

**Attachment 8 Spirometry SOP**

## I. BACKGROUND

Spirometry may be used to measure lung function volume during forced breathing maneuvers. The important measurements include: forced vital capacity (FVC) or the greatest volume of air exhaled from a maximal inspiration to a complete exhalation, the forced expiratory volume in one second (FEV1) or the volume of air exhaled in the first second of a FVC maneuver, and the ratio between these two values (FEV1/FVC). All procedures will conform to current American Thoracic Society (ATS) and the 2020 American College of Occupational and Environmental Medicine (ACOEM) guidelines.<sup>1</sup> Test results will be compared to predicted and lower limit of normal values determined from the third National Health and Nutrition Examination Survey (NHANES III) reference equations.<sup>2</sup>

## II. INDICATIONS

To detect obstructive, restrictive, and mixed lung function patterns.

## III. CONTRAINDICATIONS<sup>3</sup>

1. Hemoptysis (coughing up blood)
2. Pneumothorax (collapsed lung)
3. Chest pain, myocardial infarction (MI), or stroke within the last 3 months
4. Abdominal (belly) or cerebral (brain) arterial aneurysm
5. Eye surgery including LASIK within the last 3 months
6. Acute disorders that might affect subject performance during testing: e.g., chest, back or gastrointestinal (GI) distress/discomfort
7. Chest or abdominal surgery within last 3 months
8. Systolic Blood Pressure >180 or Diastolic Blood Pressure >110 mmHg or pulse rate > 110 beats per minute (See Appendix 4 for Blood Pressure Measurement Protocol)

If any of the contraindications are present, the technician will not proceed with the test.

## IV. DESCRIPTION OF EQUIPMENT AND SUPPLIES

Spirometry will be conducted in a private room, and the ambient temperature will be maintained between 17 and 40°C (62.6-104°F).<sup>3</sup>

- Volume Spirometer (See Appendix 2 for manufacturer contact information):
  - o Ohio 822/ 827 or SensorMedics 922 or 1022 dry rolling seal with digital volume encoder to RS232 interface
  - o OMI-HF5 spirometry software program (most recent NIOSH version) installed on a notebook computer
  - o Calibration syringe (3.00 liters- Hans Rudolph model #5530)

- o Spirometer hoses (#894787 2" ID x 28" length- SensorMedics)
  - o Spirotube mouthpieces (1/16" OD x 3 3/16 " length- SensorMedics)
  - o Mouthpiece adaptors – hose reducer (#894788 2" OD, 11/16" ID - SensorMedics)
  - o Nose clips
  - o Miscellaneous supplies: pens, log sheets, barometer, first aid kit (including ammonia capsules), tape measure, scale, germicidal disposable cloths, tissues, memory stick, stopcock grease, room thermometer, waste basket
- Flow Spirometer (See Appendix 2 for manufacturer contact information):
    - o EasyOne™ diagnostic spirometer with EasyWare™ software installed on a notebook computer and a USB Connector Spiro Screen or an EasyOnePro™ system.
    - o Calibration syringe
    - o Syringe adapter
    - o Spirette™ mouthpieces (or SDI mouthpiece)
    - o Nose clips
    - o Miscellaneous supplies: pens, log sheets, barometer, first aid kit (including ammonia capsules), tape measure, scale, germicidal disposable cloths, tissues, memory stick, room thermometer, waste basket

## **V. PREPARATION AND CALIBRATION OF EQUIPMENT**

### Before Site Visit

1. Calibrate spirometers and verify them to be in correct operating condition. Verify that software parameters are correctly defined (for volume spirometers see Appendix 1, Part A, for flow spirometers see Appendix 1, Part B).

### At Site

1. Set up equipment and connect cables. Connect power cords to grounded electrical receptacles.
2. Turn on the spirometer and then the computer.
3. Record room temperature and barometric pressure.
4. Perform volume calibration and leak check using 3-Liter syringe (repeat after every 4 hours of testing).
5. Perform biological control test at beginning and end of each testing session.

