

PULMONARY FUNCTION TEST – Hand-held EasyOne

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1. Background and rationale

Spirometry is a medical test that measures various aspects of breathing and lung function. It is one of the simplest, most effective tests available for the assessment of lung function. The spirometer registers the amount of air a participant inhales or exhales and the rate at which the air is inhaled and exhaled. The most common spirometric tests require that the participant exhale as forcefully as possible after taking a full, deep breath. The participant's effort is called the *forced expiratory maneuver*. Pulmonary function tests will be done at the Memphis and Pittsburgh Field Centers. Each eligible participant will perform several Forced Expiratory maneuvers.

Population based studies have shown an association between reduced measures of lung function such as vital capacity and FEV1 and increased mortality. The increase in mortality includes deaths from respiratory disease, cardiovascular disease and “all cause” mortality.

We will be evaluating whether a) lean body mass or isokinetic measurements of muscle strength are associated with spirometric measures independent of smoking status and b) changes in lean body mass are associated with spirometric measures such as FVC and FEV1.

2. Pulmonary Reading Center (LDS Hospital, Salt Lake City, UT)

Robert Crapo, M.D., Robert Jensen, Ph.D. and the Pulmonary Lab at LDS Hospital will provide centralized evaluation and analysis of all spirometry measurements obtained for the Health ABC protocol. The Pulmonary Reading Center will

- Collect, analyze and store pulmonary function data
- Provide quality assurance and quality control of pulmonary function data collection
 - Provide technical and logistical support for issues pertaining to pulmonary function tests
 - Transmit data to Data Coordinating Center (DCC) at specified intervals
- Participate in protocol development and publication of results

The information and methods used to acquire data must be consistent to allow uniform analysis. A standard technique for acquiring and collecting pulmonary function data will allow comparison of serial measurements of pulmonary function.

Health ABC examiners will be certified after submitting the results from 10 consecutive participants to the Pulmonary Reading Center with an average quality score of 3.5 for both flow and volume. (Scoring is graded like academic grades, A = 4.0, etc.)

Spirometry quality will be monitored by the Pulmonary Reading Center. Grades for spirometry quality will be returned to the Health ABC field centers within one week of receipt at the Reading Center.

3. Training and certification

Health ABC examiners will be trained in the following:

1. Mechanics of operating the Health NDD EasyOne™ Spirometer
2. Procedural elements of performing spirometry
3. Quality control requirements

The examiner must be observed by the QC Coordinator (or their designate) to have performed 10 consecutive tests with average scores of 3.5 or greater. Once completing this requirement, the examiner must submit spirograms to the Pulmonary Reading Center for evaluation. They will then be formally certified after submitting 10 consecutive tests to the Pulmonary Reading Center that have an average quality score of 3.5 for both flow and volume.

4. Equipment and supplies

We will use the NDD EasyOne™ Spirometer. This spirometer measures flow and volume by ultrasound transit time. This spirometer is compliant with the American Thoracic Society spirometry standards.

- NDD EasyOne™ Spirometer.
- NDD EasyOne™ Spirometer cradle and cable
- Adaptor for 3-L syringe
- Any Computer running Windows 98 or later with a USB Port and internet connectivity
- Printer
- 3 1/2 inch diskettes or other archive medium
- 3 liter calibration syringe
- EasyWare Software for use with EasyOne Spirometry
- Disposable Mouthpieces (Spirettes™) for performing spirometry
- Disposable nose clips
- General cleaning supplies
- Power strip with surge protection for printer/computer
- Facial Tissue
- AA batteries
- NDD EasyOne Instruction Manual/Instruction CD-ROM

Note: The North America service representative for NDD Medical Technologies, Inc. is Jerry Masiello.

Email: jmasiello@nddmed.com

Telephone number is (978) 470-0923 x 11

Fax: (978) 470-0924

4.1 Maintenance/cleaning

4.1.1 Spirometer

The EasyOne™ spirometer is designed to minimize the need for cleaning and maintenance (refer to EasyGuide™ users' manual). The surface of the spirometer and cradle may be cleaned by wiping with a damp cloth. If a more thorough cleaning is desired, the spirometer and its Spirette™ cavity may be cleaned with an alcohol wipe or a soft cloth that has been lightly moistened with isopropyl alcohol. **Do not let liquids flow into the Spirette™ cavity of the spirometer while cleaning.** The disposable Spirette™ eliminates the need for cleaning the spirometer between participants. The Spirettes™ are designed for single participant use only, and must be removed and disposed of after each participant.

Additional guidelines for hygiene and infection control are provided by the American Thoracic Society and include the recommendation that the examiner and participant wash their hands after testing and that proper attention be given to environmental controls in settings where tuberculosis or other diseases spread by droplet nuclei are likely to be encountered. Participants with evidence of obvious upper respiratory infections should not be tested, but rather rescheduled for testing at a later date.

4.1.2 Nose clips

Change nose clips after each person. If nondisposable nose clips are used, clean them as follows:

- a. Wash nose clip pads with cloth or brush and warm soapy water (dishwashing soap) to remove surface dirt.
- b. Thoroughly rinse soap from noseclips.
- c. Soak noseclips for 10 minutes in a 1:10 bleach solution, rinse in clear water and dry. Careful rinsing is necessary to remove bleach odor.
- d. Dry noseclips before use.

4.2 Equipment setup

4.2.1 Environmental conditions

The spirometry testing area should be relatively dust free and private. The spirometer should be located away from direct exposure to heat such as heating vents.

Testing can also be done in participants' households. The NDD EasyOne™ Spirometer is portable and has been shown to perform well in the field. The same procedures are to be followed for home testing with the exception that hard copy reports will not be generated until the examiner returns to the clinic.

4.2.2 Power requirements

The EasyOne spirometer runs on two “AA” batteries. These batteries should be changed as directed by the device. Refer to the other equipment’s directions (computer & printer) for power requirements.

