1.0 **Introduction/Background**
- Primary Care Asthma Program (PCAP) Background-Spirometry - 1 page

2.0 **PCAP Policy & Procedures**
- PCAP Spirometry Policy and Procedures (April 2012) - 10 pages
- PCAP Medical Directive for Ordering Spirometry at a Primary Care Site (Jan 2018) - 2 pages
- PCAP Medical Directive for Administration of Salbutamol for Spirometry Testing at a Primary Care Site (Jan 2018) – 2 pages
- PCAP Medical Directive for Performing Spirometry Pre & Post Bronchodilator at a Primary Care Site (Jan 2018) – 4 pages
- Sample of a Spirometry Requisition Order Form (From Coates AL et al. Spirometry in Primary Care. Can Respir J 2013; 20(1); 13-20) - 1 page
- Sample of a Spirometry Report Form (From Coates AL et al. Spirometry in Primary Care. Can Respir J 2013; 20(1); 13-20) – 1 page

3.0 **Spirometry Practicum**
- The Lung Association Spirometry Interpretation Guide (Jan 2018) - 1 page
- PCAP Spirometry Operator Checklist Tool (December 2013) – 2 pages
- Get Valid Spirometry Results Every Time (From U.S. Department of Health and Human Services : Centers for Disease Control and Prevention National Institute for Occupational Safety and Health (NIOSH)) – 1 page

4.0 **Standards**
- CTS 2013 Spirometry in Primary Care – 10 pages
- ATS/ERS Recommendations for a Standardized Pulmonary Function Report – 9 pages
- PCAP Resource Links for Standards in Spirometry – 1 page
Section 1 Introduction/Background
Introduction/Background

The Primary Care Asthma Program (PCAP) is an evidence-based asthma program intended to provide primary care providers with decision aids to support best practice regarding asthma assessment, diagnosis and management. Its development, implementation and evaluation as a pilot project were funded through the Ontario Ministry of Health and Long-Term Care, as one of the initiatives of the Asthma Plan of Action. The pilot for this program was evaluated in 8 primary care sites from 2002-2006.

Currently, the Primary Care Asthma Program is delivered within a multi disciplinary team of primary care providers with the support of a Certified Asthma/Respiratory Educator. The Certified Asthma/Respiratory Educator assists with program implementation, mentoring, education of patients and staff and ensuring the ongoing sustainability of the program. The program is modeled on fostering patient and family self-management.

Key to the success of this primary care program is the expertise of the educator who provides current evidence-based knowledge and assist with on-site objective measurements via spirometry. Spirometry, in accordance with American Thoracic Society/European Respiratory Society (ATS/ERS) 2005 Standards, will be used as the primary objective measure for the confirmation of the diagnosis of asthma and as the objective measure for the monitoring of asthma clients for all clients capable of performing this test.

This Spirometry Manual was developed by the PCAP Spirometry Working group for health care providers in the primary care setting. The purpose of the manual is to promote quality spirometry in primary care with a strong focus on technical skills set.
Section 2 PCAP Policy & Procedures
2.1 Primary Care Asthma Program (PCAP) Spirometry Policy and Procedures

Purpose:
To assist “PCAP” primary care providers with policies and procedures for performing spirometry testing in accordance with current American Thoracic Society/European Respiratory Society (ATS/ERS) Standardization of Lung Function Testing (1) as well as the Canadian Thoracic Society (CTS) guidelines for Spirometry in Primary Care (2).

Policy:
Spirometry is a non-invasive, diagnostic test that measures ventilatory capacity as a function of time, reflecting the flow resistive properties of the airways. Spirometry, pre- and post-bronchodilator, in accordance with ATS/ERS standards, will be used as the primary objective measure for clients who are able to perform the test for the confirmation of the diagnosis of asthma and as an objective measure of lung function for the monitoring of asthma clients. Refer to PCAP Generic Program Standards (GPS) # 5. (3)

Procedure:
Instrumentation, calibration, hygiene, infection control, performance of the test to meet criteria for acceptability and repeatability, reporting results for interpretation, and spirometry training recommendations are essential elements of performing spirometry that can have a significant impact on the quality of the test and the interpretation of the results.

