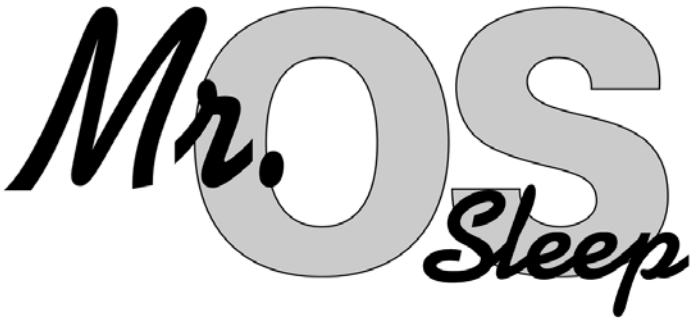

Sleep Visit 2
Spirometry
Procedure Manual

Sleep Medicine Epidemiology Program
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Boston, MA 02115
December 2010

Mr.OS Spirometry Manual

INTRODUCTION

Spirometry is a simple breathing (pulmonary function) test that in clinical settings is used to measure lung function. It can be used to help diagnose and monitor lung problems, such as asthma, emphysema, COPD and other lung conditions. In research studies such as MrOS, spirometry is performed to quantify lung function, which is a health characteristic associated with longevity, overall functioning, and other chronic health characteristics.

Lung function is divided into two main characteristics:

- The amount of air that can be inhaled or exhaled in one breath. This is referred to as the "**vital capacity**." It is a measure of ***volume of air,*** and measured in units of mL of L (liters). When this is measured having the participant use maximal effort, it is referred to as the ***Forced*** **Vital Capacity** or **FVC**.
- The rate by which air can be blown into and out of the lung passages (bronchial tubes) is a measure of flow (i.e., volume exhaled per unit of time; units: mL/sec or L/sec). When it is measured while having the participant use maximal effort during exhalation (expiration), it is referred to as the **Forced Expiratory Volume** or **FEV**. Of special interest, is the amount of air that can be blown out during the first one second of the exhalation maneuver, or the **FEV_1.**
    - It is often useful to interpret the FEV_1 as a ratio of the FVC, **or FEV_1/FVC.** Reductions in this ratio (<75%) usually mean that the airways are narrowed or easily collapse, as occurs in asthma or COPD.

Lung function not only varies with diseases, but also reflects the size of the lungs and airways, which vary by height (taller people should have larger lungs and higher levels of lung function), sex (males have larger lungs than women), age (after age 25 years, there is an expected decline in lung function), and race (for any given height, African Americans may have a shorter chest dimension relative to leg length, and thus, for height, their lung function may be predicted to be lower than whites of comparable height). All lung function measures made by spirometry can be expressed as the "percentage of predicted (% P)" based on nomograms that take into account height, sex, age and race. In general, percentage predicted values of **80 to 120%** are considered to fall in a "normal" range. However, within this range, individuals may vary, and when possible, lung function values are also interpreted in light of that individual's prior values.

Spirometry provides a relatively simple means for making these measurements, in particular, it measures the amount (volume) and/or speed (flow) of the person's capacity to move air in and out of the lungs by recording the amount and speed by which air is blown into a recording device during a series of "**maneuvers."** Spirometry is one of the most common health measurements made. It can provide very valuable information as long as care is taken to make sure the maneuvers the participant makes are optimal and the equipment is used correctly. Spirometry is not painful but does require that the participant cooperate fully and provide the best effort possible to produce accurate results.

The test is performed using a spirometer, which consists of a mouthpiece and disposable tubing connected to a machine that records the results and displays them on a graph. Both volume exhaled as a function of time (volume-time graph) and flow per volume exhaled (flow-volume graph) are used to judge the adequacy of the maneuver and identify possible disease patterns. Accurate testing requires use of a spirometer that conforms to standardization specifications developed by the American Thoracic Society.

This manual will review the materials, equipment, and approaches needed for making accurate spirometry measurements.

1.00 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 5.05.28) is installed on a notebook computer with 2000 or Windows XP.

Other Equipment and Supplies:

Calibration syringe, 3.00 liters, Han Rudolph model # 5530

Spirometer hoses, 2 feet long

Disposable mouthpieces, nose clips

Bleach (for disinfecting)

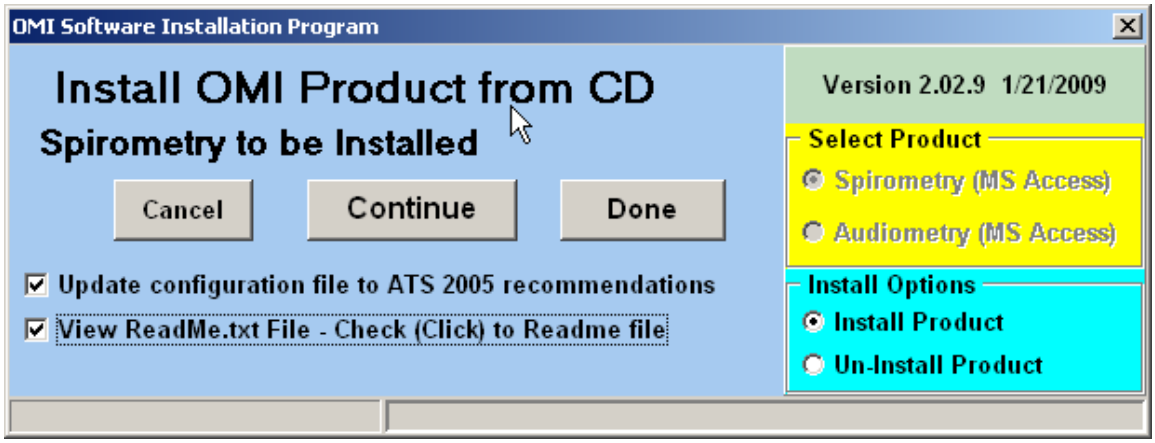
(Note: Although this spirometry system is much larger than spirometers commonly used for clinical practice (office spirometers), it is more accurate. The volume accuracy of this system is better than 1.5 percent, which exceeds the ATS-ERS recommendation accuracy within 3 %.)

> 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.

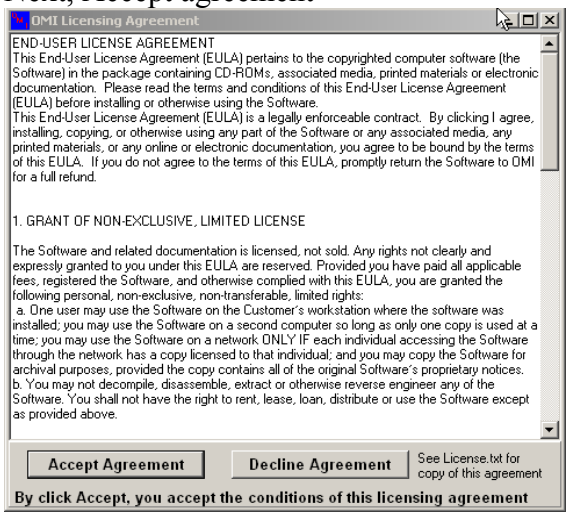
1.01 Software Installation

Insert the OMI CD in the drive. The installation process will begin. Answer each installation questions that is prompted as below.

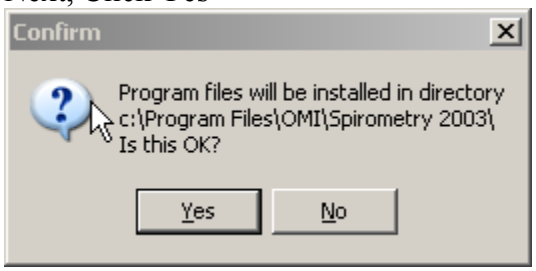
Make sure the following are checked and click continue.



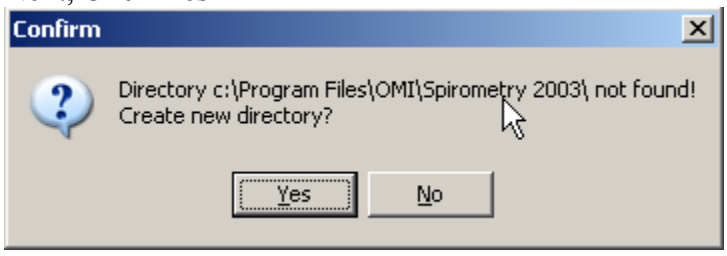
Next, Accept agreement



Next, Click Yes



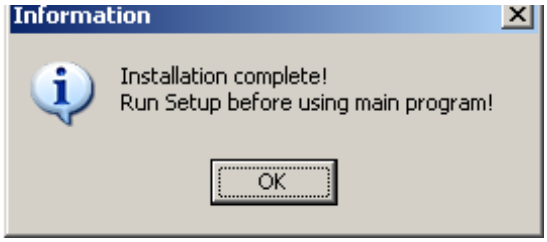
Next, Click Yes



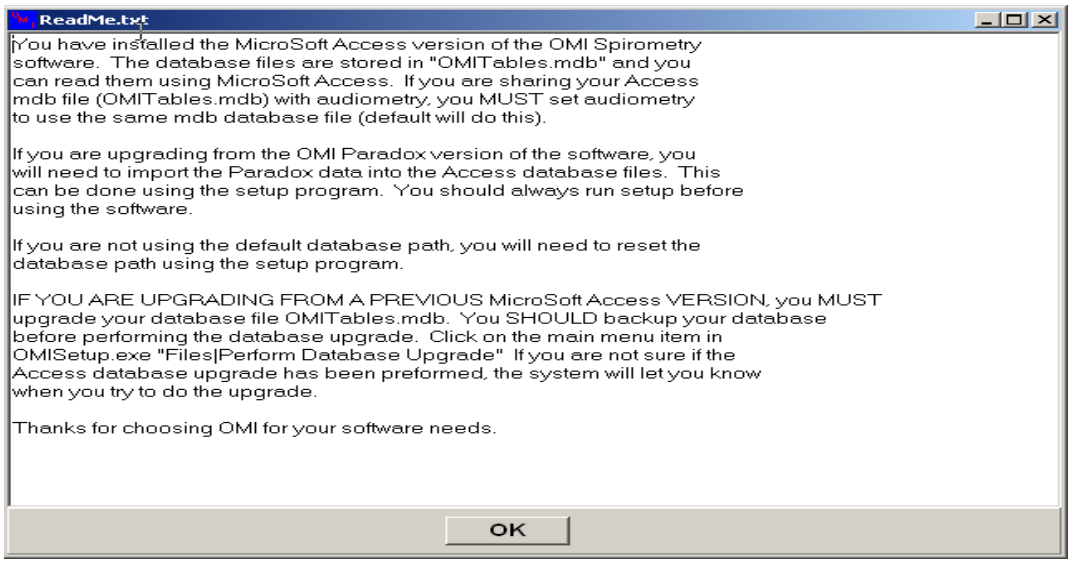
Next, select the current version of Access on the computer that software will be installed on. Access will be located in your Program file in the Microsoft Office folder. Then

Continue Installation

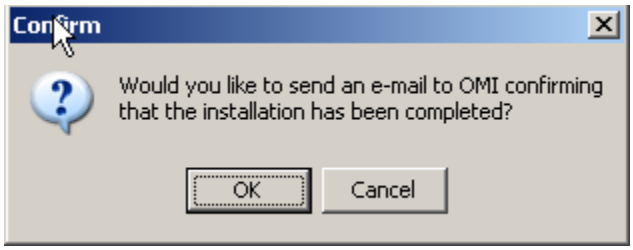
Next, click ok



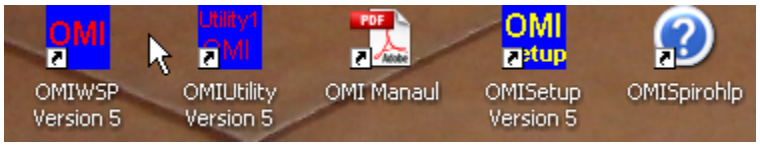
Next, Click Ok



Next Click Cancel, an email will not be sent to OMI.



Once Installation is complete there will be 5 Icons located on your desktop.

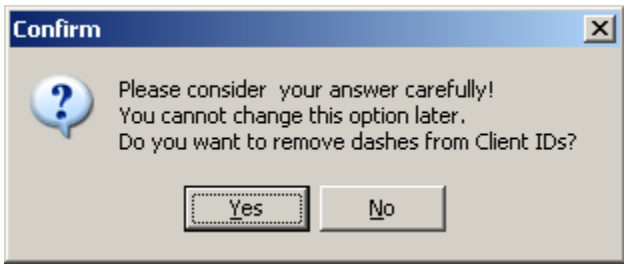


1.02 OMISETUP Program

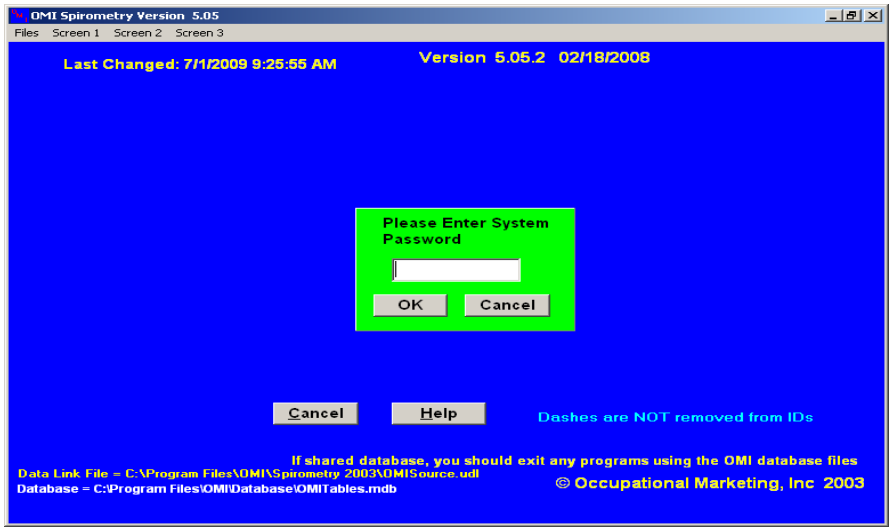
Locate the OMISETUP Program Icon 

. Double click on the Icon.