4.2.3 Calibration syringe

The 3.00 liter calibration syringe should be stored next to the spirometer so that it remains at the same temperature as the spirometer. Store the syringe with the plunger pushed all the way in. Take care not to drop the syringe.

DO NOT make any adjustments to the syringe. Do not loosen the metal rings on the shafts. This will spoil the factory calibration. If any evidence of physical damage is noticed, the Pulmonary Reading Center will check the accuracy of the syringe.

Periodically check each syringe for leaks (every three months or if a problem is suspected). Fill the syringe with air, hold your palm against the outlet snout and try to empty it. If you can expel any air with the outlet plugged, the syringe has a leak and must be repaired.

4.2.4 Syringe calibration check

Because of its technology, the EasyOne does not require calibration, however calibration should be checked. (Refer to EasyOne manual, chapter 14).

- Turn Spirometer on & choose “Check Calibration” in the main menu.
- Attach a 3-L syringe to a spirette seated in the spirometer using the syringe adaptor.
- (Be sure the piston on the syringe is fully inserted and at the stop position.)
- Press ENTER
- Wait until the baseline has been set and you hear a signal.
- Now execute one full inspiratory pump stroke followed by one full expiratory pump stroke at the various speeds listed below as demonstrated at training
 - Low: about 6 seconds for inhalation and 6 for exhalation
 - Medium: about 3 seconds for inhalation and 3 for exhalation
 - High: about one 1 second for inhalation and 1 for exhalation. (with this (fast maneuver, the examiners should be careful to avoid banging the syringe plunger against the syringe faceplate.)
- After you perform each maneuver, you will see the text “Accuracy confirmed” at the top of the display, and beneath it, the percentage deviation and average flow velocity of the pump stroke.
- If you do not observe +/- 3% accuracy, see the troubleshooting instructions in the EasyOne Manual. If this does not resolve the problem, contact Dr. Kritchevsky for instructions on acquiring a replacement device. Another resource for troubleshooting the EasyOne is to contact the North America representative for NDD. His name is Jerry Masiello. See section 4. (Equipment and supplies) of this manual for his contact information.

5. Exclusion criteria

Participants should be excluded from performing the pulmonary function test if they have a systolic blood pressure greater than 199 mm Hg or a diastolic blood pressure greater than 109 mm Hg. Before administering the pulmonary function test, check the seated blood pressure measurement that has been recorded in the Year 10 Clinic Visit Workbook. If the systolic blood pressure exceeds 199 mm Hg or the diastolic blood pressure exceeds 109 mm Hg, do not administer the pulmonary function test. Go to the Year 10 Clinic Visit Workbook, Pulmonary Function Test Tracking form, Question #9: “Was the spirometry test completed?” mark “No” and choose “Participant medically excluded” as the reason for “Why wasn’t the spirometry test completed?.”

Other exclusion criteria that should be noted on the **Pulmonary Function Test Tracking** form in the Year 10 Clinic Visit Workbook, are as follows:

- Chest or abdominal surgery within past 2 months
- Myocardial infarction (heart attack) within past 2 months
- Hospitalization for other heart problems within the past 30 days
- Detached retina at the time of testing. (If a participant has a detached retina at the time of testing or has had a detached retina in the past and is unsure whether or not they have recovered, do not test.)
- Eye surgery within past 2 months

To determine whether or not any of the above exclusions exist, read the questions that are on the Pulmonary Function Test Tracking form.

1. *Have you had any surgery on your chest or abdomen in the past 2 months?*
2. *Have you had a heart attack in the past 2 months?*
3. *Now think about the past 30 days. Have you been hospitalized for any other heart problem in the past 30 days?*
4. *Do you have a detached retina or have you had eye surgery in the past 2 months?*

If participants answer yes to the question on the Pulmonary Function Test Tracking form concerning an upper respiratory tract infection, make sure the appropriate box is marked and proceed with testing.

Have you had symptoms of a cold or respiratory infection within the past 2 weeks?

If participants are regularly using short acting beta-agonist bronchodilators for treatment of lung disease, they should use their bronchodilators before testing. To determine whether or not they use beta-agonist inhalers, refer to the Medication Inventory Form if it has been completed, look in the sack of medications that the participant is carrying, or, if you need to, ask the participant if they use an inhaler, and what it is called. A list of common beta agonist inhalers is on the Pulmonary Function Tracking form and section 7.1.2 of the operations manual. Refer to section 7.1.2 for detailed instructions.

6. Infection control

While there have been no well-documented cases of infection from pulmonary function testing equipment, the procedures do involve potential contact with saliva and respiratory secretions. Pulmonary function instruments and mouthpieces are, therefore, a potential source of infection for both examiners and participants.

Universal precautions should be followed whenever there is a potential contact with blood, body fluids, or tissues and should be used during every test. These precautions include the following:

- a. Take extra care to avoid accidental injury when handling instruments or other potentially contaminated items.
- b. Containers should be available for proper disposal of contaminated materials such as used mouthpieces/filters and nose clips
- c. Gloves should be used when there is potential for hand contact with saliva or other respiratory secretions. If the hands are contaminated, they should be washed immediately. Hands should be washed immediately when gloves are removed and before leaving the testing area. In pulmonary function testing that means that gloves should be worn when the spirometer and breathing tubes are cleaned. Mouthpieces or filters can be handled and discarded by the participant.
- d. Wash your hands before and after each participant.
- e. Facial and eye protection are only necessary if there is a risk of being splashed or sprayed with contaminated material or disinfectant solution. In pulmonary function testing this risk is small; however, take care to direct the flow of air away from you when the spirometer is emptying.
- f. The National Committee for Clinical Laboratory Standards (NCCLS) has produced several documents that address issues of protection from infectious disease risks. If your field center does not already have biohazard guidelines in place, we recommend you obtain copies of these statements from the NCCLS at 940 West Valley Road, Suite 1400, Wayne, PA 19087.
- g. M29-T2. Protection of laboratory workers from infectious disease transmitted by blood, body fluids, and tissue. Second edition; tentative guideline (1991).
- h. I17-P. Protection of laboratory workers from instrument biohazards; proposed guideline (1991)

However, if you are concerned that universal precautions are not adequate, discuss the situation with your medical advisor in private.

