Chapter 14

Spirometry

BACKGROUND

Spirometry measures how much and how fast air is forcefully expelled from fully inflated lungs. It is recommended for the diagnosis and monitoring of asthma and chronic obstructive pulmonary disease (COPD). Change in lung function over time is also a standard measure of pulmonary health and disease. Among patients with COPD, decline in the FEV_1 (the forced expiratory volume in one second) is an FDA-approved endpoint, although in general population settings, change in the forced vital capacity (FVC) and FEV1/FVC ratio are also of interest. Secondary analyses may consider incident disease based on achieving a threshold, although these are not particularly well defined in the very elderly.

The important Spiro metric measurements are (FVC) or the greatest volume of air exhaled as rapidly as possible from a maximal inspiration to a complete exhalation; FEV_1; and the ratio between these two values: FEV_1/FVC (x100%). Since FEV6 (the forced expiratory volume in six seconds) is a valid measure of FVC and easier for participants to complete, we will use this measure in place of FVC in this study. Our Spirometry test procedures conform to current American Thoracic Society (ATS) guidelines. Results for each patient is compared to predicted values determined from the National Health and Nutrition Examination Study III (NHANES III) reference equations 2 and locally derived predicted values, since many participants in this study are older than range of ages of participants in NHANES III.

We have carefully chosen the EasyOne, an accurate, diagnostic quality spirometer, to be used by all clinics and for home visits. Unlike traditional volume spirometers, this hand-held spirometer is easily carried and uses disposable mouthpieces (Spirettes) which eliminate the risk of cross-contamination and cleaning of hoses. Unlike other small flow-sensing spirometers, there are no screen or capillary tubes to become clogged.

The procedures and instructions in this manual are described as directions to the technician or nurse using the EasyOneTM Spirometer.

Training: Technicians from each Field Center will be trained centrally for pulmonary function (PF) testing. Each technician will complete a CD-ROM-based pre-course and complete a pre-test, and complete the course in spirometric testing.

Certification: The examination includes 50 multiple choice questions, calculation of spirometry results from a spirogram (25 points), and a practical demonstration of skills including calibration checks, cleaning, and testing of a naive subjects (25 points). A passing score of at least 75 points is necessary for certification. Only certified technicians will perform pulmonary function testing in this study.

PF technicians should test at least one person (participant, another technician or staff member) per week between the training session and the start of Visit 2. To retain certification, technicians must have a QC score greater than 4 for both QC (FVC) and QC (FEV1). Technicians with inadequate quality of tests (QC<=4) will need to perform 5 observed tests in order to retain full certification. If a technician's test quality persists below this level, the technician will be decertified.

Certification of new technicians *after the initial central training sessions* may be performed by a centrally trained, certified PF technician. Such certification will require the following steps:

1. Complete practical training by a centrally trained and certified technician.

2. Read the LLFS Manual of Operations, which includes the spirometry completion form, and spirometry.
3. Complete the spirometry CD-ROM training and associated questions. (These must be sent to John Hankinson to review.)
4. Pass a written examination with a score of 75 or higher.
5. Complete five observed pulmonary function exams that are satisfactory to the Spirometry Reading Center and an additional 5 unobserved exams that are satisfactory to the Spirometry Reading Center (for a total of satisfactory 10 exams)*. The latter five must be in a series of no more than seven consecutive exams.

*   Technicians should try to use novel test participants who have not participated in spirometry "recently"; this will allow the technician to learn in a real setting and will enable the Spirometry Reading Center to adequately evaluate coaching.

Site Visits: The results of the first 50 spirometry test sessions performed by each technician will be closely examined by the QC Supervisor. Copies of suboptimal quality test sessions with comments for improvements will be mailed to the technician the same day as they are evaluated.

A site visit to each of the four clinical centers may be made during the first three months of recruitment, if necessary, or subsequently for other training or QC Problems. Complete calibration, leak, and linearity check, and complete PF testing of at least three participants by each PF certified technician will be observed. Copies of suboptimal quality test sessions will be reviewed. More efficient methods as well as protocol violations will be discussed during the site visits and later in a written report.