2.1.1 Instrumentation

Spirometer equipment recommendations apply to all spirometers and are minimal requirements. Instrumentation recommendations should be followed to provide accurate spirometric data and information that is comparable from laboratory to laboratory and from one time period to another. The accuracy of a spirometry system depends on the characteristics of the entire system, from the volume or flow transducer and the use of an in-line filter, to the recorder, display or processor. Changes in any aspect of the equipment or errors at any step in the process can affect the accuracy of the results. All spirometry should be reported at BTPS (Body Temperature and Pressure Saturated) by any method (measuring temperature and barometric pressure). When a subject performs an FVC maneuver into a spirometer, the air leaving the lungs is approximately 33ºC-35ºC and saturated with water vapour. If the expired gas is assumed to be at BTPS, an error of ~1% will occur. Most volume-type spirometers assume instant cooling of the gas but this is not always the case. If the flow sensor is located further from the mouth, such as adding an in-line filter, more cooling will occur allowing for more errors. For example, if the BTPS correction factor is wrong, an accurately measured FVC will be incorrectly reported (1).

Flow-Sensing Spirometers – currently the most widely used instruments

- Utilizes a sensor that measures flow as the primary signal and calculates volume by electronic (analog) or numerical (digital) integration of the flow signal producing a FLOW-
Most commonly used flow sensors detect and measure flow from: the pressure drop across a resistance (pneumotach); cooling of a heated wire; or by electronically counting the rotation of a turbine blade.

**General Considerations (2):**

- All spirometers must meet the latest ATS/ERS standards (Please refer to section 3.0 of this manual: ATS/ERS Standardization of Spirometry)
- Exhalation-only spirometers are not recommended (e.g. Spirometers where the patient inhales to maximal lung volume, then while holding their breath, places mouth on mouthpiece and does a forced exhalation into the spirometer). This is because it requires more coordination from the patient and can cause inaccurate measurement due to leakage that occurs between the time when the patient reaches maximal lung volume and when the patient places their mouth on the mouthpiece. It is recommended that the spirometer chosen allows the patient to take tidal breaths with their mouth on the mouthpiece prior to the FVC maneuver. This allows for the person conducting the test to evaluate a proper seal around the mouthpiece and the nose clip is functioning properly. Any leakage that occurs at maximal lung volume will be captured and will be used to determine whether the test meets ATS/ERS standards.

**Display (2):**

- The Display must show both the flow-volume loop and the volume-time curve with sufficient resolution so that the person conducting the testing can determine whether test results have met the ATS/ERS standards (see page 6 of this Policy and Procedure)
- It should be possible for the person conducting the spirometry testing be able to observe both the display and the patient effort allowing for instant coaching and for the person conducting the spirometry testing to terminate the test early if the test is unacceptable
- The spirometer should be able to analyze each maneuver to determine whether each effort meets ATS/ERS standards (acceptability and repeatability) and provide “warning messages” to indicate if the maneuver was not acceptable (e.g. “end of test criteria not met – blow out longer”) Note: Most of the ATS/ERS standards are based on the adult population and many children can meet requirements with submaximal efforts and poor quality tests. This should be recognized by the person conducting the spirometry testing and an effort will be repeated even if the computerized system has accepted the test. Information about special considerations in children are available at the end of this document.

### 2.1.2 Calibration

Attention to equipment quality control and calibration is an important part of good laboratory practice, necessary for valid reliable results. At a minimum, the requirements are as follows:

(Refer to Appendix 1: PCAP Spirometry Operator Checklist)
Primary Care Asthma Program SPIROMETRY MANUAL

- A Spirometer should have a Calibrating syringe. ATS/ERS standards specify that a 3L syringe be used for checking and calibrating a spirometer daily.
- A simple leak test (to test if there is a leak in the calibration syringe) using a stopper in the calibration syringe should be done monthly by pushing or pulling the syringe (2)
- Spirometers using pre-calibrated inserts must still be checked daily for accuracy using a 3L calibration syringe. (2)
- Daily calibration log should be maintained for all equipment requiring calibration;
- Room temperature, Barometric Pressure and Relative Humidity should be measured, not estimated. If a barometer is unavailable, pressure reported from a nearby weather station can be accessed from the Environment Canada website: http://weather.gc.ca/canada_e.html and must be corrected for altitude: http://www.engineeringtoolbox.com/air-altitude-pressure-d_462.html (3)
- Calibration should be conducted with mouthpiece/filter in-line with the calibration syringe;
- Monthly normal biological tests (e.g. perform spirometry on a staff member (with no underlying lung condition) on all spirometers in the clinic on a monthly basis for comparison (must be within 150mL of each other)
- Documentation of repairs or other alterations which return the equipment to acceptable operation; & preventative maintenance, corrective actions;
- Dates of computer software and hardware updates or changes; and
- If equipment is changed or relocated (e.g. industrial surveys), calibration checks and quality-control procedures must be repeated before further testing begins.