You may encounter a situation where a participant voluntarily tells you they have an infectious illness that you consider to be dangerous. Universal precautions should be sufficient to protect study participants. If you are concerned that universal precautions are not adequate, discuss the situation with your medical advisor in private.

7. Participant and exam room preparation

7.1 Participant preparation

In order to minimize the risk of cross-contamination, examiners should wash their hands before the start of the test and should use a tissue to remove a mouthpiece (the Spirette™) from its package for the participant to use. Allow the participant to insert the clean Spirette™ into the spirometer. Be careful to ensure that the arrow on the Spirette™ is lined up with the arrow on the spirometer.

All maneuvers should be performed with the participant wearing a nose clip. This clip prevents air from moving through the nose during the test. Some individuals will not tolerate or be able to wear a nose clip. If the participant refuses to use a nose clip or if the nose clip slips, the participant can be tested without it. They can either hold their nose with their fingers or just do the test without it. If the test is done without a nose clip, the examiner should be alert to the possibility that the participant may take in additional breaths during the test giving falsely large vital capacities.

Testing should be conducted with the participant in the sitting position. A chair without wheels should be used for the testing, and the participant should sit erect with chin slightly elevated. The purpose of the chair is to support the participant in case s/he faints during the maneuver.

7.1.1 Clothing and dentures

Instruct participant to loosen any tight clothing that might restrict maximal inspiration. Some individuals may have difficulty doing the spirometry maneuver due to urinary incontinence. Offer the participant a chance to use the bathroom prior to testing.

Dentures should remain in place unless they are observed to interfere with testing. If they are removed, place them in a clean container.

7.1.2 Bronchodilator administration

If participants are regularly using **short-acting** beta agonist bronchodilators for treatment of lung disease and have not used the medication within 4 hours, they should take two puffs of their own bronchodilator, using their own technique, 15 minutes prior to testing. The dose is two puffs to be taken using a spacer. If participants did not bring a spacer for their bronchodilator, they may use the bronchodilator with their usual technique. Record the use of the bronchodilator on the Pulmonary Function Test Tracking form. The use of bronchodilators for future testing cycles should be done in the same manner as in the first testing cycle.

For reference, some of the names of short-acting beta agonist bronchodilators are: albuterol (generic name), Alupent, Brethaire, DuoNeb, Maxair Autohaler, Proventil, Tornalate, Ventolin, and Xopenix.

Other inhalers that are longer acting should not be confused with short acting bronchodilators. If the participant has used Atrovent or Combivent in the last 6 hours, Serevent, Advair, or Foradil in the last 10 hours, or Spiriva in the last 24 hours, do not administer a short acting bronchodilator. These

examples are all listed on Question #7 on page 50 of the Year 10 Clinic Visit Workbook on the Pulmonary Function Test Tracking form.

8. Detailed measurement procedures

8.1 Power-up system

1. Power-up the computer and start the EasyWare software by clicking on the NDD icon on the desk top.
2. Turn on the EasyOne spirometer and put it in the cradle connected to the computer. If the message “Remove device from cradle” appears then press the “1” key on the EasyOne while EasyOne remains in the cradle. EasyWare now connects to the spirometer—the status bar should display “connected” on the right-most indicator field at the bottom of the EasyWare window.

8.2 Enter participant and testing session data

The following information should be entered into the appropriate fields.

<u>FIELD</u>	<u>Data to be entered</u>
Name	Health ABC Acrostic
ID	Numeric portion of Health ABC ID #
Height	Height entered in centimeters
Weight	Weight entered in kilograms
Gender	Male or Female
Ethnic	Caucasian or African-American (refer to Data from Prior Visits Report)
Smoker	Leave at NO
Asthma	Leave at NO
TechID	1 (Memphis) or 2 (Pittsburgh) followed by Examiner ID number

8.3 Spirometry testing

8.3.1 Purpose of the pulmonary function test

Explain to the participant that the purpose of the pulmonary function test is to check on the health of the participant’s lungs. Emphasize that the procedure does not hurt. Explain that in order to get useful and valid results they must take in as deep a breath as possible and then blow as fast and hard as they can until all of the air is expelled from their lungs for a few seconds when told to do so and will need to repeat the procedure a few times. Participants may need repeated assurances that the pulmonary function test does not hurt or damage anything.

8.3.2 Demonstrate

Explain that the participant should position the mouthpiece past the teeth and on top of the tongue with lips sealed around the mouthpiece. Instruct the participant to take in as deep a breath as possible, and when their lungs are totally full, BLAST out the air as hard and as fast as possible. A demonstration will prevent wasted time and effort caused by the participant's lack of understanding. Use a demonstration Spirette™ mouthpiece to show the participant the correct placement of the mouthpiece. Take a deep breath and emphasize the maximal depth of inhalation. Then dramatically blast the air out as fast as possible. Remind participants not to bite the Spirette™ because this can lead to poor test results.

8.3.3 Coaching the participant

Because the accuracy of the pulmonary function test is highly dependent on participant effort, the examiners must guide the participant through the breathing maneuvers. It is extremely important to inhale maximally and to exhale forcefully and maximally. Tell the participant to take in a deep breath after putting the mouthpiece in their mouth. Then tell the participant to blast out the air and to continue exhaling for as long as possible (at least 6 seconds). Observe the body language of the participant as they attempt to follow the instructions, and encourage the participant to continue blowing out smoothly without re-breathing. Instruct the participant to remain erect and not to bend over during the maneuver, and to keep their feet flat on the floor. It is important to instruct the participant not to bite down on the Spirette.™ Doing so can result in large errors in the measurements.

