARTICIPANTS

You should first complete the first page for the Spirometry Completion Form. The spirometry exclusion criteria at the end of the manual should have already been applied to every participant.

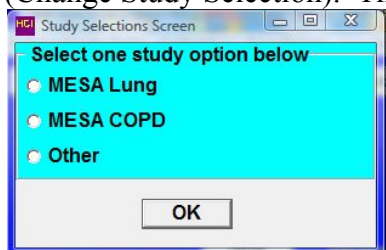
In addition, if the participant is selected for a post-bronchodilator test, you will be prompted to ask some additional questions before a decision about administering the bronchodilator is rendered by the spirometry software. Anyone meeting spirometry exclusion criteria will not start spirometry. The albuterol exclusions (which you will be prompted to administer by spirometry software) must be checked before administering the bronchodilator (albuterol).

The accuracy of spirometry depends on your skills, which influence the effort exerted by the study participant. Consequently, it is crucial that the examination protocol be observed consistently. The participant must be carefully prepared and “coached.”

The spirometry program is started by clicking on the spirometry icon located on the desktop.



Before you can do any testing, you must first select the study into which the participant is selected and consented. If the participant is selected for and consented into the MESA Lung Study, then select the “MESA Lung” button. Selecting this box implies that the participant will be asked to receive albuterol if they have airflow obstruction. If the participant is selected for and consented into the MESA COPD Study (Columbia, JHU, NWA and UCLA only), then select “MESA COPD” instead. In this case, the participant has the post-bronchodilator test. You can change the Study Selection with the last menu item under Files (Change Study Selection). The Study Selection screen is shown below:



3.1 Spirometry Instructions, Preparation and the SVC Maneuver

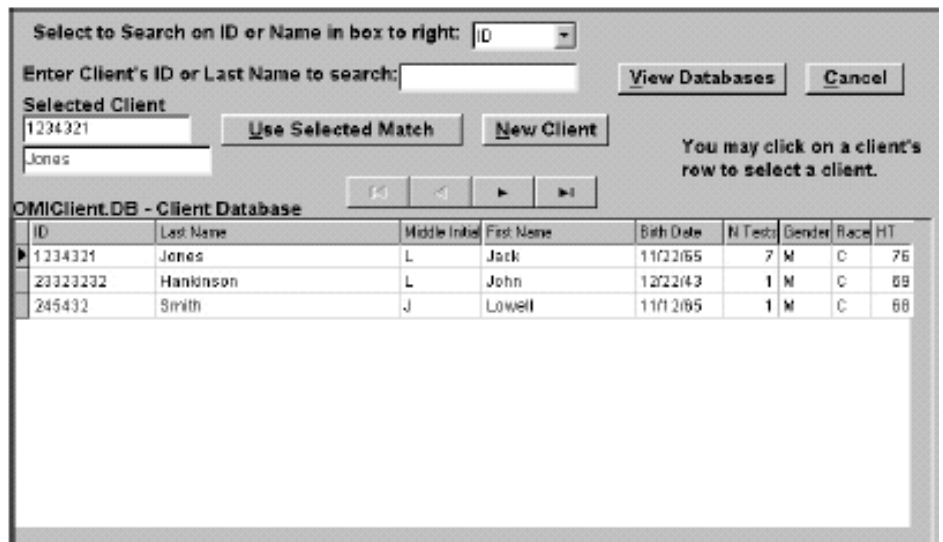
Tight clothing, such as a tie, vest, or belt, which might restrict maximal breathing efforts, should be loosened. Dentures, if they are loose, should be removed and placed in a clean denture cup, since they prevent a tight seal from being formed around the mouthpiece. If dentures are not loose, leave them in place.

2. Select “Perform/Review Test” main heading and/or “Select/Add Participant” button

3. Bring up Participant Screen



4. You can “Use Selected Match” or choose to enter a “New Participant.” Information for almost all participants will be preloaded. To search for a participant, select to search on ID or ACROSTIC; then start typing the ID or ACROSTIC in the search field. The bottom grid will display the closest match to the partial ID or ACROSTIC as it is entered. If the ID is not there, select “New Client.” Before any participant is tested, demographic information must be confirmed and edited if necessary.



5. Edit/Paste/Enter participant information. The participant’s information including ID, ACROSTIC, age, gender, race/ethnicity and height should be preloaded and appear in

the screen. Verify that the information is correct (particularly age and height) and, if it is, click “OK.” Other information on the screen does not need to be entered. If the preloaded information is wrong, double-check ID and ACROSTIC match the participant then update the incorrect information. Please use the information as recorded on the Exam 5 Anthropometry form for height and weight. For a participant who is not preloaded into the software (which should be rare and only occur for MESA COPD participants or those that have moved Field Center), enter ID, ACROSTIC, age, gender, race/ethnicity and height. For participants not preloaded in the software, you may also need to select your site or center and, for possible MESA COPD subjects, select their status code (Control, Case, Not Selected, Not Eligible, or Unknown).

The screenshot shows a software window titled "OMI Spirometry Client Screen" with a yellow background. The main heading is "Fill-out or Correct Information for Current Client". The form contains the following fields and controls:

- ID:** A text input field.
- ACROSTIC:** A text input field.
- Age:** A text input field.
- Height:** A text input field followed by "inches".
- Weight:** A text input field followed by "lbs".
- Gender:** A dropdown menu.
- Race:** A dropdown menu.
- Last Test Date:** A text input field with the value "0".
- Last Session Number:** A text input field with the value "0".
- MESA COPD:** A section containing two dropdown menus: "Select Location or Center" (with "Select Site" selected) and "COPD Selections" (with "Unknown or Missing" selected).
- Non-Printed Comments:** A large text area for entering comments.
- Buttons:** "OK", "Cancel", and "Search Client Database" are located at the bottom of the window.

6. Wash your hands.
7. Attach a clean breathing hose.
8. Explain the purpose of the SVC and the need for extra effort from the participant to get maximal results. Say “I want to measure how much you can breathe out” and explain that you want the participant to take a very, very deep breath and then breathe out slowly all the way out.
9. Demonstrate a deep inspiration: exaggerate body language, eyes wide, shoulders back, on tiptoes. Demonstrate proper placement of the mouthpiece stick out your tongue and place the mouthpiece on top of it. For the SVC maneuver, the participant does not need to ‘blast out’ but rather than exhale slowly. Use the SVC maneuver to focus on coaching Phase I (deeeeeeeep breath in) and Phase III (keeeep breathing out).
10. Ask the participant to **sit** during the examination. Encourage them to sit up straight. If participant wants to stand during the examination, they may do so.
11. Place nose-clip on their nose. It may be removed between trials. If the nose-clip falls off or is uncomfortable, try another one, or the participant may hold his nose during each maneuver.
12. Have the participant do a trial exhalation. The following instructions may be helpful:

1. "Take a great big breath of air as far as you can inhale."
 2. "Put the mouthpiece into your mouth and seal your lips tightly around it."
 3. "Breath out into the tube." (The exhalation should be made with the lips tight around the mouthpiece with maximal force and speed.)
 4. "Keep on blowing out the same breath of air, until I tell you to stop."
13. Review the procedure and correct any problems from the trial.
Proceed with Examination.

Click "Perform SVC Test" button. If a button is not visible, you can always use the top menu items of Files then Perform Test. Notice the SVC radio item is selected on the screen below.

Please verify and complete information below then click appropriate button below

Return to Main Screen Proceed with Testing Change Operator Help

ReadOnly Items

Client ID: A000001
 Last Name:
 Last Session Number:
 Session Number: 50
 Spirometer Temperature: 23 C

Pre or Post Test

Pre-Test
 Post-Test
 Bronchodilator

Test Parameters

Hose ID:
 Operator Initials: JJJ
 Barometric Pressure: 760 mmHg

Test Type

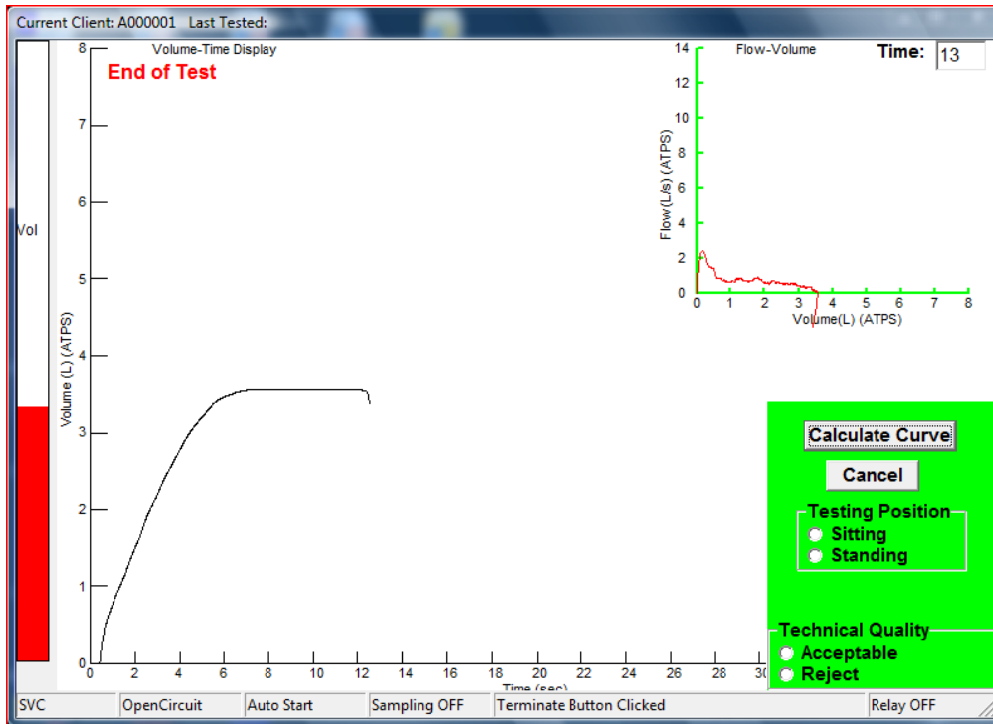
FVC
 SVC
 MVV

PFTSum The information below is provided for review purposes and cannot be edited with this screen

ID	Session	Test Date	Ht	Wt	Metric	Manual Entry	Smoker	Company
A000001	50	02/06/2010 2:11:32 PM		70	False	False		Not Listed

Select "Proceed with Testing" and a "Volume-Time and Flow-Volume Graph" screen appears. A window prompts "Start Test?" When ready, click "OK."

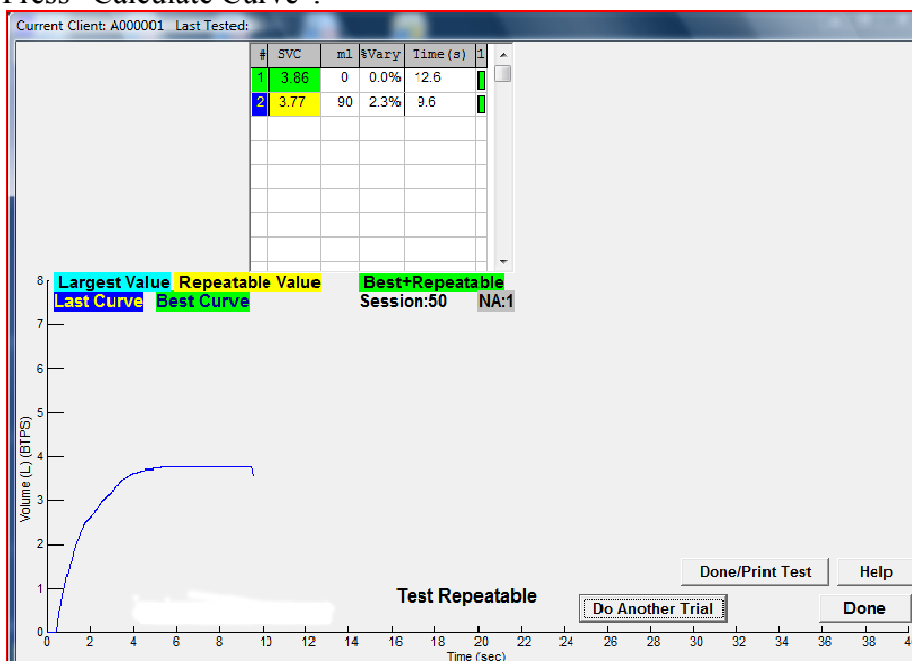
The message "Wait, Checking Spirometer" appears in red on the screen. AFTER THE MESSAGE DISAPPEARS, instruct the participant to take a deep breath, place the mouthpiece in his/her mouth, and completely exhale in a relaxed manner. The SVC maneuver is not forced, but more effort is required at the end of inhalation (completely inhale) and exhalation (complete exhale).



