FRAMINGHAM HEART STUDY



Pulmonary Function Testing

MANUAL OF PROCEDURES FOR OFFSPRING EXAMINATION 9

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1. Overview

Participants have undergone spirometry, which measures the ability to force air out of the lungs, at each exam cycle since the earliest days of the Original Cohort. Measurement of diffusion capacity, a measure of the lung's ability to exchange oxygen and carbon dioxide, has been done in the first and second examination of the Generation 3 cohort and in the 8th examination of the Offspring cohort.

A limited number of participants in Offspring (8th examination) and Generation 3 (2nd examination) have undergone post-bronchodilator spirometry, in addition to the pulmonary function testing that all participants undergo. This will be done again in the Offspring 9th examination. Selection of participants to undergo post-bronchodilator testing is based on evidence of airflow obstruction and will help discriminate between participants with reversible airflow obstruction (i.e., asthma) and those with fixed disease (i.e., chronic obstructive pulmonary disease).

For those undergoing post-bronchodilator testing, the time spent in the Pulmonary Function Testing station will be somewhat longer, as a result of the additional spirometry testing and additional time needed to allow onset of medication effect. Subjects **not** performing post-bronchodilator spirometry will proceed through the station as follows:

- 1) spirometry
- 2) diffusion effort #1
- 3) questionnaire
- 4) diffusion effort #2. At least 4 minutes should pass between diffusion maneuvers

Subjects performing post-bronchodilator spirometry will proceed through the station as follows:

- 1) spirometry
- 2) diffusion effort #1
- 3) questionnaire
- 4) diffusion effort #2 (at least 4 minutes should pass between diffusion maneuvers)
- 5) completion of all remaining exam components
- 6) administration of albuterol (at a time that ensures that post-bronchodilator spirometry will be able to be performed at least 10 minutes and no more than 15 minutes after administration)
- 7) post-bronchodilator spirometry

The timeline below summarizes the time-lines for these two alternative test protocols:

	Start	10 minutes	15 minutes	20 minutes	25 minutes	40 minutes	50 minutes
Those doing only pre- bronchodilator spirometry and diffusion	Pre- bronchodilator spirometry	First Diffusion Capacity	Respiratory Questionnaire	Second Diffusion Capacity			
Those doing pre, post bronchodilator spirometry and diffusion	Pre- bronchodilator spirometry	First Diffusion Capacity	Respiratory Questionnaire	Second Diffusion Capacity	Bronchodilator Administration	15 minute wait	Post- Bronchodilator spirometry

Table 1. Timeline for pulmonary function testing at FHS

2. Background and Glossary of Terms

Spirometry records the relationship between the rate at which air can be exhaled and the volume of air exhaled during a breathing maneuver called the FVC maneuver (forced vital capacity maneuver). Some common lung diseases reduce the rate at which air can be exhaled during a FVC maneuver. Such "obstructive" lung diseases include asthma, bronchitis and emphysema. The ratio of FEV1/FVC, a measure of how quickly air can be exhaled, is reduced in obstructive lung diseases (e.g. asthma and chronic obstructive lung disease) but may be normal in other conditions that reduce both FEV1 and FVC to the same degree (e.g. surgical removal of part of a lung, pulmonary fibrosis, or severe obesity).

A number of key terms are defined below:

FEV1 is the Forced Expiratory Volume in one second, i.e. the total amount of air that a person can blow out in one second during a maximal forced exhalation. It is reduced in many conditions that cause impairment of lung function.

<u>FVC</u> is the Forced Vital Capacity, the total volume of air that can be exhaled forcefully and as rapidly as possible from the point of maximal inhalation (lungs as full as possible) to the point of maximal exhalation (lungs as empty as possible). The subject takes as deep a breath as possible and then quickly exhales as much air as possible.

<u>FVC maneuver</u> is the maneuver of exhaling as forcefully and as rapidly as possible from the point of maximal inhalation (lungs as full as possible) to the point of maximal exhalation (lungs as empty as possible).

FEV1/FVC RATIO is the ratio of the FEV1 divided by the FVC. It is the proportion of total volume of air exhaled in an FVC maneuver that is exhaled in the first second of the maneuver. It is reduced in obstructive lung diseases such as asthma and chronic obstructive lung disease.

<u>PEF (or PEFR)</u> is the Peak Expiratory Flow Rate, i.e. the highest flow measured during the FVC maneuver.

<u>PRED</u>: is short for the "predicted value" of a pulmonary function parameter. It is determined on the basis of gender, age, and height from a regression equation derived from a large population study of apparently healthy people who have never smoked tobacco.

PERCENT PREDICTED is the value of a given pulmonary function measurement, such as FEV1, when as expressed as a percentage of the value that would be predicted for a healthy never-smoker of the same gender, age, and height as the participant. For example, an FEV1 of 50 percent predicted means that the participant's FEV1 is only 50 percent of what would be predicted for never-smokers of the same gender, age, and height.

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 is calculated as shown in the figure below:



The BEV should be less than 5% of the FVC or 0.15 L, whichever is greater, otherwise the maneuver is considered to have started too slowly.

DIFFUSION CAPACITY OF CARBON MONOXIDE: is a measure of the lung's ability to transfer gas into the bloodstream (volume of gas (carbon monoxide) transferred per minute per mmHg of mean pressure gradient). This volume is derived using the total lung capacity derived from a single breath dilution of an inert tracer gas (He, or CH₄).

3. Staff training requirements

A. Training requirements for new staff

- 1) Read and understand the manual of procedures.
- 2) Undergo pulmonary function testing.
- 3) Training session with the physician investigator overseeing lung function testing at FHS.
- 4) Perform unprompted pulmonary function testing on 5 non-participant volunteers while observed by certified technician.
- 5) Perform pulmonary function testing on 5 FHS participants while supervised by certified technician.
- 6) Perform unprompted pulmonary function testing on 1 non-participant volunteer while observed by the physician investigator overseeing lung function testing at FHS.
- 7) Complete written quiz (and review of correct responses) administered by physician investigator overseeing lung function testing at FHS.

B. Training requirements for staff previously certified to perform pulmonary function testing at FHS

- 1) Read and understand the manual of procedures.
- 2. Training session with the physician investigator overseeing lung function testing at FHS.
- 3) Perform unprompted pulmonary function testing on 1 non-participant volunteer while observed physician investigator overseeing lung function testing at FHS.
- 4) Complete written quiz (and review of correct responses) administered by physician investigator overseeing lung function testing at FHS.