- After the participant's data has been entered and selected, choose "Perform Test" in the main menu. Then either select NEW if the participant has not already been entered via a computer or RECALL if the participant's information has been entered.
- For NEW participants enter the participant specific data as specified above.
- After data has been entered, move to the "Test selection" menu and choose FVC test and confirm with ENTER.
- Have the participant insert a spirette into the instrument. Ensure that the arrow on the spirette is lined up with the arrow on the instrument.
- Put a nose clip on the participant.

If the participant refuses to use a nose clip or if the noseclip slips, the participant can be tested without it. They can either hold their nose with their fingers or just do the test without it. If the test is done without a nose clip, the examiners should be alert to the possibility that the participant may take in additional breaths during the test giving falsely large vital capacities.

- Again remind the participant about the task. When the participant is ready press ENTER. You will now hear the sensor buzzing.
- The instrument now prompts you to avoid airflow in the spirette while it sets the baseline. Block the end of the spirette that does not touch the participant's mouth to ensure that the

baseline is set precisely. An audible signal will sound when the base line is set. You will see the prompt “Blast out” on the screen.

Do not have the participant start their inhalation until you see the BLAST THE AIR OUT instruction because the computer is not ready to receive the information and lost data will result. Place a nose clip on the participant. Instruct the participant to inhale maximally, vigorously coaching them to do so. Once at total lung capacity (the volume at a maximal inhalation), instruct them to blast their air out into the mouthpiece. Encourage them to exhale for as long as possible (at least 6 seconds), try to get 8 seconds of exhalation from each participant. Encourage the participant two more times to keep going and you will be close to 8 seconds and can stop the test. **DO NOT** allow participants to inhale from the spirometer at the end of the maneuver.

Three elements are critical to getting good tests at this point:

- 1) The inhalation maneuver may be the most important element. If they do not inhale completely, nothing else really matters.**
- 2) Second, they must start the blast of air quickly and with maximal force.**
- 3) Third, they need to get at least a 6 second exhalation.**

1. Review of coaching issues
 - a. No tight clothing.
 - b. Participants should be seated in a non-rolling chair for the test. **EXCEPTION:** Participants whose weight/height (kg/cm) is greater than 0.8 (morbid obesity) should stand. A non rolling chair should be placed behind a standing participant.
 - c. Teeth and lips sealed around the mouthpiece, but not biting down on the mouthpiece.
 - d. Do an exaggerated demonstration of the maneuver. Tell them: ... “Our results will be different, but effort should be the same.”
 - e. Keep explanations short.
 - f. Make sure the nose clip is in place.
 - g. Watch for maximum effort (both during inhalation and exhalation). Instruct the participant to blast air out. After about 3 seconds have them continue to blow but ease up the effort.
 - h. The exhalation time should be at least 6 seconds. An 8 second time is optimal and the test should be terminated as soon as they reach the 8 second mark.
 - i. Listen for fixed obstructions (tongue, teeth, etc.).
 - j. Examine the mouthpiece after each maneuver to make sure it has not been deformed by the participant.
 - k. If participant is terminating early, tell him that even if he feels empty he is still getting out small amounts of air and should keep pushing and blowing. (You only feel air coming out of the large airways, not the small airways.)
 - l. Correcting technique should always be done in a positive manner, e.g., "You did a great job that time; next time do just the same, but blow a little harder at the start."

At the end of the maneuver you will see a message on the display indicating whether the maneuver was acceptable. After each exhalation, the EasyOne will show prompts indicating how the quality of the maneuver could be improved.

A minimum of 3 and maximum of 5 trials should be done on each participant. If the first three curves are not acceptable, continue testing until you have three acceptable trials or the participant has tried 5 times. Each of the three acceptable curves must meet all of the acceptability and reproducibility criteria. When these criteria have been met the spirometer will show the message “Session Complete.”

If three acceptable maneuvers cannot be obtained, end the testing session by pressing ESC.

8.4 End of testing

Reseat the spirometer in the cradle attached to the computer. It should automatically synchronize with the PC. Use the EasyWare application to view and print reports and to save data for forwarding to the Reading center.

8.5 Daily procedure summary for testing in clinic

1. Prepare the instruments
 - Power-up the computer and start the EasyWare software by clicking on the NDD icon on the desk top.
 - Turn on the EasyOne and put it in the cradle connected to the computer. If the message “Remove device from cradle” appears then press the “1” key on the EasyOne while EasyOne remains in the cradle. EasyWare now connects to the spirometer—the status bar should display ‘connected’ on the right-most indicator field at the bottom of the EasyWare window.
2. Identify the participant(s)
 - Check for the presence of exclusion criteria
 - Enter identification information
 - Take the EasyOne out of the cradle and press ESC. The EasyOne restarts, and enters the main menu.
 - Select “Perform Test” and then “Recall.” The participant entered previously using EasyWare is automatically selected. Press enter to confirm and select FVC test. Now perform the test with the participant
3. Measure FVC (FVC maneuver)
 - Have the participant insert a spirette
 - Use a new spirette for each participant
 - Initialize the spirometer
 - Obtain three acceptable quality FVC maneuvers
 - Review acceptability and reproducibility and retest if necessary
 - After the test has been performed exit by pressing ESC to go back to the main menu. Put the EasyOne in the cradle. EasyWare now re-connects to EasyOne and synchronizes the database.
4. Print the test report by selecting the top-most test, select the File/Print menu or press the printer icon on the tool bar.
5. Clean equipment at the end of the day and back-up participant database
 - Wipe the EasyOne with a damp cloth.

- Copy spirometry database to a 3.5” disk or other removable storage medium.
- Never let liquid get into the area where the spirette sits.

8.6 Weekly procedures

1. Check the EasyOne spirometer calibration with a 3-liter syringe.
2. Create two back-ups of the NDD database on removable storage media (3.5” diskette or CD). Store one on-site and one off-site.
3. Upload the most recent copy of the NDD database to the Coordinating Center.
4. Clean Spirometer with gauze and alcohol.
5. Do biologic standards test.
6. Send copies of logs to Robert Jensen.