The Need for Spirometry QC: Examination of spirograms from the Framingham Heart study revealed that more than 18% were of clearly unacceptable quality. Two more recent studies, with over 12,000 adults each, found that 40-50% of the spirometry maneuvers were of unacceptable quality. Manual measurements from spirograms are tedious and prone to error and deviations in test performances and lack of regular leak checking and calibration can result in loss of study data (16-18).

The Epidemiology Standardization Project, the American Thoracic Society spirometry standards, and recent evaluations of commercially available spirometers emphasize the importance of spirometry quality control procedures. Factors which affect spirometry quality include:

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

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

1. Daily spirometer leak and calibration checks using a 3.00 liter syringe as the "gold standard" check every maneuver immediately after it is performed.
2. Eight computerized checks of FVC maneuver acceptability and reproducibility check every maneuver immediately after it is performed.
3. The PF technician is trained to recognize the patterns of acceptable maneuvers, watching the participant during the performance, and reviewing the colorfully displayed flow-volume curves on the computer monitor.

4. The results of the calibration checks and the best 3 FVC maneuvers are stored and sent to the PF Reading Center for review by the PF QC Supervisor. Monthly reports are compiled for each technician's performance.

5. Results from all of the above are taken into account during the analysis of the data by the PF reading Center. The calibration factors, PF tech's impression of the participant and the maneuver quality, and the QC supervisor's impression of test session quality are all integrated to obtain the final FEV1 and FVC results reported to the Data Management and Coordinating Center.

6. Replicate testing will be performed on a total of 5% participants scattered throughout the recruitment period as outlined above.

Using the EasyOneTM Keys to Navigate the Menus:

- ON/OFF: Press and hold this key for about 2 seconds to turn the unit ON. It turns itself off after 3 minutes of inactivity. No data is lost.
- Enter Key: Selects highlighted menu items and enters highlighted or typed-in data items.
- Keys 1 to 9: Allows entry of numbers and letters. In fields in which both numbers and letters appear, enter letters by pressing the appropriate key in rapid succession. This causes the corresponding number and letter sequence to scroll through the highlighted position in the data field. Simply stop when the desired number or letter is displayed. Both upper case letters, numbers, and lower case letters are available (in that order). It's not necessary to use lower case letters.
- Esc (0) Key: Serves as both the numeric zero and the escape key. Press briefly to enter a zero. Press and hold the key to activate the escape function. The Escape function moves the cursor sequentially to previous menus, menu items, or data fields, depending on the cursor position. To enter a blank space, press the Esc key rapidly to toggle between the number zero and a blank space.
- Arrow Keys < >: Move the cursor. In menus, the arrow keys allow scrolling up or down through menu items. In data fields, the left arrow key either erases previously entered numbers or letters (like a backspace key), or scrolls left through a data list. The right arrow key acts either like an Enter key or scrolls right through a data list.

SPIROMETRY

FEV6 Best Value	_____ liters
FEV6% Predicted*	_____ %
FEV$_1$ Best Value	_____ liters
FEV$_1$ % Predicted*	_____ %
% FEV$_1$	_____

Contra-indications: Don't perform Spirometry testing for patients with any of the following (answered "yes", "don't know" or "refused" to Questions 5 to 7 on the Spirometry Data Collection Form):

1. Severe uncontrolled hypertension, defined as systolic blood pressure greater than 210 mm Hg or diastolic greater than 120 mm Hg earlier in the exam (Refer to Question 5 on the Spirometry Data Collection Form).

2. Unstable cardiovascular status including a myocardial infarction (heart attack) or stroke within the previous 3 months (Refer to Question 6 on the Spirometry Data Collection Form).

3. Thoracic or abdominal or eye surgery within the previous 3 months (Refer to Question 6 on the Spirometry Data Collection Form).