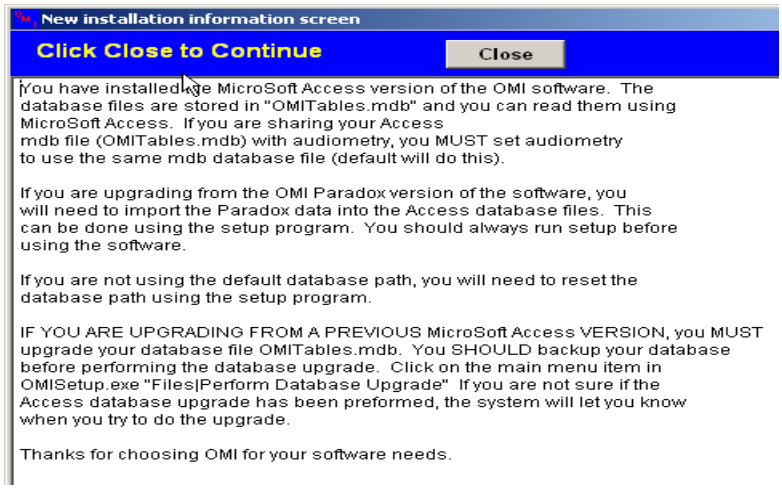
Next, a screen will appear Click No.



Next, enter the password "**omisetup**" (without the quotes-all lower case letters, all one word) DO NOT CHANGE THIS PASSWORD. Click OK.

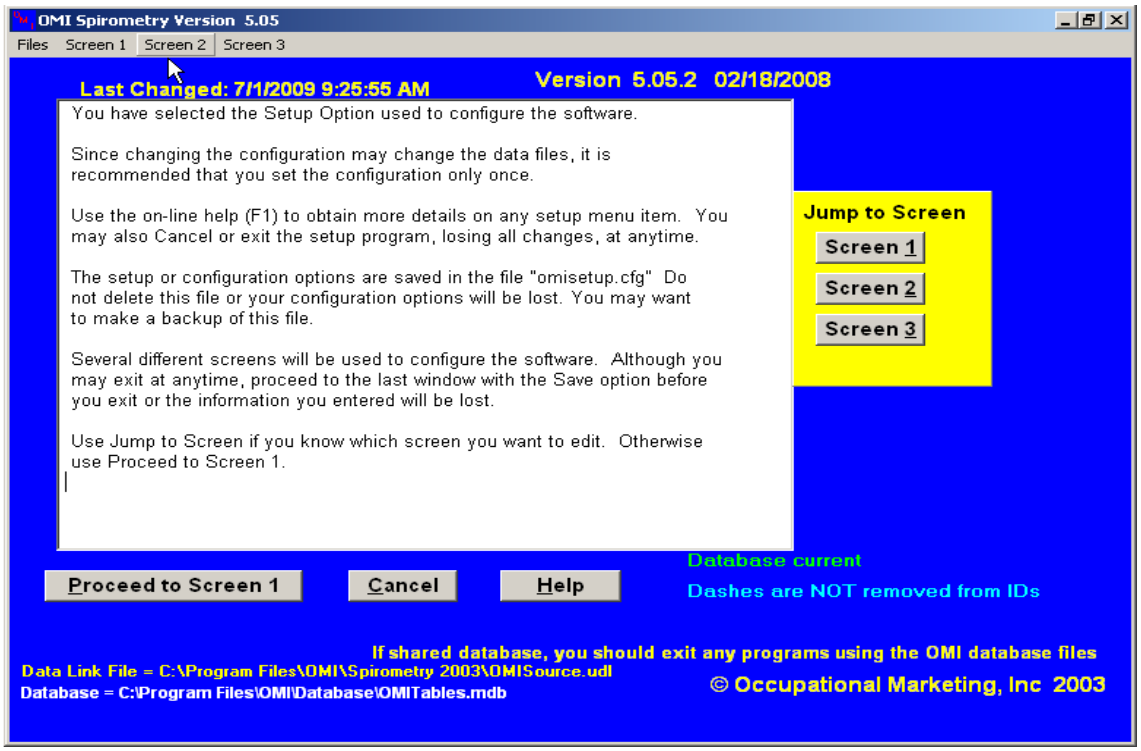


Next, Click Close



***If you receive a POP screen asking to update access now, click yes. This will allow your database to be upgraded.**

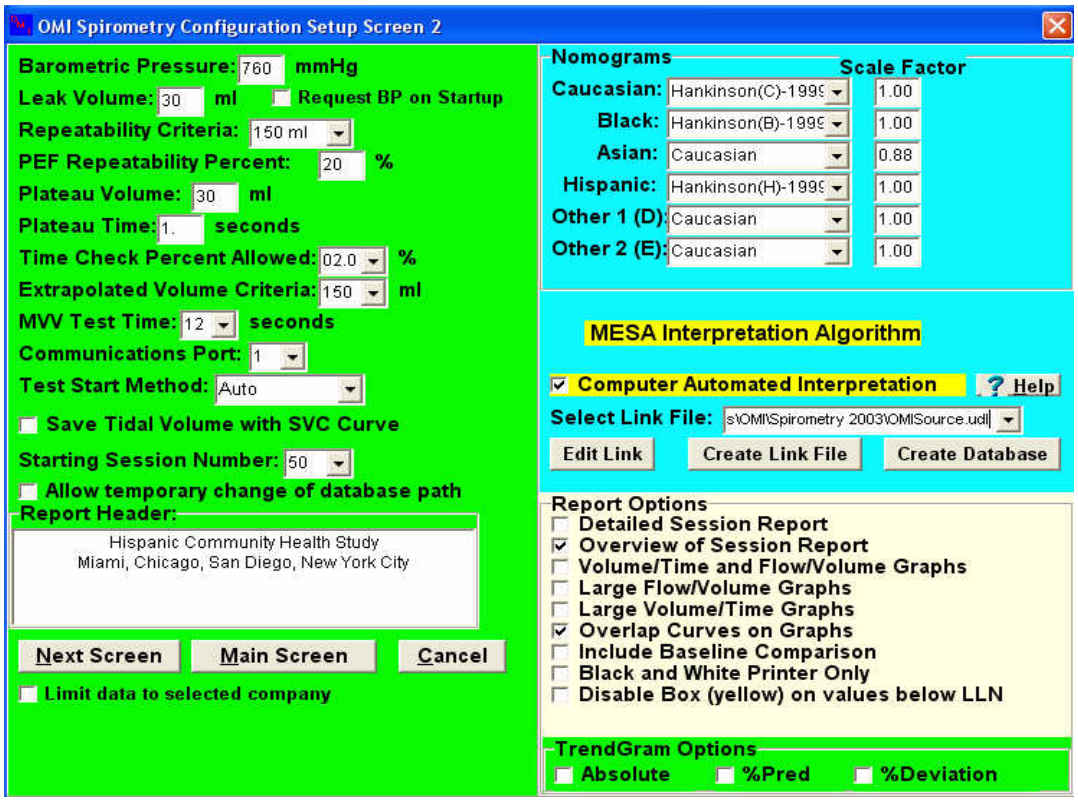
Next, Click on Proceed to Screen 1



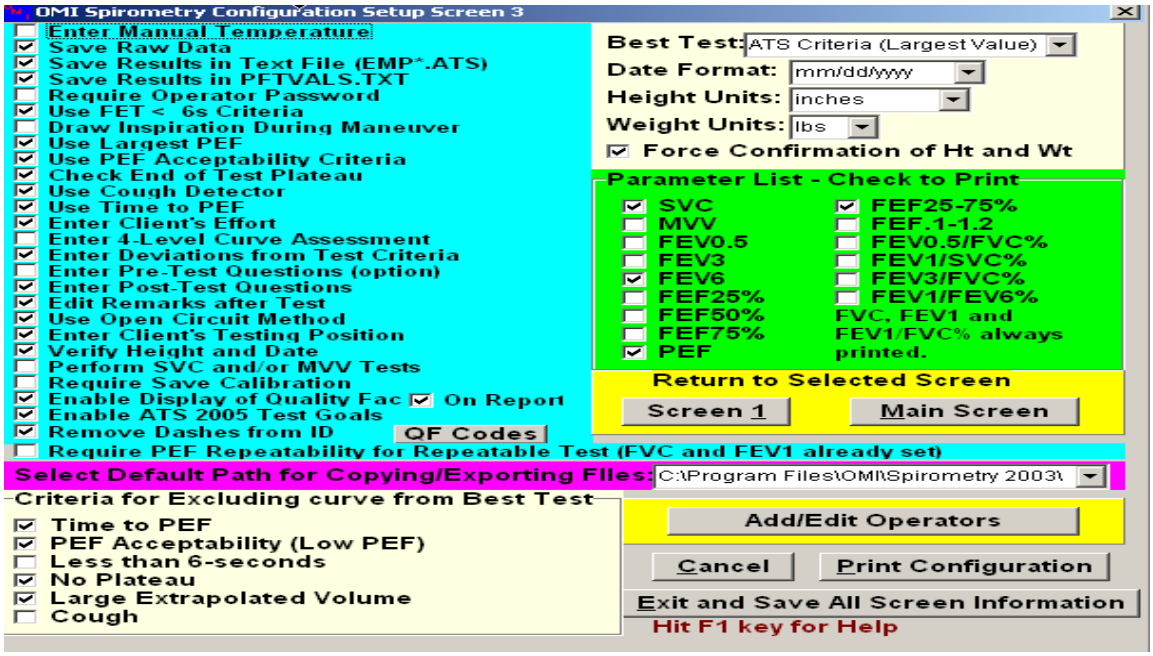
Setup Screen 1: Click on Proceed to Next Screen

Your Site Name Should be in the Header Box.

Setup Screen 2. Please update and change the settings on this screen, which have been standardized for this study. Click on the next Screen.



Screen 3: Please make any changes to match the following settings (also standardized for this study): The report header should contain the name of your instution. Click on Exit and Save All Screen Information.



1.03. <u>Initial Equipment Setup</u>

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

***The Spirometer unit should be at shoulder level, the participants mouth higher than the spirometer snout, and that the back of the unit should have open free space behind it so that the pin has room to "pull out" during an exhalation maneuver**.

2. Connect the power cords to a grounded electrical socket.
3. Turn on the spirometer.
4. Power up the laptop computer.
5. Attach the large end of the hose to the Spirometer.

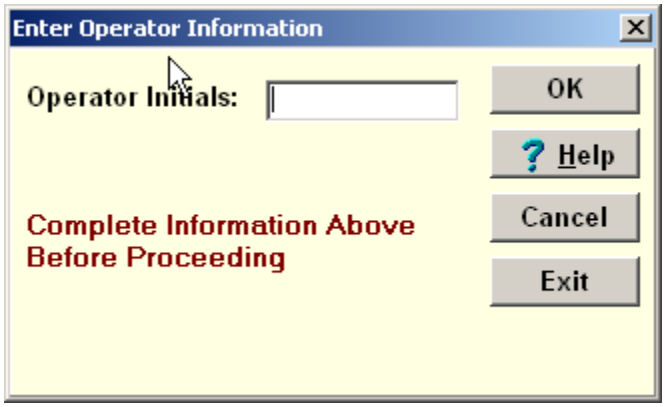
1.04 <u>Daily Leak and Calibration Checks</u>

Accurate recording of lung volumes and flows is only possible if the instruments are measuring these correctly. To ensure that measurements are being made accurately, each day, before testing the first participant, perform a leak and calibration check. *This will require use of a calibrated 3 liter syringe—one that is laboratory-certified as measuring exactly 3 liters of air.*

1. Double click “OMIWSP.exe” 

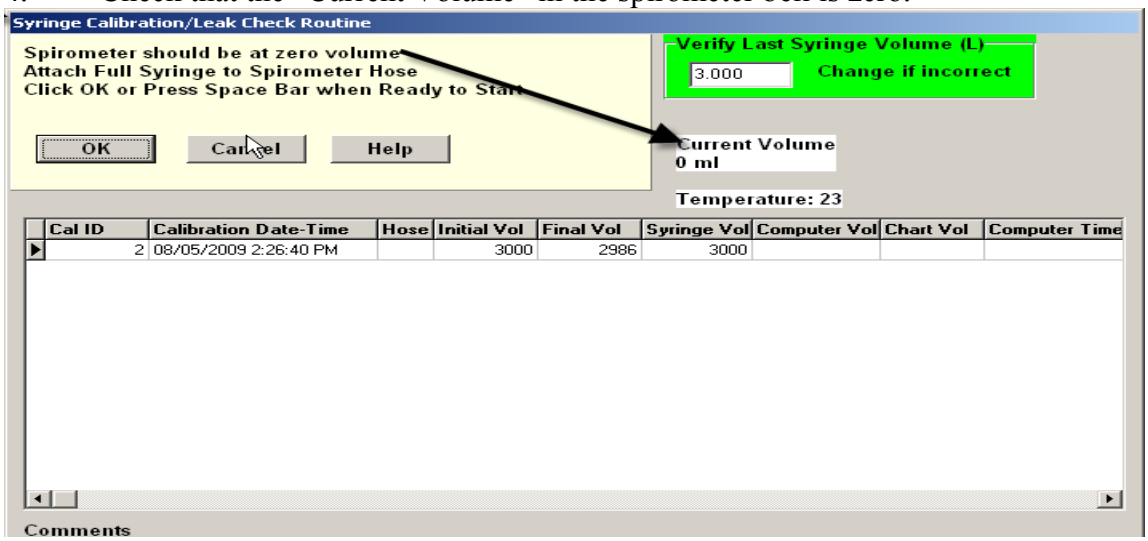
windows icon.

