Manual 4a
Pulmonary Function
September 14, 2011 - Version 1.02x
Prepared by the ARIC Pulmonary Function Expert Team

Study website - **http://www.cscc.unc.edu/aric/**

Pulmonary Function
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1. BACKGROUND

Spirometry is the simplest, most effective, and least expensive test for assessment of pulmonary function. Spirometry is done for the ARIC since it provides an objective test for detecting asthma and COPD, which are the most common chronic lung diseases. Simply asking a person about respiratory symptoms is not adequately sensitive or specific for diagnosing asthma or COPD. Lung function is also a major independent predictor of morbidity and mortality from 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 (FEV_1), which is the volume of air exhaled in the first second of the FVC maneuver; and the ratio between these two values: FEV_1/FVC. 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 used by the 4th National Health And Nutrition Examination (NHANES IV) occurring concurrently with the ARIC. This standardization of methods makes the results of these two 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 65-78ºF. 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.
- OMI spirometry software (version 5.05.11) is installed on a notebook computer with Windows XP.
- Calibration syringe, 3.00 liters, Han Rudolph model # 5530
- 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%.

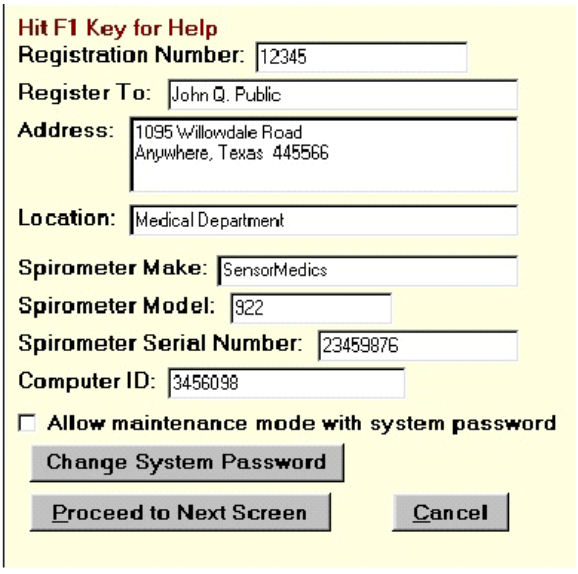
2.1. Advantages of the Sensor Medics Zero Return Spring

- 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 cmH_2O) 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.

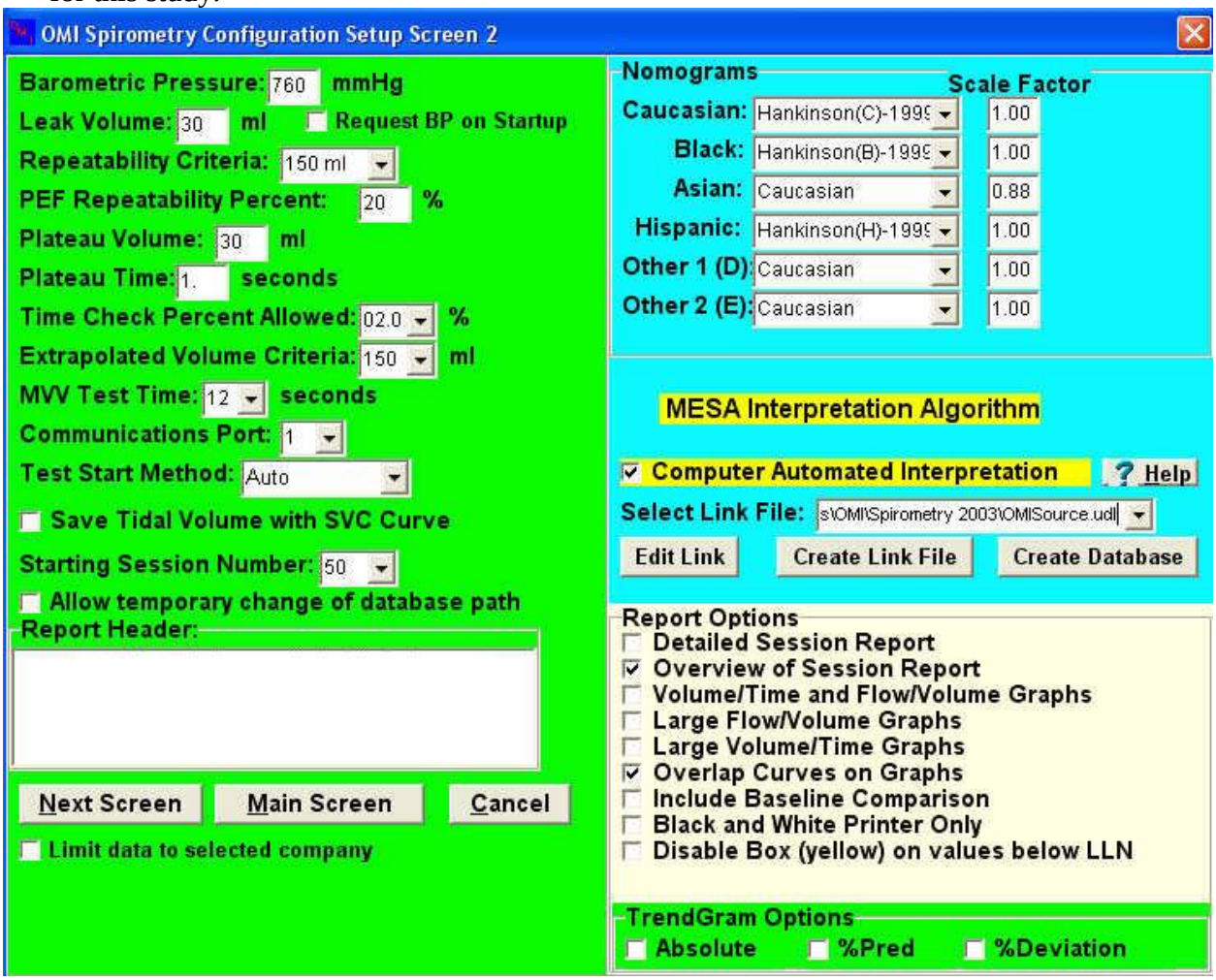
2.2. Initial Equipment Setup

1. Set up the equipment and connect cables on a solid desk or table.
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.

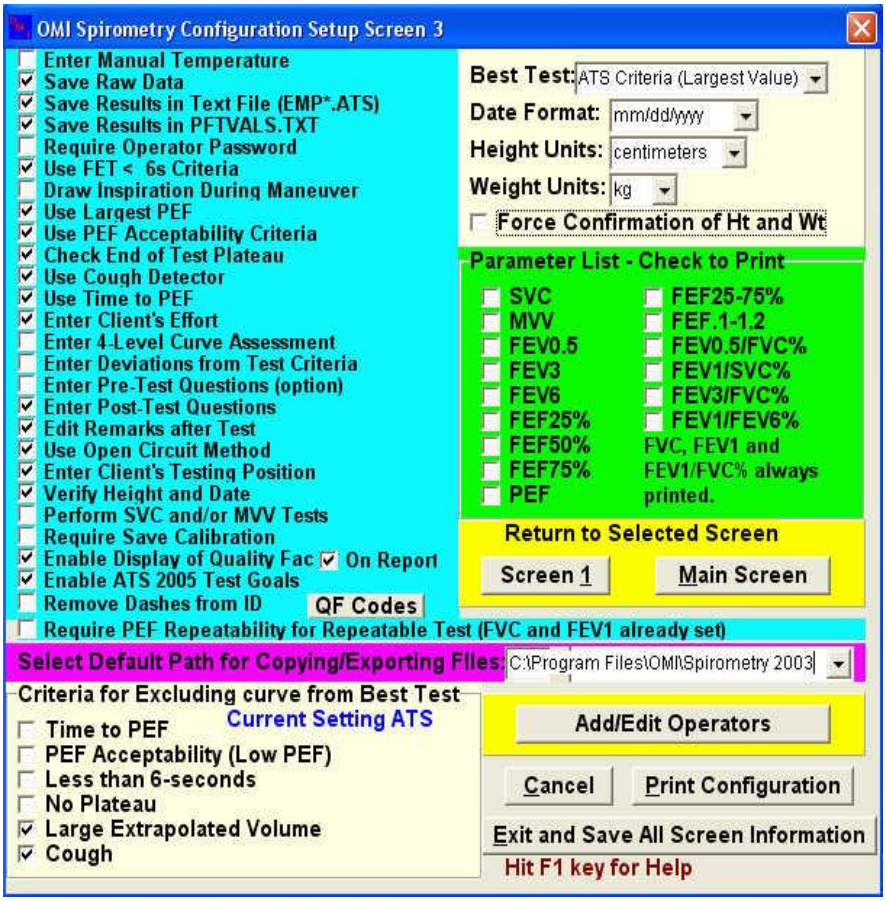
Setup Screen 1.