4. Subject selection for bronchodilator testing

As noted above, in addition to the routine spirometry and diffusion capacity measurements obtained on all participants, some participants will have spirometry measured after inhaling a medication that may relax the airways of those with airflow obstruction. This will help discriminate between participants with reversible airflow obstruction (i.e., asthma) and those with fixed disease (i.e., chronic obstructive pulmonary disease).

All participants whose current pre-bronchodilator spirometry has **EITHER** a FEV1-to-FVC ratio less than 90 % of the predicted value **OR** a FEV1 less than 85 % of the predicted value will be asked to undergo post-bronchodilator testing.

The % predicted values used to assess eligibility for post-bronchodilator testing are those that are calculated by the Collins CPL pulmonary function system using the NHANES III prediction equations (Hankinson 1999). For any participants who report their race as black or African American, the NHANES III African-American equations should be used. For all other participants, the NHANES III-Caucasian prediction equations should be used. (Note that we are not employing the NHANES "Hispanic" equations because these were derived from Mexican-American subjects, and most Hispanic participants in FHS are not of Mexican ancestry.).

5. Pulmonary function protocol summary

This section provides of summary of the protocol. Detailed step-by-step instructions for specific procedures are provided in later sections.

A. Subjects not undergoing bronchodilator testing

i) **Pre-bronchodilator spirometry**

During the test, participants will be asked to take a deep breath and then to force the air out as hard and fast as possible. The spirometer will measure these maximal flow rates and also the volume of air that has been exhaled at particular time points. As the results the testing assumes that these values are the maximum levels a participant can do, it is imperative that participants are coached to blast the air out of their lungs as hard and fast as possible.

ii) Diffusion capacity

As mentioned, diffusion capacity measures the lungs ability to exchange oxygen and carbon dioxide. A gas that does not diffuse from the lung into the blood stream (a tracer gas, methane) and carbon monoxide (CO), which is quickly taken up by the blood, are inhaled at trace amounts. Participants will hold their breath for a fixed amount of time (10-12 seconds), and then exhale. The Collins CPL system will then measure the difference between the CO and tracer gas as they are exhaled. This difference is due to the diffusion of CO and, as the time interval is known, we can calculate the rate of transfer. It is important that the participants take a deep breath (at least 90% of their vital capacity). Ideally, at least 2 maneuvers should be performed and should agree within 10%. At least 4 minutes should be allowed between diffusion maneuvers to allow sufficient time for the CO and tracer gas to wash out. If the first two attempts do not produce two acceptable maneuvers with a value for the single-breath diffusion capacity (Dsb) within 10% of the higher value, then a third maneuver should be performed after an additional 4-minute wait.

iii) Respiratory Questionnaire

Technicians will administer a respiratory questionnaire. The questionnaire will help investigators to understand whether the participant has allergies, asthma, COPD, and other pulmonary diseases. Further, the questionnaire will capture information on recent inhaler use, which may affect the spirometry.

	Short acting	Intermediate
	4-6 hours	12 hours
Drug trade	Proventil, Proair,	Serevent, Advair,
names	Ventolin, Maxair,	Foradil, Sybmicort,
	Combivent,	Dulera, Brovana,

Table 2. Common bronchodilator inhalers, Brand names and Generic names

	Maxair Xopenox, Volmax, Atrovent	Spiriva
Generic drug names	albuterol, levalbuterol, pirbuterol, iprapropium,	salmeterol, fluticasone/salmeterol, formoterol arformoterol, budesonide/formoterol, mometasone/formoterol, tiotropium

B. Subjects undergoing bronchodilator testing

Subjects undergoing post-bronchodilator spirometry will move through the Pulmonary Function Testing station exactly as those not undergoing the postbronchodilator spirometry, except that after completing all of the exam components they will receive two inhalations of albuterol metered-dose inhaler 90 ug / inhalation, and then repeat the spirometry (which is done exactly as the pre-bronchodilator spirometry). Their schedule is described below.

- 1) **Pre-bronchodilator spirometry**
- 2) Diffusion capacity
- 3) **Respiratory Questionnaire**
- 4) **Post-bronchodilator spirometry** The post-bronchodilator spirometry should be performed *no less than 10 minutes and no more than 15 minutes after* administering the albuterol.

6. Pulmonary function equipment and technical support contact information

- 1. nSpire Health 3 Litre Calibration Syringe Model #021156
- 2. nSpire Health Vitalograph Linearity Syringe Serial #CS4769

3. Contact person for PFT problems

NSpire Tech Support 800-574-7374 Techs:

NSpire NE Field Service Rep

For Supplies:

Somerset Medical 9 Loire Street Somerset, MA 02726 Phone (774) 644-1405 Fax (508) 567-1225

http://www.somersetmed.com

4. Contact person for PFT Contract Issues

nSpire Health 1830 Left Hand Circle Longmont, CO 80501 (800) 574-7374 x3285

7. Supply list For use with the Collins Comprehensive Pulmonary Laboratory (CPL) Collins 2000 Plus/SQL Software version 4.8 And the Hewlett-Packard Deskjet 845c Printer

	<u>Item</u> Lung Diffusion Mix (.3% CO, .3% CH4, 21% O ₂ , BAL N ₂) Size 200		<u>Number</u> 17852003060	Office	<u>Vendor</u> Airgas East 17 North Western Drive Salem, NH (508) 755-6815
	APC Smart-UPS Interruptible Power Supply				Mill City Connections
	HP 840c Black Ink Cartridge	e			W.B. Mason
CPL S	System Catalogue – No. 0040)10			
	KoKoFilter w/mouthpiece and nose clips	5	810580		Somerset Medical
	Balloon Kit – Set of 4 (B1, B2, B3, B4)		K70085		Somerset Medical
	CPL 1B Balloon Kit		K700889		Somerset Medical
	Disposable Hydrous Desicca Columns	tor	K021501	Sc	omerset Medical
	PFT Adaptor for CPL		212147		Somerset Medical
	Roll of 100 Segmented Tubi	ng	001426		Cardinal Health
CPL S	System Catalogue – No. 0040	000			
	Nafion Tubing		K381248		Somerset Medical
	Disposable CO2 Cannister for CPL		022556		Somerset Medical
	White Balloon Stems (refill pack)	K0223	356	Somer	set Medical

8. Pulmonary function equipment daily procedures

- 1. Turn on: Spirometer switch.
- 2. Open valves on gases. Turn counterclockwise all the way to open.
- 3. Calibrate equipment.
- 4. Print calibration report for log record.
- 5. Date log book and put ID stickers for each expected participant.
- 6. Record any/all comments if issues arise or if participant refuses test or has to stop test.
- 7. <u>Close the gas valves clockwise all the way everyday after testing is done.</u>

Note: the Spirometry computer should NOT be turned off at the end of the day. It is turned off after clinic on Fridays.

