Attachment 8 Spirometry SOP

Form Approved
OMB NO. 0920-xxxx
Expiration Date: xx/xx/20xx

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.[1] 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.[2]

II. INDICATIONS

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

III. CONTRAINDICATIONS[3]

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).[3]

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

- Spirometer hoses (#894787 2” ID x 28” length- SensorMedics)
- Spirotube mouthpieces (1/16” OD x 3 3/16 ” length- SensorMedics)
- Mouthpiece adaptors – hose reducer (#894788 2” OD, 11/16” ID - SensorMedics)
- Nose clips
- 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):

  - EasyOne™ diagnostic spirometer with EasyWare™ software installed on a notebook computer and a USB Connector Spiro Screen or an EasyOnePro™ system.
  - Calibration syringe
  - Syringe adapter
  - Spirette™ mouthpieces (or SDI mouthpiece)
  - Nose clips
  - 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.[1]

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

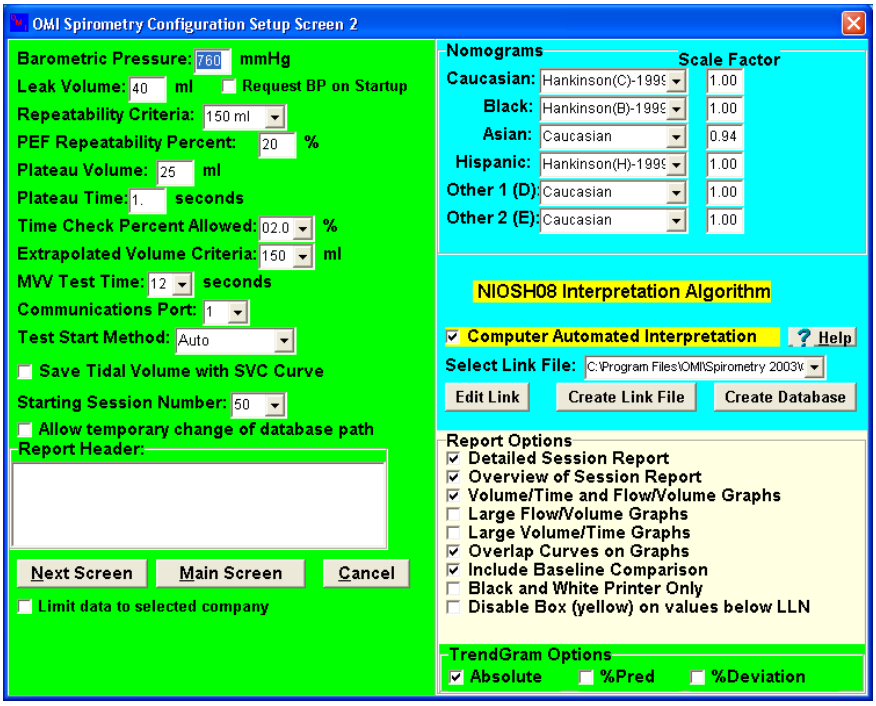
1. An emergency card will be present at the test site. This card will include:
   - Instructions to call 911.
   - Arrangement information for transportation to the nearest hospital.
   - Address and telephone number for the nearest hospital.
2. A subject who feels faint during testing will be guided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

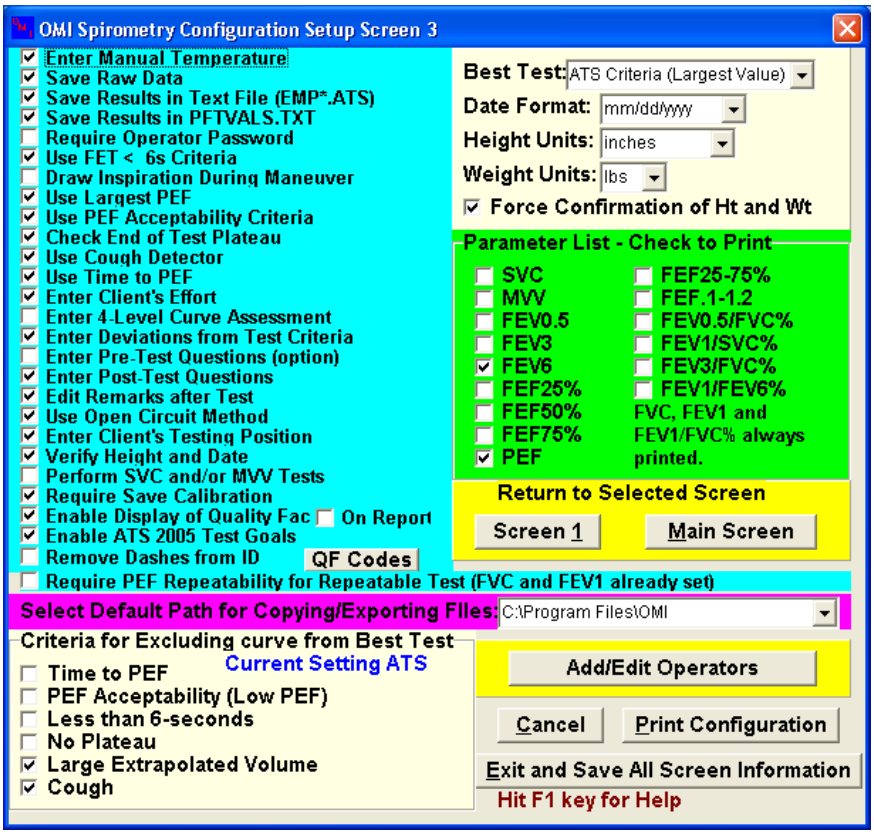
XI. REFERENCE LIST

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.