2. Enter your Tech ID under “operator initials”



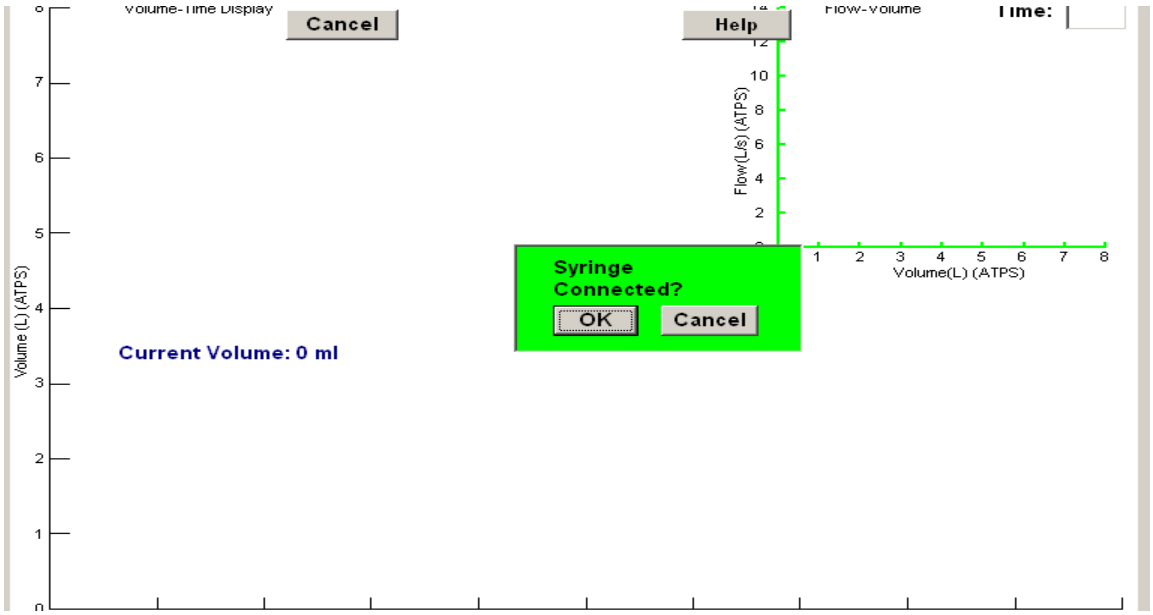
3. Select “Perform Cal/Leak Check” button on the main screen or in the “Calibration” menu.

4. Check that the “Current Volume” in the spirometer bell is zero.

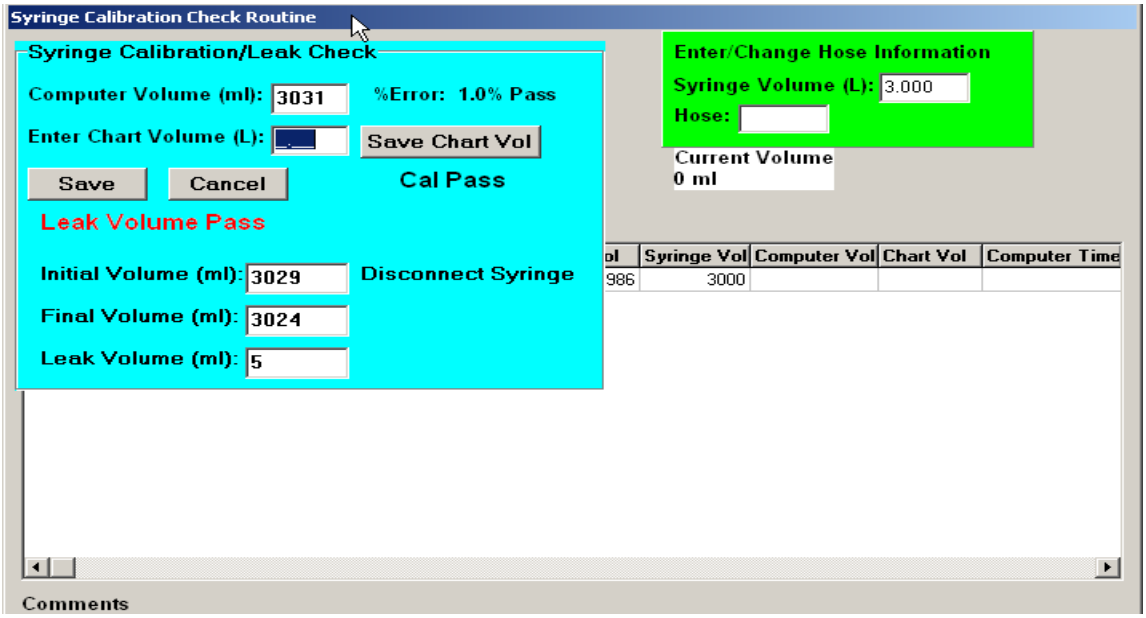


10. Fill the calibrating syringe by pulling out the plunger and connect it securely to the spirometer hose.

11. Click on “OK”, using a smooth motion, inject the full 3-liters from the syringe into the spirometer, and leave in place for 60 seconds. The Leak check will be performed in the 60 second window. (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.
The measured volume and the actual volume should be within 15 mL of the other. For leaks, there should be no more than a 10 mL change over one minute while the syringe is attached to the spirometer. Click on save.



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. If the calibration exceeds tolerance (e.g., 15 mL) repeat the procedure. If it still is out of tolerance, contact the manufacturer.

2.01. HOW TO TEST PARTICIPANTS

Spirometry Exclusion Criteria:

Check to make sure that the participant does not meet any of the Spirometry Exclusion Criteria (see Appendix). Because of the marked effort needed for the maneuvers, spirometry should not be performed on subjects who:

- Has had a heart attack, stroke, or eye surgery within the prior 3 months
- Has marked symptoms of shortness of breath, chest pain, or coughing, which is reported to be worse than baseline or in the opinion of the tester, will interfere with maximal test performance.

Also, inquire whether the participant had trouble with spirometry in the past. If the participant reported passing out or other serious problems, consult with the clinic coordinator, PI, or physician associated with the study on whether to proceed or not.

Record Information on Recent Illnesses, Tobacco Use and Bronchodilator Use

Participants will have been instructed to refrain from use of tobacco for 2 hours before testing, or use of short acting bronchodilators for 4 hours before testing, and attempts will be made to test at least 2 weeks after a respiratory illness ended. Nonetheless, some participants will present for spirometry and not have heeded these instructions. Record any of these exposures on the Spirometry data transmittal sheet. Participants who smoke occasionally for leisure/socially (a couple times a year/once a month) cigars, cigarettes, and/or pipe will be considered non-smokers when entering their client information but the type and frequency should be entered in the comment section.

Performing the Maneuver: Instruction and Coaching

The accuracy of spirometry depends on your skills, your ability to explain and demonstrate the appropriate maneuver, and your ability to motivate the participant to provide his strongest efforts. Good data also requires that you carefully observed the participant's efforts to determine adequacy of the maneuver. Consequently, it is crucial that the examination protocol be observed consistently.

The goal will be to obtain a minimum of 3 curves that meet ATS acceptability criteria and are reproducible (FVC within 150 mL of maximal). To get 3 acceptable curves, you will have the participant perform a minimum of 5 maneuvers. If 3 are not acceptable, you may attempt a maximum of 8 maneuvers. However, trying to get more than 8 maneuvers often results in fatigue without further improvement in the data.

Position the Participant-

All maneuvers will be done with the participants sitting comfortably, upright, with feet flat on the ground. (Instruct the participants to sit up straight, to keep both feet flat on the floor during the maneuvers.) Legs should not be crossed. Ask the participant to loosen any tight clothing, such as a tie, vest, or belt, which might restrict maximal breathing efforts.

Have objects in the mouth removed: 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. Also, instruct the participant to remove any gum or hard candy in his mouth to make sure it does not get in the way of the breath out and does not cause choking.

Explaining and Demonstrating the Procedure

Explain the procedure, demonstrating how you yourself would take a maximal breath in and blast out. Explain that no resistance to breathing should be felt (it will feel like blowing into a balloon). Note the importance of taking the biggest breath possible in and the need to continue to blow out; often it feels as though the lungs have emptied in a few seconds, but it is still important to keep exhaling until told to stop or unable to continue to blow out because of discomfort or lightheadedness.

Demonstrate a deep inspiration; exaggerate body language, eyes wide, and shoulders back. Demonstrate proper placement of the mouthpiece stick out your tongue and place the mouthpiece on top of it. Blast out.

Have the participants practice blowing out into a mouthpiece before attaching it the hose so they understand the maneuver and also feel comfortable using the mouthpiece. Practice placing the mouthpiece in the mouth. The participant should stick his tongue out and place lips all around the outside of the tube. The lips should surround the mouthpiece, with no leak, and with the tongue flat on the bottom of the mouth.

Also note that you will be using the "open circuit" technique—ie. to minimize any chance of transmitting infection between participants, participants will not breath in from the spirometer but will breath in room air, and then insert the mouthpiece (while at maximal breath hold), and then blast the air out into the hose and spirometer.

Key Instructions:

- Take a deep breath in until you cannot get any more in. Fill your lungs all the way until you can't get any more air in.
- Put your lips around the mouthpiece-Then, without hesitating—quickly-
- Blow fast and hard the same breath for at least 6 seconds-BLAST it out!!!

- Keep blowing, blowing…. (Until you observe a maneuver that is at least 6 seconds long and has reached a plateau.) **If a plateau has not been reached within 12 seconds you may terminate the maneuver**.

Sample instructions:

"Take a great big breath of air as far as you can inhale."
"Fill your lungs"
"Put the mouthpiece into your mouth and seal your lips tightly around it."
"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.)
"Keep on blowing out the same breath of air, until I tell you to stop." (At this point, you should be coaching loudly, instructing them to blow for at least 6 seconds)
"Keep blowing, Blow push harder".
"Tighten your stomach muscles"

Note—asking the participant to tighten his stomach muscles may increase his ability to force air out.

Interact and Watch Closely

Your active participation may also be helpful: Place your hand on the participant shoulder to encourage them to sit straight so that they do not lean forward. Watch the patient's performance closely for poor maneuvers—e.g., evidence of coughing, hesitation at the beginning of the breath, leakage of air around the nose or mouthpiece, abrupt termination of the blow, closure of the glottis, weak effort. If the effort appears unacceptable, identify the reason and instruct the patient how to perform the test better. Also, watch for any adverse reactions—if a participant looks sweating, uncomfortable or faint, remove the mouthpiece immediately and follow the instructions below (terminating the test).

Reminders:

Remind participants not to take in a second breath, if they need to take a second breath to remove the mouthpiece. Breathing out-but not in---also minimizes any chance that the spirometer becomes contaminated with infectious agents.

If a participant needs to cough, to cough with the mouthpiece in and **remove it once they need to take a second breath.**

2.02 Terminating a Test and Participant Safety Responses

Watch the patient's performance closely for poor maneuvers. If the effort appears unacceptable, identify the reason and instruct the patient how to perform the test better.

If after 8 attempts you are unsuccessful, terminate testing.

In rare cases, a participant may hyperventilate and feel dizzy during the examination. 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 nurse or physician should be summoned whenever a participant fails to recover normal breathing, faints or reports feeling ill.

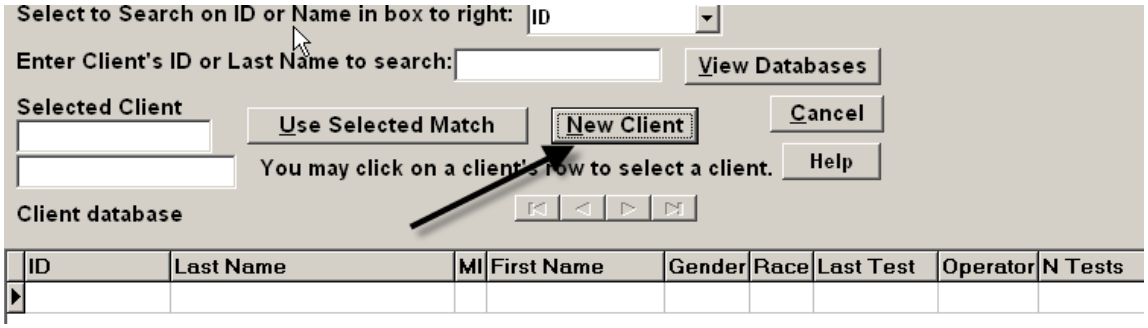
Sometimes, individuals with reactive airways will experience bronchospasm as a result of testing. If a progressive decline in FEV_1 is observed with progressively subsequent maneuvers, testing should be stopped. If a participant has an inhaled bronchodilator, he can use that then to relieve any discomfort.