Follow manufacturer’s manual for complete calibration procedures. While manufacturers are responsible for demonstrating the accuracy and reliability of the systems that they sell, it is the user who is responsible for ensuring that the equipment’s measurements remain accurate (1).

2.1.3 Hygiene and Infection Control

Each site is responsible to follow their site specific infection control policy. Each site will establish specific responsibilities and guidelines related to Spirometry for their site safety and the prevention of infectious disease transmission (Refer: Provincial Infectious Diseases Advisory Committee, Infection Prevention and Control for Clinical Office Practice, 2013(8)). The goal of infection control is to prevent the transmission of infection to patients and staff during spirometry testing. The number of documented cases of infection transmission is very small, but the potential is real. Assume all patients have the potential of acquiring and transmitting infectious disease so implementation of the nationally recognized program of Universal/Routine Standard Precautions should be followed:

- Effective hand washing before and after direct patient contact or contact with body substances.
- For infection control purposes, disposable filters are strongly recommended unless the circuitry is changed after each patient or a non-rebreathing technique is used. Some spirometers may incorporate a disposable breathing tube, making a filter unnecessary (2)
- Gloves for contact with blood, secretions, mucous membranes, non-intact skin and moist body substances.

Page 3

PCAP Spirometry Policy and Procedures Approved by PCAP Advisory December 2013; Revised January 2018
Additional barriers - gowns, masks, protective eyewear and plastic aprons when body substances are likely to soil clothing, skin or mucous membranes (10).

2.1.4 Performing the Spirometry Test

Who Can Conduct Spirometry?

- By a trained and qualified personnel in a setting with a regular quality assurance program (e.g. Trained health care professionals who are Registered Respiratory Therapist (RRT) or Registered Cardio-pulmonary Technologist, RCPT(P) or other regulated health care professionals who received formal training which included studies in anatomy and physiology of the cardiorespiratory system and who successfully completed a recognized spirometry training course, and other trained health care technologists who successfully completed a recognized spirometry training course (please refer to section 2.1.8 of this document for training programs) (2).

Reference Values:
Performing the test not only includes attention to the instrumentation, calibration and infection control but also to how the test is performed and attention to the quality of the measurements produced. All measurements are expressed as litres (L) or litres/second (L/s) and as % predicted, with the predicted values being derived from standardized data sets. Predicted values should reflect the patient population of your clinic. The current CTS guidelines recommend the use of Lower Limit of Normal (LLN). The Lower Limit of Normal (LLN) is defined as the 5th percentile (i.e. the value that marks the lower 5th percentile of the normal population). The 5th percentile is considered the threshold below which a value is considered to be abnormal. The Global Lung Function Initiative (GLI) recommends the all-age spirometry values developed by Quanjer et al. be used as reference values (age 3.5 - 90yrs). Most major spirometers have committed to implementing the Quanjer et al. reference values (www.lungfunction.org/93-manufacturers.html). Another choice of reference equations is the National Health and Nutrition Examination Survey (NHANES III) for Caucasian, African-American and Hispanics between 8-80 years of age. These equations should not be used outside this age range. This set is contained in almost all current spirometry systems. There are no reference equations for the Canadian Aboriginal population and therefore, spirometry tests involving this population should be interpreted with caution using the Caucasian reference values (2). More recently, the Canadian Health Measurement Survey (CHMS) provides reference values for the Canadian Caucasian population from 6 to 79 years of age and guidelines to approximate correction for other ethnic groups (12). Clinics may want to align with labs in their geographical region using the same reference sets understanding that if different reference sets are used only the patient’s absolute values can be compared between tests. Predicted values take into account height, age, gender, ethnic origin. Weight is normally recorded for monitoring but is not in the equation for predicted spirometry values. The height should not be estimated but measured using a measuring tape (attached to the wall) with the patient standing without shoes with his/her back flat against the wall with a right angle device making contact with the top of the head and the measuring tape. When height cannot be measured using this method (e.g. chest wall deformities) arm span (middle finger tip to middle finger tip) can be used as an approximate (2).
The spirometer selected must have specific sets of normal reference values, both adult and pediatric, pre-programmed into its software. If it does not, insist that they be installed prior to purchase (2).