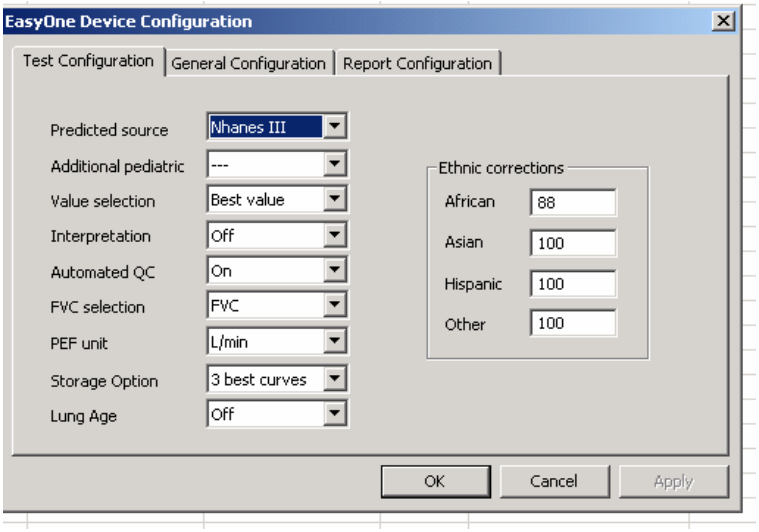
APPENDIX 1

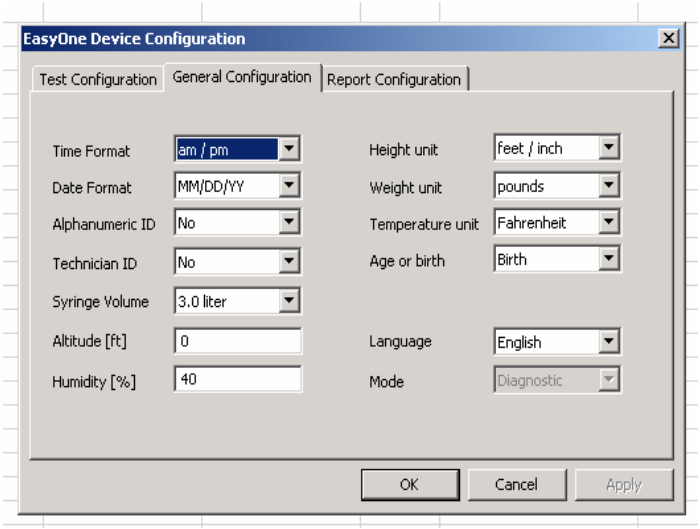
Part A: Volume Spirometer Setup Parameters

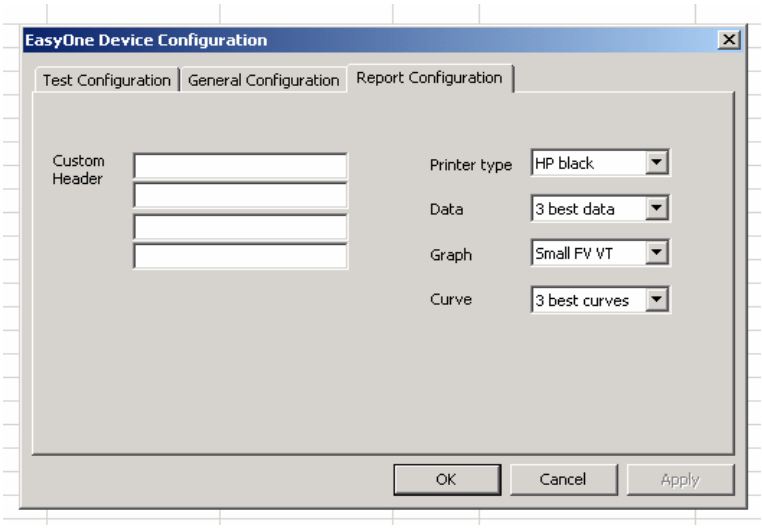




Part B: Flow Spirometer Setup Parameters







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)
ndd 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
ndd 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			

Initial when complete:	Questionnaire	Methacholine
	Spirometry	
	Bronchodilator	

Spirometry Contraindications: YES / NO
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 ≥180, diastolic BP ≥110, pulse >110 bpm

Bronchodilator Contraindications: YES / NO
History of irregular heart beat (arrhythmia)
Systolic BP >160, diastolic BP >100, pulse >100 bpm

Methacholine Challenge Contraindications: YES / NO
History of irregular heart beat (arrhythmia), known pregnancy, breastfeeding, on oral/eye drop beta-blocker medication
Systolic BP >160, diastolic BP >100, pulse >100 bpm, FEV1 <70% predicted, FEV1 <1.5 liters, poor reproducibility of FEV1

Use of short-acting bronchodilator within last 4 hours?	**YES/NO**
Use of intermediate or long-acting bronchodilator on morning of test?	**YES/NO**
Smoked within last 2 hours?	**YES/NO**
Respiratory infection within last 4 weeks?	**YES/NO**

Predicted FEV1 _____ Best FEV1 _____ Best %predicted FEV1 _____
FEV1 after MCT _____ % decline FEV1 from personal best after MCT _____
Treatment after MCT _____
Best FEV1 after treatment following MCT _____

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 (Vext) 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