2.03. How to Interact with the Spirometer

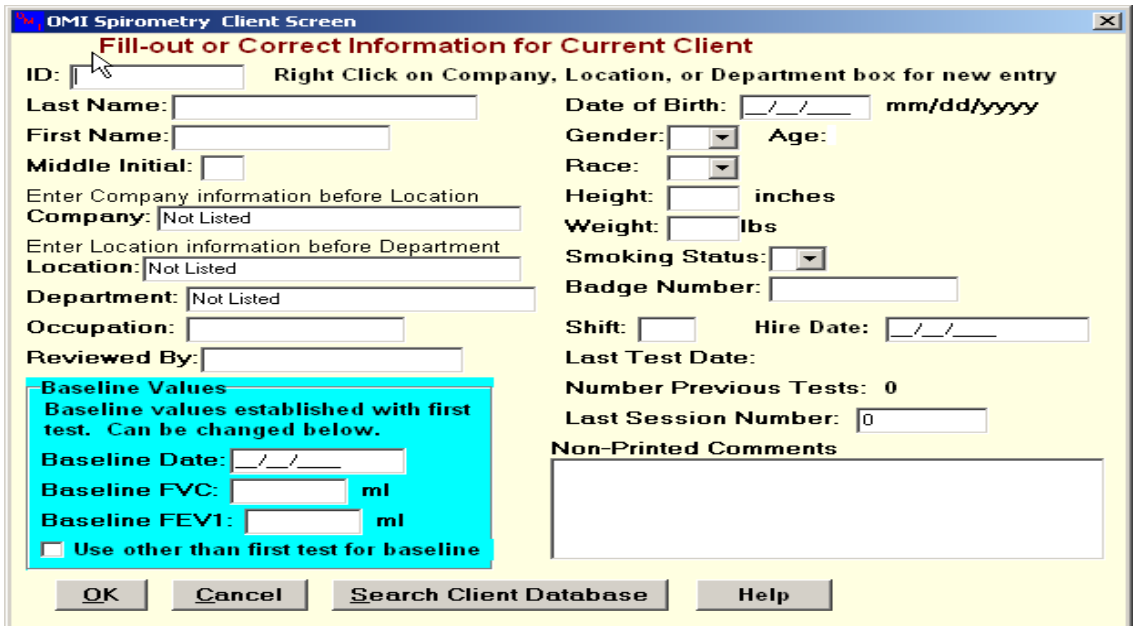
To begin a testing session, follow the steps below:

1. Select Perform/Review Tests and then Select/Add Patient

2. Select New client



3. Enter the Participant information:

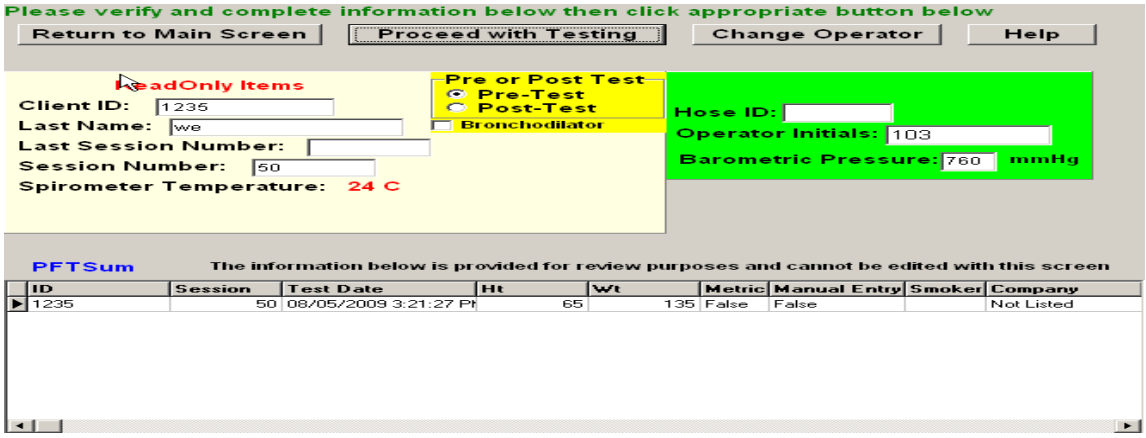


Please fill in the following, then click OK:

- ID= Participant ID (with Site code and ID number) = SD1245
- Last Name = First two letters in the acrostic
- First Name = Last two letters in the acrostic
- Date Of Birth
- Gender= Male
- Race= C= Caucasian
  B= Black
  A=Asian
  H=Hispanic
  O, D, & E=Other(automatically defaults as Caucasian)
- Badge Number= Tech ID
- Height (inches) and Weight (lbs)

4. Select Perform FVC test.

5. The Participant ID, should be visible in the Client ID box. Please verify the information located on the screen is correct.



6. Wash your hands. You also may want to use medical gloves during the procedure, especially if the participant has any open sores around his mouth.

7. Attach a clean breathing hose and mouth piece.

8. 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." Follow the instructions above "Participant Interactions."

9. Demonstrate a deep inspiration as described above (i.e., exaggerate body language, eyes wide, shoulders back). Demonstrate proper placement of the mouthpiece stick out your tongue and place the mouthpiece on top of it. Blast out.

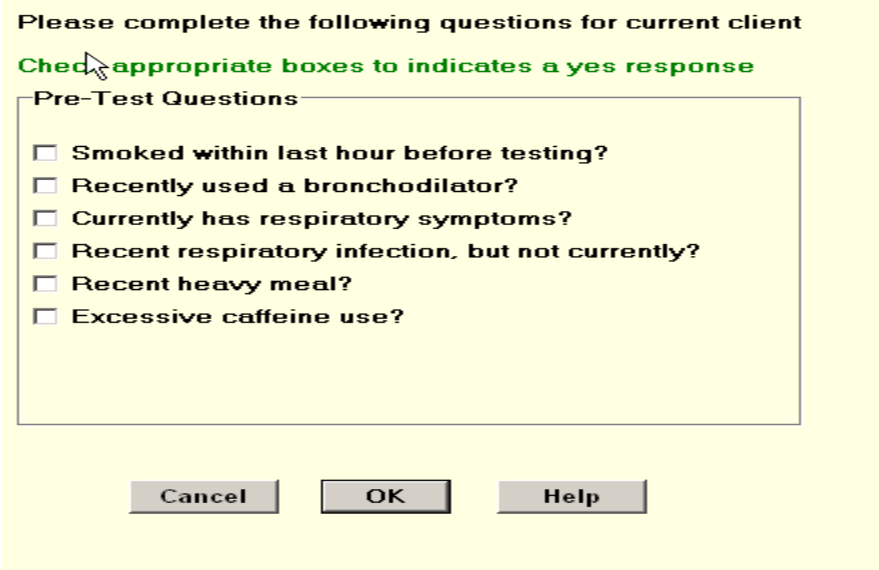
10. Place nose-clip on their nose. It may be removed between trials. If the nose-clip falls off or is uncomfortable, the participant may hold his nose during FVC maneuver.

11. Have the participant do a trial exhalation. As described above, the following instructions may be helpful:
"Take a great big breath of air as far as you can inhale."
"Put the mouthpiece into your mouth and seal your lips tightly around it."
"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.)
"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.

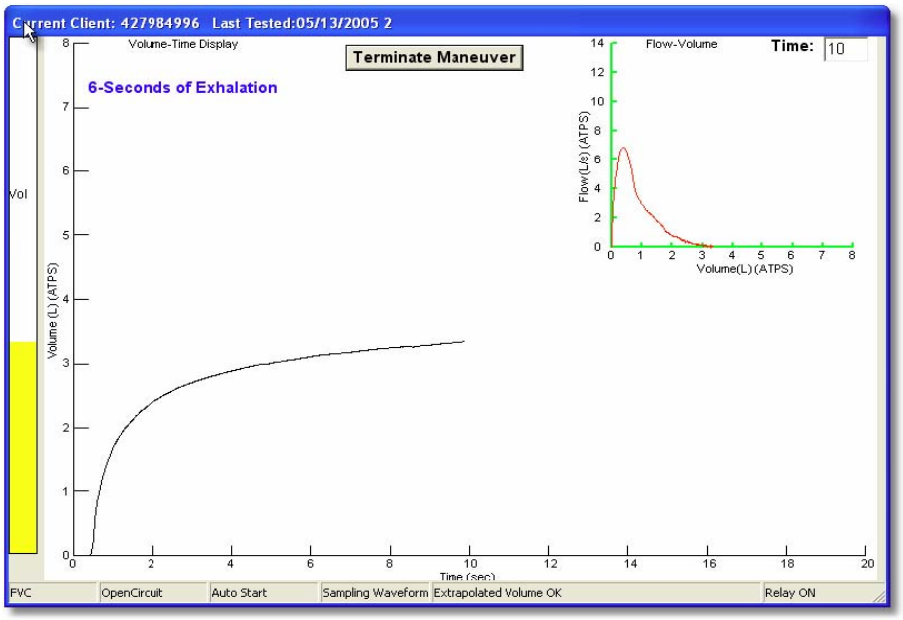
13. Select "Proceed with Testing".

14. Complete the following questions on the computer screen(if it is an option available in your program) and on the Spirometry Teleform form that will be sent to the RC. See Appendix.



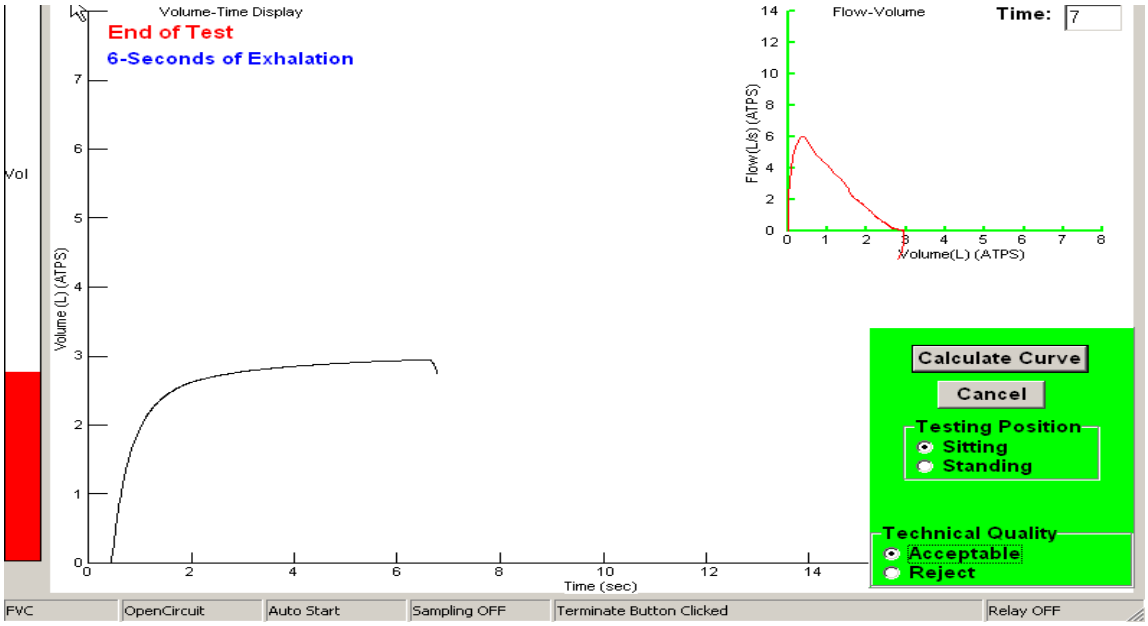
15. "Volume-Time and Flow-Volume Graph" screen appears. A window prompts "Start Test?" When ready, click "OK."

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.



16. Continue to coach the participant to exhale until the "Plateau Achieved" message is displayed and the bar on the left side turns green (**terminate maneuver once 12 seconds**

have been reached or if participants feels dizzy/light headed). Help the participant to move the mouthpiece away from their face (to reduce the risk of cross-contamination).

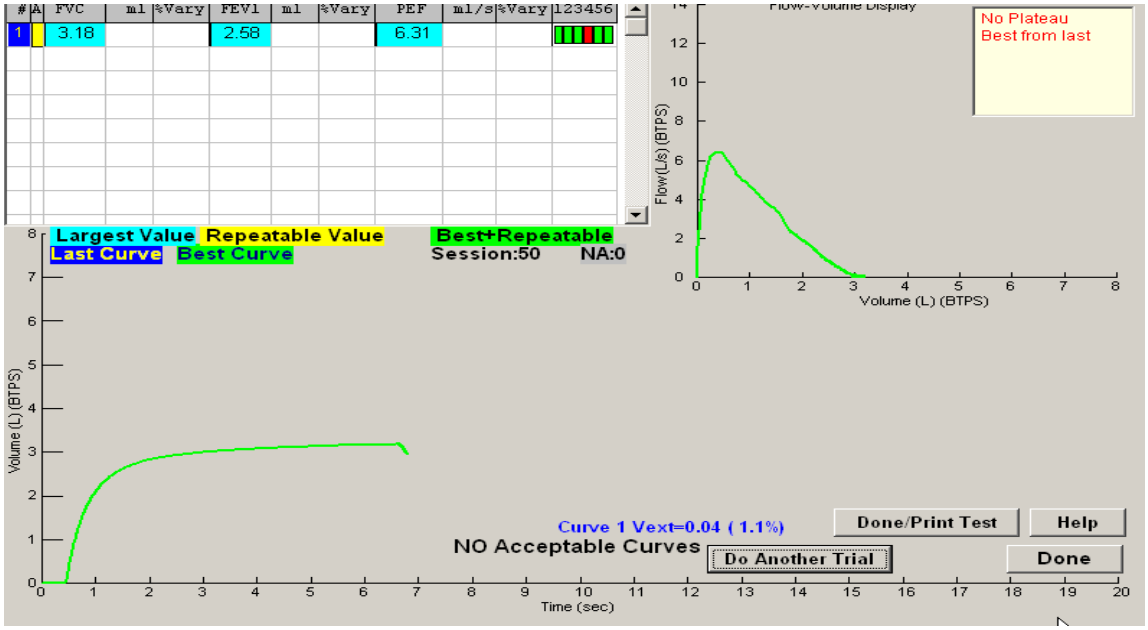


Indicate sitting and your impression of the participant's effort.