## **VI. PRE-TEST PROCEDURE**

1. Measure and record height and weight of subject without shoes.
2. Measure and record blood pressure and pulse rate of subject (see Appendix 4 for procedure for obtaining blood pressure). Record blood pressure on wallet card and give to subject for their records. If blood pressure or pulse rate is a contraindication for

spirometry (Systolic Blood Pressure >180 or Diastolic Blood Pressure >110 or pulse rate > 110 beats per minute), explain to the subject the reason the test will not be performed and advise the subject to seek immediate guidance from their physician. If blood pressure or pulse rate are elevated (Systolic Blood Pressure between 120 and 180, or Diastolic Blood Pressure between 80 and 110, or pulse rate between 100 and 110 beats per minute) and the test can still be performed, advise the subject to recheck their measurements within a week and if still elevated to seek guidance from their physician.

3. Administer the pre-test questionnaire and record if contraindications are present (see Appendix 3).
4. Do not perform test if any contraindications are present.

## VII. TEST PROCEDURES

1. Explain the purpose of the examination and the need for maximal effort from the subject to get accurate results. Tell the subject, "I want to measure how much air you can blow out and how fast you can blow it out."
2. Ask the subject to loosen any tight clothing.
3. Ask the subject to stand during the examination. If unable to perform the test standing, encourage the subject to sit up straight. Record whether subject is sitting or standing.
4. Demonstrate a deep inspiration and proper placement of the mouthpiece.
5. Blast out the air in a demonstration of the effort and length of time you expect the subject to blow.
6. Prepare the spirometry system for collection.
7. Place nose clip on subject's nose. Clips may be removed between trials. If the nose clip falls off or is uncomfortable, ask the subject to hold their nose during the FVC maneuvers.
8. Encourage the subject to stand/sit up straight and not lower chin or bend over. Emphasize not straining with the neck but pushing from the belly.
9. Give the following instructions (enthusiastic coaching is required, shouting is not):
  - a. "Open your mouth, take the largest breath of air that you can inhale, while holding the hose near your mouth."
  - b. "Quickly, put the mouthpiece into your mouth and seal your lips tightly around it. Blast your air into the tube as hard and fast as you can."
  - c. "Keep on blowing out the same breath of air until I tell you to stop."
  - d. Coach: "keep blowing, keep going, almost there," until plateau is observed.
  - e. "You can stop now."
  - f. "Okay, now catch your breath."
10. Review the procedure and correct any problems at the end of each trial. Flow-volume curves should have sharp peak flows and volume-time curves must have a plateau and at least 6 seconds of exhalation. Record your impression of the subject's effort at the end of each trial.
11. Continue testing until three acceptable trials are completed and the repeatability criteria are met or until a maximum of eight trials have been performed, or until the subject cannot or should not continue (see Appendix 5 for acceptability and repeatability criteria).

## VIII. QUALITY CONTROL PROGRAM

### Equipment

The Medical Instrumentation Laboratory (DRDS/FSB) maintains all spirometers, as well as detailed records of calibration results, equipment repairs or modifications, dates of software and hardware changes, and the dates and location of equipment use. Periodically, the accuracy and repeatability of the spirometers is evaluated over a range of mechanically-simulated exhalation maneuvers.<sup>1</sup>

### Test Quality

Every spirometry test is given two overall quality grades, one for the measurement of FVC and one for the measurement of FEV1. The grades are assigned using the following definitions:

- FVC Quality Grade:
  - A = at least three acceptable trials, highest two FVC values match within 100 ml (or within 50 ml if highest FVC from last trial)
  - B = at least two acceptable trials, highest two FVC values match within 150 ml
  - C = at least two acceptable trials, highest FVC values match within 250 ml
  - D = only one acceptable FVC trial
  - F = no acceptable FVC trials
  
- FEV1 Quality Grade:
  - A = at least three acceptable trials, highest two FEV1 values match within 100 ml (or within 50 ml if highest FEV1 from last trial)
  - B = at least two acceptable trials, highest two FEV1 values match within 150 ml
  - C = at least two acceptable trials, highest FEV1 values match within 250 ml
  - D = only one acceptable FEV1 trial
  - F = no acceptable FEV1 trials

The quality of all spirometry tests is reviewed by a quality control specialist. Quality control reports are generated and provided to each spirometry technician. If coaching deficiencies are identified during this review, technicians receive additional training prior to the next testing session.