9. Data storage and transmission

9.1 Automatic save feature

As each participant is tested, the program automatically saves testing data on the device. Test data will be automatically downloaded to the PC when the spirometer is reseated in the cradle.

9.2 Transfer of data to the Pulmonary Reading Center

At the end of each week, upload a copy of the tests performed during that week to the Coordinating Center at the Neoteris website. See Section 14.5 for instructions.

Mail **copies** of the Field Center Quality Control Log, Health ABC (NDD EasyOne) PFT Reading Center Review Log, and Log of Data Uploads and Return of Reading Center Review to the Reading Center.

Dr. Robert Jensen
Pulmonary Function Reading Center
LDS Hospital
Pulmonary Division
Eighth Ave. and C Street
Salt Lake City, UT 84143
Phone: 801-408-3146

Keep an archival copy of the NDD database separately from the computer.

9.2.1 Keep the original disks and logs in a secure, cool, dry place. The copies of the Health ABC (NDD EasyOne) PFT Reading Center Review Log will be returned with an evaluation of test quality for each participant.

10. Alternative procedures for home data collection

- Participant information can be entered directly into the EasyOne.
- Choose “Perform Test” in the main menu and then “NEW”.
- Confirm with ENTER. The instrument will now allow you enter participant data.
- Enter data in each section and confirm by pressing ENTER.
- After entering the participant information move to the “Test Selection” menu.
- Choose FVC test and confirm with ENTER. Proceed as described above.

Upon returning to the clinic, synchronize the EasyOne spirometer with the computer database, and print hard copies of the spirometry report for the participant’s chart.

11. Alert values

For tests of acceptable quality (See section 8.3.3), make the judgment about alert values using the largest FEV1 regardless of the test from which it comes. The alert value is an FEV1 < 1.0 liter or < 50% of predicted (whichever is the smaller number [see Pulmonary Function Test: Participant Results form in section 14.4]). Participants with alert values may have treatable disease and should be referred to their physician for further evaluation.

12. Quality assurance

12.1 Spirometry

On every test you will be looking for these elements:

1. 6 seconds duration
2. Acceptability (3 good trials--free of coughs, early termination, or extrapolated volume)
3. Reproducible Tests (Largest 2 FVCs and FEV1s are within 200 ml of each other.)
 - a. 2 FVCs within .2 liters
 - b. 2 FEV₁s within .2 liters
 - c. 2 Peak Flows within 10%
4. A minimum of 3 trials must be done.
5. No more than 5 trials should be done.

Note: The two best tests for FVC may be on different curves than the two best tests for FEV1.

12.2 Biological standards

Two pulmonary function examiners will act as biologic controls. They will perform three acceptable spirometric maneuvers each week in which they test participants. The curves will be submitted to the Reading Center. Tests should be coded by entering the examiner's ID # exactly where you would enter the participant's Health ABC Enrollment ID # so that they can be identified by the Reading Center.

Biologic control testing need not be performed on examiners who, in their judgment, have active respiratory tract infections.

12.3 Reading Center review

The Pulmonary Reading Center will assess quality on the tests submitted and return those assessments to the test centers and the testing examiners. A report of the Reading Center review of field center spirograms should be returned to the field centers within 7 working days of receipt by the Reading Center. There will be infrequent occasions where this deadline is not met because of travel or illness.

Each field center will maintain a Log of Data Uploads and Return of Reading Center Review to document receipt of each review and to verify that each examiner involved in any of the tests for a given report has reviewed their quality scores (see section 14.4 Forms).

12.4 Quality control checklist

Before participant arrival:

- Runs necessary calibration checks on the spirometer
- Starts EasyWare program and loads participant data if needed

After participant arrival:

- Explains procedure to participant
- Asks exclusion questions
- Asks participant if they use a beta-agonist inhaler and follows procedure if the answer is "yes."
- Asks participant to loosen tight clothing
- Follows universal precautions
- Properly enters ID information on computer
- Positions participant properly (sitting position and head position)
- Obtains three acceptable quality FVC maneuvers
 - Enthusiastically coaches

- Does exaggerated demonstration of the maneuver
- Watches for maximum effort
- Evaluates for reproducibility and retests if necessary
- Prints results
- Exits program properly
- Reviews forms for completeness
- Correctly completes forms

13. Instructions for completing forms

13.1 Logs will be sent weekly to the Pulmonary Function Reading Center.

13.2 Participants will be given a “report” of their results at the completion of their clinic visit.

13.3 Daily and weekly maintenance and calibration logs will be kept.

14. Appendices

14.1 Definitions

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 ATS promotes accurate spirometers by recommending spirometer standards.

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

BTPS stands for Body Temperature (usually 37 degrees C) and Pressure, Saturated with water vapor (100% humidity). It is the condition of air inside the lungs before it is exhaled into a spirometer. ATS standards require that volumes and flows be reported at these conditions.

CALIBRATION SYRINGE is a large (usually 3.00 liters) extremely accurate syringe used to check the volume accuracy of spirometers and, if necessary, to re-calibrate them.

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

FET is short for Forced Exhalation Time. The FET should be at least six seconds for the FVC maneuver to be considered acceptable, otherwise the FVC may be underestimated. An eight second FET is optimal for this study.

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 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.

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 is decreased.

PEF stands for Peak Expiratory Flow Rate, 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 display but not on a volume-time display.

PF is short for Pulmonary Function.

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

RESTRICTION is a decrease in lung volumes. Scarring of lung tissue (fibrosis), heart failure, pneumonia, and simple obesity are some of many causes.