Reference values must be appropriate for the age and ethnicity of the population and be able to provide the Lower Limit of Normal (LLN) (2). It is recommended that you inquire about a software update to obtain the LLN with your spirometer equipment if not already available.

The interpretation of spirometry tests should be based on the LLN (2)

Table 1: Terminology and Definitions

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forced Vital Capacity (L)</td>
<td>FVC</td>
<td>Maximum volume of air that can be expired as forcefully, quickly and completely as possible following a complete inspiration</td>
</tr>
<tr>
<td>Forced Expiratory Volume in 1 second (L/sec)</td>
<td>FEV1</td>
<td>Volume of air expired in the first second of the FVC - Used to assess airflow</td>
</tr>
<tr>
<td>Ratio of FEV1 to FVC %</td>
<td>FEV1/FVC</td>
<td>Used for the assessment of airflow obstruction</td>
</tr>
<tr>
<td>Peak Expiratory Flow (L/sec)</td>
<td>PEF</td>
<td>The maximum flow rate at the onset of the FVC maneuver – judges max effort</td>
</tr>
<tr>
<td>Forced Expiratory Flow 25-75% (L/Sec)</td>
<td>FEF 25-75</td>
<td>The average flow rate during the middle half of the FVC maneuver – reflects airflow</td>
</tr>
</tbody>
</table>

*FEF50/FIF50 = The ratio of flow at 50% of expiration and flow at 50% inspiration (Maximum flow at 50% that can be inspired as forcefully, quickly and completely as possible following a complete exhalation). Recognizing that the inspiratory loop is not always done in primary care, this loop might be useful in evaluating any upper airway obstruction (UAO). FEF50/FIF50 = 1 in fixed UAO, FEF50/FIF50 > 1 in variable extrathoracic UAO and FEF50/FIF50 < 0.3 in variable intrathoracic UAO (13).
There are two types of graphs that are commonly displayed for Spirometry: the Flow Volume loop and the Volume Time curve. Your spirometer may be formatted to print out both curves.

**Figure 1: Flow Volume loop** - This is a record of how fast the air flows in/out (Flow) versus the amount (Volume) of air exhaled or inhaled within a certain time (8).

![Flow Volume loop diagram]

Flow (Y) versus Volume (X)

**Figure 2: Volume time curve** - This is a record of the expired volume in relation to time (8).

![Volume time curve diagram]

Volume (Y) versus Time (X)
Primary Care Asthma Program  SPIROMETRY MANUAL

Test Procedures for the Spirometry / Flow Volume loop maneuver

The Provider should demonstrate the appropriate technique and follow the procedure described in Table 2 from the ATS/ERS: Standardization of Spirometry 2005.

**Table 2: Test Procedures for the Forced Vital Capacity maneuver (Flow-Volume loop)**

<table>
<thead>
<tr>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>❖ Ensure the spirometer has daily calibration performed</td>
</tr>
<tr>
<td>❖ Contraindications should be listed on the spirometry order requisition form or checklist form (2)</td>
</tr>
<tr>
<td>❖ Additional Patient Preparation/ Documentation (review contraindication as in Appendix 1-</td>
</tr>
<tr>
<td>Operator’s Checklist)</td>
</tr>
<tr>
<td>❖ Ask the patient about:</td>
</tr>
<tr>
<td>☐ Smoking</td>
</tr>
<tr>
<td>☐ Recent illness</td>
</tr>
<tr>
<td>☐ Inhaler/ medication use</td>
</tr>
<tr>
<td>Activities that should preferably be avoided prior to lung function testing</td>
</tr>
<tr>
<td>❖ Smoking within at least 1 h of testing</td>
</tr>
<tr>
<td>❖ Consuming alcohol within 4 h of testing</td>
</tr>
<tr>
<td>❖ Performing vigorous exercise within 30 min of testing</td>
</tr>
<tr>
<td>❖ Wearing clothing that substantially restricts full chest and abdominal expansion</td>
</tr>
<tr>
<td>❖ Eating a large meal within 2 h of testing</td>
</tr>
<tr>
<td>❖ Inhaler Medication (Refer to Medication Section: Post Bronchodilator Testing to withhold prior to spirometry testing)</td>
</tr>
<tr>
<td>☐ Measure weight and height without shoes</td>
</tr>
<tr>
<td>❖ Wash hands</td>
</tr>
<tr>
<td>❖ Instruct and demonstrate the test to the subject</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>❖ Perform maneuver (closed circuit method- most commonly used)</td>
</tr>
<tr>
<td>☐ Have subject assume the correct seated posture (a chair without wheels, feet flat on the ground)</td>
</tr>
<tr>
<td>☐ Attach nose clip*, place mouthpiece in mouth and close lips around the mouthpiece, perform 2-4 tidal breaths</td>
</tr>
<tr>
<td>☐ Inhale completely and rapidly with a pause of 1 s at TLC</td>
</tr>
<tr>
<td>☐ Exhale forcefully and rapidly until no more air can be expelled while maintaining upright posture (minimum 6 sec for adults and 3 sec for children ≤ 10 years of age) Please refer to the Appendix: “Special Considerations in Young Children”</td>
</tr>
<tr>
<td>❖ Assess the performance and acceptability of each flow volume loop, provide any instructions to ensure test is performed properly and repeat the test until you have obtained quality curves (as per ATS/ERS Standards- 3 minimum and 8 maximum curves</td>
</tr>
</tbody>
</table>