4. Significant prior problems with Spirometry. Significant prior problems include fainting and angina (chest pain that is thought to come from the heart). These complications are extremely rare. Other prior problems encountered with Spirometry, such as coughing, transient dizziness, seeing stars, and headache, should not be considered significant and are not a contraindication so you can proceed with testing (Refer to Question 7 on the Spirometry Data Collection Form).

If the patient is unable to understand the instructions for the procedure or has physical complaints that make them unable to perform the procedure, do not perform Spirometry. Frail patients and patients on oxygen can generally perform Spirometry adequately and safely. It is preferable for patients on oxygen to keep their oxygen on during testing.

Testing Environment: Spirometry testing should ideally be done in a quiet room, maintained at a comfortable temperature (between 65 to 80 degrees F) with humidity maintained between 20-50% (using air conditioning if necessary). Since we are only making expiratory measurements, temperature and humidity do not need to be measured or recorded. Distracting third parties should not be in the same room.

Calibration Checks: Use a 3.00 liter calibration syringe with the provided adaptor **once each week** of testing to verify the volume accuracy of each spirometer that you use for this program. To save money, you may use a single Spirette over and over again for all calibration checks.

1. Choose "Check Calibration" from the Main menu.
2. Choose "Calibration Check" from the Calibration menu.
3. Firmly insert the CAL Spirette into the spirometer, matching the arrows. Firmly attach the Spirette to the calibration syringe using the grey plastic NDD adapter.
4. Press Enter.
5. Fill the syringe with room air (listen for a click).
6. Inject the full 3-liters from the syringe smoothly into the spirometer (taking about one second), and then pull back fully on the syringe (until you hear it click again). To avoid damage, don't "slam" the syringe at the end of the injection by pushing the air out too vigorously as this may cause erroneous calibrations.
7. The goal of the calibration check is to verify that the spirometer measures FVC with better than 3% accuracy. Since a 3.00 liter syringe is used, the resulting FVC should all be between 2.90 and 3.10 liters.
8. If the cal check fails, check for correct insertion of the Spirette into the spirometer (triangular arrows aligned), ensure that you are using an NDD calibration syringe adaptor, and check for air leaks inside the syringe and at the connections. Repeat the cal check. If it fails again, try a new Spirette. If it fails again, call the Spirometry Reading Center or Jerry at NDD Customer Service (see contact information at the back of this manual). We cannot change the factory preset calibration factors, so the spirometer must be returned to the factory for repair. Do not continue to use an inaccurate spirometer. Use a different spirometer and ask for a loaner spirometer to be shipped overnight.
9. Print and save a report of the calibration check.

Monthly 3-Speed Flow Linearity Check: A calibration check utilizing multiple different injection flow rates should be performed **each month** as follows:

1. Choose "Check Calibration" from the Main menu.
2. Choose "Multi-flow Check" from the Calibration menu.
3. Firmly insert the CAL Spirette into the spirometer, matching the arrows. Firmly attach the Spirette to the calibration syringe using the grey plastic NDD adapter.
4. Press Enter.
5. Fill the syringe with room air.

6. Repeat the injection 3 times. The first time, take at least six seconds to empty the syringe very slowly. The second time, empty the syringe in about 3 seconds. The third time, quickly empty the syringe in less than a second. After each injection, the machine will prompt you that the flow rate is acceptable.
7. Print and save a report of the calibration check.

Spirometry Instructions and Preparation: If you are using the spirometer by itself (not hooked up to the laptop), skip to Item 1 below. If you are using the spirometer hooked up to the laptop (hopefully most of the time), you need to plug the USB plug of the cable into any one of the laptop's USB ports and the other end of the cable into the bottom of the spirometer. Turn on the laptop and the spirometer (neither have to be off to make this connection). The screen on the spirometer should read "PC Interface Mode" after a few blinks. On the computer, open the "EasyWare" software by double-clicking on the appropriate icon on the laptop. Under the "View" menu, select "Test On-line." The testing window will open on the laptop and the screen on the spirometer will revert to the Main menu.