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



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. Enter your initials
3. Select “Calibration”
4. Select Leak Test from pull-down “Calibration” menu.
5. 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.
6. 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.
7. 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.
8. Select “Perform Cal/Leak Check” button on the main screen or in the “Calibration” menu.
9. Check that the “Current Volume” is zero.
10. Fill the calibrating syringe and connect it securely to the spirometer hose.
11. 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

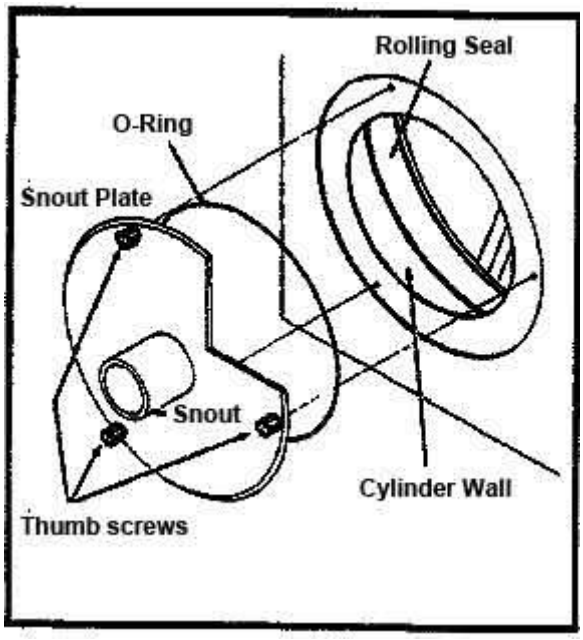
"slam" the syringe at the end of the injection by pushing the air out too vigorously as this may cause erroneous calibrations.)

12. 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.
13. Detach the calibration syringe and store it near the spirometer.
14. View Calibrations: The "View Calibrations" menu item allows you to view all previous calibration results.

2.4. How to Clean the Spirometer OPTIONAL

Since we are only performing expiratory maneuvers (no inhalating from spirometer) and are using filters, you do not need to routinely clean the inside of the spirometer.
Should you choose to clean the spirometer, directions follow:

1. Wear gloves. Unplug the power cord. Disassemble the spirometer for cleaning. 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.
2. Wipe the snout plate, O-ring and cylinder wall with a germicidal disposable cloth provided. Do not use alcohol, acetone, other volatile agents or abrasive cleaners on the rolling seal.
3. Allow the interior of the spirometer to dry thoroughly (perhaps overnight) before reattaching the snout plate.



4. Examine the O-ring for any irregularities. If damaged, replace it. Lubricate the O-ring lightly with stopcock grease provided. Fit the O-ring into the groove on the back of the snout plate.

5. Position the snout plate so that the three thumbscrews are aligned with the three holes on the spirometer housing. Tighten "finger-tight" as over-tightening can cause the spirometer to leak.

2.5. How to Clean the Hoses

You will need to clean and disinfect the hoses and accessories at daily intervals. Tubing will be cleaned and disinfected daily using a solution of Detergezyme and water according to the following protocol:

1. Add one ounce of Detergezyme to every gallon of water (can be cold or warm but not hot) in the 5-gallon bucket.
2. 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 (E.G. LEFT OVER THE WEEKEND WITHOUT CLEANING)).
3. Ideally, re-rinse hoses with water.
4. Hang hoses up to dry using clothes pegs.

3. HOW TO TEST PARTICIPANTS

The **Spirometry Exclusion Criteria** at the end of the manual should have already been applied to every participant. However, if no information is available when the pre-bronchodilator testing is completed, you may be asked some exclusion questions before a decision about administering the bronchodilator is rendered by the spirometry software. Anyone meeting exclusion criteria will not start spirometry. So, check the itinerary document (Baseline Examination Checklist Form) and ask the clinic personnel to confirm that the patient is not excluded from spirometry before proceeding. The albuterol exclusions (checked 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".

3.1. Spirometry Instructions and Preparation

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.

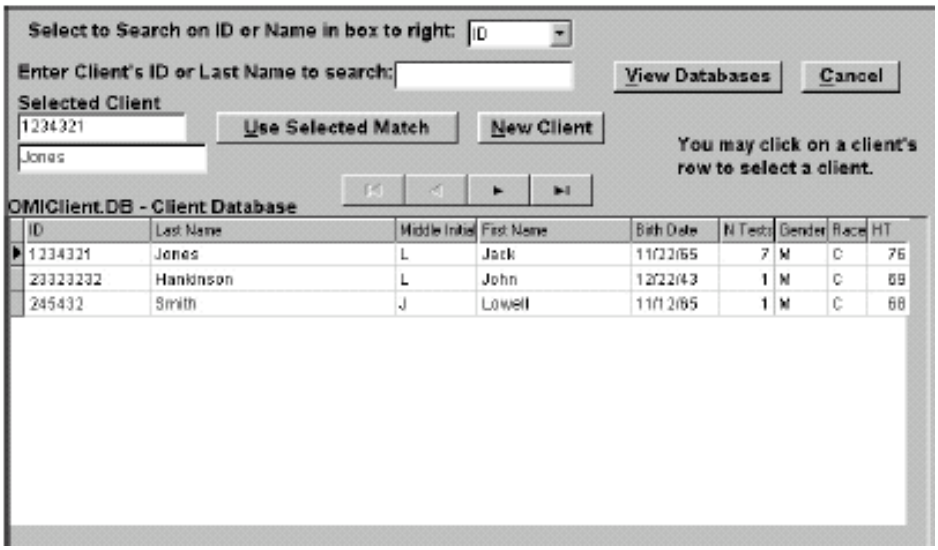
1. Wash your hands before starting.
2. If the participant Personal Information form has been previously completed, you may use the following procedures to automatically fill the Client Information Screen below:
    a) Log onto the ARIC data management system REPORTS page.
    b) Select PFT demographic report
    c) Enter the ID number of the participant
    d) When the demographic information is displayed, press the "Ctrl" and then "a" keys, and all the information on the screen should be selected.
    e) Press "Ctrl" and then "c" keys and the information from the screen should now be saved to the computer's clipboard.

f) Later when you paste the information into the Client Information screen, verify that the ID, height and other information was correctly copied to the screen.
g) Note: If height information is not available, you may need to stand the participant next to the tape measure on the wall and manually estimate the participant's height.