*Recommendation is to use Nose Clips or manual occlusion of the nares, to avoid leaks, especially for nose breathers. People must mouth breathe during the procedure*
Post Bronchodilator Spirometry/Flow-volume loop
(Please refer to ATS/ERS: Standardization for Spirometry 2005, Reversibility Testing)

Spirometry testing and the administration of bronchodilators, requires a signed requisition from the Physician or a verbal or standing order as per site specific Medical Directives and provincial regulations that should indicate whether post bronchodilator testing is requested, and which bronchodilator is to be administered for the testing and how much bronchodilator should be given for testing.

Medication to withhold prior to spirometry testing
The decision to avoid bronchodilators before testing is dependent on the reason for the test. If post bronchodilator testing is to be performed to diagnose an underlying lung condition, the patient may/should withhold the following medication prior to spirometry testing:

**Note:** It is important to tell the patient that if they need to use their rescue inhaler for symptoms, they can do so and not withhold it for the test.

### Inhaled bronchodilators (7)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Withholding time prior to Spirometry Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-Acting Beta2 Agonist (SABA)</td>
<td>4 - 8 Hours</td>
</tr>
<tr>
<td>Short-Acting Muscarinic Antagonist (SAMA)</td>
<td>6 Hours</td>
</tr>
<tr>
<td>Long-Acting Beta2 Agonist (LABA)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Long-Acting Muscarinic Antagonist (LAMA)</td>
<td>24 Hours</td>
</tr>
</tbody>
</table>

- Other medications to withhold: Theophylline: 48 hours (7), LTRA 24 hours (2)
- Antihistamines and steroids (oral and inhaled) do not need to be withheld

**Note:** if the test is to determine the response to a medication, then the referring physician may choose not to withhold the medication prior to testing. The spirometry requisition order form should indicate whether to withhold a medication before testing and specify which medication to withhold.

To standardize the evaluation of spirometry post-bronchodilator:

- Short Acting Beta Adrenergic (SABA) medications are the most commonly used bronchodilator, other drugs can be used (e.g. Short-Acting Muscarinic Antagonist (SAMA) such as Ipratropium Bromide)
- After the pre-bronchodilator test, administer SABA –
  - 4 separate doses* of 100mcg each, Total of 400 mcg salbutamol, or
  - 4 separate doses* of 40mcg each, Total of 160mcg of Ipratropium Bromide
  *Inhale separate doses from a valved holding chamber device 30 seconds apart (7)

ATS does not currently specify any recommendations for the pediatric population.
- Perform post-bronchodilator testing 15 minutes post for SABA and 30 minutes post for SAMA
2.1.5 Acceptability and Repeatability Test Criteria

Acceptability

A minimum of three (3) acceptable maneuvers must be obtained. Evidence for an acceptable test includes:

- Adequate understanding and performance of test procedure
- Unhesitating start without a variable effort
- Maximum effort with smooth continuous exhalation.
- Absence of cough, glottis closure, early termination or leakage

For complete recommendations please review - ATS/ERS Standardization of Lung Function Testing: Standardization of Spirometry 2005

Repeatability

- The FVC of the two largest accepted curves is within 150ml of each other.
- The FEV1 of the two largest accepted curves is within 150ml of each other.