8. Pulmonary function equipment calibration protocol

Read all prompts

- Minimize nSight (Patient Information)
- Shortcut to Plus CPLDiag
- Component = CPL (SN: SI0034)
- Balloon check: check all boxes and click on Inflate
- Deflate

LEAK TEST

Put round weight on bell

- Leak Test
- Component = CPL
- S Delay = 20
- Duration = 60
- Start
- \leq -20 is ok. CANNOT HAVE \geq -20. IF DO, REDO CALIBRATION (optimum = 0 to -14)

TOOLS (under nSight)

- (Follow prompts)
- Calibration
- *CPL (click on "+")
- Barometric pressure (highlight and make drop-downs visible)
- Calibrate
- Calibrate
- Temp (leave temp that is shown on screen = machine temp)
- Enter
- Humidity
- Enter
- Barometric pressure (leave barometric press that is shown on screen)
- Enter
- Continue

SPIROMETER

- Calibrate
- Calibrate (bell goes up)
- Attach syringe
- Press space bar
- Pull out syringe at constant pace
- Press space bar
- Push in at constant pace
- Press space bar
- All lines should have a green square = Valid. If not, repeat calibration
- Continue

PNEUMOTAC

- Calibrate
- Calibrate
- Continue
- Continue
- Press space bar
- Pull out syringe
- Press space bar
- Press space bar
- Push in syringe (push in before "4")
- Space bar
- Continue
- Verify
- Close

Take off syringe

DL GAS ANALYZER

- Calibrate
- Next (all must be "Valid" in green)
- Next
- If "Failed" repeat DL Gas calibration ONLY
- If "Passed" press Finish

REPORT

- Check all boxes EXCEPT MOUTH PRESSURE
- Print
- Write initials at bottom of report
- Put printouts in white binder on low shelf in front of scale

END

- Minimize nSight
- Shortcut to Plus CPL Diag
- Component = CPL
- Close
- Enlarge Raptor

9. Participant testing – detailed procedures

a. Exclusion criteria

Prior to all tests, the technician must ask the participant about pulmonary function testing exclusion criteria:

- Any of the following within 3 months: major surgery (chest, abdominal or brain), oral surgery, a heart attack, a stroke, or an aneurysm of the brain or cataract surgery. If the participant has an aneurysm, ask where it is.
- Blood pressure today greater than or equal to 210/110. Check with the MD or Tonometry in clinic for the participant's blood pressure reading. If the MD or Tonometry has not yet obtained a reading, take the participant's blood pressure according to FHS protocol. If either the systolic or diastolic exceeds this limit, do not perform the PFT.
- Ask: Do you currently have any limitations on physical activity prescribed by your doctor? If the participant answers yes to this question the technician will discuss the limitation with the clinic physician. If the clinic physician determines the limitation will not be detrimental to the participant's health if they perform the

PFT, the PFT will be performed per protocol. If the limitation puts their health at risk if they perform the PFT the exam will be aborted and notes will be put in the computer.

On the following page is a flyer that should be printed out and placed on the wall at the pulmonary function testing station to remind the technician to ask about these exclusion criteria.

(To be placed in PFT testing room)

PFT EXCLUSION CRITERIA

IN THE PAST 2 WEEKS HAVE YOU HAD:

ORAL SURGERY

IN THE <u>PAST 3 MONTHS</u> HAVE YOU HAD:

MAJOR SURGERY (Chest, abdominal, or brain, requiring hospitalization)?

- HEART ATTACK
- STROKE
- ANEURYSM OF THE BRAIN

 BP>210/110 (Participants blood pressure MUST be taken in clinic prior to performing the PFT)

• CATARACT SURGERY

DO YOU CURRENTLY HAVE ANY LIMITATION ON PHYSICAL ACTIVITY PRESCRIBED BY YOUR DOCTOR?

• Anyone with history of EPISODIC tachycardia, A-Fib *REQUIRING MEDICAL TREATMENT* or Ablation should be excluded from doing the albuterol challenge.

Note: Participants with chronic atrial fibrillation should not be excluded unless requested by participant.

b. Entering participant information

From the Windows desktop, double click on the "Plus 2000 Version 4.8" icon. On the Patient Information Screen tool bar click Search. Once the Patient Search box pops up enter the participant's FHS ID Number and click search. Once the computer finds the participants information it will display on the right side of the search box. Click on the participant's ID and hit Add to Cache. Close the search box and confirm that this is the correct participant (verify date of birth). Once this is confirmed click New Study. Update the participants Height & Weight and enter the tech number that is performing the test. Once the information card is appropriately completed, click on "Save" which will put the participant's information in the "Cache" as seen in the navigation bar (top of the screen, next to "Notes").

- **Date-** Before you update the information for the New Study, the computer will ask you (in a pop-up screen) for a date of the pulmonary function test- ensure that the date is correct.
- Name If the participant's name is not in all capital letters, retype the participant's name. Enter the participant's first name, tab to the next field then his last name. Use all capital letters.

Date of birth -Confirm DOB

- **Height** Enter the participant's measured standing height in inches (including .25-.75)
- Weight Enter the participant's weight in pounds
- **Gender-** Does not need to be changed from exam 1
- Race- If the subject self-identifies as black or African American, please select "Black – African American (NHANES)" Otherwise, please select "White – Caucasian (NHANES)"
- **Editing-** If a mistake was made when entering information, use mouse to move the cursor to the error. Then begin typing the information.

Saving the information- Once the data is satisfactorily entered, click on "Save."

c. Spirometry

The technician is the critical part of the pulmonary function testing system, since the technician must guide the participant through breathing maneuvers that are highly dependent on participant effort. The technician must coach the participant to inhale maximally and then to exhale maximally and as rapidly as possible. The technician must also judge the quality of the participant's effort. To obtain accurate results, the testing must be done in a standardized fashion.

Note: This manual refers to the participant as "he" or "him" for easy reading, although participants will be both male and female.

Position the Participant – Testing should be conducted in the sitting position in a chair without wheels. The participant should sit erect with chin slightly elevated.

Explain the Procedure – The technician should explain that the purpose of the next test is to determine how hard and fast he can exhale air, "Like blowing out dozens of candles on a birthday cake." The technician should explain that he should take in as deep a breath as possible, and when his lungs are completely full, blow out all the air as hard and fast as possible, until told to stop.

Dentures, if they are loose, should be removed and placed in a clean cup, since they will prevent a tight seal from being formed around the mouthpiece. If dentures are not loose, leave them in place.