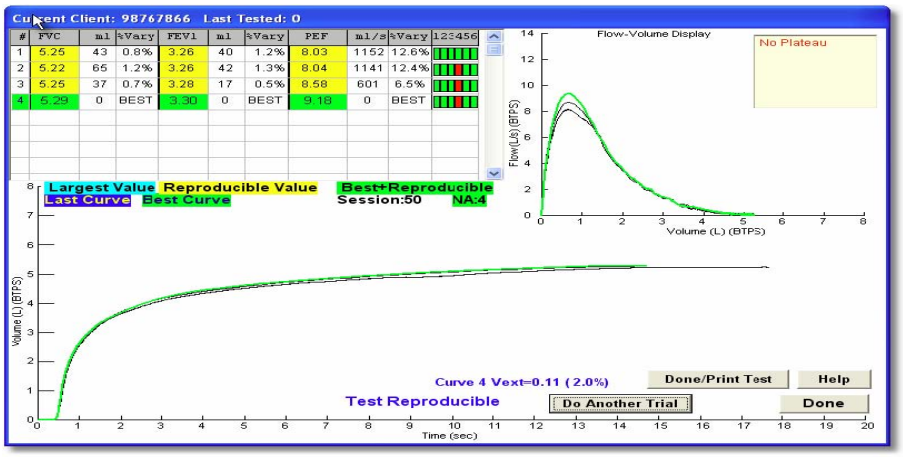
17. Press "Calculate Curve".

18. Click on Do another trial. Repeat the above steps until a total of 5 acceptable curves were performed and 3 good curves are collected (and not more than 8).

19. Click on Done/Print tests once 3 good curves have been collected.



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 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.



2.04 Assessing the Adequacy of the Testing Maneuvers

Reliable data requires the collection of a minimum of 2 acceptable forced maneuvers (although we will attempt 3) that meet ATS criteria for test acceptability. In general, curves should show be smooth (no coughs, abrupt stoppage of flow), show rapid rise in flow rates, and reach a nice plateau of volume after about 6 seconds. **See Appendix for examples**. The following criteria are used to test the adequacy of the tests:

- Start of Test Criteria- This refers to the lack of excessive hesitation at the beginning of the blast out and no coughing occurring early in the blast.. Note that this hesitation causes the spirometer to extrapolate a volume that is based on the point when flow meets a maximal rate. "Back extrapolated volumes [BEV]" of greater than 5% of the FVC or .15L are considered excessive and invalidate that curve.
- End of Test Criteria- This refers to the curve having the following characteristics indicative that a maximal volume was inspired at the start of the test and this volume was completely exhaled.
    - The duration of the exhalation is at least 6 seconds AND
    - The volume-time curve shows an obvious plateau (i.e., no change in volume (<30mL) for the last one second of the exhalation OR
    - The subject cannot continue further exhalation because of discomfort or lightheadedness
- No evidence of: a valsalva maneuver (when the glottis closes and flow stops)

- No leak (slow decline in volume)
- No obstruction of the mouthpiece

  Note that some participants, especially those with underlying obstructive airways, may not be able to completely exhale their vital capacity in 6 seconds. In general, even in those with severe airway obstruction, duration of 12 seconds should provide a reasonable estimate of their vital capacity. Thus, it is generally **not advisable to push participants to exhale beyond 12 seconds**.

If all maneuvers were inadequate the program will not save any attempted unacceptable curves. A curve must at least have either a good start or a good end to be considered and to be automatically saved by the program. Re-testing will be left up to the discretion of each individual site.

2.05 Reproducibility

Ideally, all curves should have a FEV_1 and FVC within 200 mL of the maximal FEV_1 and FVC. Failure to get this means inconsistent performance, which could mean suboptimal effort. However, poor reproducibility also may occur in individuals with lung and other health problems. Therefore, lack of reproducibility should be a trigger for you to consider how efforts can be better performed. However, if technique appears adequate, failure to achieve reproducibility may be a marker of other issues.

Common Problems

As shown in the appendix, there are a number of ways a test may produce inadequate results. By carefully examining each flow-volume and volume-time curve, problems with start and end of test can be identified and often can be corrected.

2.06 Interpreting Values.

FEV and FVC values of 80 to 120% of the predicted values and FEV_1/FVC ratios of > 75% are generally considered normal up to the age **90**.
FEV_1 <30% P
FVC < 30%P

2.07 Urgent Referrals

Most individuals with low levels of lung function have had these values for a long time, and this information does not require immediate action. The sites will be notified about urgent referrals by the Reading Center. The sites will indicate on the teleform whether an urgent alert has been noted once the Reading Center has reviewed all maneuvers. Participants and/or their primary physicians should be informed with 10 days of receipt of urgent referrals.

3.01Cleaning and Infection Control

Good procedures for cleaning and test performance reduce the chances that infections would be transmitted from participant to participant or between participant and technicians. There is a potential for infectious spread of viruses, bacteria, and tuberculosis through contact with aerosolized droplets. There could be a chance of transmitting blood-borne diseases (e.g., hepatitis, HIV) exist if there are open sores on the gums or bleeding in the mouth. The following approaches are used to prevent infection and cross-contamination:

- Use the "open-circuit" technique—whereby participants breath from room air, not the spirometer, which is only used for exhaling into –i.e., Participants do not inhale from the spirometer.
- Keep the participant's mouth higher than the spirometer snout during the maneuvers.
- Use of disposable mouthpieces, noseclips and bacterial filters for each participant
- Use of newly cleaned reusable hoses for each participant, with sterilization of the hoses before each use
- Technicians should wash hands well before and after testing each participant. Additionally, gloves should be worn if there is any open sores or gum bleeding, or at the discretion of the technician.
- Daily disinfecting of the snout with either a Cavi/Sani wipe.

3.02. How to Clean the Spirometer

Unplug the power cord. Wipe the snout plate with a germicidal disposable cloth (for example Sani/Cavi wipes). Do not use alcohol, acetone, other volatile agents or abrasive cleaners on the rolling seal. Seal will be inspected and cleaned at the same time.

3.03. How to Clean the Hoses

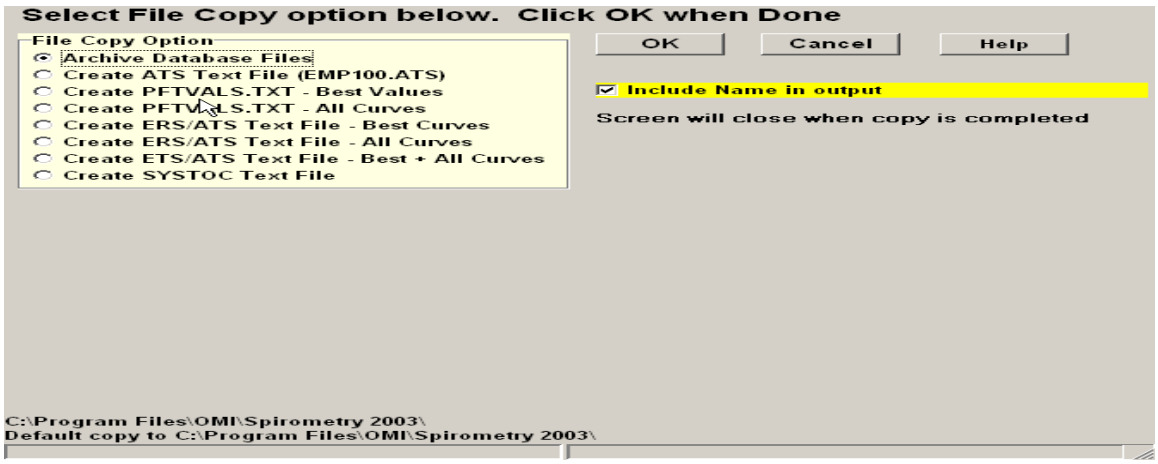
The hoses and accessories will be cleaned and disinfected after each use or daily?? Tubing will be cleaned and disinfected daily using a solution of 1 part bleach and 9 part water according to the following protocol. Hoses will be soaked for 10 minutes in the bleach solution. Rinse hoses in water after use in this solution. Hang hoses up to dry using clothes pegs.

4.01 Data exporting

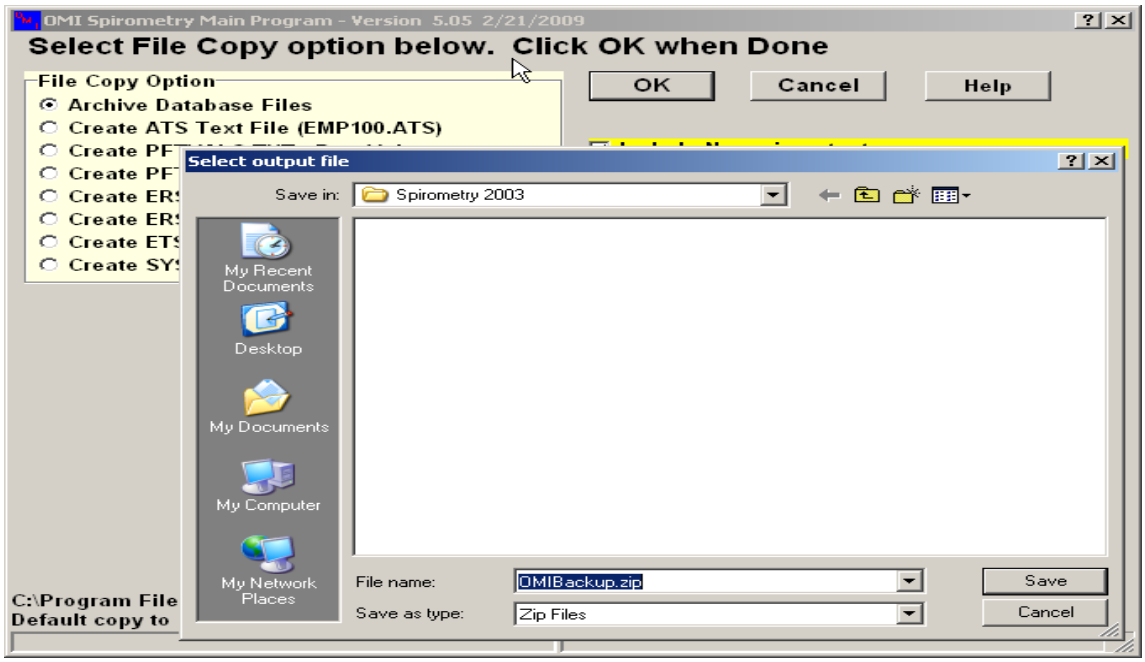
1. To transmit the database you will need to open OMIWSP. Click on Copy/File

2. Choose Back up databases

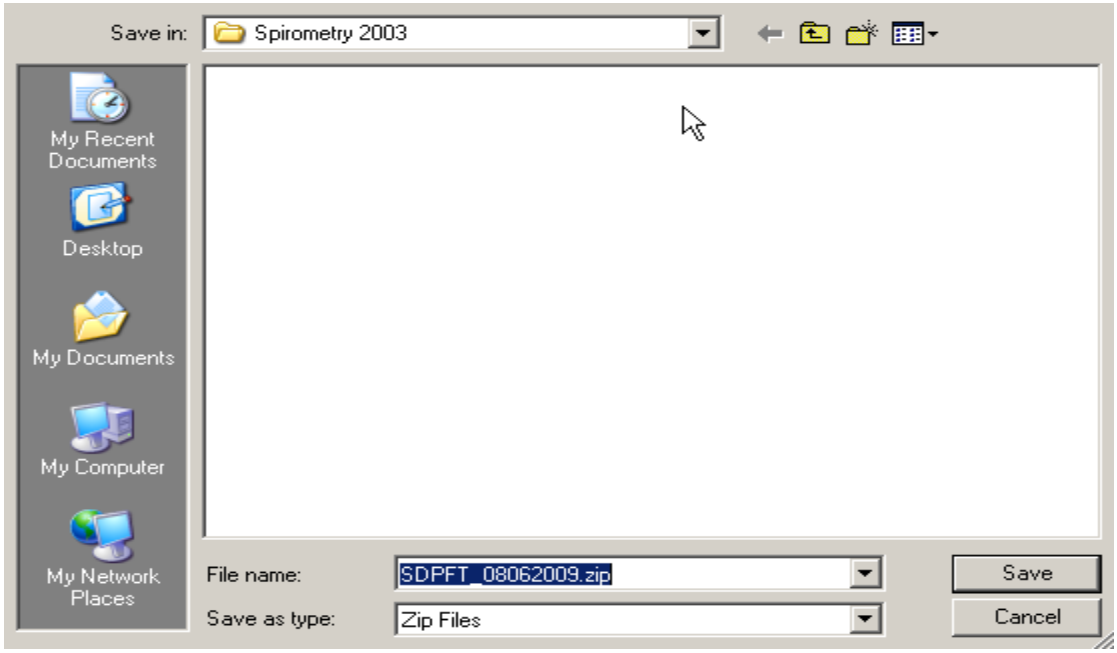
3. Select Archive Database Files, then click Ok



4. Change the File Name to Site initials PFT_date of export



Example: SDPFT_08062009 then click save. Save the File to your desktop. And follow the same 7.0 FTP instructions that are located in the Sleep Manual.