As with the FVC maneuver, the subject should obtain a 1-second plateau before ending their effort; so, quietly coach the subject to continue to exhale until a plateau is reached. Help the participant to move the mouthpiece away from their face (to reduce the risk of cross-contamination) when they remove the mouthpiece.

Indicate standing or sitting, and your impression of the participant's effort.

Press "Calculate Curve".



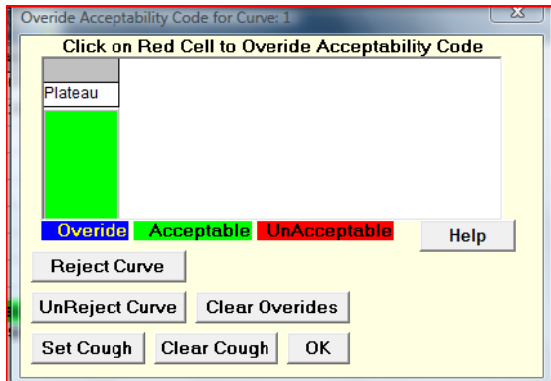
You should obtain at least two acceptable maneuvers as shown below. An important goal of testing is to match the largest and second largest SVC within 150 ml of each **other (repeatable test)**.

#	SVC	ml	%Vary	Time (s)	1
1	3.86	0	0.0%	12.6	Acceptable
2	3.77	90	2.3%	9.6	UnAcceptable

Repeatable Value Best+Repeatable

A green bar indicates an acceptable maneuver and a red bar indicates the curve is unacceptable.

Double Left Click on a row with numbers and the acceptability screen will appear. You can then click on the “Reject Curve” button if you wish to reject a curve, “Set Cough” button if you feel the computer did not correctly detect a cough, “Clear Cough” button if you feel the computer incorrectly label the curve as having a cough. Any code that is “over-riden” is colored in blue instead of red.



Proceed or Done: You decide to proceed to perform another maneuver (“Do Another Trial”), or to stop performing additional SVC maneuvers (“Done”).

Post Test Questionnaire: After test completion, the “Post Test Questionnaire” screen will appear. On this screen, indicate the testing position, participant (client) effort, and add comments, if you wish. Then click “OK.”

Please complete the following questions for current client

Check appropriate boxes to indicate a yes response

Post-Test Questions

Did any of the following Signs or Symptoms Occur?

Testing Position

Standing

Sitting

Client's Effort

Maximal

Questionable

Sub-maximal

Headache

Dizziness or lightheadedness

Coughing

Short of breath

Other

Enter Remarks Below

OK

When the SVC Test has been completed click the Ok on the above button and you will be returned to the main screen where the “Perform FVC Test” button will now be visible. Proceed with FVC testing:

1. Explain the purpose of the examination and the need for extra effort from the participant to get maximal results. Say “Now I want to measure how much *and how fast* you can breathe out.”
2. Demonstrate a deep inspiration: exaggerate body language, eyes wide, shoulders back, on tiptoes. Demonstrate proper placement of the mouthpiece stick out your tongue and place the mouthpiece on top of it. Blast out.
3. Ask the participant to sit during the examination. Encourage them to sit up straight. If participant wants to stand during the examination, they may do so.
4. Place nose-clip on their nose. It may be removed between trials. If the nose-clip falls off or is uncomfortable, try another one, or the participant may hold his nose during each maneuver.
5. Have the participant do a trial exhalation. The following instructions may be helpful:
 1. “Take a great big breath of air as far as you can inhale.”
 2. “Put the mouthpiece into your mouth and seal your lips tightly around it.”
 3. “Blast your air into the tube as hard and fast as you can.” (The exhalation should be made with the lips tight around the mouthpiece with maximal force and speed.)
 4. “Keep on blowing out the same breath of air, until I tell you to stop.”
6. Review the procedure and correct any problems from the trial.

3.2 The FVC Maneuver

Click “Perform FVC Test”

Please verify and complete information below then click appropriate button below

Return to Main Screen Proceed with Testing Test Type: FVC SVC MVV Change Operator Help

ReadOnly Items

Client ID: 12344455 Pre or Post Test: Pre-Test Post-Test

Last Name: Jones Bronchodilator

Last Session Number: 18 Above items can be changed using Main Menu

Session Number: 19 Hose ID:

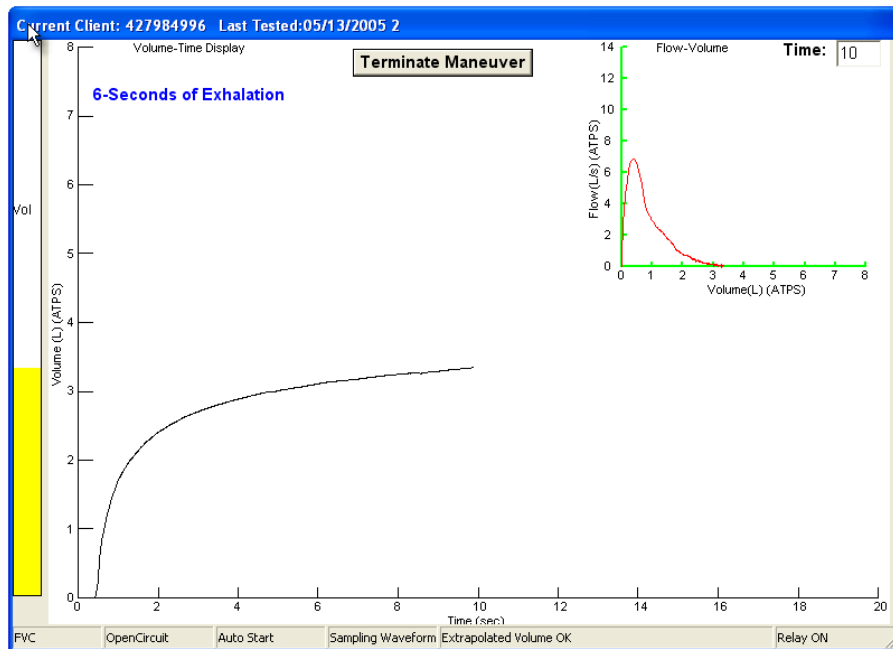
Spirometer Temperature: 0 C Operator Initials: XXXX

OMISum.db The information below is provided for review purposes and cannot be edited with this screen

ID	Session	Test Date	Test Time	FVC	FEV1	Effort	REF	MVV	SVC	N FVC	N SVC	N MVV
12344455	13	03/10/98	6:44:48 PM	0	0	M	0			1	0	0
12344455	14	03/10/98								0	0	0
12344455	15	03/11/98	9:59:13 PM	4345	3256	M	4533			6	0	0
12344455	16	03/21/98	11:47:06	0	0	M	0			1	0	0
12344455	17	03/21/98	11:48:45	0	0	M	0			2	0	0
12344455	18	03/21/98	12:10:30	0	0		0			2	0	0
12344455	19											

Select “Proceed with Testing” and a “Volume-Time and Flow-Volume Graph” screen appears. A window prompts “Start Test?” When ready, click “OK.”

The message “Wait, Checking Spirometer” appears in red on the screen. AFTER THE MESSAGE DISAPPEARS, instruct the participant to take a deep breath, place the mouthpiece in his/her mouth, and **BLAST the air out!** Watch participant.

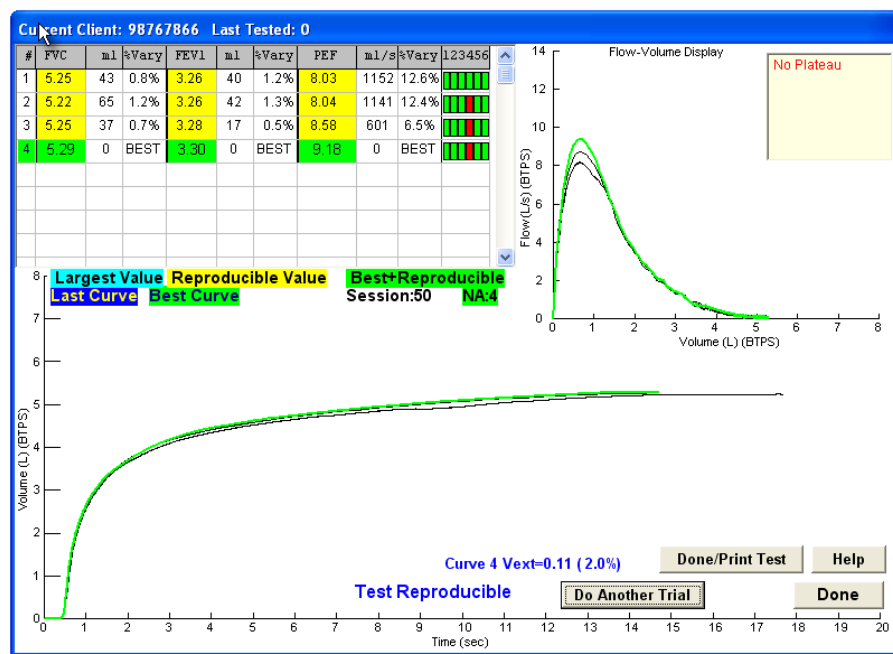


Quietly coach the participant to exhale until the “Plateau Achieved” message is displayed and the bar on the left side turns green. Just say, “Keep going...you are still getting more air out.” It is *not* helpful for them to “squeeze out the air.” Help the participant to move the mouthpiece away from their face (to reduce the risk of cross-contamination).

Indicate standing or sitting, and your impression of the participant’s effort.

Press “Calculate Curve”.

A result screen is then displayed, including Trial Number, FVC, FEV₁, and PEF (peak flow). After the second and successive trials, differences from the largest observed values and the 6-item acceptability code are displayed. All of the flow-volume and volume-time curves are also displayed superimposed. The last maneuver is highlighted in dark blue and the best curve is lime green. All of the remaining curves are black. Any deleted or unacceptable curves are red. The quality assessment information should be used to judge whether a curve should be accepted or rejected. Click on the quality code box for a description of the acceptability codes. A repeatability message is displayed.



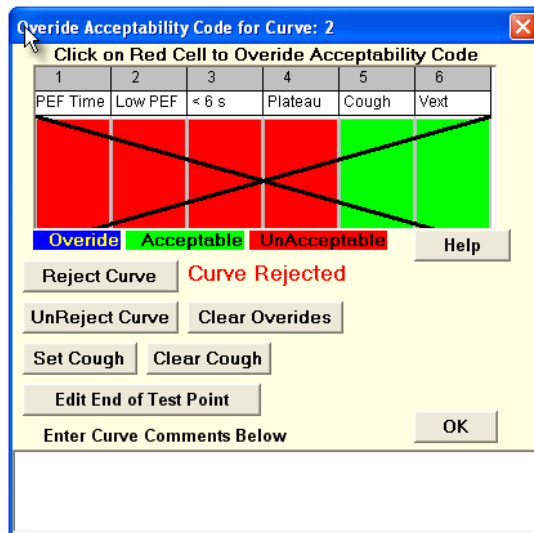
The Quality code box - A more detailed view of the maneuver values is shown below. The largest values for FVC, FEV₁, and PEF are indicted by “BEST” to the right of the value in the “%Vary” column. An important goal of testing is to match the largest and second largest FVC and FEV₁ within 150 ml of each other. This is called repeatability (formerly called repeatability).

To obtain the best test session quality grade (an A), the FEV₁ and FVC must match within 100 ml. A scroll-bar on the right can be used to scroll up or down when more than 8 maneuvers have been done (but this will rarely be necessary).