1. Chat with the patient to achieve rapport. Wash your hands (and use disposable gloves if desired).
2. Suggest that the participant use the bathroom, if they have not done so recently. The hard blowing involved with Spirometry may results in some participants loosing some urine and recent urination will minimize this.
3. On the spirometer, select "Perform Test" and "New" from the "Display Menus."
4. Enter patient acrostic, ID number, age, height (use baseline armspan if unable to stand at Visit 2) and weight (from Height/Weight form or screen), ethnicity, gender, current smoking status, and asthmatic status. The latter two items are optional and do not affect the interpretation of Spirometry results. Also enter your technician ID number (press each number button 4 times to get the number).
5. Once entered, you will see the "Test Menu."
6. Explain the purpose of the examination and the need for extra effort from the patient to get maximal results. Say "I want to measure how much and fast you can breathe out."
7. Ask the patient to loosen any tight clothing. If they have dentures that are not secure, ask them to remove the dentures for the test. (Provide clean denture cups for such patients.)
8. Take your personal Spirette (with your name written on the mouthpiece). Demonstrate a DEEP inspiration, exaggerate body language, eyes wide, shoulder, back, on your tiptoes. Demonstrate proper placement of the mouthpiece (stick out your tongue and place the mouthpiece on top of it). BLAST out the air using exaggerated body language. Note to Interviewer: Be sure to demonstrate this procedure by placing the mouthpiece inside your mouth BEFORE blasting out.
9. Ask the patient to sit up straight during the examination and not to bend over very much while exhaling. If after one maneuver you feel that the patient would give much better results while standing, it is alright, but be sure to place a solid chair directly behind them and don't encourage them to squeeze the air out towards the end of the exhalation maneuvers.
10. Get a new Spirette for the patient's use. Allow them to see the package being opened so that they know that it's clean.
11. Have the patient do a short trial exhalation using the Spirette (not attached to the spirometer). Coach them through each step of the maneuver, as follows:
    • "Place the Spirette on top of your tongue, seal it with your lips, but don't bite down on it."
    • "Take a great big deep breath of air as far as you can inhale."
    • "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 until I tell you to stop." (Tell them to pretend to blow out all of the candles on a birthday cake with one breath.)
12. Carefully watch their body language and correct any problems.

Start the Actual Maneuvers:

1. Insert and twist the patient's Spirette so that the arrow on the Spirette lines up with the arrow on the spirometer. Push the Spirette in firmly.
2. Select "FVC" to begin the testing sequence (even though we are actually testing FEV6).
3. Place a nose clip on their nose. The nose clip may be removed between the breathing maneuvers. If the nose clip falls off or is uncomfortable, try a different model of nose clip or the patient may hold his nose during the maneuver.
4. Before the first trial for each patient, you must set a no-flow baseline. The display will prompt you to "Block Spirette until prompted to Blast out." This is accomplished by leaving the Spirette partially bagged or covering the bottom of the Spirette with your thumb. It is critical that no air flows through and the sensor is still during the zeroing procedure.
5. Select "Next." You will hear a buzzing sound -- wait until it stops.
6. The display will indicate that the baseline is being set, which takes only 1-2 seconds.
7. The spirometer will then read "Blast out."
8. Hand the spirometer to the patient and coach them to take a maximal inhalation. Watch their body language. Don't hold the spirometer while they blow into it (since this would restrict their deep breaths). *If you are using laptop also, try to position the screen so that you and the patient can see the screen.*
9. Coach the patient loudly to BLAST out as hard and fast as possible immediately after taking a maximal inhalation (i.e., Tell the patient not to hold his/her breath after the maximal inhalation). After a second, quietly tell them to continue blowing out for six seconds. Watch their body language. The spirometer will give a longer beep at six seconds to let you know that you can stop the test. *If you are using the laptop also, there is a blue 'X' at 6 seconds on the volume-time graph.*
10. Tell the patient it is now okay to come off the mouthpiece.
11. Take the spirometer from the patient and observe the small flow-volume curve displayed on the LCD and/or laptop screen. Learn to recognize the patterns of unacceptable maneuvers.
12. Press "Enter" to see the quality of the curve. If the quality is less than "A", the patient will need additional coaching. If the patient looks like they're not taking a big enough breath or is not blasting out quickly enough, they will also need additional coaching.
    - Repeat the maneuvers until a quality grade of A or B is obtained. If you feel that the inspiration was inadequate, try another test regardless of the quality grade.
    - For another maneuver, press "Next."
13. It is important to perform up to 8 maneuvers if needed to achieve good quality results (a test session with a grade of A or B); however, use your judgment if the participant is becoming overly fatigued. If this does not occur after 5 trials, considering asking another technician to help by coaching the patient for the final maneuvers.
14. The spirometer will display the message "Session Complete!" when quality results are achieved.