Always Demonstrate the Maneuver. The technician should ask the participant to watch them demonstrate the FVC maneuver. Again demonstrate correct placement of the mouthpiece. If the participant does not adjust well to using the mouthpiece (i.e. strong gag reflex) the participant can use just the neck of the filter for a mouthpiece. His lips must remain tightly sealed using this also. The technician should sit up straight. Take a deep breath, throw back their shoulders, and widen their eyes to emphasize the maximal depth of inhalation. Then dramatically **BLAST** out all of their air as hard and as fast as they can.

The technician's vigorous demonstration will prevent time and effort from being wasted on unacceptable forced expiratory efforts that result from the participant's failure to understand a verbal explanation of the procedure.

FVC Maneuver Test Steps

The technician should do the following:

- 1) To begin doing the maneuvers, click on "Go to," then on "Forced Vital Capacity." This will bring up the testing page.
- 2) Ensure that the participant has a clean filter and mouthpiece, but do not connect the participant until prompted by the computer. Click on "Start test."
- 3) The spirometer will fill the bell and prompt the technician- THEN have the participant connect to the mouthpiece and breathe normally.
- 4) Ensure that the participant has a nose clip in place. If the nose clip is uncomfortable for a participant, then instruct the participant to tightly pinch his nostrils shut throughout each maneuver.
- 5) Once the participant is connected to the spirometer, nose clip in place, and is breathing normally, press the space bar. This will prompt the computer to track the regular breathing of the participant.
- 6) Once you are both ready, instruct the participant take in as **deep** a breath as possible and press the space bar while they are inspiring.
- 7) Coach the participant through the FVC maneuver, encouraging him to blow out as hard as possible for at least 6 seconds (as seen at the red vertical line on the time axis on the screen) and until the red line tracking the participant's maneuver (on the right hand graph) becomes flat. Watch the participant inspire deeply and then shout "BLAST OUT!!!" Lower your voice a bit and coach the participant by saying "keep going...keep on pushing out all that air...a little bit more..."
- 8) Watch the body language of the participant as he attempts to follow your instructions. **Pay attention to him, not the instrument**.
- 9) Once he has "pushed" for at least six seconds and the participant tracking line has become flat and the "Good Effort" message appears over graph, push the space bar again to end the test, have the participant come off the mouthpiece, remove the nose clip and breathe normally.

Example Graph of the Spirometry Maneuver:



To summarize the testing process:

- Once the participant is connected to the spirometer with a nose clip on, push the space bar.
- After a couple of normal breaths, have the participant take as deep a breath as possible.
- While the participant is inspiring, press the space bar.
- As soon as the participant has reached maximal inspiration, have him blast out all the air in their lungs.
- Once he has blown out for at least 6 seconds **and** the graph of his breathing has become flat and you see the "Good Effort" message, push the spacebar to end the test. Whether or not the "Good Effort" message is received, end each FVC maneuver once the total expiratory time has exceeded 12 seconds, as indicated on the x-axis of the volume-time curve displayed real-time during the maneuver. (We have added this 12-second rule to reduce the risk of dizziness and syncope in participants with airflow obstruction, in whom end-of-test flow criteria may not be achievable in a reasonable expiratory duration.)

The quality of the effort is seen at the top of the right hand graph- the quality is graded on (1) the initial effort (Extrapolated Volume, or EV), (2) flatness of the line or reaching of RV, Residual Volume, (End of Test, as defined by flow of less than 30mL/sec, or EOT), and (3) total expiratory time (TET).

You can repeat testing by starting again (with the participant off the mouthpiece initially) by going back to #2.

If the participant fails to perform the maneuver correctly, **again** demonstrate both the error and the correct performance yourself. You may have to repeat the demonstration after every maneuver for some participants.

The participant will be coached to perform at least 3 FVC maneuvers and to perform additional maneuvers, up to a maximum of 8, until acceptability and reproducibility goals are met, as described below.

FVC Maneuver Acceptability

According to the ATS-ERS standards, the technician should coach every participant to obtain at least three maneuvers that are "acceptable." FHS uses current ATS-ERS standards to determine acceptability. For each FVC maneuver, the Collins CPL system displays a "+" or a "-" to indicate whether each of three acceptability criteria have been met. These acceptability criteria are:

- Extrapolated volume (EV): "+" = EV less than or equal to 0.15 L
- Total exhalation time (TET): "+" = TET 6 seconds or greater
- End of test criteria (EOT): "+" = expiratory flow is close to zero (less than 30 mL/sec), i.e. the plateau on the volume-time curve appears flat

To be considered acceptable, all three criteria must be met, i.e. three "+" signs (which will appear in green) must appear for the maneuver. If one of more criteria receives a "-" sign (in which case they will appear in red), the maneuver will be considered unacceptable. There will be two exceptions to this rule:

- 1. An EV of < 5% of the FVC for a given maneuver will be considered acceptable, per ATS-ERS guidelines, even if it is not less than 0.15 L and therefore does not receive a "EV (+)" designation by the CPL system. A table of EV values that are acceptable for a given range of FVC values is posted at the lung function testing station to facilitate this determination by the technicians.
- 2. Some people with significant airflow obstruction cannot reach the EOT criterion of a flat plateau on the volume-time curve within a reasonable exhalation time that avoids substantial discomfort and a risk of dizziness or even fainting. For this reason, any FVC maneuver that appears otherwise perfect but fails to reach meet the EOT criterion despite a TET of 12 seconds or greater will be considered acceptable.

Reproducibility goal of the test session

The technician should coach every participant to obtain **at least** three maneuvers that are "acceptable," as defined above. Once three acceptable maneuvers have been performed, the technician must assess whether the reproducibility goal has been met. The reproducibility goal has two components:

- 1) The two largest values of FVC must be within 0.150 L of each other
- 2) The two largest values of FEV1 must be within 0.150 L of each other

Note that the largest FVC and the largest FEV1 may come from different maneuvers.

If the reproducibility goal is met by the three acceptable maneuvers, then the test session is complete. If the reproducibility goal is not met, then additional maneuvers should be performed, up to a maximum of 8, until the reproducibility goal is met. **Remember that ONLY acceptable maneuvers should be considered when assessing whether the reproducibility goal has been met. Also remember that the reproducibility goal requires that the largest two values (not any two values) of FVC or FEV1 be within 0.150 L of each other.**

Maximum Number of Maneuvers

Don't exhaust the participant by asking him to perform more than **eight** FVC maneuvers. If you haven't obtained 3 acceptable maneuvers and met the reproducibility goal by the time you have done 8 maneuvers, it is unlikely that you will. Click on "Notes" which will bring you to a screen where you may add comments as to why the participant was not able to successfully complete testing.