#	FVC	ml	%Vary	FEV1	ml	%Vary	PEF	ml/s	%Vary	123456
1	5.25	43	0.8%	3.26	40	1.2%	8.03	1152	12.6%	████████
2	5.22	65	1.2%	3.26	42	1.3%	8.04	1141	12.4%	████████
3	5.25	37	0.7%	3.28	17	0.5%	8.58	601	6.5%	████████
4	5.29	0	BEST	3.30	0	BEST	9.18	0	BEST	████████

For experienced technologists ONLY:

How to over-ride the acceptability criteria: Click on the quality code box (extreme right column), and a popup window is displayed, allowing you to over-ride any acceptability code or reject a curve. The repeatability criteria are then re-applied and a message as to whether the test is reproducible is displayed. For acceptability codes, a red bar indicates the criterion is unacceptable. Click on the “Reject Curve” button if you wish to reject a curve, “Set Cough” button if you feel the computer did not correctly detect a cough, “Clear Cough” button if you feel the computer incorrectly label the curve as having a cough. Any code that is “over-riden” is colored in blue instead of red.



Criteria for an acceptable maneuver: no hesitation or false starts; the volume of back-extrapolation (Vext) less than 5% of the FVC or 0.15 L (whichever is greater). No coughing during the first second; no glottis closure, no mouthpiece obstruction by tongue or dentures. There should be a plateau at the end of the volume-time graph; and the maneuver should last at least 6 seconds.

Criteria for a repeatable test session: after three acceptable maneuvers, the two highest values for FVC and FEV₁, taken from acceptable forced expiratory maneuvers, must show minimal

variability. The two largest FVC values should agree within 150 ml; the two largest FEV₁ values should agree within 150 ml. Testing should continue until three acceptable tests (all green in the code box) and repeatability criteria are met (yellow values), until a maximum of eight tests have been performed, or until the participant cannot or should not continue. To obtain the highest quality rating, the FEV₁ and FVC repeatability must be within 100 ml.

Proceed or Done: You decide to proceed to perform another maneuver (“Do Another Trial”), or to stop performing additional FVC maneuvers (“Done”).

Post Test Questionnaire: After test completion, the “Post Test Questionnaire” screen will appear. On this screen, indicate the testing position, participant (client) effort, and add comments, if you wish. Then click “OK.”

Please complete the following questions for current client

Check appropriate boxes to indicate a yes response

Post-Test Questions

Did any of the following Signs or Symptoms Occur?

<input checked="" type="radio"/> Standing	<input type="checkbox"/> Headache
<input type="radio"/> Sitting	<input type="checkbox"/> Dizziness or lightheadedness
<input type="checkbox"/> Client's Effort	<input type="checkbox"/> Coughing
<input checked="" type="radio"/> Maximal	<input type="checkbox"/> Short of breath
<input type="radio"/> Questionable	<input type="checkbox"/> Other
<input type="radio"/> Sub-maximal	

Enter Remarks Below

OK

3.3 Coaching Breath-holding for the *Lung* CT Scan

Accurate and precise CT scanning of the lungs requires a deeeeeeeep breath-hold in exactly the same way that accurate and precise spirometry requires a deeeeeeeep breath in Phase One of the spirometry maneuver. The *lung* CT scan is italicized in this section because, while the CT tech will ask the participant to take a deep breath for the cardiac scan also, the accuracy and precision of the cardiac scan is less dependent on the deep breath than is the *lung* CT scan. Hence, we are particular focused on getting a really deeeeeeeep breath for the *lung* scan.

Please therefore prepare the participant for the *lung* CT scan by telling them, after completing spirometry, that they will need to take as deep a breath as they can for the *lung* CT scan, just like they did for spirometry. The only difference is that they will hold the deep breath for about 10 seconds during the *lung* CT scan and then breathe out normally – instead of ‘blasting out’ for the FVC maneuver. Please demonstrate for them (emphasizing the deep breath and hold) and have them practice (unless they are too tired after spirometry).

There are several reasons why we wish *you* to explain the breath-hold for the *lung* CT scan to the participant. Both you and the CT techs have been trained and certified in MESA Lung spirometry and *lung* CT scanning, respectively. However, you have established a relationship with the participant, you know how important breathing is for these tests, and you speak the participant’s language. The CT tech does not know the participant as well, is sometimes more focused other aspects of the CT protocol, and may not speak the participant’s language.

The Lung CT Reading Center has produced videos to show you the *lung* CT scan being performed. Please watch the 6-minute video at:

<http://www.youtube.com/watch?v=aEocwG08iq0>

You will be asked for a username and password:

username: iowaimagingtraining
password: iowait2010

(please note that the actor portraying the CT tech was over-aggressive in his portrayal of coaching breath-holding; we are in the process of correcting this).

If you are interested, there is additional (optional) background information on the measures that we obtain from the lung CT scans at the link below (same username and password):

http://www.youtube.com/watch?v=_Jz_rVNZBQM

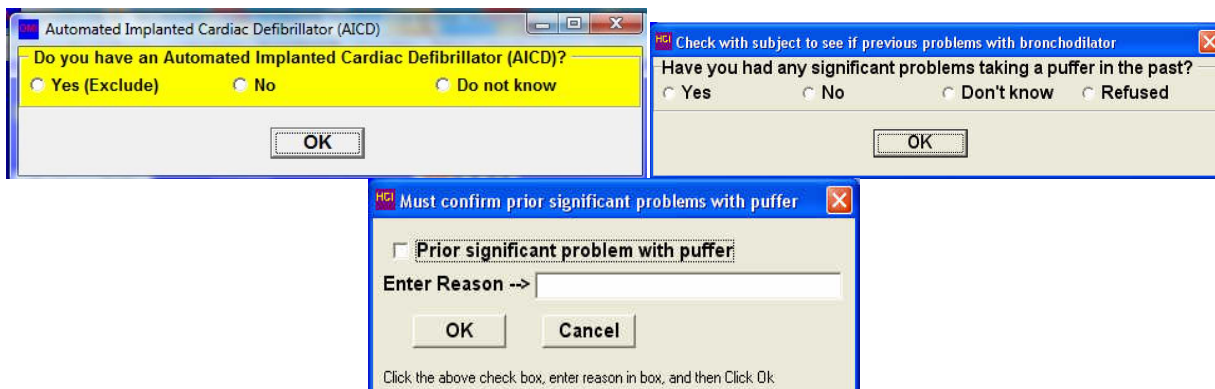
There is no certification test for this section. Thank you for your help!

4. BRONCHODILATOR TESTING

The MESA Lung participants who have airflow obstruction and all participant in the MESA COPD Study (Columbia, JHU, NWU, UCLA only) will be offered post-bronchodilator spirometry to determine if the airway obstruction is reversible (indicating that asthma is more likely than COPD). For this purpose, airway obstruction is defined as a FEV1/FVC below Lower Limit of Normal (LLN) calculated using the NHANES III reference equations or FEV1/FVC below 0.70. Selected participants will receive albuterol if they have no contraindications to albuterol administration (see Spirometry and/or Albuterol Exclusions Section).

The following screen will appear if the participant is selected for post-bronchodilator spirometry and has no contraindication based on information collected earlier in the exam. These screens are to check to see if the subject has had an automated implanted cardiac defibrillator or any SIGNIFICANT problems with a bronchodilator puffer in the past. Ask the participant about “any SIGNIFICANT problems taking a puffer in the past” and show the puffer to the participant (this is much faster than trying to explain what a puffer is; the puffer is immediately recognizable to participants who have taken them in the past).

NOTE: Bronchodilators frequently cause a brief coughing spell. Cough is a normal response to a bronchodilator. Cough should NOT be considered a significant problem with a puffer. In other words, if a participant reports cough following bronchodilator administration, click “No” and proceed with bronchodilator testing.



The screen (above-left) will appear for anyone who meets the study criteria for a bronchodilator test. Note the participant can refuse the bronchodilator test at this point by selecting “Refused.” If you click “Yes”, you must verify your selection by clicking the “Prior significant problem with puffer” checkbox (above right) and by entering the prior significant problem in the text box. Doing so will abort the post-bronchodilator testing protocol.

You will also be asked to check the participant’s medications to make sure that they are not taking one of the medications on the lists provided (see panel below).

NOTE: Although these lists are long, all of these medications are prescribed rarely – even in patients with cardiac disease and depression. Anti-arrhythmics are prescribed only for a few patients with or at risk for severely abnormal heart rhythms (i.e., NOT for the much more common “heart disease” [coronary heart disease] and generally not for atrial fibrillation). MAO inhibitors and tricyclic antidepressants are both older types of antidepressants that are rarely

prescribed for depression these days. Tricyclic antidepressants (particularly amitriptyline [Elavil]) are still occasionally prescribed for chronic nerve pain.

Medications that prevent bronchodilator testing

Please confirm that participant's medicines do not include Class 1 anti-arrhythmic drug, monoamine oxidase inhibitor, or tricyclic antidepressants?

None (Do Not Exclude Subject) Yes (Exclude Subject) Drug --> If Yes, enter drug below

Double Click on Drug to Select Use Unknown if no information (Click Yes) -> Unknown

Anti-Arrhythmics That Exclude Participants		MAO Inhibitors that Exclude Participants	
Amiodarone (Cordarone)	Rhythmol (Propafenone)	Isocarboxazid (Marplan)	
Bretium (Bretylol)	Tambocor (Flecainide)	Phenelzine Sulfate (Nardil)	
Bretylol (Bretylum)	Tocainide (Tonocard)	Tranylcypromine Sulfate (Parnate)	
Cardioquin (Quinidine, Quinalan, Quinidex, Quinaglute)	Tonocard (Tocainide)	Phenelzine Sulfate	
Cordarone (Amiodarone)	Quinaglute (Cardioquin, Quinidine, Quinora, Quinalan, Quinidex)	Tranylcypromine Sulfate	
Disopyramide (Norpace)	Quinidine (Quinora, Quinalan, Cardioquin, Quinidex, Quinaglute)		
Dofetilide	Quinalan (Quinora, Cardioquin, Quinidex, Quinaglute, Quindine)	Tricyclic Antidepressants that Exclude Participants	
Enkaid (Encainide)	Quinora (Quinidine, Quinalan, Cardioquin, Quinidex, Quinaglute)	Amitriptyline (Elavil, Vanatrip, Endep)	
Ethmozine (Moricizine)	Quinora (Quinidine, Quinalan, Cardioquin, Quinidex, Quinaglute)	Amoxapine (Asendin)	
Flecainide (Tambocor)	Xylocaine (Lidocaine, Xylocard)	Clomipramine (Anafranil)	
Ibutilide	Xylocard (Lidocaine, Xylocaine)	Desipramine (Norpramin, Pertofrane)	
Lidocaine (Xylocaine, Xylocard)		Doxepin (Sinequan, Zonalon, Adapin)	
Mexiletine (Mexiti) Mexiti (Mexilitine)		Imipramine (Tofranil)	
Moricizine (Ethmozine)		Maprotiline (Ludiomil)	
Norpace (Disopyramide)		Nortriptyline (Aventyl, Pamelor)	
Procainamide (Pronestyl, Procan SP)		Protriptyline (Vivactil, Triptil)	
Procan SP (Procainamide, Pronestyl)		Trimipramine (Surmontil)	
Pronestyl (Procan SP, Procainamide)			
Propafenone (Rhythmol)		Other	
		Automatic implanted cardiac defibrillator (AICD)	

If you check “Yes (Exclude Subject)”, you should enter the “Drug” by typing it or double-clicking on a drug from the bottom panels. If the participant did not bring their medications AND does not know what medications they are taking AND has abnormal heart rhythm, depression or chronic pain, enter “Unknown” for the Drug and click “Yes (Exclude Subject).”

One of the two following panels will then appear. If a participant is selected for and has no contraindications to bronchodilator testing, the “Bronchodilator Testing Recommended” box (left) will appear and you should proceed with bronchodilator testing (Section 4.1). If a subject has a contraindication for a bronchodilator, the “RESTRICTED, No Bronchodilator Testing” message will appear instead (right). Note that the screens below appear after completion of the pre-bronchodilator FVC maneuver and you MUST complete the pre-bronchodilator SVC maneuver as appropriate – see text at bottom of screens below.