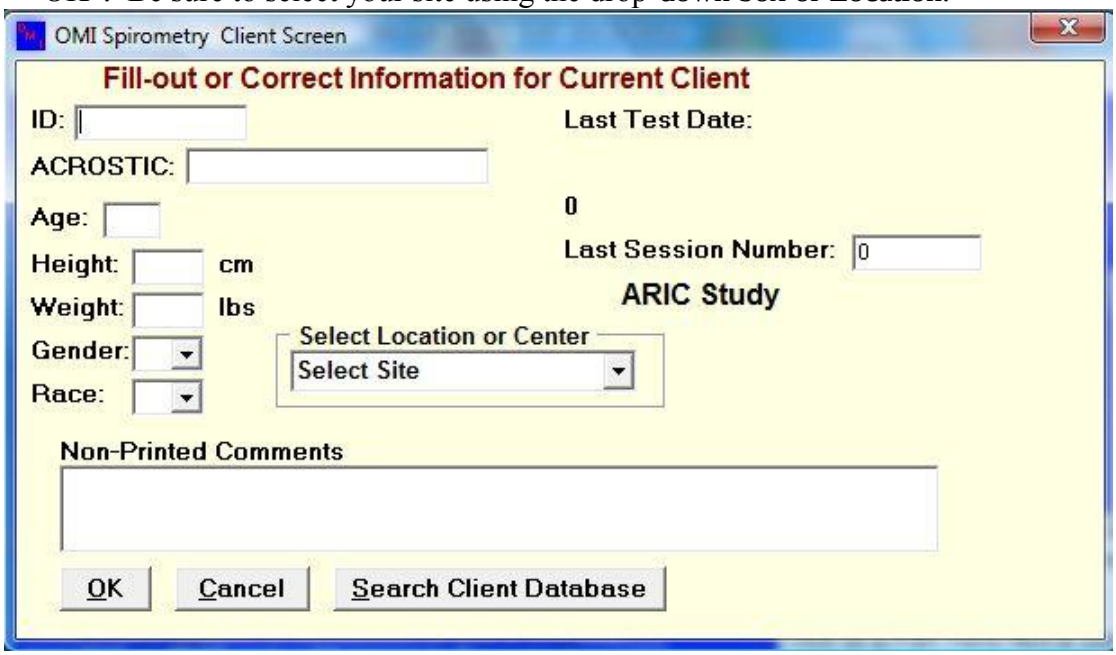
5. Select "Perform/Review Test" main heading and/or "Select/Add Participant" button

2. Bring up Participant Screen

3. You can "Use Selected Match" or choose to enter a "New Participant". To search for a participant (e.g., a participant who may be returning for a bronchodilator test), select to search on ID or Last Name; then start typing the ID or Last Name in the search field. The bottom grid will display the closest match to the partial ID or Last Name as it is entered. Before any participant is tested, demographic information must be collected and stored in the database.

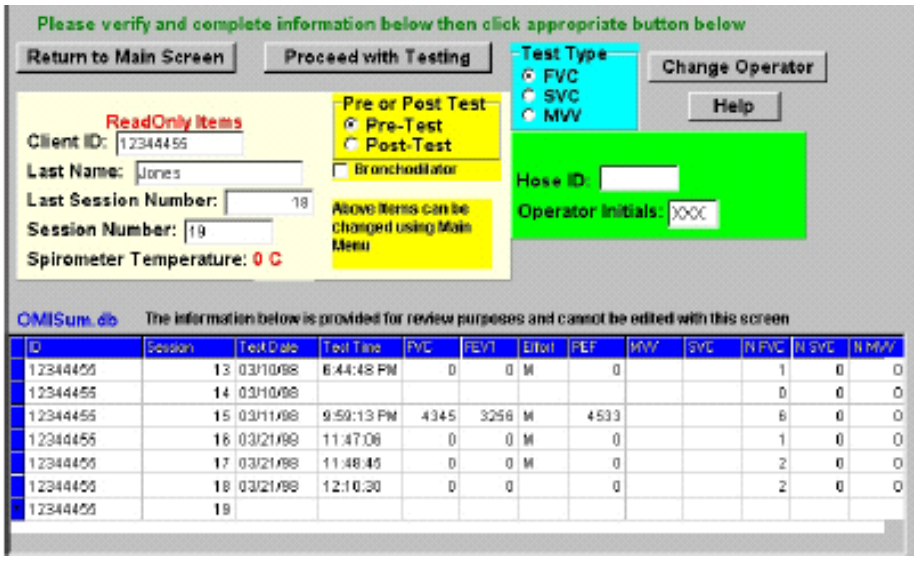


4. Edit/Enter participant information. Verify that the information entered is correct and click "OK". Be sure to select your site using the drop-down box or Location.



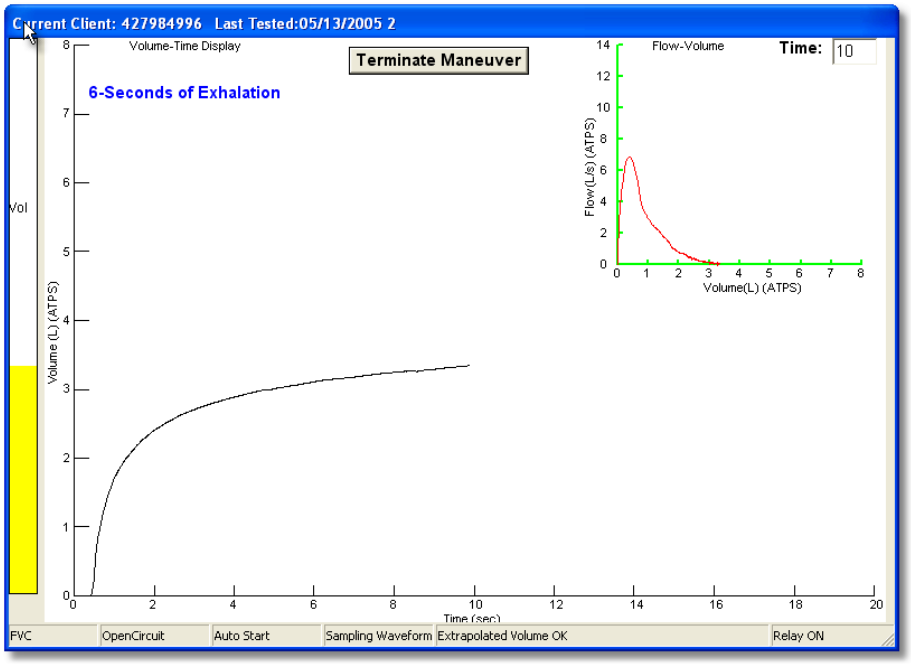
6. Attach a clean breathing hose and new filter-mouthpiece using the beige hose adapter. A cardboard mouthpiece may be used if the subject can obtain a better seal around a cardboard mouthpiece.
7. Explain the purpose of the examination and the need for extra effort from the participant to get maximal results. Say "I want to measure how much and fast you can breathe out."
8. 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.
9. Ask the participant to sit during the examination. Encourage them to sit up straight. Make make sure that they main good head alignment – ie: chin not thrust forward.
10. Place nose-clip on their nose. It may be removed between trials. If the nose-clip falls off or is uncomfortable, the participant may hold his nose during FVC maneuver.
11. Have the participant do a trial exhalation. The following instructions may be helpful:
    a) "Take a great big breath of air as far as you can inhale."
    b) "Put the mouthpiece into your mouth and seal your lips tightly around it." Should the subject require the cardboard mouthpiece, check to make sure the subject does not bite down on it – this is not an issue with the plastic filter-mouthpieces which are rigid.
    c) "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.)
    d) "Keep on blowing out the same breath of air, until I tell you to stop."
12. Review the procedure and correct any problems from the trial.
13. Proceed with Examination.

Click "Perform FVC Test"



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.

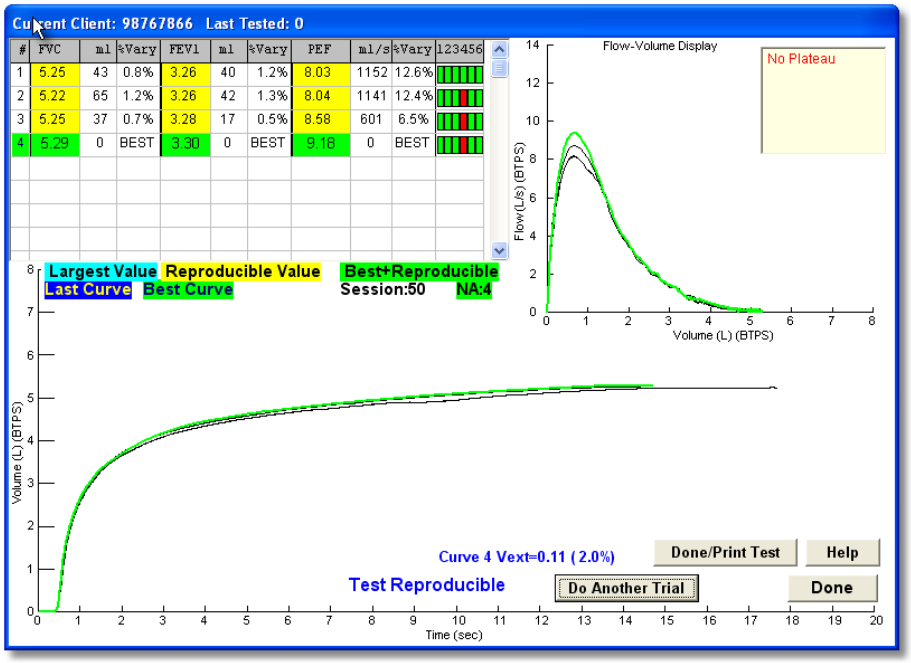


Continue to coach the participant to exhale until the "Plateau Achieved" message is displayed and the bar on the left side turns green. Help the participant to move the mouthpiece away from their face (to reduce the risk of cross-contamination).

