BUILDING TRADES NATIONAL MEDICAL SCREENING PROGRAM

BTMed Spirometry Handbook

Quality Assurance Standards for Spirometry Testing

www.btmed.org
1-888-464-0009
1-800-866-9663

Table of Contents

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BACKGROUND

Participants in the BTMed national screening program have worked in jobs where they potentially experienced exposure to a variety of different respiratory hazards, including asbestos, silica, beryllium, and welding fumes, among others. These exposures can result in conditions such as Chronic Obstructive Pulmonary Disease (COPD), Asbestos-related lung disease (including Asbestosis), Silicosis, Chronic Beryllium Disease, or even lung cancer. Spirometry is a useful tool to understand whether there are any signs of these conditions, which can prompt referral for additional evaluation and may also help a participant in evaluation for possible benefits under the Department of Labor's Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program.

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).

BTMed expects its spirometry providers to maintain high quality spirometry equipment, capable of performing at the levels expected to be in line with recommended guidelines for technique and interpretation. All procedures will conform to current American Thoracic Society (ATS) guidelines.[4] 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) also known as Hankinson 1999 reference equations.[3]

This handbook is meant to serve as a guide for performance of spirometry for BTMed participants. The guidance here is based on current field spirometry practices of the National Institute for Occupational Safety and Health (NIOSH)[5], with references to the recommendations of the ATS[4] and the American Association for Respiratory Care (AARC)[1]. If any of the contraindications or performance characteristics at an individual spirometry lab are more conservative than those mentioned in the guide, please contact the BTMed Medical Director to discuss those discrepancies.

I. INDICATIONS

To detect obstructive, restrictive, and mixed lung function patterns. See Appendix 1 for a form that can be used to document screening for contraindications.

II. ABSOLUTE CONTRAINDICATIONS – Do NOT perform Spirometry

1. Systolic Blood Pressure >180 or Diastolic Blood Pressure >110 mmHg or pulse rate >110 beats per minute[5]
2. Myocardial infarction (MI) within the last 1 month[4]
3. Unstable angina[1,2] (cardiac chest pain at rest or escalating; angina not controlled with medication).
4. Current hemoptysis of unknown origin (coughing up blood)[(1,2]
5. Unrepaired aortic aneurysm > 6 cm in size or described as "bulging." [2]

6. Unrepaired brain arterial aneurysm [1,2]

III. RELATIVE CONTRAINDICATIONS – Consider seeking physician guidance prior to performing Spirometry

1. Current Pneumothorax (collapsed lung) – Can be performed 2 weeks after successful treatment [2]
2. Recent eye surgery within the last 1-3 months – Eye surgery may require 6-12 weeks for optimal recovery, depending on surgical procedure. For Lasik surgery, spirometry can occur after 1 month[2].
3. Recent thoracic, abdominal, or brain surgery within the last 1-2 months – Adequate healing may require up to 6 weeks. Perform at least 6 weeks post-operatively.[2]

IV. CONDITIONS THAT MAY AFFECT OPTIMAL TEST PERFORMANCE – Test can be completed, but if able to schedule at a time when the condition is resolved, results may be of higher quality.

1. Acute disorders including chest, back or gastrointestinal (GI) distress/discomfort – May indicate an underlying acute issue or affect subject performance during testing. [4]
2. Oral or facial pain exacerbated by a mouthpiece – May interfere with an air-tight seal.[4]
3. Stress incontinence – Performance of a forced maneuver may trigger an episode of incontinence.[4]
4. Dementia, altered mental status, confusion – May be unable to make an optimal effort for adequate testing.[4]
5. Recent use of atropine, albuterol, or other corticosteroid that affects the airway – Impacts the quality of the test if occurred within the last 12-24 hours, depending on the drug. If has been taken, note in test comments and continue testing.[4]
6. Recent ear surgery or current ear infection. Performance of forced maneuver may worsen ear pain and participant may not provide a full effort.[2]
7. Active infection, such as tuberculosis (TB), influenza, pneumonia, or viral infection. For spirometry screening purposes, would delay testing until infectious process has resolved, as it may affect results. Testing can be performed with attention to standard infection control practices, including scheduling patients with communicable respiratory illnesses at the end of the session/day.[1]

The technician should ask the subject if any of these contraindications are present and document in the subject's medical record. If any of the absolute contraindications are present, the technician should NOT proceed with the test. If a relative contraindication is present, the technician will determine if there is either a significant health risk that would limit optimal testing before proceeding with the test. If the technician is considering cancelling the test, they should discuss this with the supervising clinician.