Session	FVC	FEV1	FEV1/FVC
Observed	3.33	2.68	80.6%
Predicted	34.72	26.25	75.5%
%Predicted	9.6%	10.2%	106.9%
Lower Limit	29.05	21.45	65.8%

Reference Values: Hankinson(C)-1999
* Compare LLN to Observed
Possible MESA COPD Study Control subject

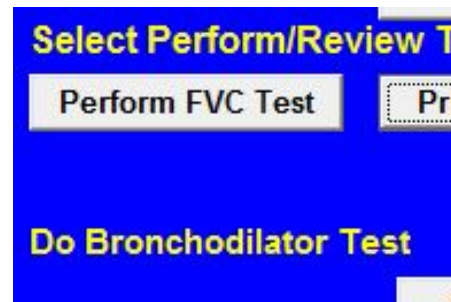
Complete Pre-Bronchodilator SVC maneuvers as appropriate.
Bronchodilator Testing Recommended

Session	FVC	FEV1	FEV1/FVC
Observed	3.70	3.06	82.6%
Predicted	35.59	26.86	74.4%
%Predicted	10.4%	11.4%	110.9%
Lower Limit	29.76	21.93	64.8%

Reference Values: Hankinson(C)-1999
* Compare LLN to Observed
MESA Lung Study

Complete Pre-Bronchodilator SVC maneuvers as appropriate.
RESTRICTED, No Bronchodilator Testing

Appendix B shows a flow chart for determining whether albuterol is administered for a post-bronchodilator test. After administering albuterol, perform first the SVC Test and then the FVC Test as before. Notice that a message that you should be performing a post-bronchodilator test will appear on the main screen.



If you have any concerns about administration of albuterol in a given participant, if you believe the participant should not have been selected for albuterol administration or if you have other questions or uncertainty about albuterol administration, then contact the PI or the MESA Lung/COPD PI (Dr. Barr) for further assessment prior to proceeding.

4.1. Confirmation of Eligibility for MESA COPD

Coordinating Center software will track participant consent into COPD, as well as their current age, an exclusion criterion for MESA COPD. The majority of potential COPD participants will have been previously selected for eligibility in MESA COPD based upon information provided in prior exams.

At the end of post-bronchodilator testing, the software will tell you that the participant qualified based upon spirometry for the MESA COPD Study. For cases, this is based upon a post-bronchodilator FEV_1/FVC ratio < 0.70 . For controls, it is based upon a pre-bronchodilator FEV_1/FVC ratio ≥ 0.70 and the $FVC > LLN$. Appendix C shows a detailed flow chart for determining eligibility for the MESA COPD Study.

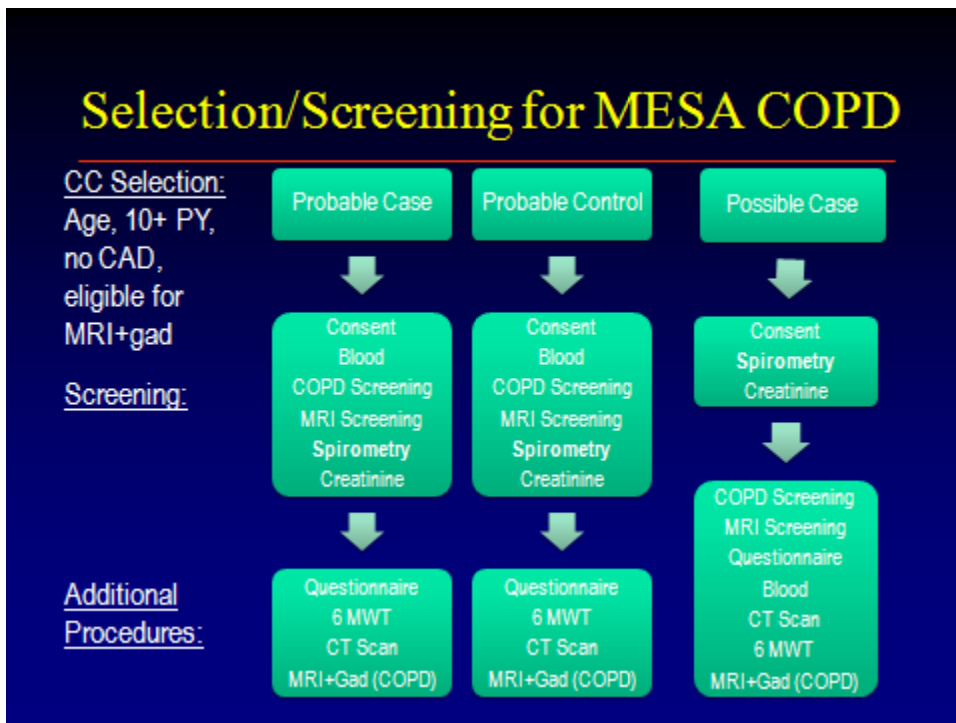
If the spirometry software says “The participant is eligible to continue in MESA COPD,” and was previously selected for MESA COPD by the Coordinating Center, mark on the Spirometry Completion Form item #8, that the participant is indeed eligible for inclusion in the MESA COPD Study based upon spirometry “Eligibility for MESA COPD Confirmed”. These participants should have already consented to the study and had the appropriate blood draw. The participant should continue with the other MESA COPD procedures of MESA COPD: Screening form (if not already completed) Six Minute Walk, Lung CT scan, COPD questionnaire and MESA COPD MRI protocol. Note that final inclusion in COPD is based not only upon spirometry but the MESA COPD Screening protocol as well as no MRI exclusions.

Some participants may not have been selected by the Coordinating Center for MESA COPD but are eligible based upon their spirometry. For these participants, the spirometry software will say, “The participant was not selected for but is eligible for MESA COPD.” These participants must meet the other eligibility criteria. The Coordinating Center software will prompt if the participant is not eligible based upon age. If the participant is in the correct age range and these participants are eligible, mark on the spirometry Completion Form item #8 “Eligible but not selected for MESA COPD”. Ask the participant if they wish to participate in the MESA COPD study, obtain consent and update records (Clinic Reception Form, etc) as appropriate. If they agree and consent, proceed with the MESA COPD Screening form and the MRI Exclusion form to confirm that the participant has no other exclusions. If no other exclusions, proceed with the Six Minute Walk, Lung CT scan, COPD questionnaire and MESA COPD MRI protocol. These

participants will need (although are not required) to provide an additional blood (10 ml heparin tube +/- CBC tube, the latter if not collected by MESA Epigenetics Study).

If the spirometry software says “The participant is NOT eligible to continue in MESA COPD,” mark on the Spirometry Completion Form that the participant is NOT eligible for inclusion in the MESA COPD Study based upon spirometry. The participant can and should continue in the MESA Lung Study, if consented, and complete the Lung CT scan as part of MESA Lung.

These three potential scenarios whereby a participant may be eligible for MESA COPD are summarised in the figure below.



4.2. How to Give Albuterol

1. Shake the MDI. Point it away from faces, and then activate it once to verify aerosol delivery.
2. Attach a clean spacer
3. Hold the MDI and spacer in front of the participant's open mouth.
4. Ask the participant to exhale
5. As the participant inhales *slowly*, activate the MDI while instructing the participant to continue to inhale slowly and completely. Count to five slowly.
6. Instruct the participant to hold his breath 5 seconds and then to exhale slowly.
7. Wait one minute and repeat above steps to administer another puff of albuterol.
8. Wait 10-15 minutes and then repeat spirometry
9. Click on the main menu item “Perform/Review Test”
10. Click on “Add Post Bronchodilator Test”
11. Perform FVC test as previously described
12. Click on main menu item “Print Report”
13. Click on “Print Participant Report” menu item
14. Click “Print All”
15. Click on “Apply Selection” button
16. Click on check box “Print report to screen only” so that it is checked
17. Click “Print Report” button

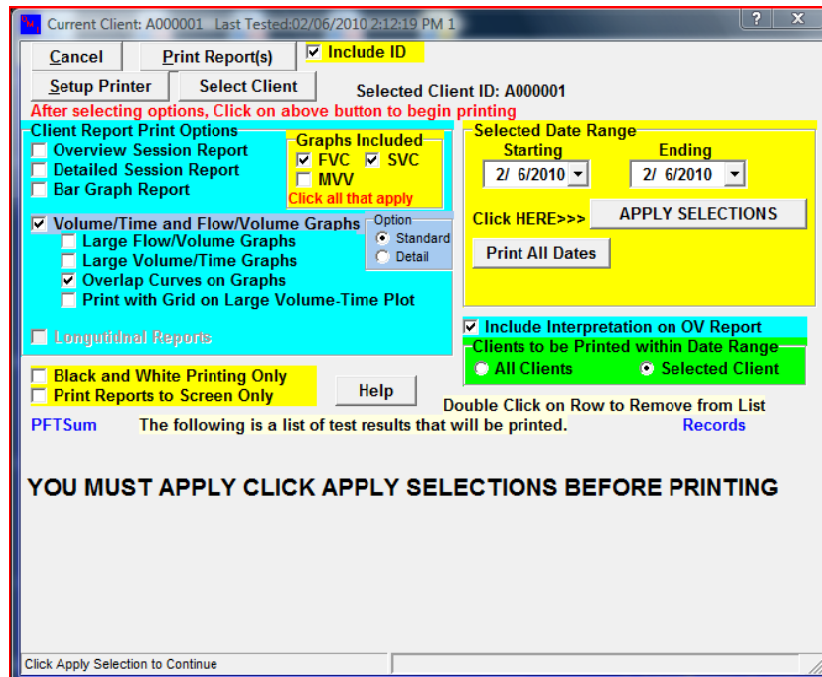


4.3 Possible Side-Effects of Albuterol

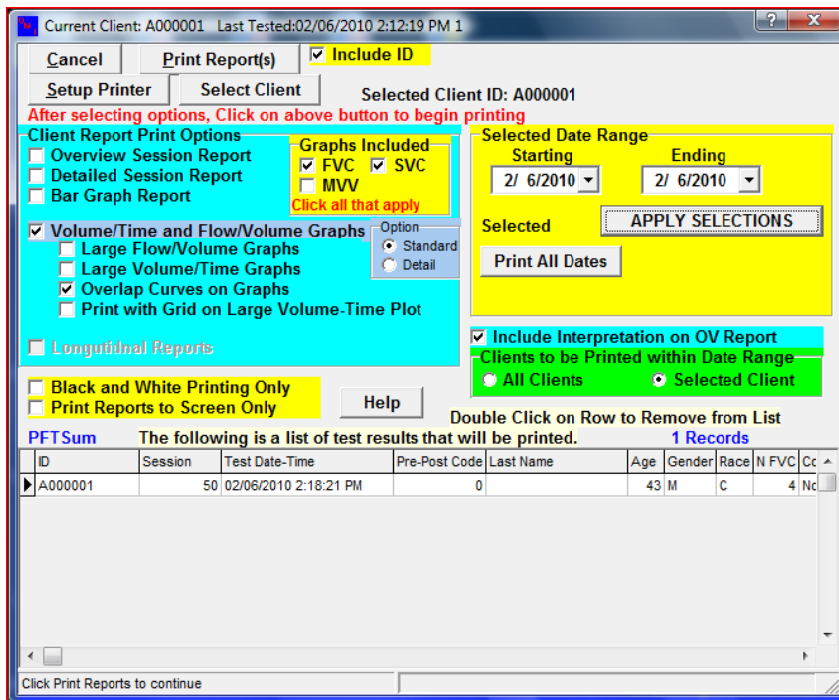
Albuterol is a mild stimulant, like caffeine, so some people (especially those who don't drink coffee or tea regularly), may experience mild nervousness, lightheadedness, a slight tremor, or a headache for up to an hour after inhaling albuterol. These are not worrisome symptoms and will subside before the end of the visit. Albuterol may also increase the heart rate, but does not cause arrhythmias, even in older people. Albuterol is used by tens of thousands of patients with asthma or COPD every day as a “rescue” inhaler to relieve shortness of breath.