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

Press "Calculate Curve".

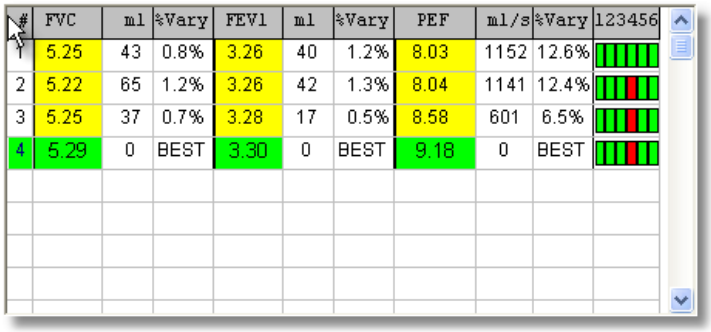
A result screen is then displayed, including Trial Number, FVC, FEV_1, and PEF (peak flow). After the second and successive trials, differences from the largest observed values, and the 6-item acceptability code are displayed. All of the flow-volume and volume-time curves are also displayed superimposed. 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 reproducibility message is displayed.



#	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	

The Quality code box - A more detailed view of the maneuver values is shown below. The largest values for FVC, FEV_1, and PEF are indicted by "BEST" to the right of the value in the "%Vary" column. They are also are lime in color. An important goal of testing is to match the largest and second largest FVC and FEV_1 within 150 ml of each other. To facilitate comparison, the columns immediately after the FVC and FEV_1 liter values ("%Vary" column) are in milliliters. Verify that at least one FVC and one FEV_1 value is less than 150 ml (colored yellow). This is called repeatability (formerly called reproducibility).

To obtain the best test session quality grade (an A), the largest and second largest FEV_1, and the largest and second largest 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).



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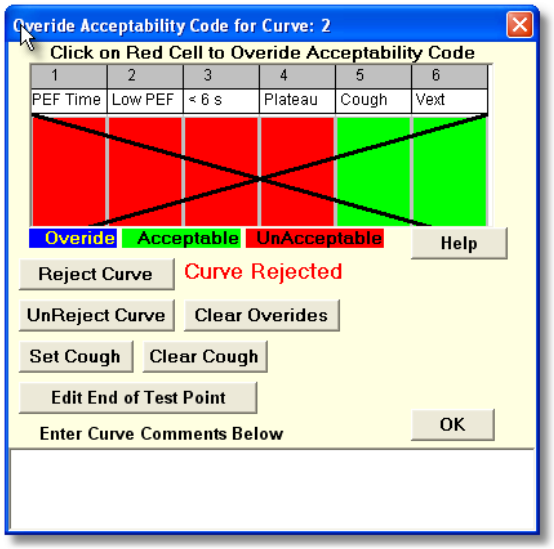
3	5.25	37	0.7%	3.28	17	0.5%	8.58	601	6.5%	
4	5.29	0	BEST	3.30	0	BEST	9.18	0	BEST	

For the experienced technologists:

How to over-riding 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 reproducibility 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-ridden" is colored in blue instead of red.



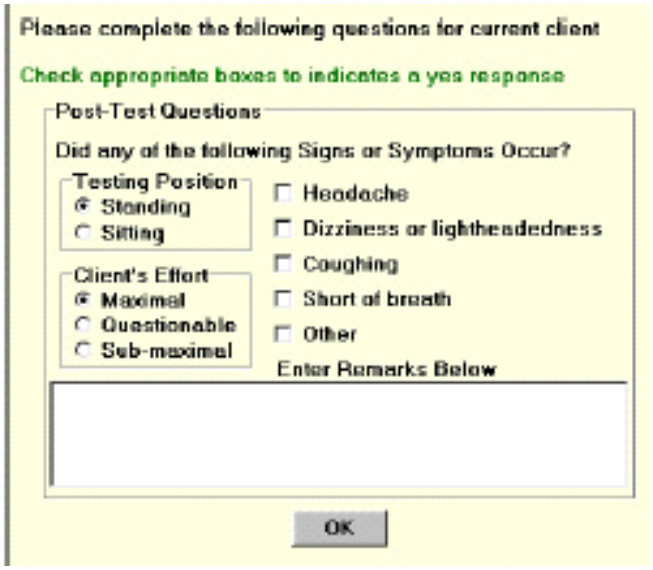
Criteria for an acceptable maneuver: no hesitation or false starts; the volume of back-extrapolation (Vext) less than 5% of the FVC or 0.15 L (whichever is greater). No coughing during the first second; no abrupt termination (glottis closure), no mouthpiece obstruction by tongue, biting on mouthpiece, or dentures. There should be a plateau in 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 FEV_1, taken from acceptable forced expiratory maneuvers, must show minimal variability. The two largest FVC values should agree within 150 ml; the two largest FEV_1 values should agree within 150 ml. Testing should continue until three acceptable tests (all green in the code box) and reproducibility 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 FEV_1 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").

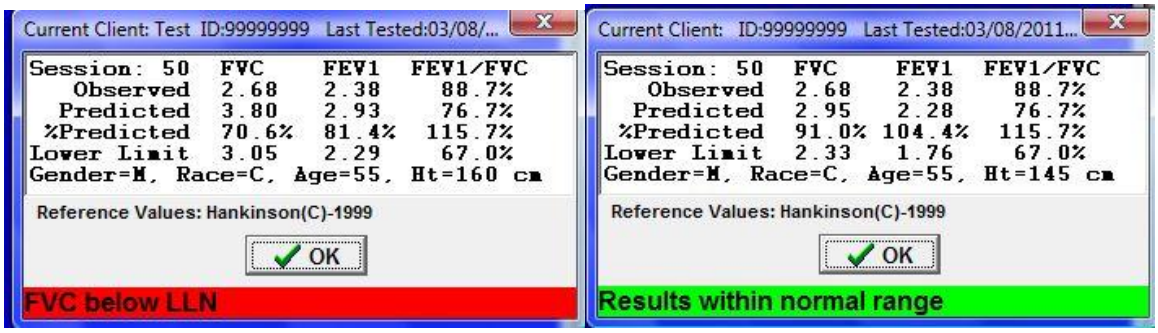
Post Test Questionnaire: After test completion, the "Post Test Questionnaire" screen will appear. On this screen, indicate the testing position, participant (client) effort, and add comments, if you wish. Then click "OK."



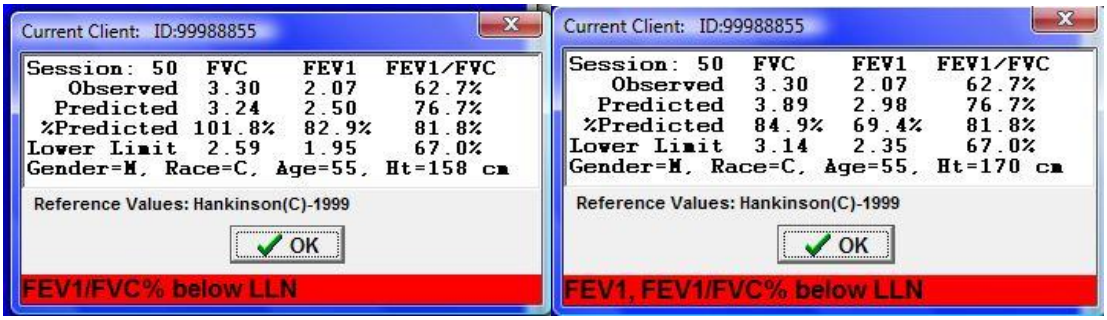
4. BRONCHODILATOR TESTING

The subset of study participants who have airway obstruction 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 FEV_1/FVC below Lower Limit of Normal (LLN) calculated using the NHANES III reference equations. Selected participants will receive albuterol if they have no contraindications to albuterol administration (see Spirometry Exclusions Section).