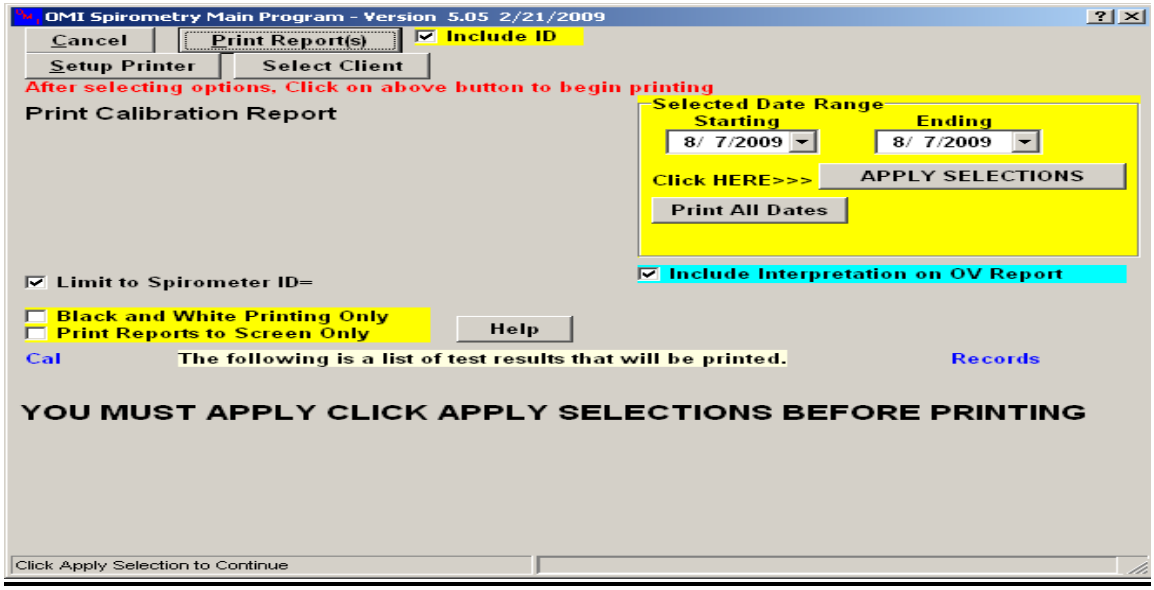
4.02 Calibration log Print Out

1. Click on your OMIWSP icon.

2. Click on Print Report.

3. Choose Print Calibration Log.

4. Select the start date to be the Monday of the week and the end date to be the Friday of that same week



5. Click Apply Selection.

6. Select print all dates. Then Select Print reports.

7. This report will be faxed along with the Spirometry Log.

4.03 FTP

1. Rationale for Secure FTP

As with all methods of electronic transfer, security continues to be a concern to be addressed. Uploading of data to the Sleep Reading Center will be done via Secure (SSH) File Transfer Protocol (SFPT), which provides additional security for research data during transmittal. Sites uploading data will need FTP client software installed on the designated computer and may need to configure their firewall to allow outgoing traffic for SFTP on port 22. The site institution's IT personnel should be able to assist in this configuration if needed. In order to ensure data security all data that is sent to the Sleep Reading Center must be placed in a zip file that has been encrypted.

2. Requirements: FTP Client Software and Registration for User Name and Password at PRC Website

3.1 FTP Client Software

The FTP Client Software being used to transmit the PSG files will also be used to transmit the Spirometry files. Detailed instructions on setting up the FTP and encrypting the zip files can be located in Section 7 of the PSG MOP.

3.2 Registration for User Name and Password

Usernames and passwords provided by PSG Reading Center can also be used for transmitting the Spirometry data. Once you have received your user name and password (usually via e-mail) you can then proceed to set up ftp client software and/or transfer spirometry data.

For any questions contact Susan Surovec (ssurovec@partners.org) at 216-702-6050.

4.04 Spirometry Inventory Form

The Spirometry Log form will be filled out at the end of each Participant session. Please record the date, Participant ID, Tech ID, the number of maneuvers attempted, and the date the file was sent. This form will be converted to pdf and sent to the Reading Center via FTP on a weekly basis (Friday). If Spirometry was not performed, the form will be sent via FTP with the words "None Collected" for the week. **See Appendix A**.

5.01 Training

A practical demonstration of skills including leak and calibration checks, cleaning, and testing participants will be done at Training. Each technician at training will have to demonstrate that a minimum of 3 adequate curves were obtained on 2 volunteers. Additionally, centrally trained technicians will perform Spirometry on 8 additional volunteers (a minimum of 3 curves each) to total 10 certification. The trainee does have the option to perform Spirometry once again on the same volunteer to reach the goal of 10 certification. An ideal volunteer would be someone who doesn't have any knowledge of Spirometry. Centrally trained technicians need to minimally test one individual per week until MrOS testing begins, a minimum of 4 participants need to be tested per month.

Certification of new technicians after the initial central training sessions may be performed by a centrally trained, certified PF technician. Ten volunteers should be tested, with 3 acceptable curves obtained for each, and sent to the RC for review. Maintenance of certification requires submission of four sets of acceptable curves (3 each) per month. Testing of the first five participants tested by a locally trained technician should also observed by a previously certified (preferably centrally trained) technician. Technicians who do not maintain study quality control grades may require re-training.

6.01 OTHER SAFETY PROCEDURES

- All equipment must be plugged into a grounded electrical outlet.

6.02 Daily Procedures Summary

- Calibrate Instruments Power-up workstation Perform Cal/Leak Check
- Identify each participant
  1. Select participant's ID number
  2. Administer spirometry questionnaire
  3. Verify name, age, and height.
- Administer Mr.Os Clinic Spirometry Teleform.
- 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
- Fill out the daily Spirometry log with the Participant information.
- Clean Equipment- Clean breathing hoses Rinse and dry overnight

6.03 Weekly Procedures

Friday afternoon: FTP Spirometry Log and Calibration Log to BWH - If Spirometry wasn't performed for the week, sent the inventory sheet with "None Performed". Upload every week the spirometry data to PF Reading Center via FTP-site.

7.01 Supplies and Troubleshooting

Micro bacterial filter mouthpieces (one for each participant)
-Nose clips (to be disinfected in between participants)
-39 inch hoses (to be disinfected in between participants)
The supplies can be purchased directly from Occupational Marketing, Inc (OMI).

Occupational Marketing, Inc.
19424 Park Row, Suite 110
Houston, Texas 77084
281-492-8250
800-869-6783
Fax: 281-492-0036
http://www.occupational.com/

Micky Sullivan (MSullivan@occupational.com) is our main contact at OMI. He can help with all troubleshooting issues.
Claudia Montero is our main contact at OMI for ordering supplies.

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

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

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

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 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 FEV1/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.

Appendix A:

Spirometry Log Sheet

Spirometry Log Sheet

Site ID ____________

Beginning Week Date ___ ______ ______ ___ ___ ___

Page ___ of ____

End Week Date ___ ______ ______ ___ ___ ___

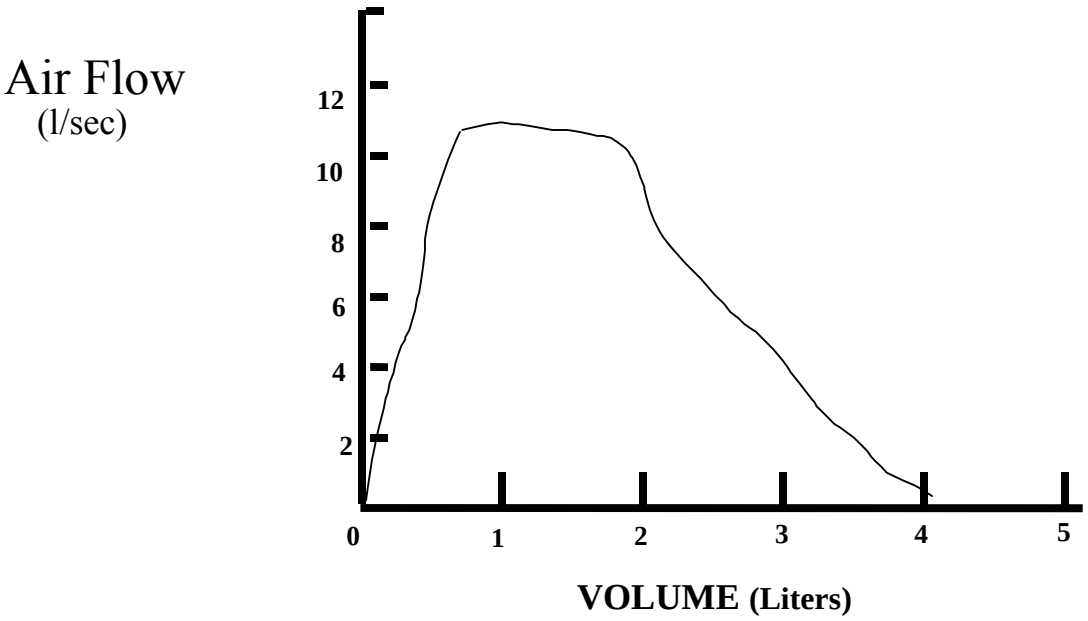
Date Spirometry Performed:	Participant Study ID	Participant Acrostic	Total # Maneuvers Performed	Tech ID	Height (inches)	Weight (lbs)	Date of Birth
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___
___ ___\ ___ ______ ___							___ ___\ ___ ______ ___

Please remember to send this inventory sheet every Friday once the last Spirometry session was performed and include it when sending the data files FTP.

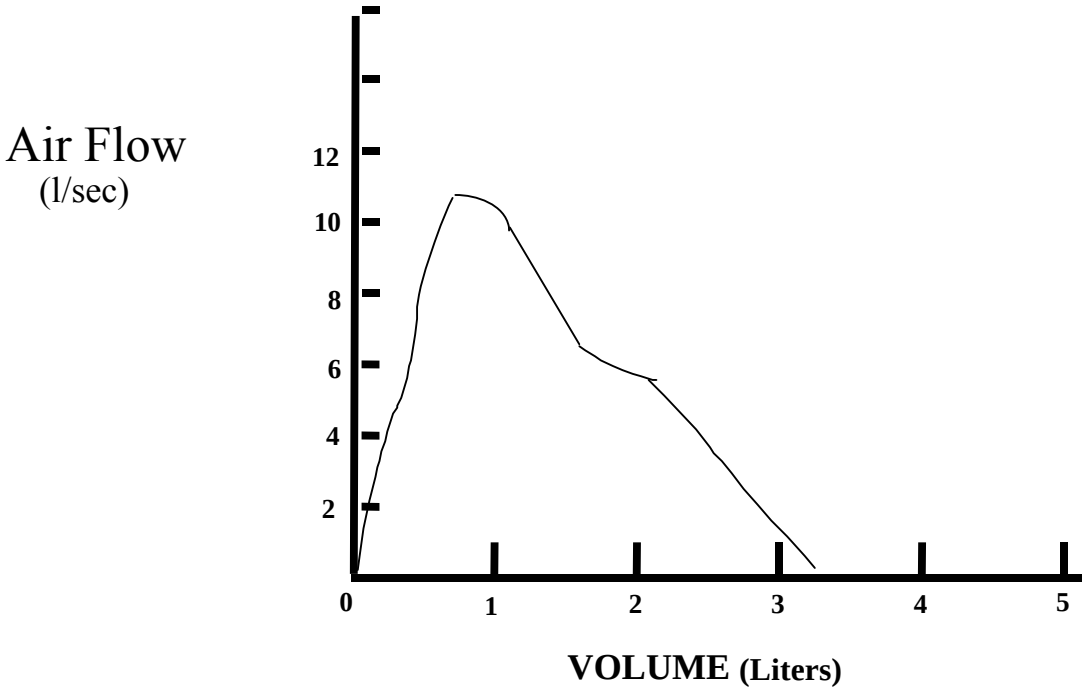
If you have questions contact: Michael Morrical 857-307-0332
mmorrical@partners.org

Appendix B:

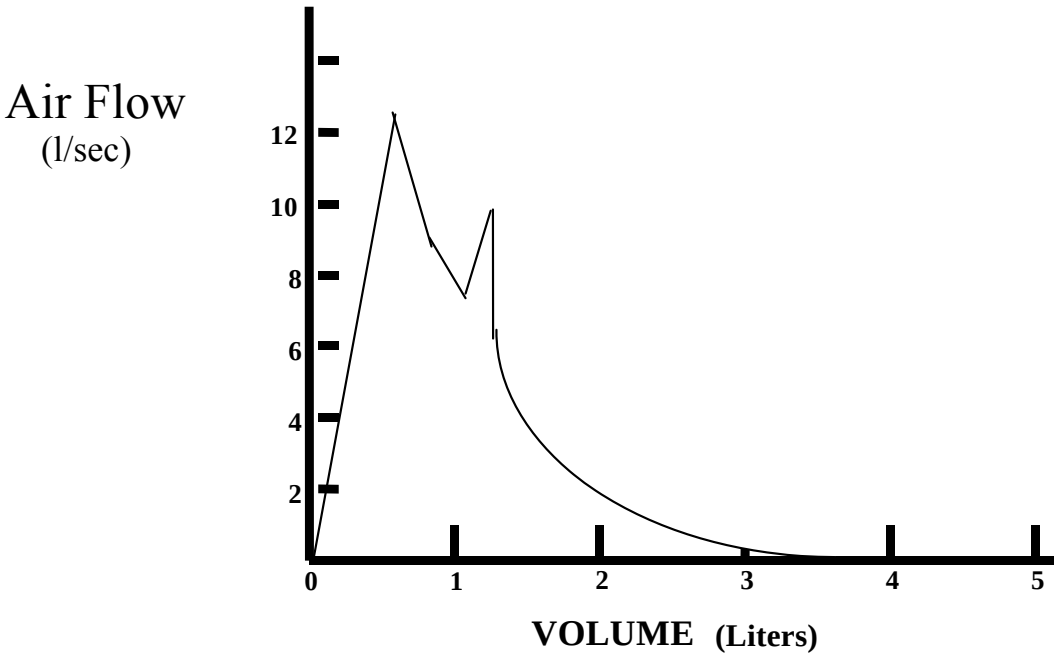
Spirometry Curve Examples



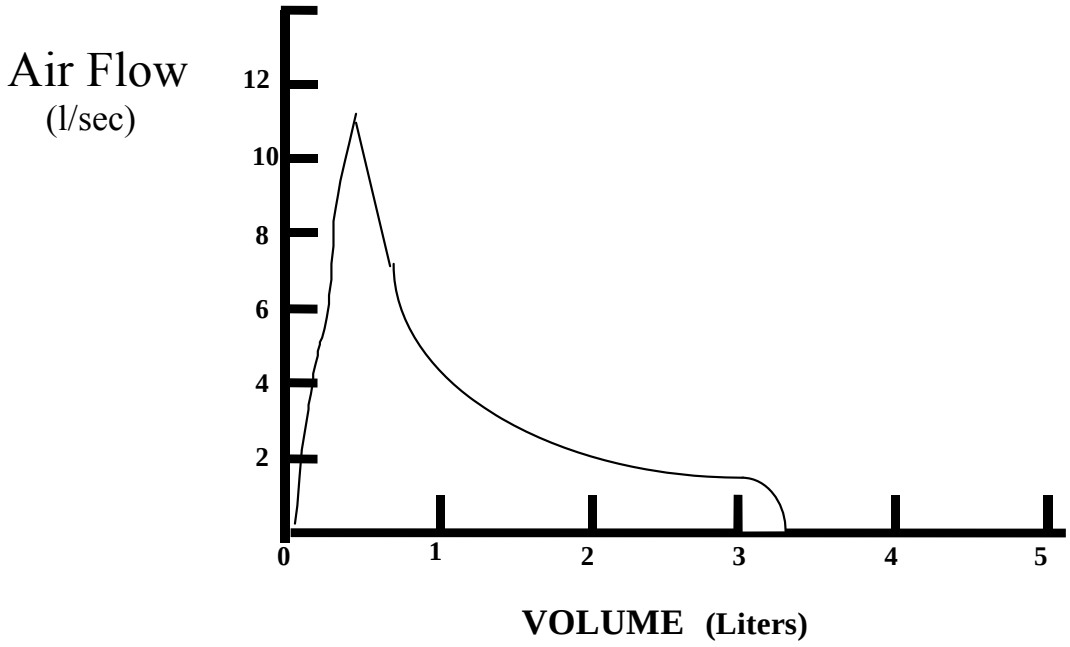
The tracing shows both a delayed start and poor peak flow. Instruct the subject to start blowing out faster and harder.



This is a good quality flow-volume tracing. The "knee" in the tracing is a normal variant. It should be distinguished from a plateau, which indicates poor effort or upper airway obstruction.

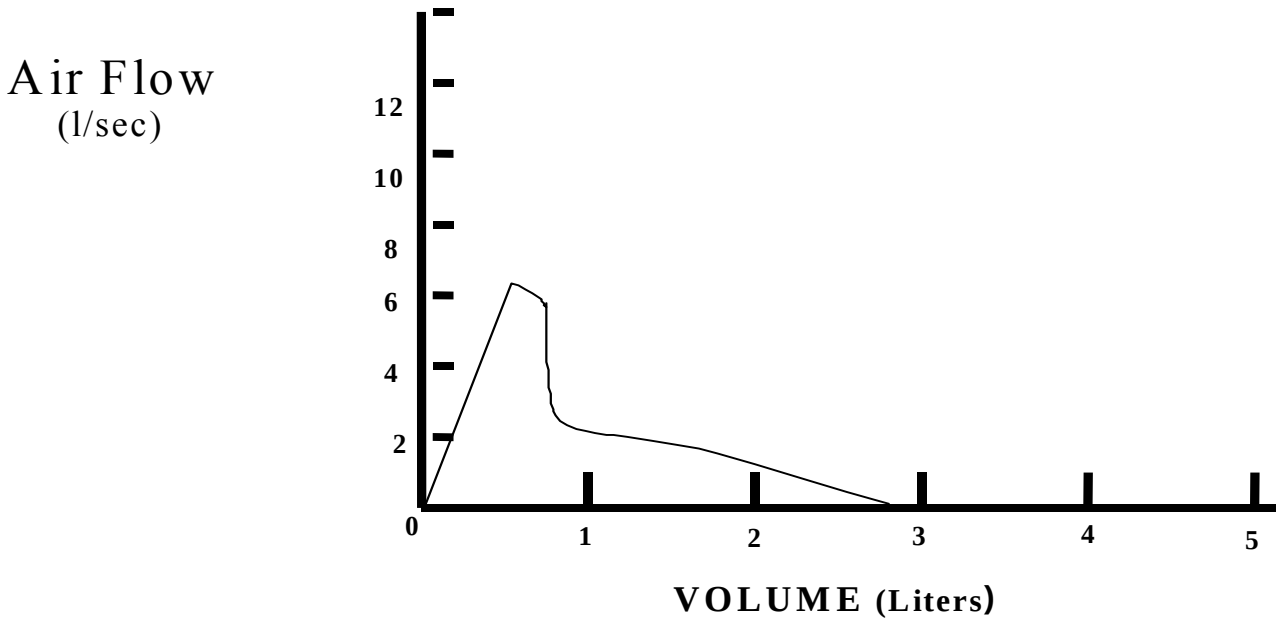


This flow-volume tracing starts with a good flow, but there is a sudden reduction in flow. This is most often caused by coughing, although temporary occlusion of the mouthpiece by the tongue can also produce this type of trace.

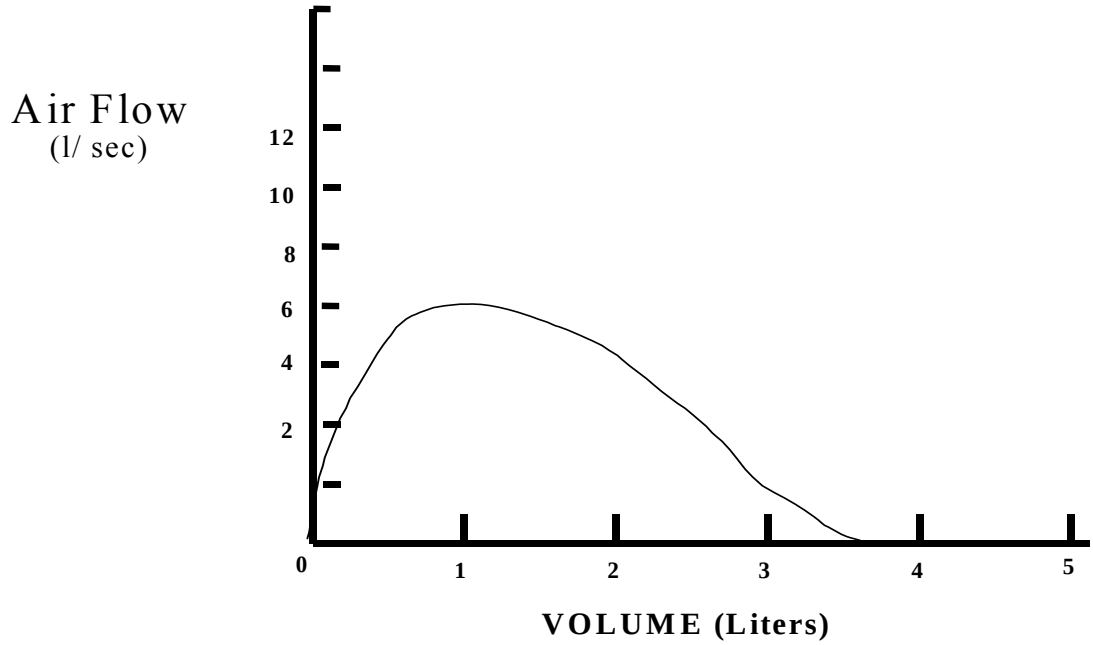


This maneuver has a good start and good peak flow, but it is stopped too soon, causing the drop in flow at the end. This type of trace is one of the most common problems you will encounter. This is mostly due to the subject quitting too early, although occlusion of the mouthpiece by the tongue can also produce this type of trace. Instruct the subject to continue blowing out longer.

Courtesy of Study of Asthma and Sleep Cohort



Flow-volume tracing in COPD or during asthma exacerbation. Note the low flow rates throughout the maneuver.



This is a smooth tracing, but the initial peak flow is delayed and not as high as it should be. The subject should be instructed to start blowing out faster and blast the air out.

Courtesy of Study of Asthma and Sleep Cohort

Appendix C:

Program Sample Reports

ID:	1235	Gender:	M
Badge#:	103	Race:	Caucasian
Name:	we, we	DOB:	01/12/1978
Company:	Not Listed	Tst Age:	31 [Yrs]
Location:	Not Listed	Tst Ht:	65 [in]
Department:	Not Listed	Tst Wgt:	135 [lbs]
Smoker:		Session:	50

Calibration date: 08/05/2009 Hose# Temp: 24.0 C. BP: 760 mmHg BTPS Factor: 1.0789
Normals Used: Hankinson(C)-1999 Interpretation algorithm: Hankinson-1998 RA Factor: 1.00
Spirometer: Sensormedics 1022, ID (Serial#): OMI Version: 5.05

Pulmonary Function Overview Report 08/05/2009

		Observed	Pred	%Pred	LLN
FVC	L	3.91	4.65	84.0%	3.85
FEV1	L	3.22	3.83	84.1%	3.15
FEV1/FVC%	%	82.4%	81.7%	100.9%	72.0%
FEF25-75%	L/s	3.24	3.97	81.6%	2.60
PEF	L/s	**6.93**	9.17	**75.6%**	7.17
FEV6	L	3.90	4.59	84.9%	3.81
FET	sec	6.0			

Baseline (08/05/2009) FVC:3.91 (0.0%); FEV1:3.22 (0.0%)

Repeatable Test. FVC, FEV1 and PEF repeatable.
3 of 3 trials met criteria for acceptable start of expiration; 0 for acceptable plateau.
3 of 3 trials were used for best test values.

Session Effort: Not Entered, Position: Sitting

INTERPRETATION - 08/12/2009 (COH)

Normal
Normal expiratory flows and a normal FVC.

Additional Test Session Comments:

ID:	1235	Gender:	M
Badge#:	103	Race:	Caucasian
Name:	we, we	DOB:	01/12/1978
Company:	Not Listed	Tst Age:	31 [Yrs]
Location:	Not Listed	Tst Ht:	65 [in]
Department:	Not Listed	Tst Wgt:	135 [lbs]
Smoker:		Session:	50

Calibration date: 08/05/2009 Hose# Temp: 24.0 C. BP: 760 mmHg BTPS Factor: 1.0789
Normals Used: Hankinson(C)-1999 Interpretation algorithm: Hankinson-1998 RA Factor: 1.00
Spirometer: Sensormedics 1022, ID (Serial#): OMI Version: 5.05

Pulmonary Function Detail Report 08/05/2009 3:34:16 PM

Test	Date	Time	FVC L		FEV1 L		FEV1/FVC%		FEF25-75% L/s		PEF L/s		FET s	Vext%	123456
1	08/05/2009	3:31P	3.18	68.3%	2.58	67.5%	81.3%	99.6%	2.52	63.5%	6.31	68.8%	6.35	1.1%	...F..
2	08/05/2009	3:33P	3.90	83.9%	3.22	84.1%	82.5%	101.0%	3.24	81.6%	6.93	75.6%	5.91	0.9%	..FF..
3	08/05/2009	3:34P	3.91	84.0%	3.18	83.1%	81.5%	99.8%	3.06	76.9%	6.93	75.6%	6.68	1.5%	...F..