5. HOW TO PRINT A REPORT

At the end of each test session, use the “Print Report” main menu item to print all test results. The “Print Current Test” menu item under “Perform/Review Test” is used, while participant information and results are still current in the computer. The right mouse button can also be clicked to display a popup menu with the “Print Current Test” menu item. Notice both the FVC and SVC check boxes are checked. You must click “Apply Selections” to complete the selection of tests to be printed.

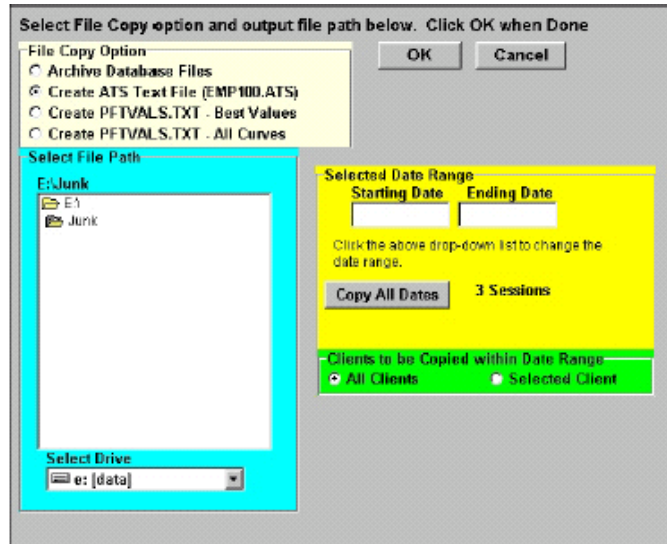


After Clicking “Apply Selections” the Test to be printed will appear in grid box. Click “Print Reports” to send the results to the printer.



5.1. Copy File

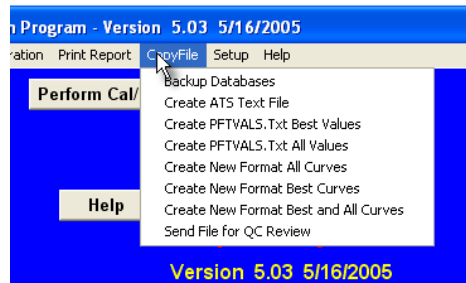
The “Copy File” main menu item provides you with a convenient means of backing up the data files. The sub-menu items under “Copy File” allow you to select several types of files to copy, some with selected date range limitations. You may select the output path using a file dialog box or use the default setting established in the setup program. The text files (EMP100.ATS and PFTVALS.TXT) can be limited by specified date range or for a selected participant. The backup files allow you to backup all the database files - compressed into one PKZIP compatible file. Again, the user can select the path for this file or the default path established in setup will be used. When you click the “OK” button, the list of database files is shown in the left list box, and as each individual file is placed in the backup zip file, it is listed in the right list box. Progress bars for both the individual files and for all files are shown. A default name of “OMIBackup.Zip” is used unless you specify another file name. The computer checks to see if the file already exists and prompts you to replace or update the file or exit and rename the backup file.



Copy Text File Screen

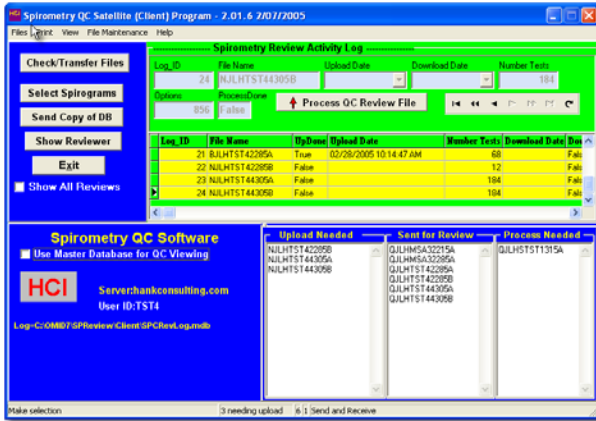
5.2. Send File for Review every Friday

The “Send File for Review” menu item, located under “Copy File” on the main screen is used to send data to the quality control center within the main spirometry program. Clicking on “Send File for QC Review” or the “SpRevParticipant” desktop icon runs the program which will select participant spiromograms to be sent for review.



Copy File Menu - Send File for QC Review

Start Send File Program - Clicking on *Send File for QC Review* or desktop icon will execute the transfer program, see below. The yellow grid in the middle of the screen shows a list of files uploaded to the QC Reviewer and the transmission dates. Click on “*Send Copy of DB*” button to send a copy of the latest results to the QC Reviewer. The first time you run the program, you will be asked to select your field site (see figure on right).

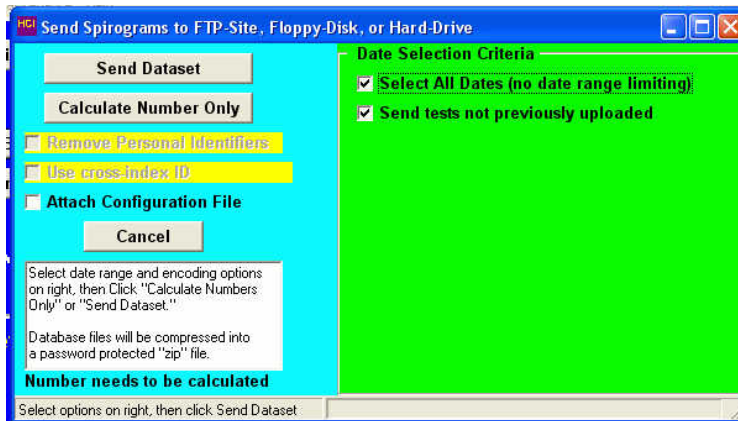


File Selection Program - Main Screen

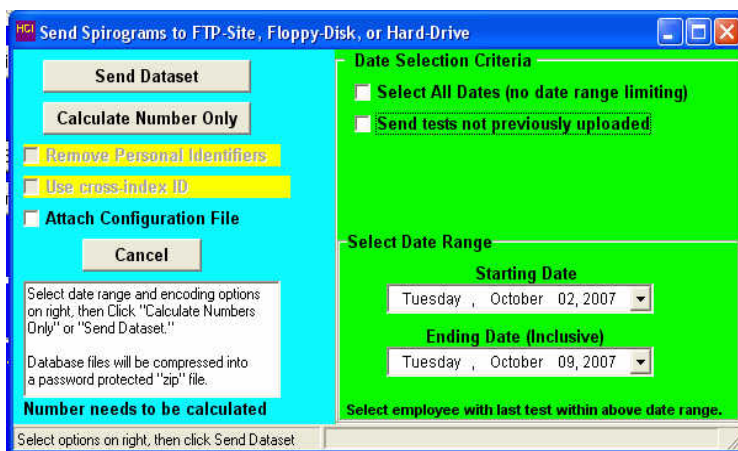


Select Site (User ID)

Selecting Date Range - The *Send Copy of DB* button will cause the *send spiromograms selection screen* to appear. Use the Standard option below (both boxes on right checked). However, you may need to select the dates or date range of tests to include in the transmission if you need to resend some tests. The default starting date is the day after the date of your last transmission and the default ending date is the current date. The default settings of *Remove Personal Identifiers* and *Use cross-index ID* should remain checked.

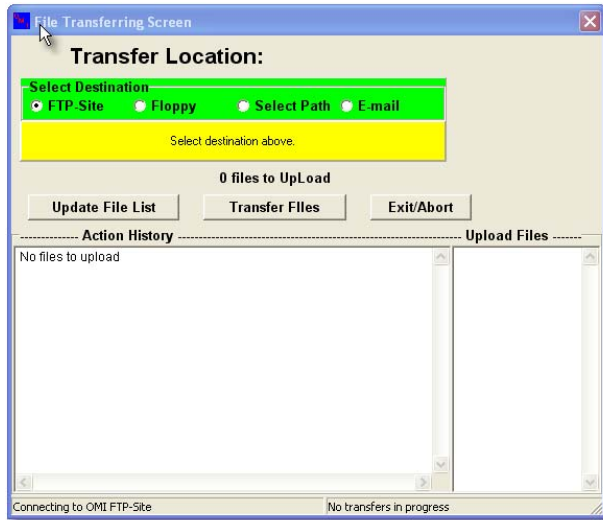


Send Spirograms Selection Screens (Standard)



Send Spirograms Selection Screen (by Date)

Transmitting Data - After verifying that the dates are correct, click the “Send Dataset” button to continue the transmission of the spirometry results. If you receive a warning message that you are about to a replacing an existing file, click OK as this file is no longer needed. The Transfer Location screen will appear where you can select where you want the file to be sent. You should copy the file to a USB memory stick via the “Select Path” option. Transfer the file on the USB memory stick to the MESA computer then email to the Spirometry Reading Center. The default is to use the Select Destination option shown in the screen below (FTP-site).



File Transfer Option Screen

After the file has been transmitted, you may exit the File Transfer Option Screen and the File Selection Program and return to the main spirometry screen.

6. QUALITY ASSURANCE

Upon completion and review of each batch of incoming data, you will be notified quickly of any errors with calibration and procedures. Each month, statistics will be compiled for each technician summarizing the quality of the tests done and the results of calibration checks. The reports may indicate that you may need additional training.

6.1. Training

Technicians from each Field Center will be trained centrally. Training will also include completion of a web-based spirometry training course, including answering all the review questions. Chapter 5 (hand-measurements) is optional. Retraining may be done by an experienced on-site technician.

6.2 Certification

The examination includes a formal web training, 50 multiple choice questions (written exam), and a practical demonstration of skills including leak and calibration checks, cleaning, and testing of a naive participants. A passing score of at least 70 points is necessary for certification for the written exam. Only certified technicians will perform pulmonary function testing in this study. A web-training account can be obtained from john@hankconsulting.com.

In addition, the slides from the spirometry training are on the MESA Lung website, <http://www.uwchsc.org/MESALung/MesaLung2.aspx> under the link, “[Spirometry for MESA Lung Webinar - February 2010](#).” These should be reviewed, if not seen in Central Training, and provide a useful reference as the study goes on. The user name and password for the MESA Lung website are the same as for the main MESA website.

PF technicians should test at least one person (participant, another technician or staff member) per week between the training session and the start of recruitment. To retain certification, technicians must test at least ten participants each month.

Certification of new technicians following the initial central training sessions may be performed by the project coordinator. The written exam is available on the training web-site, and the first 5 PF test performed will be observed by a certified PF technician or project coordinator and then examined by the PF Center and found to be satisfactory before the new technician is certified.

6.3. Site Visits

The results of the first 50 spirometry test sessions performed by each technician will be closely examined by the QC Supervisor (John Hankinson). Copies of suboptimal quality test sessions with comments for improvements will be sent to you the same day as they are evaluated.

A site visit to each of the four clinical centers may be made during the first three months of recruitment. Complete calibration, leak, and linearity check, and spirometry testing of at least three participants by each 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.