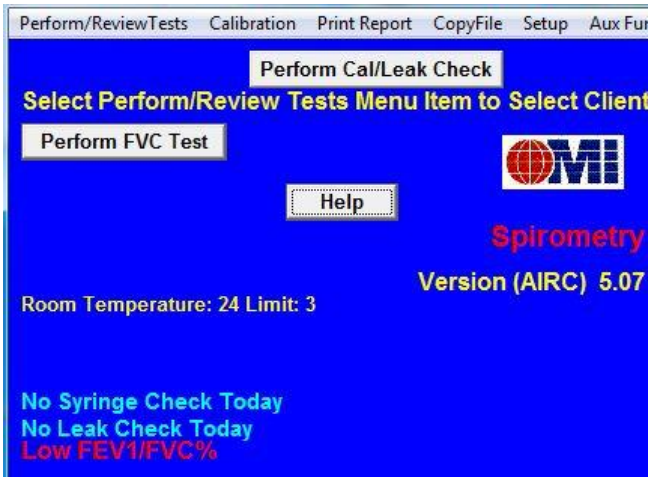
The following possible screens will appear after spirometry has been completed. Participants with an FEV1/FVC% below the LLN (red background will blink) will be selected for post-bronchodilator spirometry if there are no contraindications based on information collected earlier in the exam. In the following screens, the subject would not be administered albuterol as their FEV1/FVC% is above the LLN or their percent predicted FEV1 is greater than 100%.



In the following three examples, a post bronchodilator test would be performed, if there are no contraindications, since the FEV1/FVC% is below the LLN and the percent predicted FEV1 is less than 100% for all three of these examples. Note the red background of the message will **blink** if a post brochodilator test criteria are met due to spirometry results.



After you click OK, the following message will appear on the main screen, indicating a low FEV1/FVC%, with a percent predicted FEV1 > 100%, was observed on the previous test result.

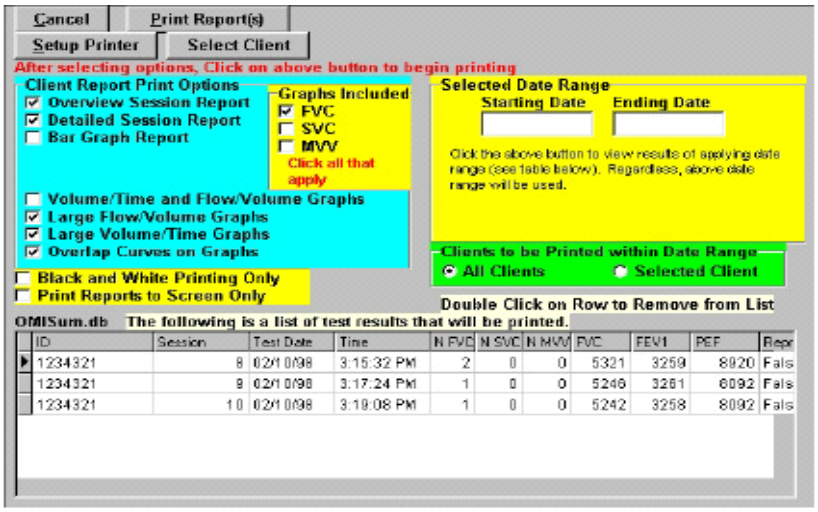


4.1. How to Give Albuterol

a) Shake the MDI. Point it away from faces, then activate it once to verify aerosol delivery.
b) Attach a new, disposable spacer to the MDI.
c) Ask the participant to exhale fully.
d) Have the participant place mouth on spacer.
e) Instruct the participant to breathe in slowly, immediately activate the MDI and tell the participant to raise their hand when inhalation is complete.
f) When participant raises hand, count to 5 silently and then tell participant to exhale slowly
g) Wait one minute and repeat steps c-e to administer another puff of albuterol.
h) Wait 10-15 minutes and then repeat spirometry
i) Click on the main menu item “Perform/Review Test”
j) Click on “Add Post Bronchodilator Test”
k) Perform FVC test as previously described
l) Click on main menu item “Print Report”
m) Click on “Print Participant Report” menu item
n) Click “Print All”
o) Click on “Apply Selection” button
p) Click on check box “Print report to screen only” so that it is checked
q) Click “Print Report” button

5. HOW TO PRINT A REPORT

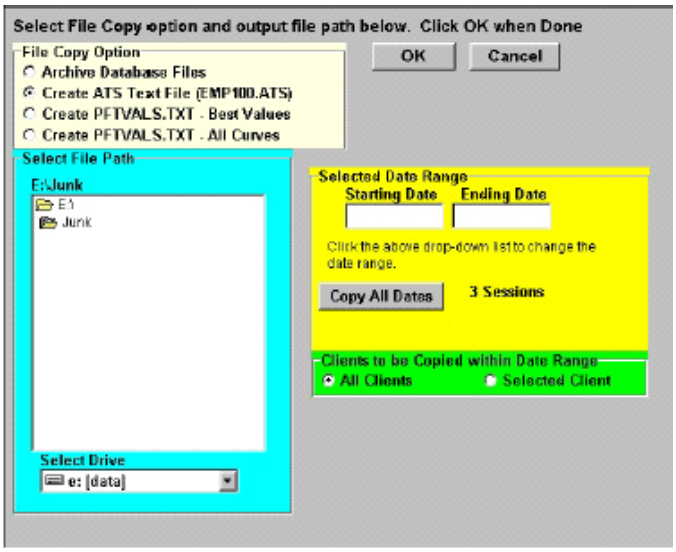
At the end of each test session, use the “Print Report” main menu item to print all test results. The “Print Current Test” menu item under “Perform/Review Test” is used, while participant information and results are still current in the computer. The right mouse button can also be clicked to display a popup menu with the “Print Current Test” menu item.



Pre-Print Menu Screen

5.1. Copy File

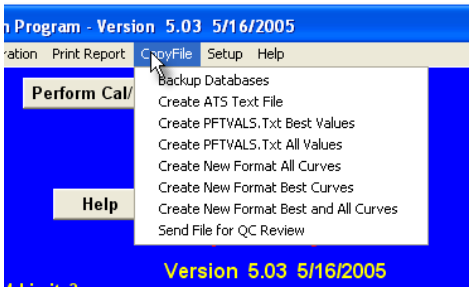
The “Copy File” main menu item provides you with a convenient means of backing up the data files. The sub-menu items under “Copy File” allow you to select several types of files to copy, some with selected date range limitations. You may select the output path using a file dialog box or use the default 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 use 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 of update the file or exit and rename the backup file.



Copy Text File Screen

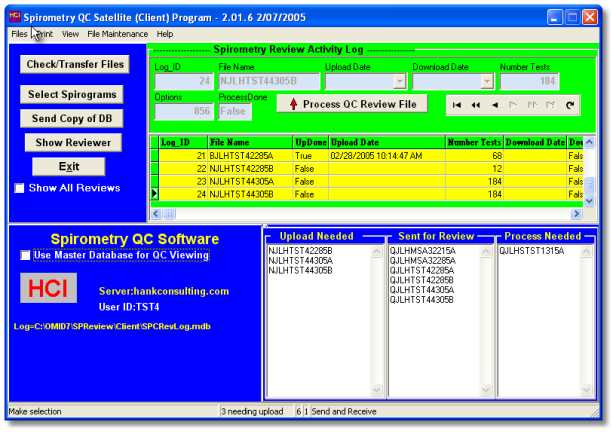
5.2. Send File for Review *(Performed weekly and at the end of a study site.)*

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 spirograms to be sent for review.