**Figure 3: Flow chart on application of Acceptability & Repeatability criteria.**
2.1.6 Reporting Results (3)

□ When considering a spirometer, consider whether it is compatible with your Electronic Medical Record (EMR)

□ Flow and volume measures are reported at body temperature and pressure saturated with water vapor (BTPS)
□ The largest FVC and FEV1 from acceptable maneuvers is reported, even though the values may not come from the same maneuver
□ Largest PEF is reported
□ All other flows i.e. FEF25-75% are reported from the “best curve” (defined as the maneuver with the largest sum of FVC and FEV1)
□ Final reports should include the technologist’s comments regarding the patient performance, recent use of bronchodilators, quality of testing and whether or not the results were acceptable and reproducible (e.g. Patient had good effort, results reproducible, unable to perform reproducible curves, unable to attain residual volume, etc.)

Note: Please refer to Appendix A in this spirometry manual for what a sample report (2) should look like.

Who Can Interpret Spirometry?

□ Primary Care physicians and Nurse Practitioners who interpret spirometry should have completed a spirometry interpretation course or specific training in spirometry interpretation (2). Please refer to Page 11 of this policy and procedure for recommended courses.

2.1.7 Technical Support (2):

□ A spirometer must be sufficiently robust to be unaffected by drops or bumps. If a spirometer is dropped, a calibration check is recommended before continuing testing
□ Ensure the vendor who provided you with the spirometer provide sufficient training initially in the use of a spirometer. They should also be able to provide technical support for addressing problems with the operation of the spirometer. If your spirometer needs to be checked, request a loaner device. There should be regular notification of any software upgrades and the spirometer should be thoroughly checked on a regular basis for any upgrades.

2.1.8 Training Recommendations for Performing Spirometry

Purpose:
This policy will provide guidelines on the minimum criteria and core components of training based on the ATS/ERS/CPSO guidelines for personnel with regards to performing spirometry.
Policy:
The following minimum criteria are recommended by ATS/ERS to establish competency in spirometry testing:

- Knowledge of theory and practical aspect of applied techniques, measurements, calibrations, hygiene, quality control, basic background in lung physiology and pathology;
- Introduction to the standards of spirometry, review of spirometry role in the diagnosis, management of asthma and assess contraindications;
- Test performance: Proper technique for performing spirometry including how to coach for best results (practical workshop or hands on training);
- Discuss predicted values and actual/absolute values;
- Review reporting process.

Spirometry training can be attained through an accredited Institution. Recommended institutions:

**Certification in conducting spirometry:**

**Additional Supports:**
- The Lung Association Provider Education Program (PEP). Spirometry Interpretation workshop and e-modules [http://olapep.ca/](http://olapep.ca/)
- Job shadowing with a local/regional expert can enhance practical training objectives. This can be available but limited according to resources. Please contact PCAP Provincial Coordinator for more information ([http://www.lungontario.ca/PCAP](http://www.lungontario.ca/PCAP))

*Please Note:

Permission and proper acknowledgement is required in any modification of the PCAP tools as per the PCAP process
## APPENDIX 1: PCAP SPIROMETRY OPERATOR CHECKLIST (Page 1)

| ☐ Barometric Pressure, Relative Humidity and Temperature updated daily |
| ☐ Daily calibration performed according to manufacturer’s and ATS/ERS Standards |
| ☐ Relative Contraindications (Refer to the list on the reverse side of this page) |
| ☐ Minimum of three acceptable FVC performed, with two repeatable maneuvers, maximum eight performed (ATS/ERS 2005) |

### ☐ Assess Patient Performance: (Acceptability)
- Maximum peak effort
- No hesitation or cough within first second of exhalation
- Extrapolated volume < 150 ml or 5% of FVC
- No glottis closure, cough or early termination of effort
- No leak observed or obstruction of mouthpiece
- Six seconds of exhalation collected (3 sec for <10 yrs)

### ☐ Assess Measurements: (Repeatability)
- Are the 2 largest FVCs within 150 ml of each other?
  - If $FVC < 1.0\ L$ then criteria is within $100ml$ of each other
- Are the 2 largest FEV1s within 150 ml of each other?
  - If $FVC < 1.0\ L$ then criteria is within $100ml$ of each other

☐ Technical comments recorded on spirometry report
## APPENDIX 1: PCAP SPIROMETRY OPERATOR CHECKLIST (Page 2)