14.2 Equations

BTPS Correction Factor (ATPS to BTPS):

$$\left[\frac{273 + 37}{273 + T}\right] \times \left[\frac{PB - PH_2O}{PB - 47}\right]$$

T = spirometer temperature (20-30 °C)

PB = barometric pressure (625-760 mm Hg)

PH₂O = water vapor pressure (17-30 mm Hg)

Factor to convert inches to centimeters: Inches x 2.54

To convert degrees Fahrenheit to Centigrade:

$$\left(\frac{5}{9}\right) \times (^\circ\text{F} - 32)$$

14.3 NDD Configurations Settings (at initial use of the device)

Test Settings:

- 1) Predicted = “NHANES III”
- 2) Add Ped = “Blank”
- 3) Value Sel = “Best Value”
- 4) Interpretation = “OFF”
- 5) Lung Age = “OFF”
- 6) Automatic QC = “ON”
- 7) FVC Selection = “FVC”
- 8) PEF unit = “L/sec”
- 9) African ethnic = 88%
- 10) Asian = 100%
- 11) Hispanic = 100%
- 12) Other ethnic = 100%
- 13) Curve Storage = “3 Best Curves” <Very Important!!! >

General Settings:

- 1) Time Form = 24 hr
- 2) Date Format = “DD/MM/YY”
- 3) Date = Enter correct date
- 4) Time = Enter correct time
- 5) Alpha-ID = “NO”
- 6) Tech ID = “YES”
- 7) Syringe Vol = 3.0 Liter
- 8) Height Unit = “m/cm”
- 9) Weight Unit = “kg”
- 10) Age/Birth = “AGE”
- 11) Contrast = 40% or adjust as needed
- 12) Language = “ENGLISH”
- 13) Altitude = 0 or set to approximate (500 meter increments)
- 14) Op Mode = “DIAGNOSTIC”
- 15) Temp = “C”
- 16) Rel Humidity = Best average guess (0 to 100%)

Report Settings:

- 1) Printer Type = Set to printer type that is used
- 2) Result Data = “3 Best Values”
- 3) Number of Curves = “3 Best Curves”
- 4) Graph Types = “FV & VT small”
- 5) Header 1 to 4 = “Text that you want to print on the report”

14.4 Forms

Pulmonary Function Test Tracking Form

Pulmonary Function Test: Participant Results

Spirometry Checklist

Field Center Quality Control Log (Daily, Weekly)

PFT Reading Center Review Log

Log of Data Uploads and Return of PFT Reading Center Review

Pulmonary Function Test: Participant Results

Lung Function Test	Your Value	Usual Normal Range
FVC: total amount of air you blew out of your lungs	_____ % of Predicted	80% and greater
FEV1: FEV1 is the amount of air you were able to blow out in the first second)	_____ % of Predicted	80% and greater
FEV1/FVC: FEV1/FVC is the ratio of the other two volumes	_____	65% and greater

- The lung function test was not performed or lung function could not be determined accurately.
- Your values are within the normal range or above; your lung function is normal.
- Your values are below the usual range; your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range.
- If either of your values is less than 50% of your predicted normal value, or if your FEV1/FVC ratio is less than 50%, your function is substantially reduced.

Health ABC Spirometry Checklist

Participant Name: _____ Date: _____ Time of Day _____

Health ABC ID Number _____ Staff ID Number _____

Spirometry QC Information

Tracing Number						
BEV < 5%						
Acceptable Initial Effort						
Acceptable Inspiration						
No cough in 1st second						
No glottic closure in 1st second						
Exhalation > 6 seconds						
No early termination						
Three acceptable tests						
FVC & FEV1 Vary <0.2 L						

Field Center Quality Control Log (Daily, Weekly)

FIELD CENTER: Memphis
 Pittsburgh

WEEK BEGINNING: _____ / _____ / _____
 Month Day Year

Daily Checks

Date (ddmmyy)							
Time (hhmm)							
Cleaning							
Spirometer							
Nose Clips							

Weekly Check :

Spirometry Volume Calibration (x3)

- 1
- 2
- 3

Date (ddmmyy)

Time (hhmm)

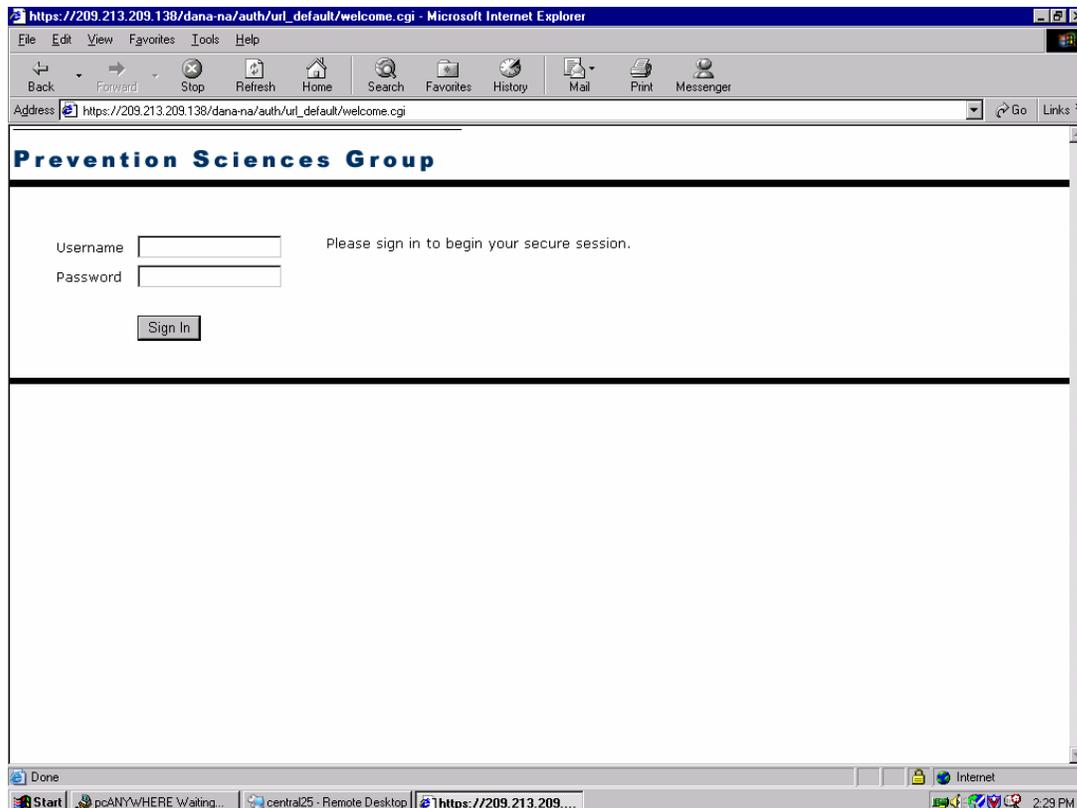
14.5 PFT Data Transmission Instructions for Clinic Sites