View the Results: On the spirometer, choose "Data" or "View Results" to see the actual and predicted values, best test curves, and test session quality information (including variability in parameters and quality grade). The spirometer uses regression equations from NHANES III to calculate predicted normal (reference) values for the measured parameters. These equations require the age, gender, race, and height that you enter for a particular patient to complete the calculation. The predicted values represent the expected values that a healthy person of that age, gender, race, and height would produce during a maximal Spirometry effort. On the display, the predicted normal values (PRED) are compared to the patient's values to calculate the percent of predicted values (%PRED). A more detailed display is shown on the laptop. The "Best" values are shown in the left column of the "Test Results" box. Use these "Best" values for reports.

On occasion, you may not get a $FEV_1\%$ or FEV6% predicted from the spirometer (if the participant is particularly old and/or short). If that occurs, still record the other values.

Recording Results: Record the best results on the Spirometry Data Collection form and on the Spirometry Report form. Give the Spirometry Report form to the participant.

If you should ever want to print an entire report from the spirometer, follow instructions 1-5 below. Printing is not a necessary component of this study.

1. Connect the Cradle to the printer. Ensure that the printer is ready.
2. Place the spirometer in the cradle.
3. Select "Print Results" from the Main Menu.
4. Choose "Single Test" and scroll using the arrows until the desired record is found, and press Enter to print it.
5. If you should ever want to print an entire report from the computer, go to the relevant screen in EasyWare and print.

If using the spirometer with the laptop, you need to close the "On-line Test" window in order to move on to the next participant. Always close this window after completing testing/recording a participant's results.

Back Up and Transmit the Data: The spirometer automatically stores the results of patients in its internal memory (about 200). Every time the spirometer is connected to the laptop, the data stored in the spirometer will be sent to the laptop automatically. Since you will be using more than one spirometer at your Field Center, make sure that ALL spirometers have been connected to the laptop EVERY WEEK BEFORE copying all data for transfer to the Coordinating Center

1. Connect the cradle to the computer, using the serial cable.
2. Place the spirometer in the cradle.
3. Press and hold the number "1." (This will synchronize the spirometer with the computer and transfer the data).
4. To view the stored data, double click on the EasyWare software icon.
5. The individual data will be displayed by name in the order in which the tests were performed.
6. Click on an individual entry to view the flow-volume and volume-time plots as well as the numerical data in column form.
7. Toggle between data from the two spirometers by selecting "View" and then the specific "configuration device."

QUALITY ASSURANCE PROGRAM

Despite the accuracy of new spirometers, the quality of Spirometry testing done in primary care settings is often poor, resulting in false-positive and false-negative interpretations for the presence of lung disease. FVC and FEV6 maneuvers involve unfamiliar breathing maneuvers that require athletic-type efforts. Unlike most other medical tests where the patient remains passive, an effective interaction between the technician and patient is essential to obtain accurate Spirometry results. Technician training and supervised experience, with rapid feedback on performance, are essential.

This study includes all of the components of an optimal Spirometry quality assurance program. These include technician training, use of accurate spirometers (the same model for each site), weekly verification of spirometer accuracy, automated maneuver and test session quality checks, quality messages after each maneuver is performed, test session quality grades displayed and printed on test reports, appropriate reference values, ATS interpretations, and central review and reporting of technician and spirometer quality.