V. DESCRIPTION OF EQUIPMENT MAINTENANCE

Spirometry should be conducted in a private space, and the ambient temperature will be maintained between 17 and 40°C (62.6-104°F).[3]

At the test site

1. Calibrate spirometers per manufacturer recommendations and verify them to be in correct operating condition. Verify that software parameters are correctly defined.
2. Set up equipment and connect cables. Connect power cords to grounded electrical receptacles.
3. Record room temperature and barometric pressure.
4. Perform volume calibration and leak check per NIOSH recommendations either automatically or manually using 3-Liter syringe (repeat after every 4 hours of testing) according to specifications for the particular spirometer's manufacturer's recommendations.
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 (preferably without shoes).
2. Measure and record blood pressure and pulse rate of. Record blood pressure.
   a. 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 that their blood pressure or heart rate is too high to safely perform the test currently. Advise the subject to seek guidance from their physician.
   b. 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 – do perform the test. Advise the subject to recheck their measurements within a week and, if still elevated, to seek guidance from their physician.
3. Perform and document pre-test screening for contraindications. An optional form is provided for this in Appendix 1.
4. Do not perform test if any absolute 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. Although current guidelines suggest that spirometry can be performed in the seated or standing positions,[1,4] **BTMed requests that spirometry be performed in the seated position** in order to avoid potential instability that can lead to a fall. Encourage the subject to assume a seated position and sit up straight.
4. Demonstrate a deep inspiration and proper placement of the mouthpiece.
5. Blast out a full breath of 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 sit up straight and not lower chin or bend over. Emphasize not straining with the neck but pushing from the belly and diaphragm.
9. Give the following instructions (enthusiastic coaching is required, shouting is not):
    a. 'Take the largest breath of air that you can inhale.'
    b. 'Quickly 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 or for as long as you can.'
    d. Coach: 'Keep blowing, keep going, almost there,' until a 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.

Continue testing until at least three acceptable trials are completed and the repeatability criteria are met (where the top two highest values for FEV1 and FVC are within 150 ml of each other) up to a maximum of eight trials have been performed, or until the subject cannot or should not continue - whichever comes first (see Appendix 3 for acceptability and repeatability criteria). Examples of acceptable maneuvers and common errors can be viewed at https://www.cdc.gov/niosh/docs/2011-135/. Additional technical resources are included in **Section XI** of this handbook.

VIII. QUALITY CONTROL PROGRAM

Equipment

Each testing site is responsible for maintaining equipment and calibration. BTMed recommends that sites maintain 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 should be evaluated over a range of mechanically-simulated exhalation maneuvers.[4]

Test Quality

If automatic quality grading is available on the spirometer, please activate it and report it. The goal is to obtain A and B level quality spirometry, according to current NIOSH specifications. The grades are often assigned using the following definitions:[5]

- 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 BTMed staff. Quality control reports are generated and provided to spirometry clinical sites. If coaching deficiencies are identified during this review, clinical site directors should consider providing additional training to their technicians.

See Appendix 2, Quality Assessment, for more information about test validity and reliability.

IX. SAFETY PROCEDURES

1. To prevent electrical shock, all equipment will be plugged into a grounded electrical outlet.
2. Infection control measures:
   a. When a volume spirometer is used, a clean hose or mouthpiece filter will be used for each subject.
   b. Only disposable mouthpieces should be used.
   c. Mouthpieces are handled only by the subject.
   d. Spirometers and accessories will be cleaned and disinfected daily.
3. Ideally, technicians will have successfully completed a NIOSH spirometry training course or be a Certified Pulmonary Function Technician through the National Board of Respiratory Care and will have been supervised while testing 20 subjects by a trained and experienced technician.
4. Subjects in wheelchairs may perform the test while seated in their wheelchairs. Wheelchair wheels must be locked prior to testing.
5. Encourage subjects to sit for the test, the expected practice for BTMed participants.

X. EMERGENCY PROCEDURES

1. Spirometry clinical sites should have an emergency plan in place to handle patient care issues requiring an escalated level of care. This should include:
   a. Instructions to call 911.
   b. Arrangement information for transportation to the nearest hospital.
   c. Address and telephone number for the nearest hospital emergency room.
2. A subject who feels faint during testing will be allowed to rest in a seated position and encouraged to lower their head towards their knees and to breathe slowly and deeply until

recovered.

3. Contact BTMed to notify the national office if a medical emergency occurs in the context of performing spirometry at 1-888-464-0009 (Kim Cranford, RN) or 1-800-866-9663 (Anna Chen).