The following instructions explain the process for transferring data securely between the HABC sites, the PFT Reading Center, and the Coordinating Center. We have set up a website: <http://ive.psg-ucsf.org>

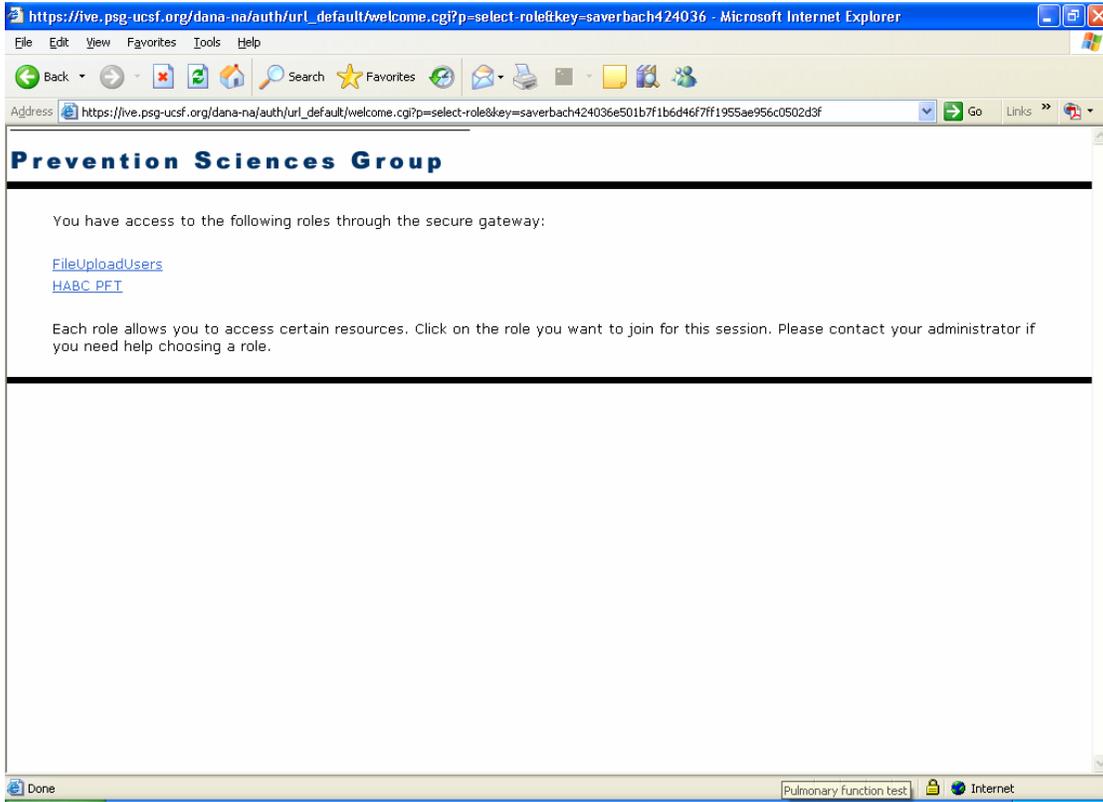
Please use the following naming conventions for the PFT files:

For Memphis: MEMPFT*mmddyy*.zip, where *mmddyy* is the date transmitted.
For Pittsburgh: PITPFT*mmddyy*.zip, where *mmddyy* is the date transmitted.

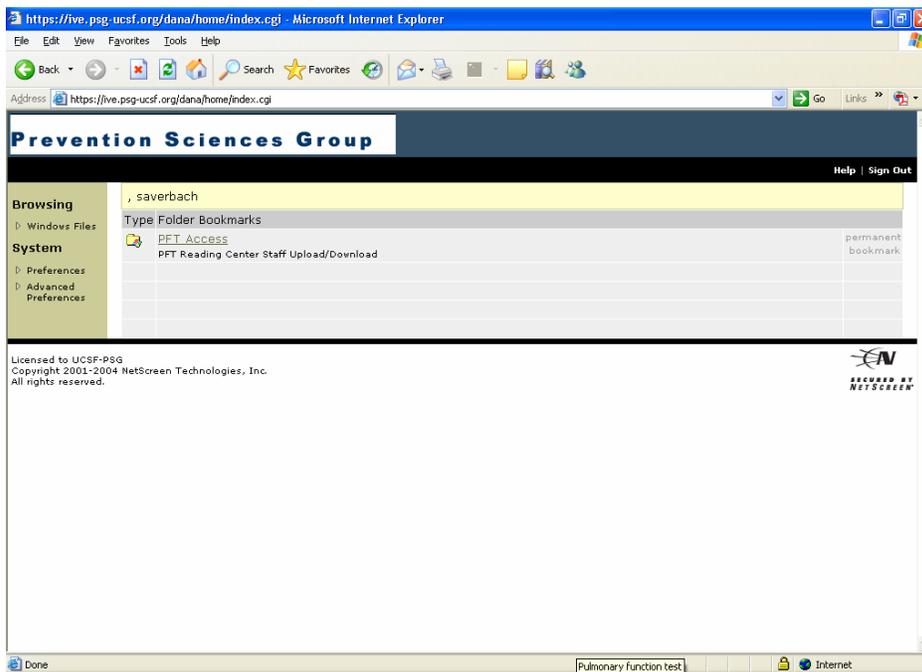
In any browser go to site <http://ive.psg-ucsf.org> Enter your username and password.