Saving the Results

Once you have obtained three acceptable maneuvers and have met the reproducibility goal (or failed to do so after 8 tries and documented the why in the "notes" field), testing is complete. Now click on "Save."

d. Diffusion capacity

Setting up

After completing the FVC maneuvers-

- Click on "Go to"
- Click on "Diffusion Capacity"
- Click on "START TEST"

Preparing the participant

While the machine prepares, explain to the participant that he will be asked to breathe normally and then to blow all his air out, just like the Vital Capacity maneuver. Once his lungs are as empty as possible, the participant will be asked to breathe in as deeply and quickly as possible and hold his breath for 10-12 seconds. The machine will close a valve, helping him to hold his breath and making it impossible for air to leak out- he will not be able to breathe while on the mouthpiece until the tester tells the participant to blow all his air out for the second time.

Starting the Test

1) You will get a series of messages as the machine prepares. The machine includes the volume of the filter in the calculations.

- 2) The computer will then display the following message- "OK." Click OK and then once the next box pops up, have the participant connect to the mouthpiece. "Press the spacebar when the patient is connected to the mouthpiece and breathing normally." Ensure that the participant's lips are tightly sealed around the mouthpiece and that the nose clip is in place. Once the participant is attached and breathing normally, press the spacebar.
- 3) The graph will show the participant's tidal breathing. Once the participant is comfortable, have him breathe all the way out to Vital Capacity (the point at which the graph of his breathing becomes flat). Coach him, saying "Push, push, push" just as you would for the spirometry.
- 4) Once he has pushed all the air out, press the spacebar and **IMMEDIATELY** instruct him to take as deep an inspiration as possible. Ideally, the deep inspiration should take one to two seconds.
- 5) Once the graph of his breath has flattened out again at maximal inspiration, tell him to hold his breath.
- 6) Push the "V" key, as soon as his breath has flattened out at maximal inspiration, to close the valve and keep air from escaping. He must hold his breath for 10-12 seconds for the maneuver.
- 7) Once the participant's graph crosses the vertical line on the screen, IMMEDIATELY instruct him to blow out all the air (if you closed the valve, it will open automatically at 12 seconds), just as though he was performing spirometry.
- 8) Have the participant keep blowing until the red line becomes horizontal.
- 9) Once the red line is horizontal, press the spacebar, ending the test.
- 10) After each diffusion hit save.

To summarize-

- Once in the Diffusion Capacity menu, Click on "Start Test" and prepare the participant
- Once the machine is set up and you clicked ok, ensure that the participant is comfortable on the mouthpiece, with a good seal, and with a nose-clip in place.
- Press the spacebar.
- After several breaths, have the participant blow out all the air he can.

- Once the graph flattens out horizontally, push the spacebar, then **IMMEDIATELY** have him breathe in as deeply and quickly as possible and hold his breath.
- Once the participant has taken as deep a breath as possible and the graph flattens out again, push the "V" key to keep him from breathing out.
- When the graph of the participant's breath hold crosses the vertical line, **IMMEDIATELY** have him blow out all the air he can, much like with the spirometry maneuvers.
- Once the graph flattens out at maximal expiration, push the spacebar, ending the test.

Grading the Test

The screen will change, and the effort is graded at the top of the graph on the left. Five criteria are applied- Start of Test (SOT), Breath holding Time (BHT), End of Test (EOT), Air leak during breath hold (DRP), and Mouth Pressure (MP). If all five are acceptable, they will be displayed in green. If one criterion is not met, then all three appear in red. The failed criterion will have a (-) sign next to it. Review how to improve this result with the participant.

As with spirometry, maneuvers must be reproducible. For DLCO, two acceptable (all green effort marks) maneuvers must be within 10% of each other (i.e. 10% of the higher value).

Per ATS standards allow 4 minutes between tests. Note that the machine takes several minutes to set up. Use the clock on the computer to time the 4 minutes.

Repeat the maneuver from "Starting the Test" until you have two acceptable and reproducible maneuvers.

Limit the number of attempts for DLCO to 3 per participant.

Example Graph of the DICO Maneuver:



e. Respiratory questionnaire administration

The technician administers this questionnaire to the participant before starting the FVC. (Other questionnaires may be administered between diffusions). The questionnaire must be administered exactly as written. The answers are recorded in numbers, as indicated in the answer keys to the right of the questions. The technician follows the prompts on the questionnaire for the progression to follow, based on 'Yes', ("if yes fill in ...") and 'No' responses.

If a participant reports that he/she uses an inhaler "as needed" and it was last used more than 48 hours ago, code as 88.

f. Bronchodilator administration and post-bronchodilator spirometry

i) Subject selection

The selection of subjects who will undergo bronchodilator administration and postbronchodilator spirometry is described earlier in section 4. Briefly, all participants whose current pre-bronchodilator spirometry has **EITHER** a FEV1-to-FVC ratio less than 90 % of the predicted value **OR** a FEV1 less than 85 % of the predicted value will be asked to undergo post-bronchodilator testing.

ii) Bronchodilator administration

Albuterol information- We will administer 2 inhalations of albuterol HFA A. metered-dose inhaler 90 micrograms per actuation. Albuterol is a medication usually used to treat breathing problems like asthma or chronic obstructive pulmonary disease (COPD). The effects of albuterol last 3-4 hours. Participants with a history of adverse reactions to albuterol should not undergo this part of the protocol. Participants with episodic tachycardia or atrial fibrillation or ablation for AF should not be administered albuterol. At the doses we are using for FHS, only a small minority of participants would be expected to have side effects, and these side effects are listed in the "Consent Form." The side effects include: lightheadedness, an increase in heart rate (pulse) or symptoms of jitteriness or shakiness (tremors). For women who are < 55 years old and they qualify for albuterol (and do not have AF, tachycardia, cardiac ablasion, and have not refused albuterol): Check physician exam (after ppt has seen physician): IF the ppt is in menopause, has had a hysterectomy or tubal ligation = does not need pregnancy test prior to abuterol administration If ppt is NOT in menopause, has NOT had a hysterectomy or tubal ligation: MUST HAVE PREGNANCY TEST PRIOR TO ALBUTEROL **ADMINISTRATION**

В.

The administration of the albuterol will not take place until the participant has completed all other components of the exam. This will ensure that no other data will be affected by the possible side effects of albuterol.