6.4. The Need for Spirometry QC

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

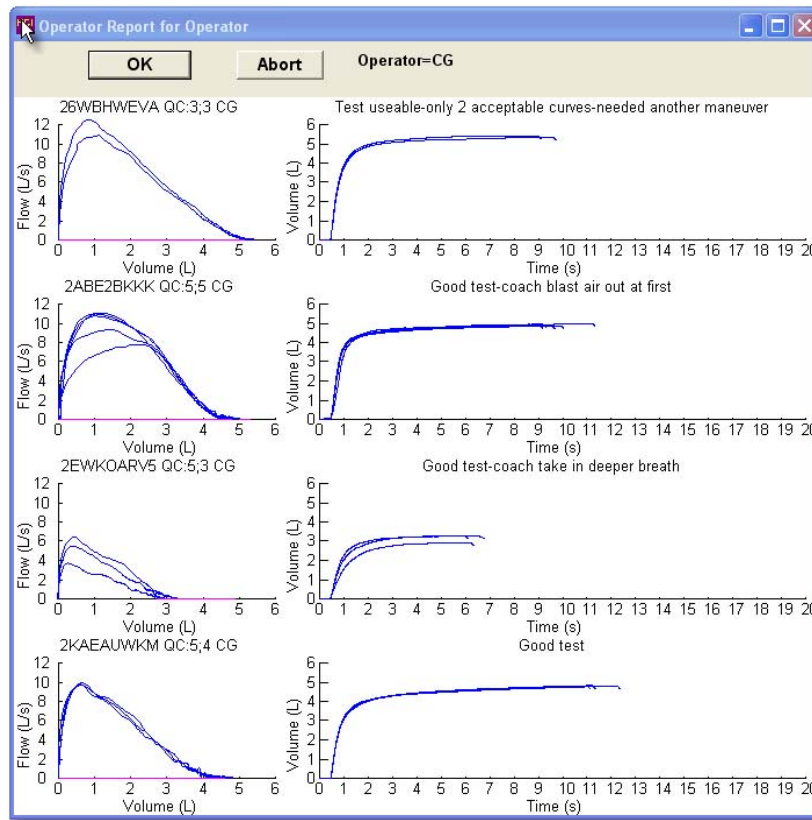
Evaluations of commercially available spirometers emphasize the importance of spirometry quality control procedures. Factors affecting spirometry quality include:

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

6.5. Implementation of QC Procedures

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

1. Daily spirometer leak and calibration checks using a 3.00 liter syringe as the “gold standard” check maneuver immediately after it is performed.
2. Eight computerized checks of FVC maneuver acceptability and repeatability check every maneuver immediately after it is performed.
3. The PF technician is trained to recognize the patterns of acceptable 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 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. The calibration factors, PF tech’s impression of the participant and the 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. An operator report will be sent by e-mail to each technician periodically and at a minimum at the completion of testing at a study site. The operator report (password protected “pdf” file) contains copies of all tests performed by a technician with flow-volume, volume-time curves, FVC and FEV₁ quality factor codes, and specific comments (see below).



7. The following statistics are reported each month by the quality supervisor:
- Average number of acceptable maneuvers, by technician.
 - Percentage of participants with non-repeatable tests results, by technician.
 - Percentage of participants with less than 3 acceptable maneuvers, by technician
 - Percentage of participant with less than 2-acceptable maneuvers, by technician.
 - Average FVC quality score, by technician.
 - Average FEV₁ quality score, by technician.

Quality grades (A-F) are computed for FEV₁ and for the FVC (quality codes) based in part on the number of acceptable maneuvers. An acceptable maneuver for FEV₁ quality purposes is no cough or large extrapolated volume. At least 6-seconds of exhalation and a plateau in the volume-time curve (30 ml in one second) are needed for an acceptable quality FVC. However, a maneuver that does not have a plateau but the exhalation is longer than 15-seconds is considered acceptable.

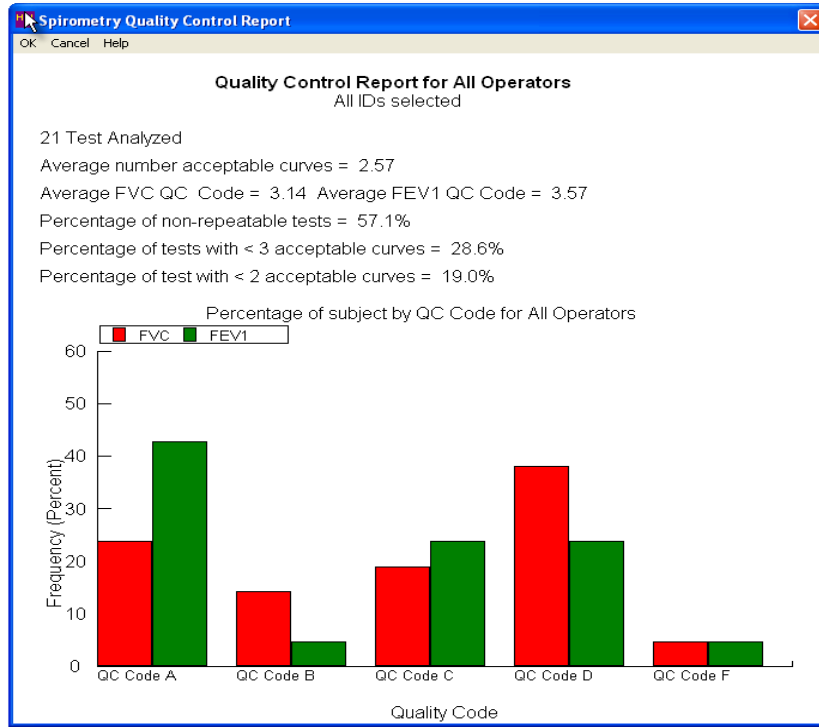
Test session QC grades are assigned as follows:

- A = 3-acceptable curves, plus largest and second largest value within 100 ml
- B = 2-acceptable curves, plus largest and second largest value within 150 ml
- C = 2-acceptable curves, plus largest and second largest value within 200 ml
- D = 1 acceptable curve plus no end of test requirement for FVC QF
- F = no acceptable curves

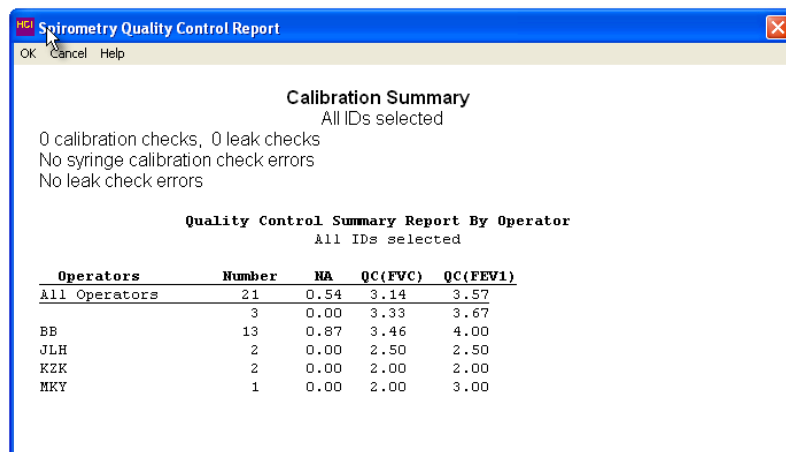
The QC supervisor may assign a slightly higher QC grade for participants with obvious airways obstruction where it is difficult to obtain a plateau or reproducible test. A lower

grade may also be assigned if a curve is judged to be unacceptable because the FVC or FEV₁ cannot be accurately measured.

- In addition to the quality control summary report, a calibration summary report is also provided. Trends of average FVC and FEV₁ quality scores will be monitored during the study to determine if quality issues need to be addressed. Sample quality control reports (individual technician reports are similar to the All Operators report) are shown below:



Quality Control Report - All Operators Combined

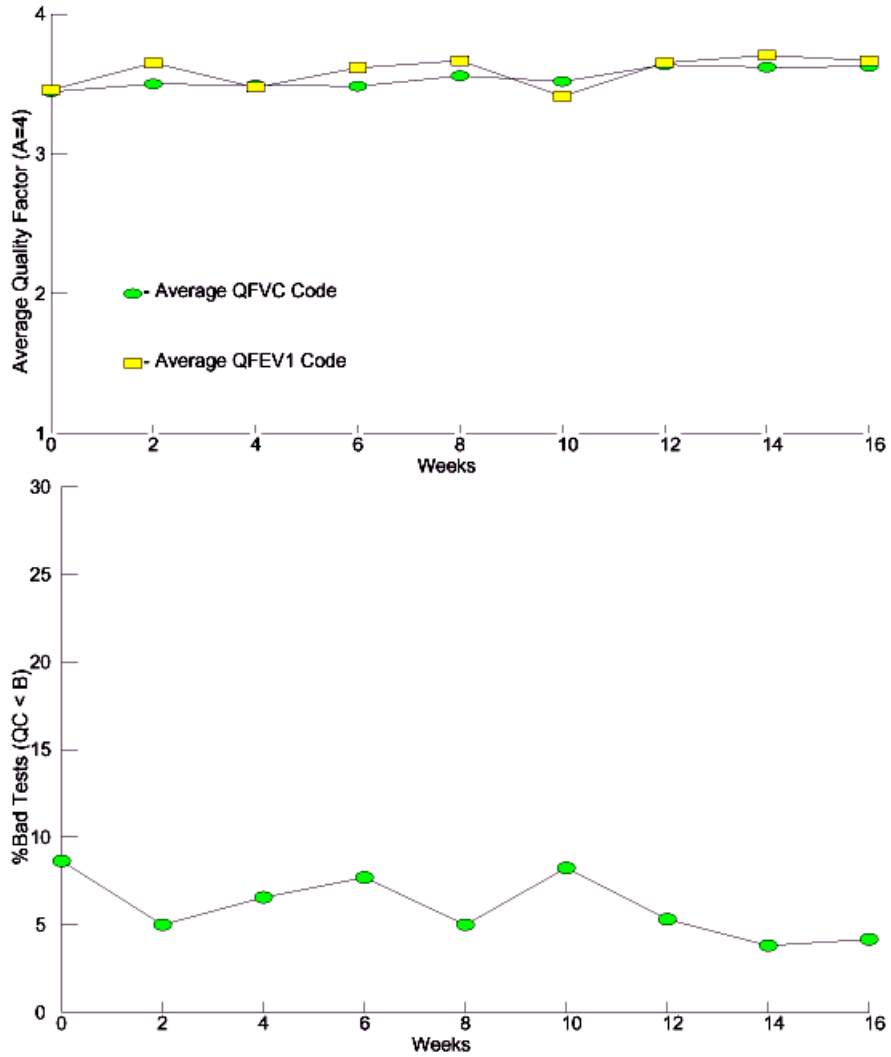


Calibration and Quality Control Summary Report

Trend Period 10/1/2003 to 2/15/2004 (18 weeks)

Week	N	QFVC	QFEV1	%Bad	Week	N	QFVC	QFEV1	%Bad	Week	N	QFVC	QFEV1	%Bad
0	81	3.44	3.46	8.6%	2	80	3.50	3.65	5.0%	4	61	3.49	3.48	6.6%
6	91	3.48	3.62	7.7%	8	120	3.56	3.67	5.0%	10	85	3.52	3.41	8.2%
12	132	3.64	3.65	5.3%	14	105	3.62	3.70	3.8%	16	24	3.63	3.67	4.2%

QC Code Trends for All Operators; 4=A, 3=B, 2=C, 1=D, 0=F



Quality Control Trend Analysis

7. SAFETY PROCEDURES

All equipment must be plugged into a grounded electrical outlet.

To minimize cross-contamination:

- Use a clean hose for each participant
- Use disposable mouthpieces
- Keep the participant's mouth higher than the spirometer snout.
- Participants do not inhale from the spirometer.
- The spirometer and accessories will be cleaned and disinfected at regular intervals.
 1. Tubing will be cleaned and disinfected daily (see Section 2.5)
 2. Instruments will be cleaned at the end of each testing session (see Section 2.4)
 3. Seal will be inspected and cleaned at the same time.

For participants that do not understand English, Spanish Versions of the exam instructions will be provided.

In rare cases, a participant may hyperventilate and feel dizzy during the examination. Ammonia capsules are available in the event of a participant becoming faint. A participant who feels faint should be guided onto the chair with head down towards knees and encouraged to breathe slowly and deeply until recovered. A physician should be summoned whenever a participant fails to recover normal breathing, faints or reports feeling ill.

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Appendix A: The OMIWSP Setup Program

There are three configuration screens. It is important that these configurations are selected, otherwise the data needed for the study and subsequent analyses may not be stored.