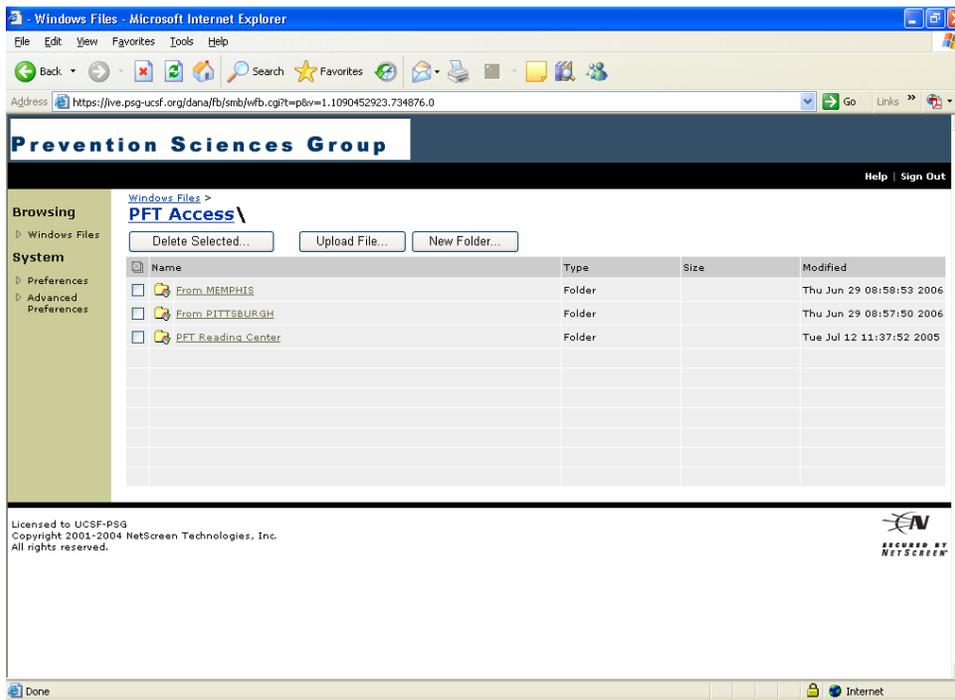
Click on HABC PFT.



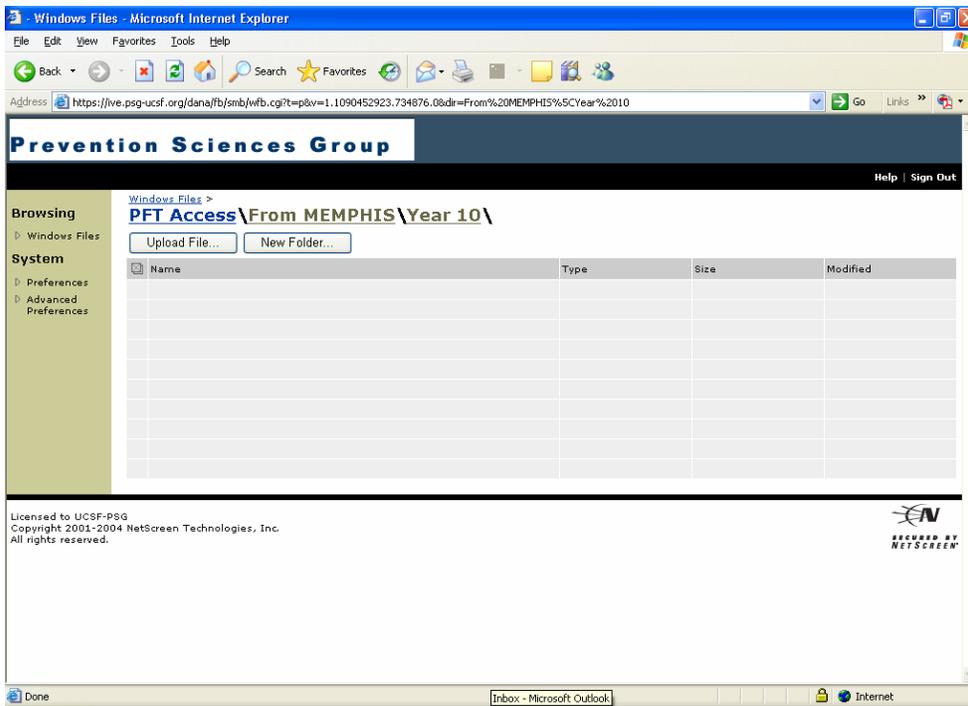
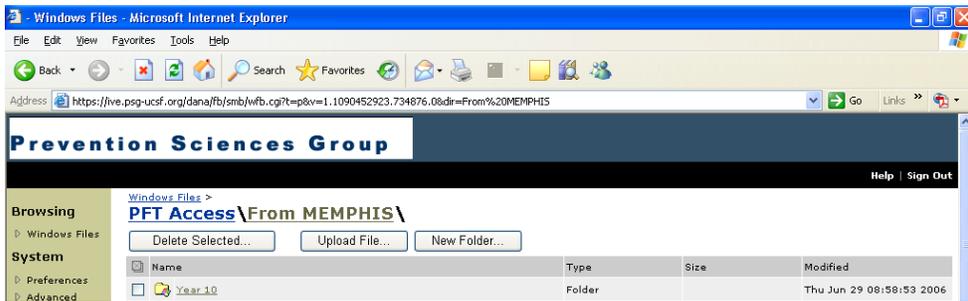
Click on "PFT Access."



If you are from HABC Memphis or HABC Pittsburgh, you select "From Memphis" or "From Pittsburgh," respectively.



Click on Year 10



Select "Browse" to locate the files for uploading. Using the naming convention below, enter the name in the "Save As:" box, then select "Upload"

For Memphis: MEMPFT $mmddyy$.zip, where $mmddyy$ is the date transmitted.
For Pittsburgh: PITPFT $mmddyy$.zip, where $mmddyy$ is the date transmitted.