- C. The participant will inhale two puffs of albuterol through a spacer. You should allow the participant to breathe normally for about a minute between inhalations, and there should be *no less than 10 minutes and no more than 15 minutes* between the administration of albuterol and the post-albuterol spirometry.
- D. Detailed step-by-step protocol for bronchodilator administration:
 - 1. Take the cap off the inhaler.
 - 2. Shake the inhaler.
 - 3. After shaking the inhaler, activate the inhaler in the air to check that it is operating adequately. Do this at arm's length from the technician and not near a participant, such that neither technician nor participants inhales it.(Note: When a new inhaler is being used for the first time, or if an inhaler has not been used for 2 weeks, activate 4 times before testing the first participant.)
 - 4. Attach the inhaler to one end of a tube spacer. (Note: Each tube spacer, which is disposable and for single participant use, is a 6-inch length of segmented tubing cut from a 100-foot roll.)

- 5. Have the participant breathe all the way out in a relaxed manner; there is no need to reach maximal exhalation (residual volume) by forcing out the maximum amount of air possible.
- 6. Insert just the tip of the spacer into the participant's mouth.
- 7. Have the participant start to take a **slow**, deep breath in.
- 8. Just as the participant starts to inhale, activate the inhaler **once** while encouraging the participant to keep inhaling all the way until he/she has reached the point of maximal inhalation (total lung capacity).
- 9. At that point of maximum inhalation, have the participant hold his/her breath for about 10 seconds. After this, instruct the participant to exhale normally and relax.
- 10. Wait 1 minute and repeat for another inhalation.
- 11. Following the second inhalation of albuterol, allow at least 10 minutes and no more than 15 minutes before doing post-bronchodilator spirometry.

g. Data Procedures after Participant Testing

Inserting Test Comments

At the end of testing, you may wish to insert comments regarding the ability of the participant to comply with testing. This is added at the end of testing, under the "Reports" menu.

- 1) Click on "Notes"
- 2) Type in your comments
- 3) Save & close

"Notes" Option

There is a tab on the upper left portion of the "Patient Information" page. If the technician has a comment regarding a participant that may be helpful for clinical interpretation (e.g. "patient having pain with deep breath due to bruised ribs after fall yesterday") or for quality review ("e.g. patient refused to go on after two efforts"), then this should be entered under "Technician Notes," followed by clicking "Save and Exit."

Examples of notes that should be put in computer:

- Reasons for unacceptable tests
- Reasons for aborted tests
- Refusals/Physical symptoms affecting performance of PFT

Printing Reports

The PFT report is printed after the test is reviewed and graded by a FHS physician (pulmonologist). After grading the test, this physician will select the "File" tab and click on "Print Report". The HP Deskjet 845c. is selected and 1 copy is printed.

Log Book

All participants are entered into the "PFT Daily Log, Comment, and Calibration" binder. Enter, by date, each participant name. An FHS generated sticker with the name and ID number can be used.

Participants Completing the PFT

Once the PFT is done (or not done), complete Procedures Sheet:

	Spirometry	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
	Image: Reason Spirometry not done	e 1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
II	Post Albuterol Spirometry	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
	Reason Post Alb. Spir. not done	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
	Diffusion Capacity	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
	Reason Diffusion not done	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other

Participants Not Having a PFT

Participants not having a PFT during their Clinic visit are also put in the "PFT Daily Log" binder with the reason that the PFT was not done.

Participants Refusing Bronchodilator Response Testing

Occasionally a participant who is asked to participate in the post-bronchodilator test refuses to do so. This refusal is recorded next to the participant's identifying sticker in the PFT Daily Log Book and the refusal reason is also noted under "technician notes" in the computer. Before the participant is asked to change and exited from the clinic, a second technician should ask the participant if he/she might be willing to perform the bronchodilator response testing.

Participant and MD Notification – PFT

Once a week the FHS pulmonary specialist comes into FHS and interprets with pulmonary function tests performed in clinic. He types a clinical interpretation on the participant's report and prints and signs one copy. He then delivers them to the Research Clinic Coordinator. The Research Clinic Coordinator makes a copy of each of the reports and gives them to the Statistical Technician. The Statistical Technician files the original copy in the participant's chart and the second copy is mailed to the participant's physician.

For incorrectly previously entered Data:

*Pull up the participant information by using the incorrect ID number and add to cache.

*Then, enter the correct number and fill in all of the correct information. (name, birth date, height, weight, technician number, gender and race.) <u>MAKE SURE TO ENTER</u> <u>THE ACTUAL TEST DATE.</u>

In the composition book PFT Log Book, write in the incorrect information (ID, DOB, etc) and then write in the correct information along with the date of exam. This log book will be used for any information that data may need (ID changes, machine changes, etc.)

10. Quality control observations of pulmonary function technicians by supervisor

Every three months, the clinic supervisor will observe each technician conduct a full pulmonary function test session on a participant. The supervisor will complete the following checklist for each observed session. Results will be reviewed with the technician and with physician-investigator overseeing pulmonary function testing at FHS. Constructive feedback will be provided as warranted. (Additional quantitative quality-control assessment of all pulmonary function data will be performed by the physician-investigator, with ongoing monitoring of study quality for each technician. Technician-specific feedback will be provided to optimize quality of all test procedures.)

Date:	Tech ID#	Quarter:
Supervisor:	Participant Label	

PFT Supervisor Checklist Clinic

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	PFT Instructions
		Ask the participant: In the past 3 months have you had: major
		surgery (chest, abdominal, or brain, requiring hospitalization),
		heart attack, stroke, aneurysm of the brain, cataract surgery,
		check BP(see list on wall) (Participants blood pressure MUST
		be taken prior to PFT Testing if not done by MD or Tonometry)
		Ask the participant: Do you currently have any limitation on
		physical activity prescribed by your doctor?
		If the participant is found to be ineligible due to the exclusion
		criteria the test is aborted and only the respiratory questions are
		completed & the reason is documented.

Yes	No	Spirometry/Forced Vital Capacity
		Position the Participant – Testing should usually be conducted
		in the sitting position on a chair without wheels. Ask the
		participant to sit erect with chin slightly elevated.
		Explain the Procedure - Explain that the purpose of the next
		test is to determine how hard and fast he can exhale air, "Like
		blowing out dozens of candles on a birthday cake." Explain
		that he should take in as deep a breath as possible, and when his
		lungs are completely full, blow out all the air as hard and fast as
		possible, until told to stop. Loose dentures should be removed.
		Always Demonstrate the Maneuver. Ask the participant to
		watch you perform the FVC maneuver. Again demonstrate
		correct placement of the mouthpiece. If the participant does not
		adjust well to using the mouthpiece (i.e. strong gag reflex) the
		participant can use just the neck of the filter for a mouthpiece.
		His lips must remain tightly sealed using this also. Sit up
		straight. Take a deep breath, throw back your shoulders, and
		widen your eyes to emphasize the maximal depth of inhalation.
		Then dramatically BLAST out all of your air as hard and as fast
		as you can.
		Have the participant connect to the spirometer with a nose clip
		on, push the space bar.
		After a couple of normal breaths, have the participant take as
		deep a breath as possible.