Screen 1

Registration Information
Registration Number- set by OMI
Address: your address
Location: your location
Computer ID: take your pick
Maintenance Mode – Disabled

Spirometer Information
Spirometer make: SensorMedics
Spirometer Model: 1022
Spirometer Serial Number: to be entered

Screen 2

Report Header - (enter up to 4 lines)

Site Name

Site address

Phone #

Spirometry Report

Adjustable Parameters

Barometric Pressure - 760

Leak Volume – 20ml

Repeatability Criterion: 150ml

PEF Repeatability Percent - 20

Plateau Volume -40

Plateau Time - 1

Time Check Percent Allowed - 02.0

Extrapolated Volume Criteria - 150

MVV Test Time - 12

Communications Port - 1

Test Start Method - Auto

Starting Session Number - 50

Automated Interpretation - Yes

Interpretation Level - 95%

Interpreter Algorithm - MESA

Selected data path - C:\Program Files\OMI\Database

Use Program Dr. for Cal Path - No

Allow temporary database path change – No

Nomograms Scale

Caucasian – Hankinson-1999 1.00

Black- Hankinson-1999 1.00

Asian- Caucasian 0.88

Hispanic – Hankinson-1999 1.00

Other 1 - Caucasian 1.00

Other 2 - Caucasian 1.00

Report options

Detailed Session Report - No

Overview of Session Report - No

Volume/Time & Flow Volume Graphs - No

Large Flow/Volume Graphs - No

Large Volume/Time Graphs - No

Overlap Curves on Graphs - Yes

Include Baseline Comparisons - No

Black & White Printer - No

Disable Box (yellow) if below LLN - No

Absolute Values Trend - Yes

Percent Predicted Trend - No

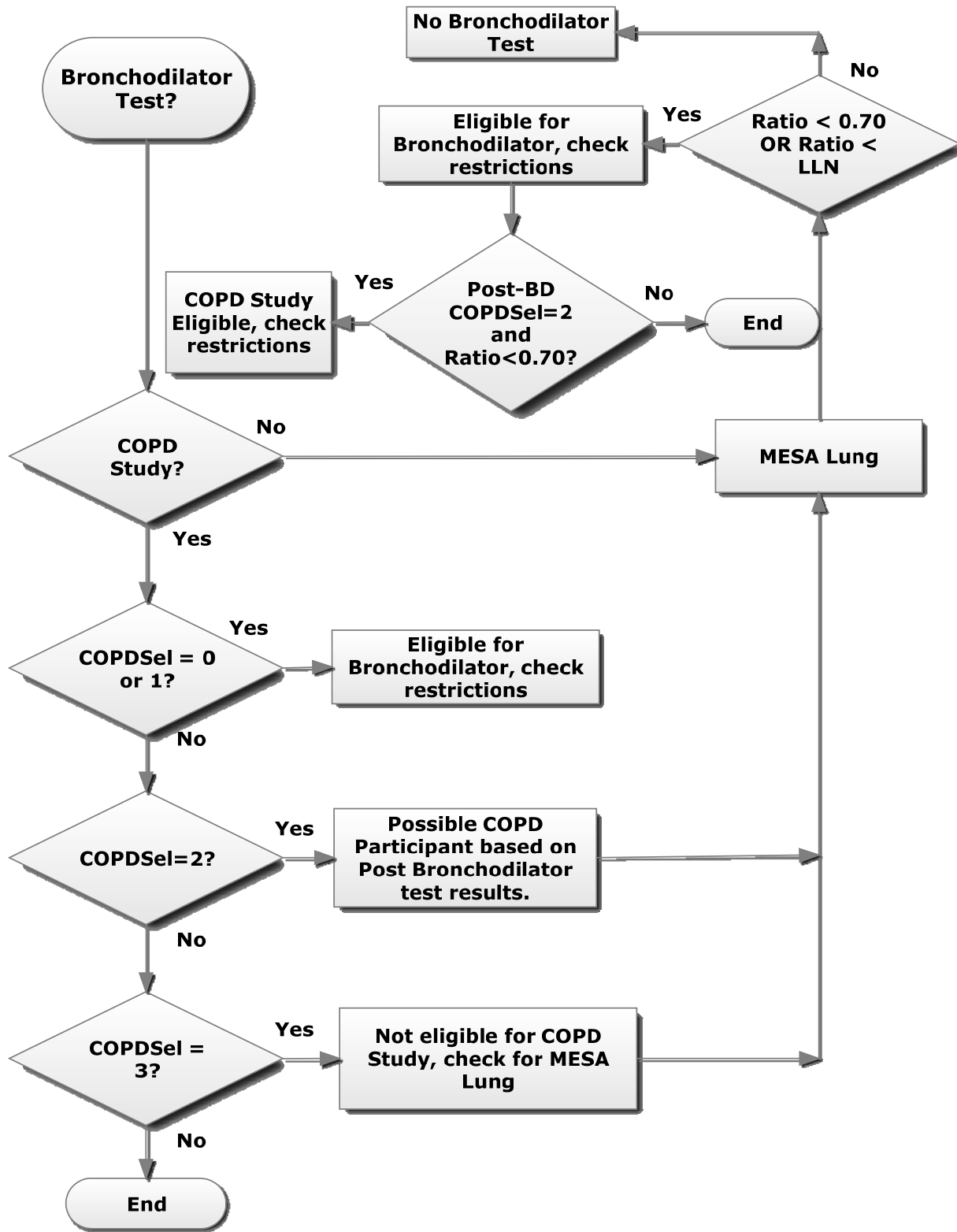
Percent Deviation Trend - No

Screen 3

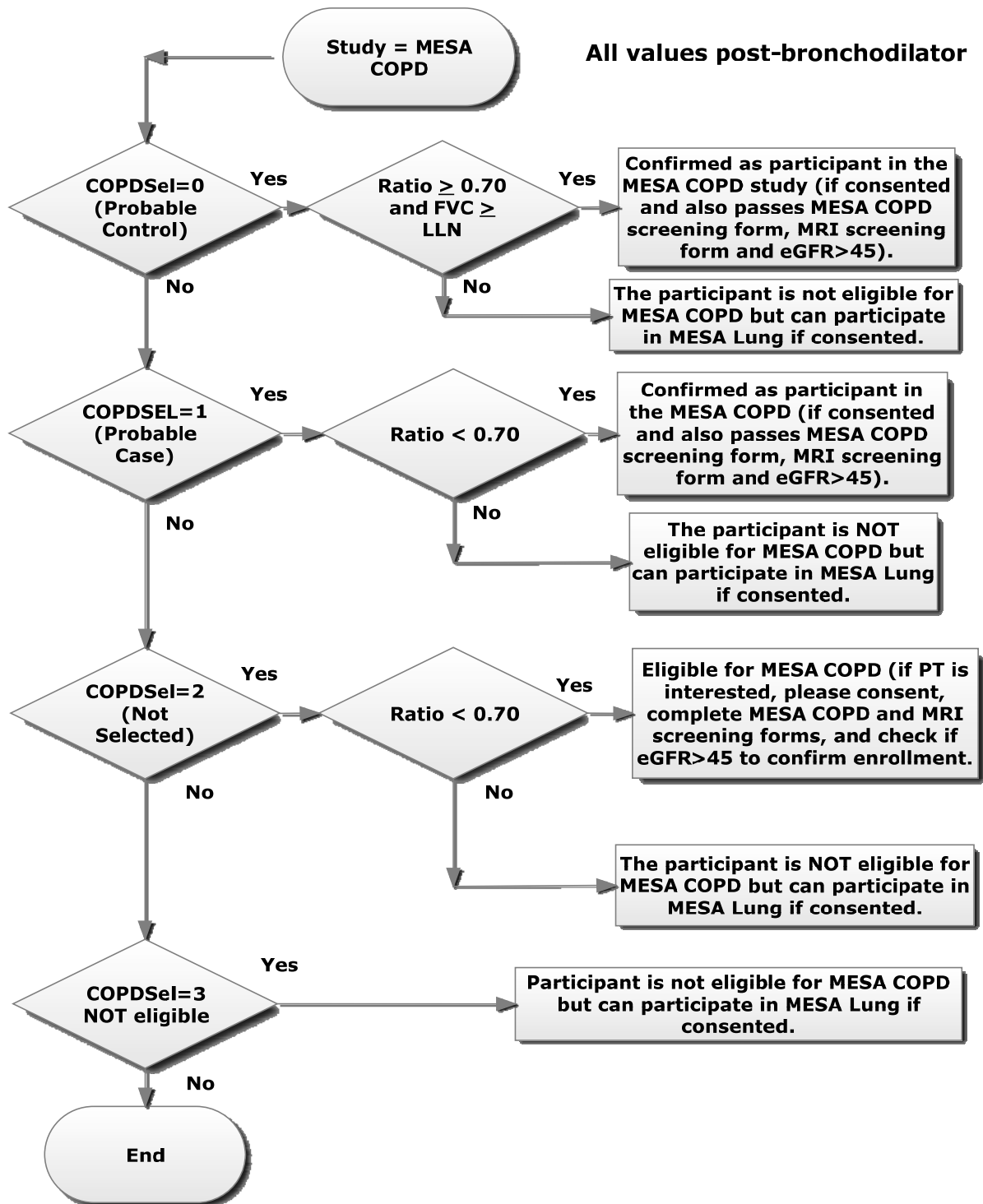
Adjustable Parameters Backup File Path - C:\Program Files\OMI\OMI Spirometry
Enter Manual Temperature - No Parameter Print List
Save Raw Data - Yes SVC – Yes
Enter Participant’s Testing Position - Yes MVV – No
Save Results in Text File - Yes FEV_{0.5} – No
Verify Height and Date - No FEV₃ – No
Save Results in Enhanced Text File - Yes FEV₆ - Yes
Perform SVC and/or MVV Tests -Yes FEF_{25%} - No
Require Operator Password - No FEF_{50%} - No
Require PEF Repeatability - No FEF_{75%} - No
Use FET < 6s Criteria - Yes PEF - Yes
Draw Inspiration – No FEF_{25-75%} - No
Use Largest PEF - Yes FEF_{0.1-1.2} - No
Use PEF Acceptability Criteria - Yes FEV_{0.5}/FVC% - No
Check End of Test Plateau - Yes FEV₁/SVC% - No
Use Cough Detector - Yes FEV₃/FVC% - No
Use Time to PEF - Yes FEV₁/FEV₆% - No
Enter Participant’s Test Effort - Yes
Enter 4-Level Curve Assessment- No
Enter Deviations from Test Criteria - No
Enter Pre-Test Questions - No
Enter Post-Test Questions – Yes
Edit Remarks after Test - Yes
Use Open Circuit Method - Yes
Other Options
Best Test - ATS Criteria (Largest Value)
Date Format - mm/dd/yyyy
Height Units - inches Weight -lbs.
Force Confirmation of Ht & Wt. – No

Exclusion Criteria
PEF Repeatability - No
Time to PEF - No
<6-seconds - No
No Plateau - No
Large Vext - Yes
Cough - Yes

Appendix B: Flow Chart for Determination of Post-Bronchodilator Test



Appendix C: Flow Chart for COPD Study Selection



CONTACT INFORMATION

PERSONNEL

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Athens, GA 30605
Phone: (706) 742-8986
Email: john@hankconsulting.com
Spirometry Information and Installation Web Site: <http://occspiro.com/mesa>
User ID: **mesa**
Password: [**FEV1ratio**] be sure to include brackets

EQUIPMENT

SensorMedics / Viasys / CareFusion

(manufactures the dry-rolling seal spirometer)

22705 Savi Ranch Parkway

Yorba Linda, CA 92887-4645

phone (714) 283-1830 or (800) 520-4368

Occupational Marketing, Inc (OMI)

(OMI added the computer interface to the spirometer and provides software support)

11211 Kathy Freeway Ste, 420, Houston, Texas 77079

phone (800) 869-6783; 281-492-8250

Hans Rudolph, Inc. (makes the calibration syringe)

7200 Wyandotte, Kansas City, MO 64114

Phone (816) 363-5522

SUPPLIES

Thes following items will be provided centrally. Specifications and contact details are provided for your information.

Nose Clips: “Snuffer” Alliance Tech Medical. Contact person Romney Fischer, 800-848-8923, Order number 555 0047, #100.

Hoses: # 1011-xx Clean-Bor Tubes 1-3/8" (35mm) ID, 34" (Box of 50 1011-34-BULK)
Available at <http://www.vacumed.com/zcom/product/Product.do?compid=27&prodid=682>.