### Relative Contraindications for Spirometry (2)
- Recent Indicates within 6 weeks.

<table>
<thead>
<tr>
<th>Relative Contraindications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral aneurysm</td>
<td>Spirometry may lead to increased intraocular pressure in most patients and a 3-4 week recovery post-surgery is recommended before testing.</td>
</tr>
<tr>
<td>Recent brain surgery</td>
<td></td>
</tr>
<tr>
<td>Recent concussion</td>
<td></td>
</tr>
<tr>
<td>Recent eye surgery</td>
<td></td>
</tr>
<tr>
<td>Significant glaucoma</td>
<td></td>
</tr>
<tr>
<td>Recent sinus surgery or middle ear surgery or infection</td>
<td>There is a risk that forced manoeuvres can cause pain and even ear drum ruptures in cases of middle ear infection.</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>*Spirometry causes increases in intrathoracic and intra-abdominal pressure that may increase blood pressure.</td>
</tr>
<tr>
<td>Significant aortic aneurysm*</td>
<td>†Physiotherapy and coughing has been shown to be beneficial after cardiothoracic and abdominal surgery. Cough increases intrathoracic pressure up to 400cmH2O compared with 70cmH2O-200cmH2O during spirometry. The risk is therefore low in most patients.</td>
</tr>
<tr>
<td>Recent thoracic surgery†</td>
<td></td>
</tr>
<tr>
<td>Recent abdominal surgery</td>
<td></td>
</tr>
<tr>
<td>Pregnancy†</td>
<td></td>
</tr>
<tr>
<td>Systemic hypotension or severe hypertension (e.g., &gt;200/120mmHg)</td>
<td>§exercise testing one week after MI appears to be safe, however, caution is necessary where persistent myocardial ischemia exists. The use of beta2-agonists when doing post-bronchodilator spirometry can also be a risk for people with these conditions, although the risk of a single administration is likely to be minimal.</td>
</tr>
<tr>
<td>Significant atrial/ventricular arrhythmia</td>
<td></td>
</tr>
<tr>
<td>Noncompensated heart failure</td>
<td></td>
</tr>
<tr>
<td>Recent myocardial infarction (MI)¶ or pulmonary embolus</td>
<td></td>
</tr>
<tr>
<td>History of syncope related to forced exhalation/cough</td>
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<td>Hepatitis B</td>
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<td>Hemoptysis or oral bleeding</td>
<td></td>
</tr>
<tr>
<td>Inability to follow direction (e.g., confusion, dementia, young age, language barrier)</td>
<td>In some cases, successful spirometry can be done with increased coaching and aid of an interpreter.</td>
</tr>
</tbody>
</table>
APPENDIX 2: Special Considerations in Young Children (2)

- Children have higher elastic recoil of the lungs than adults and therefore, have faster emptying of the lungs (some children are able to exhale completely in 1 sec).
- Minimum expiratory time is 3 sec for children ≤ 10 years of age rather than 6 sec for adults. However, the requirement of a plateau < 25mL in the final 1 sec of exhalation remains (ATS/ERS standards 2005)
- If the child can exhale their lung volume in < 2 sec, the technologist must override the automatic rejection of the test.
- ATS/ERS repeatability is 150mL between tests for FEV1 and FVC or 100mL for FVC or FEV1 < 1L
- The back-extrapolated volume used for the beginning of the test must be ≤ 150mL or 5% of FVC, whichever is greater.
- When a child performs spirometry testing, they must rapidly inspire to maximal lung volume and prevent breathholding prior to forced exhalation (ATS/ERS 2005)
- Ensure an appropriately sized mouthpiece for a better seal
- Ensure the use of nose clips
APPENDIX 3: Quality Assurance Considerations (2)

Documentation of Quality Assurance components includes:

- Daily Calibration of the spirometer with a 3L calibration syringe and a monthly assessment of repeatability of the measures using biological controls and an evaluation of a log of calibration results
- Documentation of repairs/modifications/software upgrades to the spirometry equipment
- Qualification of all personnel conducting spirometry testing, including education and training.
- Documented infection control procedures

Please note:

Permission & Proper acknowledgement is required in any modification of the PCAP Tools as per PCAP process.
References


3. Primary Care Asthma Program, Generic Program Standards, PCAP Group, June 2013


[NAME OF PRIMARY CARE SITE]
Medical Directive: Ordering Spirometry

Approval Date: ________________

Review Date: ________________

Approved by: ____________ Family Physician (Lead)
____________ Executive Director

Background Information

The Primary Care Asthma Program (PCAP) is an evidence-based asthma program intended to provide primary care providers with decision aids to support best practice regarding asthma assessment, diagnosis and management. Its development, implementation and evaluation as a pilot project were funded through the Ontario Ministry of Health and Long-Term Care, as one of the initiatives of the Asthma Plan of Action. The pilot for this program was evaluated in 8 primary care sites from 2002-2006.