XI. ONLINE SPIROMETRY QUALITY AND TRAINING RESOURCES

GENERAL GUIDANCE ON PERFORMANCE OF SPIROMETRY

- AARC Clinical Practice Guideline - http://www.rcjournal.com/cpgs/spirupdatecpg.html
  - This document describes spirometry procedure, indications, contraindications, hazard / complications, and assessment of test quality.

- ATS/ERS Task Force: Standardisation of Lung Function Testing. - http://www.thoracic.org/statements/resources/pft/PFT2.pdf
  - This document describes the standards of spirometry testing for both the American Thoracic Society (ATS) and the European Respiratory Society (ERS). It includes a description of the measured values, quality control measures, and flow loop examples.

- JOEM Spirometry in the Occupational Health Setting 2011 Update - https://journals.lww.com/joem/Fulltext/2011/05000/Spirometry_in_the_Occupational_Health_Setting_2011.16.aspx
  - This document provides useful information for all users of spirometry test results and discusses equipment performance, conducting tests, comparing results with reference values, and evaluating results over time.

- Cooper 2006. Update on Contraindications for Lung Function Testing. Thorax 2011.- http://thorax.bmj.com/content/thoraxjnl/66/8/714.full.pdf
  - A publication that discusses different absolute and relative contraindications for Spirometry.

TRAINING GUIDANCE

- NIOSH Spirometry Poster - https://www.cdc.gov/niosh/docs/2011-135/
  - This document provides concise information on how to identify and correct technical and equipment errors encountered during spirometry testing. Graphic examples and descriptive text enable easy identification of testing problems.

- NIOSH Spirometry Quality Assurance: Common Errors and their Impact on Test Results - https://www.cdc.gov/niosh/docs/2012-116/default.html
  - This booklet describes technical criteria for normal spirometry testing procedures, quality assurance guidelines, and 12 common errors of testing. Each error includes a description of the problem, typical values, identification criteria, implications for test results, and solution.

- NIOSH Spirometry Training Program - https://www.cdc.gov/niosh/topics/spirometry/training.html
  - This website lists all of the approved NIOSH-sponsored spirometry courses throughout the United States, has additional training materials, and links to essential components of a quality spirometry program.

- NIOSH Spirometry Training Guide - https://www.cdc.gov/niosh/docs/2004-154c/
    - This guide is intended for individuals who are responsible for conducting spirometry in the workplace, including physicians, nurses, and other health professionals. It is an adjunct training guide that is not a self-instructional package.

TRAINING GUIDANCE (cont.)

- NIOSH Spirometry Training Courses - https://www.cdc.gov/niosh/topics/spirometry/training.html
    - This website provides a list of NIOSH-approved spirometry courses, locations, and schedules.

- NIOSH Learning Curves Spriometry Testing Training Video - https://www.cdc.gov/niosh/docs/video/2017-167/
    - This spirometry training video provides information on how to correctly administer a spirometry test using current guidelines, recognize errors, and report valid test results.

REFERENCES from PROFESSIONAL ORGANIZATIONS and PREDICTIVE VALUES

- 2005 ATS/ERS Spirometry Recommendation Changes - https://www.cdc.gov/niosh/topics/spirometry/files/2005-ats-ers-changes-for-2004-niosh-manual.pdf
    - This document describes the updated changes for American Thoracic Society and European Respiratory Society Recommended Changes to different aspects of spirometry technique.

- AJRCCM Spirometric Reference Values from a Sample of the General U.S. Population - https://dynamicmt.com/nhanesIII.pdf
    - This document, sometimes referred to as 'Hankinson,' discusses the establishment of reference values for three different race groups: Caucasians, African-Americans, and Mexican-Americans.
- NIOSH Spirometry Reference Tables - https://www.cdc.gov/niosh/topics/spirometry/nhanes.html
    - References values for FEV1, FEV6, FVC, PEF, PEF25-75, FEV1/FVS, and FEV6/FVC for Men and Women of African-American, Caucasian, and Mexican-American descent.

- NIOSH Spirometry Reference Value Calculator - https://www.cdc.gov/niosh/topics/spirometry/RefCalculator.html
    - This online calculator provides the percent predicted spirometry values based on gender, age, race, and height.

- OSHA Spirometry Testing in Occupational Health Programs - https://www.osha.gov/Publications/OSHA3637.pdf
    - This publication describes spirometry testing, interpretation of test results, quality assurance reviews, procedures, and recordkeeping.