Mouthpieces: White disposable cardboard mouthpieces, Catalog number 1027-250 (250 in a box); Nominal size: 34 mm ID, 36.5 mm (1-3/8") OD, 2.5" long [Vacumed.com](http://www.vacumed.com); [1-800-235-3333](tel:1-800-235-3333)

Small mouthpieces: Pink disposable cardboard mouthpieces, Catalog number 1023-100 (100 in a box), Nominal size: 25 mm ID, 27.2 mm (1-1/16") OD, 2.5" long [Vacumed.com](http://www.vacumed.com); [1-800-235-3333](tel:1-800-235-3333)

Spacers: Cardinal Health order number 001427. 5 ft tubes, segmented. 800.964.5227
Cut these into six inch lengths to make disposable spacers for the albuterol MDIs

Detergent: Detergezyme (enzymatic presoak and cleaning solution). Metrex Corp. #10-4500, 1 gallon bottle. Cardinal Health

Stop-cock grease (if needed): Any silicone-based variety (available at local hardware stores). Do not use petroleum-based grease.

DEFINITIONS AND SYMBOLS

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 (V_{ext} , EV or BEV) 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.

BD is bronchodilator. We are using the classic rapid-onset, short-acting bronchodilator: albuterol.

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.

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.

DIAPHRAGM is the large, dome-shaped muscle between the lungs and the abdomen. Its strength is measured by the MIP test.

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. Unfortunately, the FET cannot be seen on a flow-volume curve, and must be displayed separately.

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%.

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 participant takes as deep a breath as possible and then quickly exhales as much air as possible. The FVC is reduced with restrictive disorders.

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

PEF stands for Peak Expiratory Flow, the highest flow measured during the FVC maneuver. It is a good index of effort used at the onset of the maneuver. It can be seen on a flow-volume curve but not on a spirogram.

PF (or PFT) is short for Pulmonary Function (lung tests).

Post-BD is short for spirometry done after albuterol.

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.

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

SPIROGRAM is an older term for the volume-time graph produced by water-sealed spirometers.

VOLUME-TIME TRACING is the graph produced directly by volume-sensing spirometers. It is traced by a pen connected to the spirometer bell with volume on the vertical axis.

Vext (see Back extrapolation)

METHODS SUMMARY

Daily Procedures

Calibrate Instruments

- Power-up workstation
- Check spirometer water level
- Run leak and volume checks (CAL)

Identify each participant

- Select participant's ID number (STATIONS)
- Administer spirometry questionnaire
- Verify name, age, and height (NEW then INF)

Perform Spirometry Test (FVL)

- Demonstrate FVC maneuver
- Attach clean tube & mouthpiece
- Obtain 3 acceptable FVC maneuvers
- Review maneuver quality
- Obtain another 2-5 FVC maneuvers

When indicated, administer albuterol and perform post-BD spirometry

Add comments (FIN)

Clean Equipment

- Clean the breathing hoses
- Rinse and dry the hoses overnight

Weekly Procedures (Friday afternoon):

- Upload week of spirometry data to PF Reading Center via e-mail
- Clean the breathing hoses
- Check the spirometer for leaks
- Rinse and dry hoses over the weekend

Spirometry and/or Albuterol Exclusion Criteria

Questionnaire Exclusion Items on Completion Form:

1. Have you had a heart attack, a stroke, or eye surgery in the last 3 months?
Yes – STOP (Do not perform spirometry or administer albuterol)
No – Proceed
2. Have you had any significant problems doing spirometry in the past?
Yes (Do not perform spirometry or administer albuterol)
No – Proceed
3. [FOR PTS SELECTED FOR BRONCHODILATOR ONLY] Have you had any significant problems taking a puffer [SHOW ALBUTEROL METERED DOSE INHALER] in the past?
Yes (OK to perform spirometry but do not administer albuterol)
No – Proceed

Automated Exclusion Item:

1. Systolic blood pressure \geq 200 mmHg or diastolic blood pressure \geq 110 mmHg – assessed earlier in Exam and leads to exclusion from all exam components, including spirometry and bronchodilator administration.

Other Albuterol Exclusions Items Assessed by Spirometry Software:

1. Report of use of Class 1 anti-arrhythmic drug, monoamine oxidase inhibitor, or tricyclic antidepressant (assessed on the Medication history form) leads to exclusion from bronchodilator administration. All of these drugs are very rarely prescribed and the risk of inhaling albuterol is theoretical. If any of the following prescribed medications are reported on the Medication form, **avoid giving albuterol**:

Anti-Arrhythmics:

Amiodarone (Cordarone)
Bretylum (Bretylol)
Bretylol (Bretylum)
Cardioquin (Quinidine, Quinalan, Quinidex, Quinaglute)
Cordarone (Amiodarone)
Disopyramide (Norpace)
Dofetilide
Enkaid (Encainide)
Ethmozine (Morcizine)
Flecainide (Tambocor)
Ibutilide
Lidocaine (Xylocaine, Xylocard)
Mexiletine (Mexitil) Mexitil (Mexilitine)
Morcizine (Ethmozine)
Norpace (Disopyramide)

Procainamide (Pronestyl, Procan SR)
Procan SP (Procainamide, Pronestyl)
Pronestyl (Procan SP, Procainamide)
Propafenone (Rhythmol)
Rhythmol (Propafenone)
Tambocore (Flecainide)
Tocainide (Tonocard)
Tonocard (Tocainide)
Quinaglute, Quinidine, Quinalan, or Quinora
Xylocaine (Lidocaine, Xylocard)
Xylocard (Lidocaine, Xylocaine)

MAO Inhibitors:

Isocarboxazid (Marplan)
Phenelzine Sulfate (Nardil)
Tranlycypromine Sulfate (Parnate)
Phenelzine Sulfate
Tranlycypromine Sulfate

Tricyclic Antidepressants:

Amitriptyline (Elavil, Vanatrip, Endep)
Amoxapine (Asendin)
Clomipramine (Anafranil)
Desipramine (Norpramin, Pertofrane)
Doxepin (Sinequan, Zonalon, Adapin)
Imipramine (Tofranil)
Maprotiline (Ludiomil)
Nortriptyline (Aventyl, Pamelor)
Protriptyline (Vivactil, Triptil)
Trimipramine (Surmontil)

2. Also avoid giving albuterol to patients with an automatic implanted cardiac defibrillator.
-

Spirometry Completion Form

Purpose

Page 1 of the Spirometry Completion Form is designed to evaluate if subjects are medically able to perform spirometry (Questions 1 and 2), to assess potential short-term influences on spirometry (Questions 3 and 4), and to document completion of spirometry (Question 5).

Materials/Equipment

None.

Definitions

None.

Methods

General Instructions

This is an interviewer-administered form. Please administer questions before starting spirometry exam. The questions can be answered by filling in a bubble or a blank with a number or word. Most questions are self-explanatory. Specific instructions are given for some questions.

Specific instructions

Q.1. Have you been told that you had a heart attack, stroke, or eye, chest or abdominal surgery in the last 3 months?

- If the participant answers “yes” that they have been told that he/she had a heart attack or stroke in the LAST 3 MONTHS or surgery on the EYE, CHEST or ABDOMEN in the LAST 3 MONTHS, fill in the bubble next to “Yes” and DO NOT PROCEED with spirometry. Answer Questions 5 and 8 only, and fill in your Technician ID number at the bottom of page 2. If the participant reports a transient ischemic attack (TIA) in the last 3 months, follow the same procedure and do not perform pulmonary function testing. If the participant had a more remote heart attack/stroke/TIA or more remote eye/chest or abdominal surgery, in general it is fine to proceed with spirometry. We presume that

participants will complete spirometry sometime in their clinic visit after blood pressure measurement. Participants with very high blood pressure (>210/120 mmHg) will therefore be excluded by the MESA protocol from performing pulmonary function testing. If not sure, consult MESA-Lung Principal Investigator Dr. Barr or Spirometry Consultants Drs. Enright and Hankinson before performing the test.

- If the participant has NOT been told that he/she had a heart attack or stroke in the last 3 months, proceed to Question 2.

Q.2. Have you had any significant problems doing spirometry in the past?

Ask if the participant has had any significant problems doing spirometry in the past. If the participant has never done spirometry in the past, answer ‘no.’ If the participant has done spirometry in the past and did have a significant problem, then answer ‘yes’ and describe the problem in the comments box. If the problem was indeed significant and likely to recur with retesting, DO NOT PROCEED with spirometry. Complete Questions 5, stating the reason that spirometry were not performed. If you are uncertain if the problem is significant and/or likely to recur, consult with the Project Coordinator, Field Center Principal Investigator, and/or MESA-Lung Principal Investigator (Dr. Barr) or Spirometry Consultants (Drs. Enright and Hankinson) before performing the test.

Q.3. Did you have any caffeinated coffee, tea, or cola, or other caffeinated drink, in the past 2 hours?

Select “yes” or “no” or “don’t know”. This question is asked for information purposes only; proceed with spirometry regardless of answer.

Q.4. Did you smoke a cigarette, pipe or cigar during the last hour?

Select “yes” or “no”. This question is asked for information purposes only; proceed with spirometry regardless of answer.

Q.5. Pre-Bronchodilator Spirometry was:

- If pre-bronchodilator spirometry was completed, fill in the bubble next to “**Completed,**” and record the time at completion (hours AND minutes, AND fill in a bubble next to am

or pm). FOR THE PURPOSE OF THE COMPLETION FORM ONLY, COMPLETED IS DEFINED AS THE PARTICIPANT COMPLETING AT LEAST ONE CURVE (MANEUVER).

(note that we do not based the definition of “complete” on whether or not the curves are reproducible)

- If pre-bronchodilator spirometry was not completed, fill in the bubble next to “**Not completed. If not completed,**” specify the reason(s) why the spirometry was not completed. Select one or more from the provided options “refused” “physically unable” “cognitive unable” “equipment problem”. For other reasons the spirometry was not completed, check “Other” and specify in the provided blank.

Continue with Page 2 on the **Spirometry Completion Form** on the following page.

Q.6. If selected for albuterol?

- Participants may be selected for albuterol either by the spirometry software if they have airflow limitation (in the MESA Lung Study) or if they are in the MESA COPD Study. See Appendix B for details.
- If the “**Yes, randomly selected**” box is checked by the Coordinating Center software, the participant is selected and should have been consented into the MESA COPD Study. *All* participants in the MESA COPD Study are selected for albuterol and post-bronchodilator spirometry. You probably already entered that the participant is selected and consented into the MESA COPD Study at the beginning of the spirometry procedures. Alternatively, if the “**Yes, randomly selected**” box is not checked, the participant may still be selected for albuterol if they have airflow obstruction on pre-bronchodilator spirometry. In this case, the software **will prompt you that they** are selected for albuterol and post-bronchodilator spirometry. Follow the prompts and check off the “**Yes, by spirometry software**” box.
- In either case, administer 2 puffs of albuterol as per Section 4 above and record the time. After a minimum of 15 minutes, proceed with post-bronchodilator spirometry as per Section 4 above and complete Item 7 on completion of post-bronchodilatory spirometry.

- If neither box on Item 6 is checked and the spirometry software does not select the participant for albuterol, check off the “**No**” box, do not administer albuterol and skip to end.

Q.7. Post-Bronchodilator Spirometry was:

- If post-bronchodilator spirometry was completed, fill in the bubble next to “**Completed,**” and record the time at completion (hours AND minutes, AND fill in a bubble next to am or pm). “Completed” is defined as in Item 5 above.
- If post-bronchodilator spirometry was not completed, fill in the bubble next to “**Not completed. If not completed,**” specify the reason(s) why the spirometry was not completed. Select one or more from the provided options “refused” “physically unable” “cognitive unable” “equipment problem”. For other reasons the spirometry was not completed, check “Other” and specify in the provided blank.

Q.8. Final Selection for MESA COPD

- Participants are selected into MESA COPD based upon a combination of their spirometry results and MESA COPD screening form eligibility. A final determination will be made at the completion of post-bronchodilator spirometry.