## IX. SAFETY PROCEDURES

1. To prevent electrical shock, all equipment will be plugged into a grounded electrical outlet.
2. Infection control measures:
  - When a volume spirometer is used, a clean hose or mouthpiece filter will be used for each subject.
  - Only disposable mouthpieces will be used.
  - Mouthpieces are handled only by the subject.

- Spirometers and accessories will be cleaned and disinfected daily.
- 3. Technicians will have successfully completed a National Institute for Occupational Safety and Health (NIOSH) spirometry training course and will have been supervised while testing 20 subjects by a trained and experienced technician.
- 4. Subjects in wheelchairs will perform the test while seated in their wheelchairs. Wheelchair wheels will be locked prior to testing.
- 5. A non-rolling chair will be placed behind subject during the test.
- 6. Subjects that become faint or tired may sit for the remainder of the test.

## **X. EMERGENCY PROCEDURES**

1. An emergency card will be present at the test site. This card will include:
  - Instructions to call 911.
  - Arrangement information for transportation to the nearest hospital.
  - Address and telephone number for the nearest hospital.
2. A subject who feels faint during testing will be guided onto a stationary chair and encouraged to lower their head towards their knees and to breathe slowly and deeply until recovered.

## **XI. REFERENCE LIST**

1. Miller MR, Hankinson J, Brusasco V, et al, ATS/ERS Task Force. Standardisation of spirometry. *Eur Respir J*. 2005 Aug; 26(2):319-338.
2. Hankinson JL, Odencrantz JR, Fedan KB. Spirometric reference values from a sample of the general U.S. population. *Am J Respir Crit Care Med* 1999; 159:179-187.
3. AARC (American Association for Respiratory Care) clinical practice guideline. Spirometry: 1996 update. *Respir Care* 1996; 36:629-636.

# APPENDIX 1

## Part A: Volume Spirometer Setup Parameters

**OMI Spirometry Configuration Setup Screen 2**

Barometric Pressure: 760 mmHg  
 Leak Volume: 40 ml  Request BP on Startup  
 Repeatability Criteria: 150 ml  
 PEF Repeatability Percent: 20 %  
 Plateau Volume: 25 ml  
 Plateau Time: 1 seconds  
 Time Check Percent Allowed: 02.0 %  
 Extrapolated Volume Criteria: 150 ml  
 MVV Test Time: 12 seconds  
 Communications Port: 1  
 Test Start Method: Auto  
 Save Tidal Volume with SVC Curve  
 Starting Session Number: 50  
 Allow temporary change of database path  
 Report Header:  
 Limit data to selected company

**Nomograms**

	Scale Factor
Caucasian: Hankinson(C)-1996	1.00
Black: Hankinson(B)-1996	1.00
Asian: Caucasian	0.94
Hispanic: Hankinson(H)-1996	1.00
Other 1 (D): Caucasian	1.00
Other 2 (E): Caucasian	1.00

**NIOSH08 Interpretation Algorithm**

Computer Automated Interpretation [? Help](#)

Select Link File: C:\Program Files\OMI\Spirometry 2003\

Edit Link Create Link File Create Database

**Report Options**

Detailed Session Report  
 Overview of Session Report  
 Volume/Time and Flow/Volume Graphs  
 Large Flow/Volume Graphs  
 Large Volume/Time Graphs  
 Overlap Curves on Graphs  
 Include Baseline Comparison  
 Black and White Printer Only  
 Disable Box (yellow) on values below LLN

**TrendGram Options**

Absolute  %Pred  %Deviation

Next Screen Main Screen Cancel

**OMI Spirometry Configuration Setup Screen 3**

Enter Manual Temperature  
 Save Raw Data  
 Save Results in Text File (EMP\*.ATS)  
 Save Results in PFTVALS.TXT  
 Require Operator Password  
 Use FET < 6s Criteria  
 Draw Inspiration During Maneuver  
 Use Largest PEF  
 Use PEF Acceptability Criteria  
 Check End of Test Plateau  
 Use Cough Detector  
 Use Time to PEF  
 Enter Client's Effort  
 Enter 4-Level Curve Assessment  
 Enter Deviations from Test Criteria  
 Enter Pre-Test Questions (option)  
 Enter Post-Test Questions  
 Edit Remarks after Test  
 Use Open Circuit Method  
 Enter Client's Testing Position  
 Verify Height and Date  
 Perform SVC and/or MVV Tests  
 Require Save Calibration  
 Enable Display of Quality Fac  On Report  
 Enable ATS 2005 Test Goals  
 Remove Dashes from ID  QF Codes  
 Require PEF Repeatability for Repeatable Test (FVC and FEV1 already set)