XII. REFERENCE LIST

1) American Association for Respiratory Care (AARC) Clinical Practice Guideline. Spirometry: 1996 update. Respir Care 1996; 36:629-636.
2) Cooper, Brendan G. An update on contraindications for lung function testing. BMJ Thorax 2011 66:714-723.
3) 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.
4) Miller MR, Hankinson J, Brusasco V, et al, ATS/ERS Task Force. Standardisation of spirometry. Eur Respir J. 2005 Aug; 26(2):319-338.
5) National Institutes for Occupational Safety and Health (NIOSH) Division of Respiratory Disease Studies- Field Studies Branch, Baseline Spirometry, Standard Operating Procedures. Personal communication, Kathy Fedan, February 15, 2018.

APPENDIX 1 – BTMed Spirometry Screening Form*

Name			
Birthdate	Age	Gender	
Height (Nearest ½ inch)	Weight (pounds)	Blood Pressure	Pulse
Current Medications/Eye Drops/Inhalers *(Note also if patient has taken inhaled medications within the last 24 hours):*			

Absolute Contraindications:	**YES**	**NO**	**Relative Contraindications:**	**YES**	**NO**
Systolic Blood Pressure >180 or Diastolic Blood Pressure >110 mmHg or pulse rate >110 beats per minute[5]	□	□	Current Pneumothorax: spirometry can be performed 2 weeks after successful treatment[2]	□	□
Myocardial infarction (MI) within the last 1 month[4]	□	□	Recent eye surgery within the last 1-3 months: Eye surgery may require 6-12 weeks for optimal recovery, depending on surgical procedure. For Lasik surgery, spirometry can occur after 1 month.	□	□
Unstable angina[1,2]	□	□			
Current hemoptysis of unknown origin (coughing up blood)[1,2]	□	□			
Unrepaired aortic aneurysm > 6 cm in size or described as "bulging." [2]	□	□	Recent thoracic, abdominal, or brain surgery within the last 1-2 months: Adequate healing may require up to six weeks. Schedule at least 6 weeks post-op[4]	□	□
Unrepaired brain arterial aneurysm[1,2].	□	□			

*Use of this form is optional. Footnotes refer to citations in reference list.

APPENDIX 2 – 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 or hiccupping 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

APPENDIX 3 – QA Graphic

Spirometry Quality Criteria

Acceptability Criteria

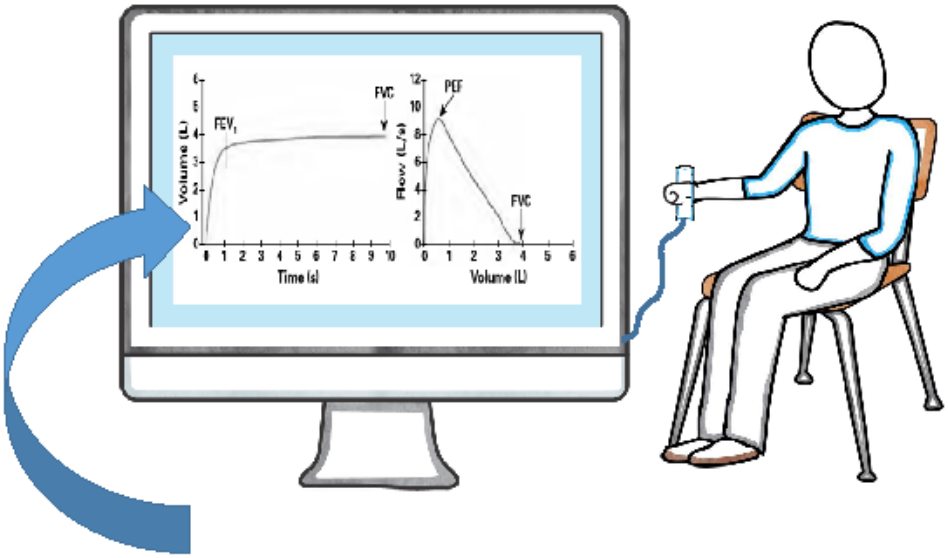
No hesitation or false starts
No coughing or hiccupping in first second
No glottis closure
No mouthpiece obstruction by tongue or dentures
No extra breaths
No leaks
The volume of back extrapolation (Vext) < 5% of the FVC, or 150 ml, whichever is greater
Volume/time curve plateaus within 6 seconds of exhalation

3 Acceptable Trials

Repeatability Criteria

The two largest FVC values should agree within 150 ml

The two largest FEV1 values should agree within 150 ml



All 3 trials should look like this

When you have 3 trials that look like this:
Compare the 2 largest FVC values – are they within 150 ml?
Compare the 2 largest FEV1 values – are they within 150 ml?