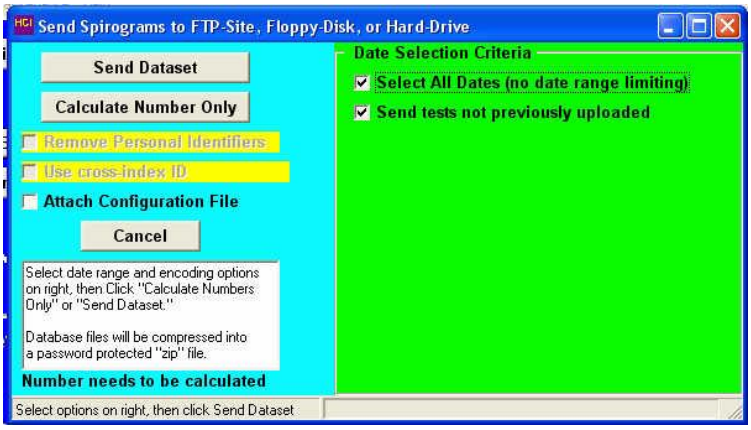
Copy File Menu - Send File for QC Review

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).

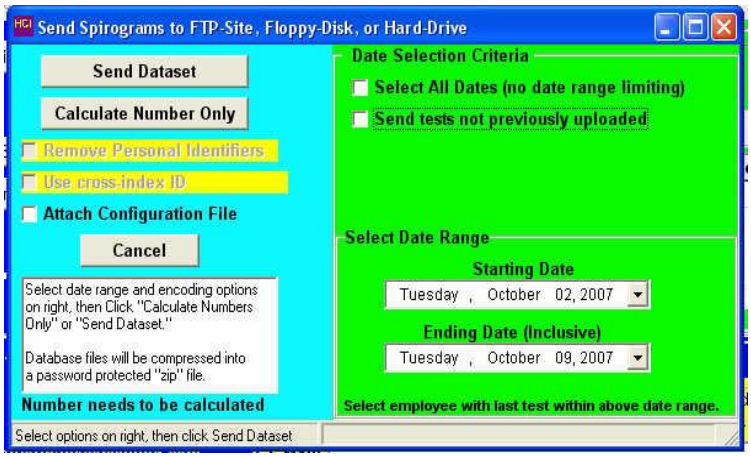


File Selection Program - Main Screen **Select Site (User ID)**

Selecting Date Range - The *Send Copy of DB* button will cause the send *spirograms 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.

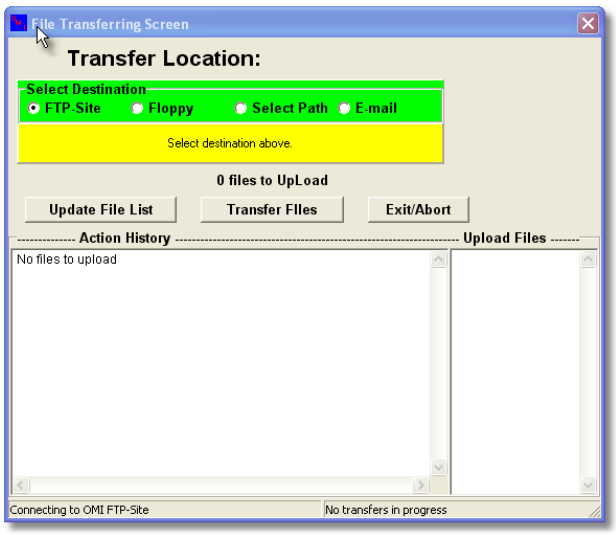


Send Spirograms Selection Screens (Standard)



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 spirograms. 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 FTP screen will appear where you can select where you want the file to be sent. You can send the file to the default FTP-site, copy it to a floppy disk, select a path on any available disk drive, or attach the compressed zip file to an e-mail message. 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.

6.2. Certification

The examination includes 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. An web-training account can be obtained from john@hankconsulting.com

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 during the recruitment period.

Certification on new technicians after the initial central training sessions may be performed by a centrally trained, certified PF technician. The written exam is available on the training web-site, and the first 20 PF test performed will be observed by a certified PF technician 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:

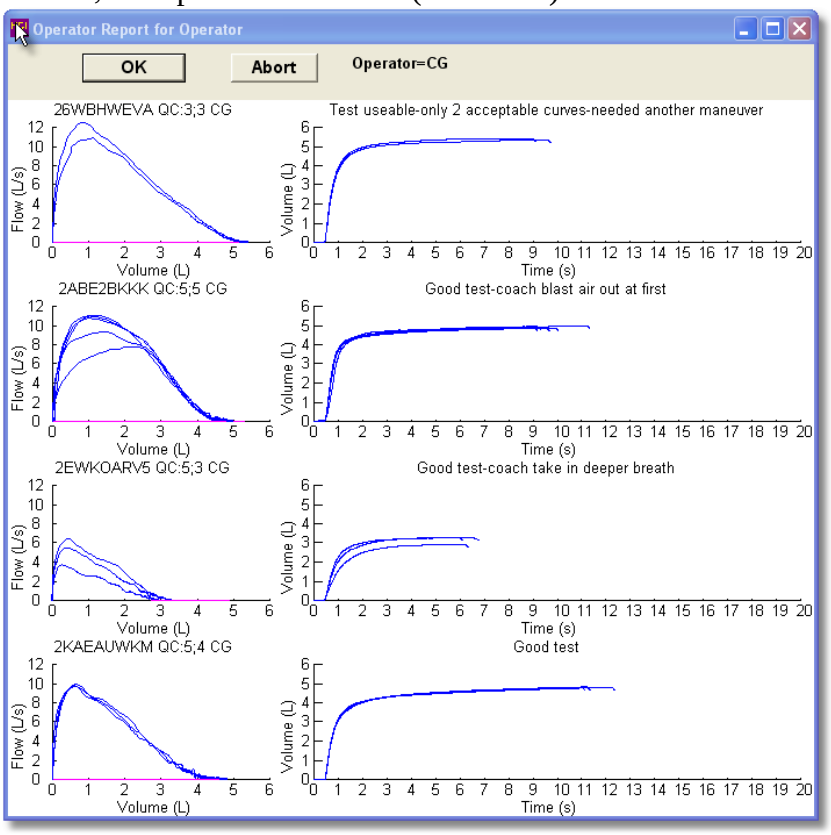
1. Participant
2. Maneuvers
3. Technician
4. Equipment
5. Analysis

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 reproducibility 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 FEV_1 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 FEV_1 quality factor codes, and specific comments (see below).



6. 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 FEV_1 quality score, by technician.

Quality grades (A-F) are computed for FEV_1 and for the FVC (quality codes) based in part on the number of acceptable maneuvers. An acceptable maneuver for FEV_1 quality purposes is no cough or large extrapolated volume. For FVC quality purposes, the requirement of at least 6-seconds of exhalation and a plateau in the volume-time curve (30 ml in one second) is added to the FEV_1 acceptable maneuver definition. However, a maneuver that does not have a plateau but the exhalation is longer than 15-seconds would be considered an acceptable maneuver. You do not need to go beyond 15 seconds if no plateau has been achieved.

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

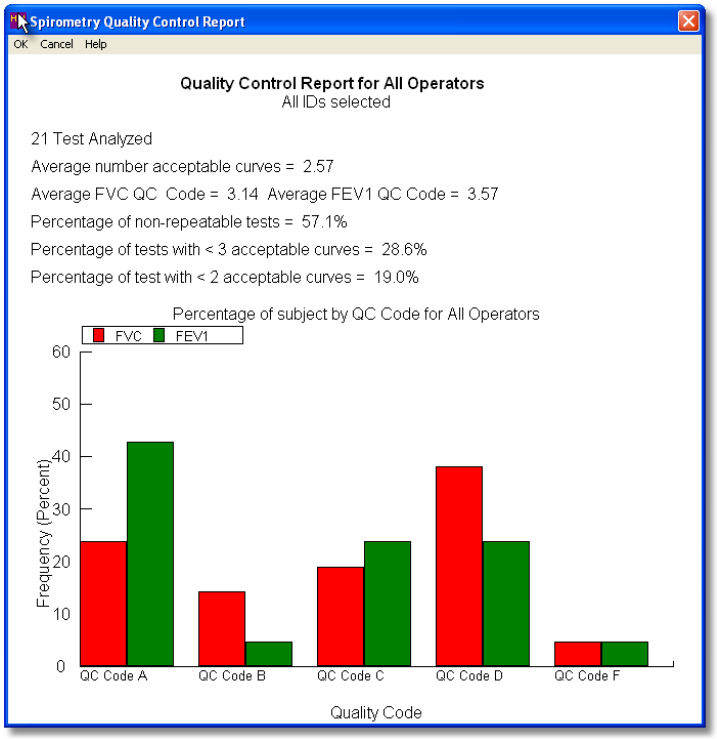
C = 2-acceptable curves, plus largest and second largest value within 200 ml