Technician Training: Spirometry technicians must have successfully completed a Spirometry training course and have been supervised while testing more than 10 patients. The accuracy of the Spirometry examination depends on the effort exerted by the patient and the conscientiousness of the technician. Insufficient effort on the part of the patient will cause the test results to be inadequate for analysis. To achieve accuracy, the technician must instruct the patient properly, encourage maximal effort and be able to detect deviations from this effort. An experienced technician is "a combination bully and cheerleader as he or she strives to elicit maximal response."   Spirometry technicians who are unable to maintain good quality test success rates of better than 75% for two months in a row will receive considerable attention.

Maneuver Quality Checks: The EasyOneTM spirometer has been preprogrammed to check the acceptability and repeatability of each FVC maneuver, according to ATS recommendations. The details of these checks are as follows:

- The back extrapolated volume (BEV) must be <150 mL or <5% of the FVC, whichever is greater. If this is not achieved, the patient may have leaked air before the initial blast or hesitated once the blast has begun. The message "Don't hesitate" is displayed.
- The time to peak flow (PEFT) must be <120 msec. If this is not achieved, the patient did not blast out hard and fast. The message reads "Blast out faster."
- The forced expiratory time must be >6.0 seconds and the effort must not be ended abruptly (>100 mL of accumulated volume in the 0.5 second interval preceding the end-of-test interval). The end-of-test (EOT) interval is defined as the last 2 seconds of the maneuver during which less than 30 mL of volume is exhaled. If the exhalation time was too short or the effort ended abruptly, the patient should be coached to continue blowing out until the lungs are empty or until the spirometer terminates the test.
- After the first or second acceptable effort, the quality message will state "Good Effort, Do Next," indicating that the patient has performed well. Additional maneuvers will be needed to assure repeatability of the key variables. In the "Test Results" section of the report, a number sign (#) next to the trial number indicates that the trial is considered unacceptable.

Test Session Quality Grades: The quality of each Spirometry test session is graded as follows:

- A = 3+ acceptable maneuvers, AND FEV_1 and FEV_6 match within 150 mL
- B = 2+ acceptable maneuvers, AND FEV_1 and FEV_6 match within 150 mL
- C = 2+ acceptable maneuvers, AND FEV_1 and FEV_6 match within 250 mL
- D = Only 1 acceptable maneuver, OR the FEV_1 or the FEV_6 from the best 2 acceptable maneuvers do not match within 250 mL
- F = No acceptable maneuvers.

"Session Complete! Good Job" is displayed when a grade of A or B within the first 4 trials, or C or better after 5 or more trials is obtained.

Central Review and Reporting of Test Quality: Upon completion and review of each batch of incoming data, technicians will be notified of any serious errors with calibration and procedures. The Tech QC reports will be furnished to each user for his/her review. Additional training or supervision may be indicated.

Safety Procedures: The use of disposable Spirettes eliminates the need for cleaning the spirometer between patients and minimizes the risk of cross-contamination (transmission of infection from one patient to another). The Spirette is for single patient use only, and must be removed and thrown away after each patient has completed Spirometry testing. You may dispose of the Spirette in the same manner in which you dispose of items such as used tongue depressors or tissues (or give it to the patient as a souvenir).

At the end of each day, the spirometer should be cleaned. Wear gloves. Clean the spirometer and its Spirette cavity using an alcohol wipe, or a soft cloth lightly moistened with isopropyl alcohol.

Seat patients for Spirometry tests in a non-rolling chair. If the patient must stand in order to achieve quality results, a chair (non-rolling) should be placed behind him/her during the test.

Use caution when attempting to examine patients who are unable to comprehend the instructions for the Spirometry procedure. Failure to follow the correct procedures regarding positioning and use of the mouthpiece may present some risk to patients. If unsure about the patient's ability to perform the test adequately, don't do it.

If the patient speaks a language other than English, attempt to locate a relative or friend who could translate for the patient. If no translator can be found, and if the instructions cannot be communicated to the patient successfully by demonstration, the patient should be excluded from the exam.