Best Test: ATS Criteria (Largest Value)  
 Date Format: mm/dd/yyyy  
 Height Units: inches  
 Weight Units: lbs  
 Force Confirmation of Ht and Wt

**Parameter List - Check to Print**

<input type="checkbox"/> SVC	<input type="checkbox"/> FEF25-75%
<input type="checkbox"/> MVV	<input type="checkbox"/> FEF.1-1.2
<input type="checkbox"/> FEV0.5	<input type="checkbox"/> FEV0.5/FVC%
<input type="checkbox"/> FEV3	<input type="checkbox"/> FEV1/SVC%
<input checked="" type="checkbox"/> FEV6	<input type="checkbox"/> FEV3/FVC%
<input type="checkbox"/> FEF25%	<input type="checkbox"/> FEV1/FEV6%
<input type="checkbox"/> FEF50%	FVC, FEV1 and
<input type="checkbox"/> FEF75%	FEV1/FVC% always
<input checked="" type="checkbox"/> PEF	printed.

Return to Selected Screen  
 Screen 1 Main Screen

Select Default Path for Copying/Exporting Files: C:\Program Files\OMI

**Criteria for Excluding curve from Best Test**

Time to PEF **Current Setting ATS**  
 PEF Acceptability (Low PEF)  
 Less than 6-seconds  
 No Plateau  
 Large Extrapolated Volume  
 Cough

Add/Edit Operators  
 Cancel Print Configuration  
 Exit and Save All Screen Information  
 Hit F1 key for Help





## Part B: Flow Spirometer Setup Parameters

**EasyOne Device Configuration**

Test Configuration | **General Configuration** | Report Configuration

Predicted source: Nhanes III  
Additional pediatric: ---  
Value selection: Best value  
Interpretation: Off  
Automated QC: On  
FVC selection: FVC  
PEF unit: L/min  
Storage Option: 3 best curves  
Lung Age: Off

Ethnic corrections:  
African: 88  
Asian: 100  
Hispanic: 100  
Other: 100

OK Cancel Apply

**EasyOne Device Configuration**

Test Configuration | **General Configuration** | Report Configuration

Time Format: am / pm  
Date Format: MM/DD/YY  
Alphanumeric ID: No  
Technician ID: No  
Syringe Volume: 3.0 liter  
Altitude [ft]: 0  
Humidity [%]: 40

Height unit: feet / inch  
Weight unit: pounds  
Temperature unit: Fahrenheit  
Age or birth: Birth  
Language: English  
Mode: Diagnostic

OK Cancel Apply

**EasyOne Device Configuration**

Test Configuration | **General Configuration** | Report Configuration

Custom Header: [ ]  
Printer type: HP black  
Data: 3 best data  
Graph: Small FV VT  
Curve: 3 best curves

OK Cancel Apply

## **APPENDIX 2**

### Manufacturer Contact Information

SensorMedics Spirometer  
22705 Savi Ranch Parkway  
Yorba Linda, CA 92887-4645  
Phone: (714) 283-1830  
(800) 520-4368

OMI –HF5 spirometry software program  
Occupational Marketing, Inc.  
11211 Kathy Freeway Ste 420  
Houston, TX 77079  
Phone: (713) 468-3201

EasyOne™ Spirometer (including EasyWare™ software)  
nnd Medical Technologies  
17 Progress Ave  
Chelmsford, MA 01824  
Phone: (978) 244-0620

Spirotube mouthpieces  
Occupational Marketing, Inc.  
11211 Kathy Freeway Ste 420  
Houston, TX 77079  
Phone: (713) 468-3201