D = 1 acceptable curve plus no end of test requirement for FVC QF

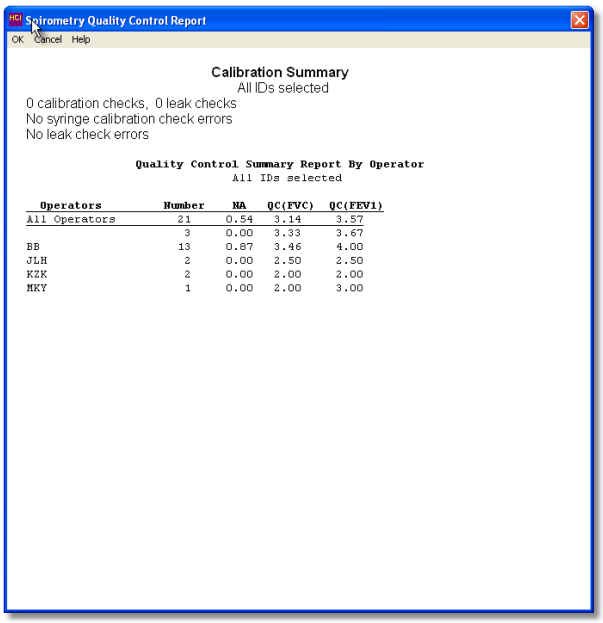
F = no acceptable curves

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 FEV_1 cannot be accurately measured.

7. In addition to the quality control summary report, a calibration summary report is also provided. Trends of average FVC and FEV_1 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:



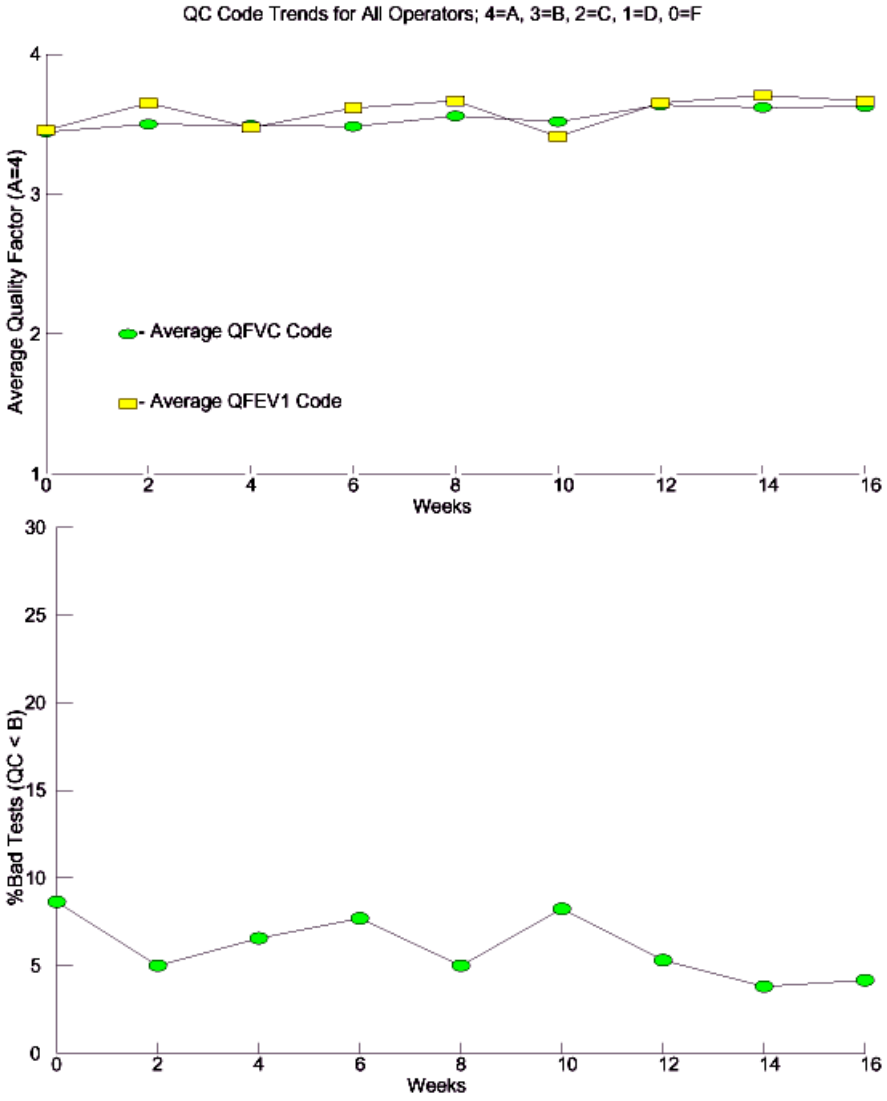
Quality Control Report - All Operators Combined



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%



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.
  e) Tubing will be cleaned and disinfected daily (see Section 2.5)
  f) Instruments will be cleaned at the end of each testing session (see Section 2.4)
  g) 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: 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
Reproducibility Criterion: 100ml
PEF Reproducibility Percent - 20
Plateau Volume -40
Plateau Time - 1
Time Check Percent Allowed - 02.0
Extrapolated Volume Criteria - 150
MVV Test Time - 12
Communications P ort - 1
Test Start Method - Auto
Starting Session Number - 50
Automated Interpretation - Yes
Interpretation Level - 95%
Interpreter Algorithm - MESA

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

Selected data path - C:\Program Files\OMI\Database
Use Program Dr. for Cal Path - No
Allow temporary database path change – No

Screen 3

Adjustable Parameters — Backup File Path - C:\Program Files\OMI\OMI Spirometry

Enter Manual Temperature - No
Save Raw Data - Yes
Enter Participant's Testing Position - Yes
Save Results in Text File - Yes
Verify Height and Date - No
Save Results in Enhanced Text File - Yes
Perform SVC and/or MVV Tests -No
Require Operator Password - No
Require PEF Reproducibility - No
Use FET < 6s Criteria - Yes
Draw Inspiration – No
Use Largest PEF - Yes
Use PEF Acceptability Criteria - Yes
Check End of Test Plateau - Yes
Use Cough Detector - Yes
Use Time to PEF - Yes
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

Parameter Print List

SVC – No
MVV – No
$FEV_{0.5}$ – No
FEV_3 – No
FEV_6 - No
$FEF_{25\%}$ - No
$FEF_{50\%}$ - No
$FEF_{75\%}$ - No
PEF - Yes
$FEF_{25-75\%}$ - No
$FEF_{0.1-1.2}$ - No
$FEV_{0.5}$/FVC% - No
FEV_1/SVC% - No
FEV_3/FVC% - No
FEV_1/FEV_6% - No

Exclusion Criteria

PEF Reproducibility - No
Time to PEF - No
<6-seconds - No
No Plateau - No
Large Vext - Yes
Cough - Yes

CONTACT INFORMATION

PERSONNEL

Direct all questions regarding hardware, software, QC, and uploading of tests to:

John Hankinson, Ph.D. (Spirometry Reading Center co-I)
1860 Barnett Shoals Rd
Suite 103, PMB 505
Athens, GA 30605
Email: john@hankconsulting.com

Direct other questions to:

Stephanie London, MD, Dr.P.H.
National Institute of Environmental Health Sciences
Room MD A3-05
P.O. Box 12233
RTP, NC 27709
Email: london2@niehs.nih.gov

Paul Enright, M.D. (Spirometry Reading Center PI)
CDC-NIOSH, Morgantown, WV
Email: lungguy@gmail.com

EQUIPMENT

SensorMedics / Viasys
(manufactured 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

For all of these items, inform the person you speak with that you're from the ARIC Study:

Nose Clips: Alliance Tech Medical. Contact person Romney Fischer, 800-848-8923, Order number 555 0047, order a couple boxes of 100 each to start.