Emergency Procedures: The Spirometry examination poses minimal risk to the patient. The breathing maneuvers may occasionally cause dizziness and very rarely, actual fainting. The risk is minimized by having the patient seated during the test. A patient who feels faint should be guided onto the chair with head down towards knees and encouraged to breathe slowly and deeply until recovered. A physician should be summoned whenever a patient fails to recover normal breathing, faints or reports feeling ill. A physician should be notified immediately, and will assume command of the emergency response. A physician should always be consulted if there is any question regarding a patient's status during the exam. Follow local procedures for problems in the clinic or home.

Initial Configuration of the EasyOne: It is critical that all spirometers used for this study be configured identically. The factory-set default configuration will not store the numeric results and the curves from the three 3 best maneuvers. Once configured for this study, please don't change the configurations. If you get a loaner spirometer, be sure to configure it before use. The custom configuration is retained by the spirometer even if the batteries are removed or become dead.

Operating Mode: Use the "Diagnostic" mode (not the Front-Line mode). The diagnostic mode allows the EasyOne to display the flow-volume curve after each maneuver, and store the 3 best curves from the pre and post-bronchodilator test sessions. Select "Configuration" from the Main Menu and then choose "General Settings." Press "Enter" until you see "Mode." Use the arrow key to select "Diagnostic." There are three categories of configuration settings to be selected from the CONFIGURATION menu: Test Settings, General Settings, and Report Settings. First select "Test Settings."

Bolded settings are NOT factory default and need to be set by you.

The Test Settings:
- Adult Normals: choose "NHANES III"
- Additional Pediatric Normals: choose "None"
- Best Value Selection Criteria: Choose "Best Value"
- Interpretation: choose either "NHLEP" or "Gold"
- Lung Age: choose "Off"
- Automated Test QC: Choose "On"
- FVC Selection: Choose "FEV6"   **VERY IMPORTANT**
- Peak Flow Units: Choose "L/s"
- African-American Ethnic: Choose "88%"
- Asian, Hispanic, and Other Ethnic Corrections: Choose "100%"
- Storage: Choose "3 Best"   **VERY IMPORTANT**

<u>The General Settings:</u>
- Time Format: Choose "am/pm"
- Date Format: Choose "mm/dd/ yy"
- Date and Time: Enter the current date and time
- Alpha-numeric ID: Choose "No"
- Technician ID: Choose "Yes"
- Calibration Syringe Volume: Choose "3.00 L"
- Height Units: Choose "m/cm"
- Weight Units: Choose "lbs"
- Age Entry: Choose "Age".
- LCD Contrast: Adjusts display contrast to maximize visibility
- Language: Choose "English"
- Altitude: Choose "zero" (assuming at sea level)
- Operating Mode: Choose "Diagnostic"   **VERY IMPORTANT**
- Temperature Units: Choose "°F"
- Humidity: Choose "40%"

<u>The Report Settings:</u>
- Printer Type: Select "Canon" (or whatever printer you are using)
- Data Option: Choose "3 Best Data"
- Curve Option: Choose "3 Best Curves"
- Graph Options: Choose "Small FV and VT"
- Report Headers: Enter "Long Life Family Study"

The entries for humidity, altitude, and temperature only affect the accuracy of measured inspired flows. Even if they are entered incorrectly or change over time, the accuracy of the FEV_1 and FEV_6 will not be affected. It is very important to configure the spirometer by selecting "3 Best Curves" under the curve options, so that all of the data is saved.

Other Helpful Information:

<u>Contact Information:</u>   Columbia University
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*See the NDD website for additional information about their products and how the
ultrasonic flow sensor works.*   *www.nddmed.com*

*Call NDD Customer Service (Patti Peters) to order additional Spirettes, if you
repeatedly get error messages, or for spirometer malfunctions*.

Study Documents Referred to in this Chapter:
- Spirometry Data Collection Form
- Medical History Data Collection Form