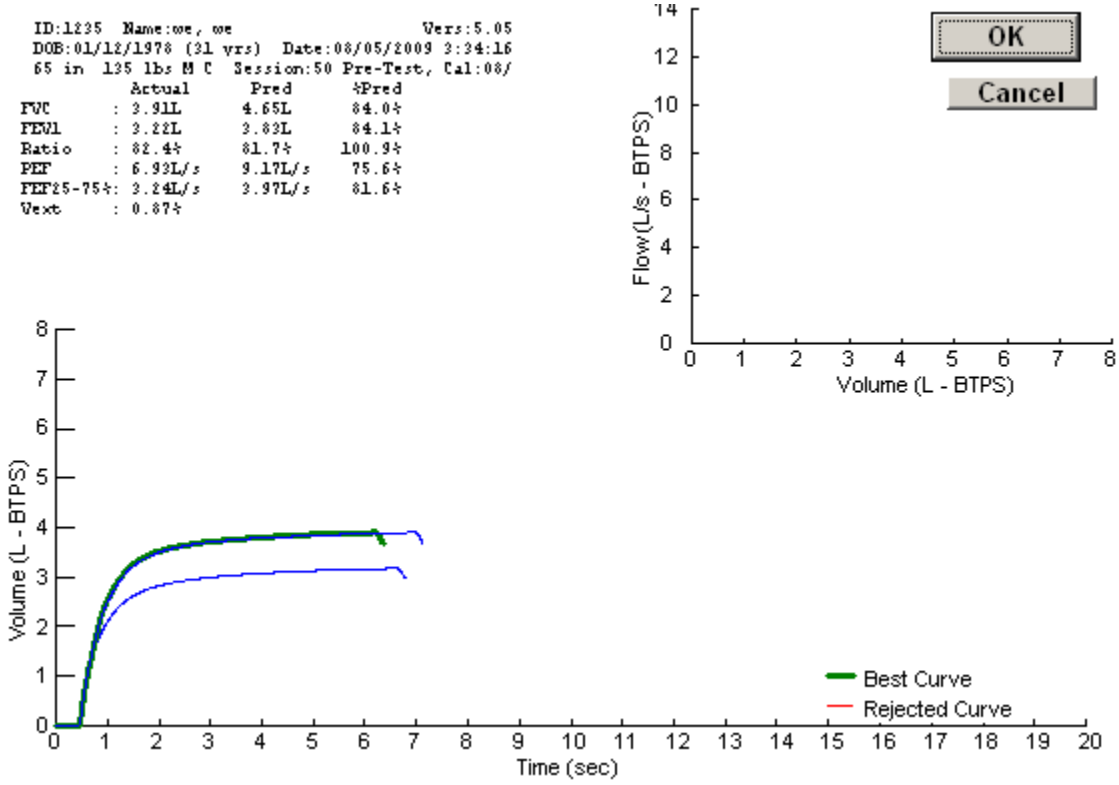
#	FVC	ml	%Vary	FEV1	ml	%Vary	PEF	ml/s	%Vary	ACC 123456
1	3.18	729	18.7	2.58	633	19.7	6.31	625	9.0	...F..
2	3.90	6	0.2	3.22	0	BEST	6.93	3	0.0	..FF..
3	3.91	0	BEST	3.18	35	1.1	6.93	0	BEST	...F..

Acceptability columns:
"." - Test Acceptable
"F" - Test not acceptable
"0" - Operator Overrode PC
X - Rejected Curve

1: Time to Peak Flow too Large
2: Low Peak Flow
3: FET < 6 seconds
4: No ATS Plateau
5: Cough
6: Back Extrapolated Exceeded.

FVC w/in 150 ml
FEV1 w/in 150 ml
PEF w/in 20 percent

Operator: 103


ID:1235 Name:we, we Vers:5.05
DOB:01/12/1978 (31 yrs) Date:08/05/2009 3:34:16
65 in 135 lbs M C Session:50 Pre-Test, Cal:08/
Actual Pred %Pred
FVC : 3.91L 4.65L 84.0%
FEV1 : 3.22L 3.83L 84.1%
Ratio : 82.4% 81.7% 100.9%
PEF : 6.93L/s 9.17L/s 75.6%
FEF25-75%: 3.24L/s 3.97L/s 81.6%
Vext : 0.87%
OK
Cancel
Flow (L/s - BTPS)
Volume (L - BTPS)
Volume (L - BTPS)
Time (sec)
Best Curve
Rejected Curve

Appendix D:

Spirometry Teleform

Spirometry

64554

Office Use Only--
MrOS ID# | Acrostic | Spirometry Staff ID#

NOTE: Please ensure that the participant has not had any active respiratory symptoms (exacerbation, new cough, or wheezing), obvious respiratory distress, or recent onset of chest pains in the past two weeks. If so, please reschedule visit in two weeks.

(1) SPIROMETRY EXCLUSION CRITERIA:

a. Have you had a heart attack, a stroke, or eye surgery in the past three months?
○ Yes ○ No
↓
NOT ELIGIBLE

b. Do you have any of the following problems: coughing up blood; a past history of an air leak in your lungs; or past history of an aneurysm in your chest? ○ Yes ○ No
↓
NOT ELIGIBLE

c. Have you had any significant problems doing spirometry in the past?
○ Yes ○ No ○ Don't Know
↓
Please describe: _____
_____
If the problem was indeed significant and likely to recur with retesting, participant is NOT ELIGIBLE. DO NOT PROCEED with spirometry measurements.

(2) Did the participant complete the spirometry test? ○ Yes ○ No
↓
Why not? ○ Refused ○ Not eligible ○ Physical/Medical Problem ○ Equipment Problem ○ Other _____

(3) PRE-TEST:

a. Did you smoke within the last two hours? ○ Yes ○ No

b. Did you use an inhaled bronchodilator within the last four hours? ○ Yes ○ No

c. Have you had a cold or minor respiratory illness (not listed above) in the last two weeks (i.e., sinus issue)? ○ Yes ○ No

d. Date of Birth: ☐☐ / ☐☐ / ☐☐☐☐
Month / Day / Year

e. Height: ☐☐☐ inches

f. Weight: ☐☐☐ lbs

(4) POST-TEST:

a. Did any of the following occur during testing? (mark all that apply)
○ Headache ○ Dizziness or lightheadedness ○ Coughing
○ Shortness of breath ○ Other _____

b. How many manuevers were attempted? ☐ manuevers

Appendix E:

Height and Weight Conversions

Height Conversion Chart

Height Conversion Chart					
cm	feet	in	cm	feet	in
129.5	4'3"	51	168.9	5'6.5"	67
130.8	4'3.5"	52	170.2	5'7"	67
132.1	4'4"	52	171.5	5'7.5"	68
133.4	4'4.5"	53	172.7	5'8"	68
134.6	4'5"	53	174.0	5'8.5"	69
135.9	4'4.5"	54	175.2	5'9"	69
137.1	4'6"	54	176.5	5'9.5"	70
138.4	4'6.5"	55	177.8	5'10"	70
139.6	4'7"	55	179.1	5'10.5"	71
141.0	4'7.5"	56	180.3	5'11"	71
142.2	4'8"	56	181.6	5'11.5"	72
143.6	4'8.5"	57	182.9	6'0"	72
144.8	4'9"	57	184.2	6'0.5"	73
146.0	4'9.5"	58	185.4	6'1"	73
147.3	4'10"	58	186.7	6'1.5"	74
148.6	4'10.5"	59	188.0	6'2"	74
149.8	4'1"	59	189.2	6'2.5"	75
151.1	4'11.5"	60	190.5	6'3"	75
152.4	5'0"	60	191.8	6'3.5"	76
153.7	5'0.5"	61	193.0	6'4"	76
154.9	5'1"	61	194.3	6'4.5"	77
156.7	5'1.5"	62	195.6	6'5"	77
157.5	5'2"	62	196.9	6'5.5"	78
158.7	5'2.5"	63	198.1	6'6"	78
160.0	5'3"	63	199.4	6'6.5"	79
161.2	5'3.5"	64	200.7	6'7"	79
162.5	5'4"	64	202.0	6'7.5"	80
163.8	5'4.5"	65	203.2	6'8"	80
165.1	5'5"	65	204.5	6'8.5"	81
166.4	5'5.5"	66	205.7	6'9"	81
167.7	5'6"	66			

Weight Conversion Chart

Kgs to Lbs Conversion Table									
kg	lbs	kg	lbs	kg	lbs	kg	lbs	kg	lbs
36.3	80	59.0	130	81.7	180	104.4	230	127.1	280
36.8	81	59.5	131	82.2	181	104.9	231	127.6	281
37.2	82	59.9	132	82.6	182	105.3	232	128.0	282
37.7	83	60.4	133	83.1	183	105.8	233	128.5	283
38.1	84	60.8	134	83.5	184	106.2	234	128.9	284
38.6	85	61.3	135	84.0	185	106.7	235	129.4	285
39.0	86	61.7	136	84.4	186	107.1	236	129.8	286
39.5	87	62.2	137	84.9	187	107.6	237	130.3	287
40.0	88	62.7	138	85.4	188	108.1	238	130.8	288
40.4	89	63.1	139	85.8	189	108.5	239	131.2	289
40.9	90	63.6	140	86.3	190	109.0	240	131.7	290
41.3	91	64.0	141	86.7	191	109.4	241	132.1	291
41.8	92	64.5	142	87.2	192	109.9	242	132.6	292
42.2	93	64.9	143	87.6	193	110.3	243	133.0	293
42.7	94	65.4	144	88.1	194	110.8	244	133.5	294
43.1	95	65.8	145	88.5	195	111.2	245	133.9	295
43.6	96	66.3	146	89.0	196	111.7	246	134.4	296
44.0	97	66.7	147	89.4	197	112.1	247	134.8	297
44.5	98	67.2	148	89.9	198	112.6	248	135.3	298
44.9	99	67.6	149	90.3	199	113.0	249	135.7	299
45.4	100	68.1	150	90.8	200	113.5	250	136.2	300
45.9	101	68.6	151	91.3	201	114.0	251	136.7	301
46.3	102	69.0	152	91.7	202	114.4	252	137.1	302
46.8	103	69.5	153	92.2	203	114.9	253	137.6	303
47.2	104	69.9	154	92.6	204	115.3	254	138.0	304
47.7	105	70.4	155	93.1	205	115.8	255	138.5	305
48.1	106	70.8	156	93.5	206	116.2	256	138.9	306
48.6	107	71.3	157	94.0	207	116.7	257	139.4	307
49.0	108	71.7	158	94.4	208	117.1	258	139.8	308
49.5	109	72.2	159	94.9	209	117.6	259	140.3	309
49.9	110	72.6	160	95.3	210	118.0	260	140.7	310
50.4	111	73.1	161	95.8	211	118.5	261	141.2	311
50.8	112	73.5	162	96.2	212	118.9	262	141.6	312
51.3	113	74.0	163	96.7	213	119.4	263	142.1	313
51.8	114	74.5	164	97.2	214	119.9	264	142.6	314
52.2	115	74.9	165	97.6	215	120.3	265	143.0	315
52.7	116	75.4	166	98.1	216	120.8	266	143.5	316
53.1	117	75.8	167	98.5	217	121.2	267	143.9	317
53.6	118	76.3	168	99.0	218	121.7	268	144.4	318
54.0	119	76.7	169	99.4	219	122.1	269	144.8	319
54.5	120	77.2	170	99.9	220	122.6	270	145.3	320
54.9	121	77.6	171	100.3	221	123.0	271	145.7	321
55.4	122	78.1	172	100.8	222	123.5	272	146.2	322
55.8	123	78.5	173	101.2	223	123.9	273	146.6	323
56.3	124	79.0	174	101.7	224	124.4	274	147.1	324
56.8	125	79.5	175	102.2	225	124.9	275	147.6	325
57.2	126	79.9	176	102.6	226	125.3	276	148.0	326
57.7	127	80.4	177	103.1	227	125.8	277	148.5	327
58.1	128	80.8	178	103.5	228	126.2	278	148.9	328

Appendix F:

Participant Feedback Report

Short Report

Mr. OS Sleep **Spirometry Report**

ID:	**Acrostic:**
Date of Study:	12/3/2009

Gender: M Race: H Age: 78 years

The spirometry test measured your lung function. Your lung function test results are summarized below. Regardless of the results of the tests, if you have breathing problems while at rest or with exertion you should discuss this with your doctor.

Pulmonary Function Test Results 12/3/2009

	Volume (Liters)	% Predicted
FVC (Breathing Capacity):	3.26	80.1%
FEV1 (Expiratory Flow):	2.99	95.9%

FVC and FEV1 are shown as volume in Liters, and as "percent predicted" which compares your results to values that would be expected from men of similar age and height. Levels of greater than 80% of predicted are generally considered to be in the "normal" range.

Interpretation:

You tested in the normal range. This indicates that your breathing capacity (the amount of air you are able to breathe in and out, "FVC") and breathing flow rates (how quickly you can exhale a big breath, "FEV1") is within the range expected for someone of your age, sex, and race.

Long Report

Mr. OS Sleep **Spirometry Report**

ID:	Acrostic:
Date of Study:	12/3/2009

Gender: M Race: H Age: 78 years

The spirometry test measured your lung function. Your lung function test results are summarized below. Regardless of the results of the tests, if you have breathing problems while at rest or with exertion you should discuss this with your doctor.

Pulmonary Function Test Results 12/3/2009

		Observed	Predicted	% Predicted
FVC	L	3.26	4.07	80.1%
FEV1	L	2.99	3.12	95.9%
FEV1/FVC	%	84.3%	73.0%	115.5%
FEF25-75%	L/s	3.50	2.41	145.2%
PEF	L/s	7.29	7.51	97.1%
FEV6	L	3.48	3.98	87.2%
FET	sec	9.0		

Observed values are shown as well as "predicted" values that would be expected from men of similar age and height. Levels of greater than 80% of predicted are generally considered to be in the "normal" range.

Interpretation:

You tested in the normal range. This indicates that your breathing capacity (the amount of air you are able to breathe in and out, "FVC") and breathing flow rates (how quickly you can exhale a big breath, "FEV1") is within the range expected for someone of your age, sex, and race.