Hoses: order 35 white breathing hoses (39") from OMI, (800) 869-6783, contact person Claudia. Order number PS9411.

Filters: order 1000 yellow filter mouthpieces from Alliance Tech Medical, order number 555 6100. See above for contact information. Order 1000 to start, will need ~4000 total.

Spacers:

LiteAire Albuterol dual valved holding chamber. Part #1306. Thayer Medical. http://www.thayermedical.com/lite_aire.htm. This disposable spacer has a one-way valve that prevents contact between the MDI and subjects' exhaled breath.

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 (Vext, EV or BEV) is the standard method used to determine "time zero" when measuring the FEV_1. The amount of slowly exhaled volume at the start of the maneuver excluded from the FEV_1 by this technique is called the back extrapolated volume (BEV or EV). The BEV should be less than 5% of the vital capacity, otherwise the maneuver is considered to have started too slowly.

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

CALIBRATION SYRINGE is a large metal cylinder with a rubber sealed piston used to check the volume accuracy of spirometers. The ATS recommends that it be 3.00 liters in size.

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.

FEV_1 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.

FEV_1/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 FEV_1/FVC ratio and the FEV_1 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 is short for Pulmonary Function (lung tests).

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

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 FEV_1/FVC ratio is normal or increased.

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

Vext (see Backextrapolation)

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

Measure Maximal Respiratory Pressures (MRP)

Explain the test
Demonstrate MIP maneuver
Obtain 3 MIP maneuvers
Review maneuver quality

Add comments (FIN)

Clean Equipment
Clean breathing hoses
Rinse and dry overnight

Weekly Procedures

Friday afternoon:

Upload week of spirometry data to PF Reading Center via FTP-site or e-mail
Clean hose
Check spirometer for leaks
Rinse and dry overnight

Spirometry Exclusion Criteria

Questionnaire Exclusion Items:

1. Have you had a heart attack, a stroke, eye surgery, or surgery to the chest and abdomen in the last 3 months?

Yes – STOP
No – Proceed

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

Yes
No – Proceed

3. Have you been told by a doctor that you have had bleeding inside an eye or the retina, or a retinal tear or detachment?

Yes
No – Proceed

4. [FOR PTS SELECTED FOR BRONCHODILATOR ONLY] Have you had any significant problems taking a puffer [SHOW ALBUTEROL METERED DOSE INHALER] in the past?

Yes
No – Proceed

Automated Exclusion Items:

1. Systolic blood pressure ≥ 200 mmHg or diastolic blood pressure ≥ 110 mmHg – assessed earlier in Exam and leads to exclusion from all exam components, including spirometry and bronchodilator administration.
2. Pregnancy/lactation – assessed earlier in Exam and leads to exclusion from spirometry and bronchodilator administration.
3. Report of use of Class 1 anti-arrhythmic drug, monoamine oxidase inhibitor, or tricylic antidepressant – assessed elsewhere in Exam and leads to exclusion from bronchodilator administration.
4. Automatic implanted cardiac defibrillator (AICD) – assessed earlier in Exam and leads to exclusion from bronchodilator administration.

MOP Specific instructions

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

- If the participant answers "yes" that they have been told that he/she had a heart attack, stroke or eye surgery in the LAST 3 MONTHS, fill in the bubble next to "Yes" and DO NOT PROCEED with spirometry. Answer Questions * and * 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/eye surgery, in general it is fine to proceed with spirometry. If not sure, consult Spirometry Reading Center Principal Investigator Dr. Barr before performing the test.
- If the participant has NOT been told that he/she had a heart attack, stroke or eye surgery 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 measurements. Complete Questions * and *, stating the reason that spirometry and MIP 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 Spirometry Reading Center Principal Investigator (Dr. Barr) before performing the test.

Q.3. Have you had any significant problems taking a puffer in the past?

After the participant has done pre-bronchodilator spirometry and if the participant is selected for post-bronchodilator spirometry, ask the participant if s/he has had any significant problems taking a puffer in the past. Show the participant the puffer (not connected to the spacer). The "puffer" is a metered dose inhaler containing albuterol, a beta-agonist. Trade names for albuterol include Ventolin, Proventil, Maxair, Combivent (with ipratropium). If the participant has never taken a puffer in the past, answer 'no.' If the participant has taken a puffer in the past and did have a significant problem, then answer 'yes' and describe the problem in the comments box. Patients often get a cough after taking a puffer; this is NOT a significant problem and, if that is the only problem, you should reassure the participant and continue with administration of albuterol. If the problem was indeed significant and likely to recur with retesting (e.g., allergy [extremely rare], chest pain [also unusual]), DO NOT PROCEED with administration of albuterol and do not perform post-bronchodilator spirometry. Complete Questions * and *, stating the reason that the puffer was not performed. If you are uncertain if the problem is significant and/or likely to recur, consult with the Project Coordinator, and/or Spirometry Reading Center Principal Investigator (Dr. Barr) before performing the test.

Automated Exclusion Items:

The ARIC protocol collects other information that is relevant to spirometry and bronchodilator exclusions. The following exclusion criteria are likely to be rarely encountered in the ARIC visit and therefore will not be reassessed at the time of spirometry.

1. Systolic blood pressure ≥ 200 mmHg or diastolic blood pressure ≥ 110 mmHg – assessed earlier in the Exam and leads to exclusion from all exam components, including spirometry and bronchodilator administration.
2. Pregnancy – assessed earlier in Exam and leads to exclusion from spirometry and bronchodilator administration. Spirometry is generally safe in pregnancy, other than potentially at full term; however, spirometry results are affected by pregnancy (except in the first trimester) and so spirometry will not be performed. Bronchodilators, like all drugs, should not be administered during pregnancy unless clinically necessary.
3. Report of use of Class 1 anti-arrhythmic drug, monoamine oxidase inhibitor, or tricylic antidepressant – assessed on the Medication history form and leads to exclusion from bronchodilator administration. All of these drugs are very rarely prescribed and risk related to 180 mcg of albuterol is mainly theoretical; therefore, in the event that the Medication history form is not completed prior to spirometry examination, these items will not be assessed. Instead, if the data are not available, the question should be asked "Are you taking medication for a serious heart rhythm problem? If the subject response "YES" – exclude from bronchodilator. If any of the following prescribed medications are reported on the Medical history form, the bronchodilator will not be administered:

Anti-Arrhythmics That Exclude Participants from Bronchodilator Testing:

Amiodarone (Cordarone)
Bretylium (Bretylol)
Bretylol (Bretylium)
Cardioquin (Quinidine, Quinalan, Quinidex, Quinaglute)
Cordarone (Amiodarone)
Disopyramide (Norpace)
Dofetilide
Enkaid (Encainide)
Ethmozine (Moricizine)
Flecanide (Tambocor)
Ibutilide
Lidocaine (Xylocaine, Xylocard)
Mexiletine (Mexitil) Mexitil (Mexilitine)
Moricizine (Ethmozine)
Norpace (Disopyramide)
Procainamide (Pronestyl, Procan SR)
Procan SP (Procainamide, Pronestyl)
Pronestyl (Procan SP, Procainamide)
Propafenone (Rhythmol)
Quinaglute (Cardioquin, Quinidine, Quinora, Quinalan, Quinidex)
Quinidine (Quinora, Quinalan, Cardioquin, Quinidex, Quinaglute)
Quinalan (Quinora, Cardioquin, Quinidex, Quinaglute, Quinidine)

Quinora (Quinidine, Quinalan, Cardioquin, Quinidex, Quinaglute)
Rhythmol (Propafenone)
Tambocore (Flecainide)
Tocainide (Tonocard)
Tonocard (Tocainide)
Xylocaine (Lidocaine, Xylocard)
Xylocard (Lidocaine, Xylocaine)

MAO Inhibitors that Exclude Participants from Bronchodilator Testing:

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

Tricyclic Antidepressants that Exclude Participants from Bronchodilator Testing:

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).

4. Automatic implanted cardiac defibrillator (AICD) – assessed earlier in Exam and leads to exclusion from bronchodilator administration.