Calibration syringes  
Hans Rudolph, Inc.  
7200 Wyandotte  
Kansas City, MO 64114  
Phone: (816) 363-5522

Nose clips  
Medical Graphics Corporation  
350 Oak Grove Parkway  
St. Paul, MN 55127  
Phone: (651) 484-4874

Spirette mouthpieces  
nnd Medical Technologies  
2 Dundee Park  
Andover, MA 01810  
Phone: (877) 904-0090

**APPENDIX 3**

Control Card

**Project Name**

Subject ID	Name		
Birthdate	Age	Gender	
Height (Nearest ½ inch)	Weight (pounds)	Blood Pressure	Pulse
Current Medications/Eye Drops/Inhalers			
<b>Initial when complete:</b>	Questionnaire	Methacholine	
	Spirometry		
	Bronchodilator		

<p><b>Spirometry Contraindications: YES / NO</b>                  Within the last 3 months: chest pain (angina), heart attack, stroke, eye surgery (including LASIK surgery), chest/abdominal surgery                  Ever: coughing up blood, collapsed lung, arterial aneurysm of the belly or brain                  Current: gastrointestinal distress, chest discomfort, back discomfort                  Systolic BP <math>\geq</math>180, diastolic BP <math>\geq</math>110, pulse &gt;110 bpm</p>	
<p><b>Bronchodilator Contraindications: YES / NO</b>                  History of irregular heart beat (arrhythmia)                  Systolic BP &gt;160, diastolic BP &gt;100, pulse &gt;100 bpm</p>	
<p><b>Methacholine Challenge Contraindications: YES / NO</b>                  History of irregular heart beat (arrhythmia), known pregnancy, breastfeeding, on oral/eye drop beta-blocker medication                  Systolic BP &gt;160, diastolic BP &gt;100, pulse &gt;100 bpm, FEV1 &lt;70% predicted, FEV1 &lt;1.5 liters, poor reproducibility of FEV1</p>	
	<p>Use of short-acting bronchodilator within last 4 hours? <b>YES/NO</b>                  Use of intermediate or long-acting bronchodilator on morning of test? <b>YES/NO</b>                  Smoked within last 2 hours? <b>YES/NO</b>                  Respiratory infection within last 4 weeks? <b>YES/NO</b></p>
<p><b>Predicted FEV1</b> _____ <b>Best FEV1</b> _____ <b>Best %predicted FEV1</b> _____  <b>FEV1 after MCT</b> _____ <b>% decline FEV1 from personal best after MCT</b> _____                  Treatment after MCT _____                  Best FEV1 after treatment following MCT _____</p>	



## APPENDIX 4

### Blood Pressure Measurement Protocol

1. Ask the subject to refrain from smoking or ingesting caffeine for 30 minutes prior to blood pressure measurement.
2. Have the subject sit quietly for at least 5 minutes before taking blood pressure.
3. Seat the subject with feet flat on the floor. Ask the subject to bare their upper arm. Support the subject's arm at heart level.
4. Select appropriate cuff size (bladder should encircle at least 80% of the upper arm).
5. Measure and record blood pressure.
6. If Systolic Blood Pressure  $>180$  or Diastolic Blood Pressure  $>110$ , then wait 2 minutes and take and record a second blood pressure measurement. If Systolic Blood Pressure  $\leq 180$  and Diastolic Blood Pressure  $\leq 110$  on the second measurement, use the second measurement when determining contraindications.

## **APPENDIX 5**

### Quality Assessment

#### Acceptability Criteria

The following criteria will be used to judge whether a trial is acceptable:

- No hesitation or false starts
- The volume of back-extrapolation ( $V_{ext}$ ) must be less than 5% of the FVC or 150 ml, whichever is greater
- No coughing during the first second
- No glottis closure
- No mouthpiece obstruction by tongue or dentures
- No leaks
- A plateau in the volume-time curve is achieved with at least 6 seconds of exhalation
- No extra breaths

#### Repeatability Criteria

After collecting three acceptable trials, the following criteria will be used to judge whether a test is repeatable:

- The two largest FVC values from acceptable trials should agree within 150 ml
- The two largest FEV1 values from acceptable trials should agree within 150 ml