While the participant is inspiring, press the space bar.
As soon as the participant has reached maximal inspiration,
have them blast out all the air in their lungs.
Once s/he has blown out for at least 6 seconds and the graph of
his breathing has become flat and you see the "Good Effort"
message, push the spacebar to end the test.
If the participant fails to perform the maneuver correctly, again
demonstrate both the error and the correct performance
yourself.
The participant is not asked to perform more than eight FVC
maneuvers
Once the participant has 3 acceptable tests, click Save.
The technician correctly assessed reversibility of the 3
acceptable tests.
Staff looks at the FEV1/FVC ratios and, if they are <70%, the
staff member asks the participant if he would do a reversibility
testing with albuterol and a brief explanation of this is given.

Yes	No	Diffusion Capacity
		After completing the FVC maneuvers-
		• Click on "Go to"
		Click on "Diffusion Capacity"
		Click on "START TEST
		Preparing the participant: While the machine prepares, explain
		to the participant that he will be asked to breathe normally and
		then to blow all his air out, just like the Vital Capacity
		maneuver. Once his lungs are as empty as possible, the
		participant will be asked to breathe in as deeply and quickly as
		possible and hold his breath for 12 seconds. The machine will
		close a valve, helping him to hold his breath and making it
		impossible for air to leak out- he will not be able to breathe
		while on the mouthpiece until the tester tells the participant to
		blow all his air out for the second time.
		1 <u>Starting the Test:</u> The box will pop up on the computer, hit
		ok. Do not have them attach to the mouthpiece until this
		done. The computer then will display the following
		message- "Press the spacebar when the patient is connected
		to the mouthpiece and breathing normally." Ensure that the
		participant's lips are tightly sealed around the mouthpiece
		and that the nose clip is in place. Once the participant is
		attached and breathing normally, press the spacebar

2 The graph will show the participant's tidal breathing. Once
the participant is comfortable, have him breathe all the way
out to Vital Capacity (the point at which the graph of his
breathing becomes flat). Coach him, saying "Blow it out,
blow it out" just as you would for the spirometry
3 Once he has pushed all the air out, press the spacebar and
IMMEDIATELY instruct him to take as deep an inspiration
as possible. Ideally, the deep inspiration should take one to
two seconds.
4 Once the graph of his breath has flattened out again at
maximal inspiration, tell him to hold his breath. He must
hold his breath for 10-12 seconds for the maneuver.
Push the "V" key, as soon as his breath has flattened out at
maximal inspiration, to close the valve and keep air from
escaping.
Once the participant's graph crosses the vertical line on the
screen, IMMEDIATELY instruct him to blow out all the air (if
you closed the valve, it will open automatically at 12 seconds),
just as though he was performing spirometry.
Have the participant keep blowing until the red line becomes
horizontal
Once the red line is horizontal, press the spacebar, ending the
test.
Wait 4 minutes between each maneuver. Do not start the set up
until 2 minutes have passed.
Repeat the maneuver from "Starting the Test" until you have
two acceptable and reproducible maneuvers.
Grading the test: Confirm that both tests are acceptable, they
will be displayed in green. If one criterion is not met, then all
three appear in red. The failed criterion will have a (-) sign next
to it. Review how to improve this result with the participant.
Then do another maneuver.
Limit the number of attempts for DLCO to 3 per participant.
Once the participant has 2 acceptable test click save.
If there is a comment regarding a participant that is beneficial
and should be saved, enter the comment under "Technician
Notes" and then click on "Save and Exit."

Yes	No	Albuterol Participants/Spirometry/FVC
		Any participant that has a FEV1/FVC ratio of <70% (either pre-
		identified or identified in clinic) is asked to participate in the
		albuterol challenge.
		The administration of the albuterol is given after all of the other

Framingham Heart Study

Manual of procedures for pulmonary function testing – Offspring cohort, Exam 9 v. April 1, 2011

6	exam components have been completed.			
	Getting ready			
	1. Shake the inhaler.			
	2. Take the cap off the inhaler.			
	3. Attach the spacer to the inhaler.			
	Using the MDI			
	1. Have the participant breathe all the way out.			
	2. Insert just the tip of the spacer into the participant's mouth.			
	3. Have the participant start to take a deep breath.			
	4. As the participant starts breathing in slowly through their			
	mouth, actuate the inhaler (press down on the inhaler) one			
	time.			
	5. Have the participant keep breathing in slowly , as deeply as			
	they can.			
	5			
	6. Have the participant hold their breath as you count to 10			
	slowly, if they can.			
	7. Wait about 1 minute between puffs.			
	8. Allow at least 15 minutes and no more than 30 minutes			
	before doing post-bronchodilator spirometry.			
r	The spirometry/FVC protocol is performed according to the			
	same protocol above.			
	F			

Yes	No	PFT Completion
		Respiratory questionnaire is administered. Questions are asked exactly as they are listed on the page.
		All participants are entered into the "PFT Daily Log, Comment, and Calibration" binder. Enter, by date, each participant name. An FHS generated sticker with the name and ID number can be used.
		Once the PFT is done, fill out Procedures Sheet
		Participants not having a PFT during their Clinic visit are also put in the "PFT Daily Log, Comment and Calibration" binder with the reason that the PFT was not done.
		PARTICIPANTS REFUSING THE ALBUTEROL CHALLENGE: Occasionally a participant who is asked to participate in the post-bronchodilator test refuses to do so. This refusal is recorded next to the participant's identifying sticker in the PFT Daily Log Book and the refusal reason is also noted.
		· · ·

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?

Did the technician ask the questions exactly as written on the form?
Did the technician correctly clarify any questions the participant had?
Did the technician correctly use the answer key?
Did the technician score the participant's responses correctly?
Did the technician review the form for completeness?

Yes	No	Deviations			
		Did the tech perform any minor deviations?			
		Did the tech perform any major deviations?			
Comm	Comments/Corrections/Deviations:				
Superv	Supervisor Signature:				
Date:					

11. Pulmonary function data back-up

Backing up the PFT Database:

Cumulative backup is performed once a week by the Desktop Support Specialist.

- 1. Login to the computer as FHS-DT-PFT\Valued Customer.
- 2. Close the nSight Program, if open.
- 3. Go to Start \rightarrow All Programs \rightarrow nSpire Health \rightarrow nSight \rightarrow Database Backup Wizard
- 4. Select "nSight DB2" from the database list and click Backup.
- 5. Save the backup on the desktop with the filename "PFTBackupmmddyyy.bak".
- 6. Once the backup is complete, connect to using the

FHS\Clinic domain account. (Note: There should be a mapped drive in My Computer to this location.

7. Create a folder called "PFT Backup mmddyyyy".

8. Copy and paste (or drag and drop) the backup file from the desktop to the newly

created folder. (Note: This may take a few minutes to copy.)

- 9. Once you verify the backup is in the proper folder, delete the backup off of the desktop.
- 10. Log out or lock the computer once you are finished.

Backup Storage:

Data stored in the ClinicUsers folder is backed up weekly to data tape by the FHS IT Department. These tapes are then sent offsite monthly for storage with Retrievex. Please contact **Mathematica**, FHS IT Manager with questions or access to the offsite data.

Other Database Tasks:

Before manipulating the database to do any other tasks except for using the nSight program or database backup, it is recommended that you contact the product's Technical Support to ensure you do not damage the database.

Updated: October 2011 by for FHS-DT-PFT.fhs.org

12. Pulmonary function equipment maintenance schedule

Maintenance information taken from:

<u>The Instruction Manual for the Collins Comprehensive Pulmonary Laboratory (CPL)</u> No. 760096, Version August 2000

<u>Item</u> Cleaning of CPL Covers and External Components	<u>Frequency</u> As Needed
Replacing CO ₂ Absorbent Cartridge	Every 3 Months
Replacing Desiccator Columns	When Blue Granules turn Pink
Replacing Balloon Cuffs in Valve*	As Needed
Cleaning of Balloon Valve	As Needed
Change Nafion Tubing	Every 4 months
3.00 Liter Hans Rudolph	Annually
Send to: Calibration Syringe nSpire Health 1830 Lefthand Circle	

1830 Lefthand Circle Longmont, CO 80501

* The balloons must be inflated and deflated 50 times before use. We have an extra balloon valve so that a full set of balloons are prepped and readied for use. The valves are switched with the prepped balloons already attached when needed.

13. Calibration syringe exchange

Once the replacement syringe is received at FHS, remove it from the shipping box for usage and **<u>immediately</u>** insert the syringe FHS has been using into the same box for return to nSpire Health via FHS carrier of choice. It is **<u>important</u>** that RMA 16672 is written on the outside of this box and also insert the fax sheet into the box. Ship the syringe to: nSpire Health, 1830 Lefthand Circle, Longmont, CO 80501. File the enclosed calibration certificate in the FHS logbook or files.

Calibration Syringe Care

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 syringes.

ALBUTEROL LOT NUMBERS

EACH TIME A NEW ALBUTEROL INHALER IS OPENED, PLEASE RECORD THE STOP DATE OF THE PREVIOUS ONE AND THE LOT NUMBER AND START DATE OF THE NEW ONE.

LOT NUMBER	START DATE	STOP DATE

Maintenance Tracking Form

	PFT PERIODIC MAINTENANCE 2008						
Cleaning CPL Covers	Replacing CO2 Absorbent Cartridge	Replacing Dessicator Columns	Replacing Balloons (and Prepping)	Balloons Valve	Change Nafion Tubing	Collins Syringe Calibra- tion	Mainte- nance
(prn)	(q.3mos)	(blue pink)	(prn)	(prn)	(q.4mos)	(annually)	(annually)

Air Gas Order Form

Air Gas 1-800-562-3815



PFT DAILY CALIBRATION

Read all prompts

- Minimize nSight (Patient Information)
- Shortcut to Plus CPLDiag
- Component = CPL (SN: SI0034)
- Balloon check: check all boxes and click on Inflate
- Deflate

LEAK TEST

Put round weight on bell

- Leak Test
- Component = CPL
- S Delay = 20
- Duration = 60
- Start
- ≤ -20 is ok. CANNOT HAVE ≥ -20. IF DO, REDO CALIBRATION (optimum = 0 to -14)

TOOLS (under nSight)

- (Follow prompts)
- Calibration
- *CPL (click on "+")
- Barometric pressure (highlight and make drop-downs visible)
- Calibrate
- Calibrate
- Temp (leave temp that is shown on screen = machine temp)
- Enter
- Humidity
- Enter
- Barometric pressure (leave barometric press that is shown on screen)
- Enter
- Continue

SPIROMETER

- Calibrate
- Calibrate (bell goes up)
- Attach syringe
- Press space bar
- Pull out syringe at constant pace
- Press space bar
- Push in at constant pace
- Press space bar
- All lines should have a green square = Valid. If not, repeat calibration
- Continue

PNEUMOTAC

- Calibrate
- Calibrate
- Continue
- Continue
- Press space bar
- Pull out syringe
- Press space bar
- Press space bar
- Push in syringe (push in before "4")
- Space bar
- Continue
- Verify
- Close

Take off syringe

DL GAS ANALYZER

- Calibrate
- Next (all must be "Valid" in green)
- Next
- If "Failed" repeat DL Gas calibration ONLY
- If "Passed" press Finish

REPORT

- Check all boxes EXCEPT MOUTH PRESSURE
- Print
- Write initials at bottom of report
- Put printouts in white binder on low shelf in front of scale

END

- Minimize nSight
- Shortcut to Plus CPL Diag
- Component = CPL
- Close
- Enlarge Raptor

Daily PFT Log – Offspring Exam #9/Omni Exam #4

Date	Participant	Comments	Tech

PFT PERIODIC MAINTENANCE

r					1	1
	Replacing		Replacing			
	CO2	Replacing	Balloons	Cleaning	Change	Collins
Cleaning	Absorbent	Dessicator	(and	Balloon	Nafion	Syringe
CPL Covers	Cartridge	Columns	prepping)	Valve	Tubing	Calibration
(prn)	(q. 3mos)	(bluepink)	(prn)	(prn)	(q. 4 mos)	(annually)
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PFT NOTE	S					
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Yearly Maintence by Field Service Tech

ALBUTEROL LOT NUMBERS

EACH TIME A NEW ALBUTEROL INHALER IS OPENED, PLEASE

RECORD THE STOP DATE OF THE PREVIOUS ONE AND

THE LOT NUMBER AND START DATE OF THE NEW ONE.

LOT NUMBER	START DATE	STOP DATE