CONDITIONS OF DELEGATING SPIROMETRY BY MEDICAL DIRECTIVE

The practitioner follows the _______ [ORGANIZATION ] procedure for performing spirometry, which follows the American Thoracic Society/European Respiratory Society (ATS/ERS) standards for spirometry.

All staff ordering spirometry is aware of the _________ [ORGANIZATION ] policies and procedures for performing spirometry.

The practitioner is aware of the risks of ordering/performing spirometry including all contraindications within the primary care site setting.

All new staff (RRTs, RNs, RN (EC)s, and MDs) are made aware of the policies and procedures concerning spirometry testing.

I authorize the ___ [ORGANIZATION NAME ] RRTs, RNs, RN (EC)s and to order spirometry testing according to the __________________________
[ORGANIZATION ] policy and procedure when all conditions of this directive are met.

Approved by (Medical Director of Organization):

________________________________________
Signature followed by Printed Name

________________________________________
Date
[NAME OF PRIMARY CARE SITE]

Medical Directive: *Administration of Salbutamol for Spirometry Testing*

Approval Date: __________________

Review Date: __________________

Approved by: ___________ Family Physician
____________ Executive Director

Background Information

The Primary Care Asthma Program (PCAP) is an evidence-based asthma program intended to provide primary care providers with decision aids to support best practice regarding asthma assessment, diagnosis and management. Its development, implementation and evaluation as a pilot project were funded through the Ontario Ministry of Health and Long-Term Care, as one of the initiatives of the Asthma Plan of Action. The pilot for this program was evaluated in 8 primary care sites from 2002-2006.

**CONDITIONS OF DELEGATING THE ADMINISTRATION OF SALBUTAMOL WHEN PERFORMING SPIROMETRY**

The practitioner follows the ____________________ [ORGANIZATION ] procedure for administering salbutamol (which is a beta 2 adrenergic medication).

This drug is only to be administered by the above-mentioned health care professionals when being used during a post bronchodilator spirometry test.

The practitioner is aware of the risks of administering salbutamol via Metered Dose Inhaler (MDI) and holding chamber (spacer with a valve) for spirometry testing within the community setting.

All new staff (RRTs, RNs, RN (EC)s and MDs) are made aware of policy and procedures concerning the administration of salbutamol MDI for the purpose of performing spirometry.
The physician(s) indicated below approves the act of delegating the administering of salbutamol to be used in post bronchodilator spirometry testing.

I authorize ______________[ORGANIZATION NAME ] RRTs, RNs, RN (EC)s to administer salbutamol via MDI and valved holding chamber, for post bronchodilator spirometry testing. This is to be done according to the ______________ policy and procedure when all conditions of this directive are met.

APPROVED BY (Medical Director of Organization):

Signature followed by Printed Name

__________________________________________
Date
[NAME OF PRIMARY CARE SITE]
Medical Directive: Spirometry Pre & Post Bronchodilator

Approval Date: __________________

Review Date: __________________

Approved by: ___________ Family Physician
____________ Executive Director

Background Information

The Primary Care Asthma Program (PCAP) is an evidence-based asthma program intended to provide primary care providers with decision aids to support best practice regarding asthma assessment, diagnosis and management. Its development, implementation and evaluation as a pilot project were funded through the Ontario Ministry of Health and Long-Term Care, as one of the initiatives of the Asthma Plan of Action. The pilot for this program was evaluated in 8 primary care sites from 2002-2006.

Setting where medical directive to be Implemented:
In house spirometry testing at ________ [ORGANIZATION NAME]

Note: not to be used for referral for external spirometry testing (since an external lab cannot bill for a spirometry test ordered by an RN (EC) or a Registered Respiratory Therapist [RRT])

Professional Staff covered by the Directive: Authorized staff that have been observed and trained to perform spirometry according to American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines under ____________ [ORGANIZATION NAME] quality assurance and quality control policies for spirometry testing and that the undersigned presently holds the designation and college certification in good standing as within their respective regulated health colleges.

CONDITIONS OF DELEGATING SPIROMETRY BY MEDICAL DIRECTIVE

The practitioner is aware of and follows the __________ [ORGANIZATION NAME] procedure for performing spirometry, and administering salbutamol that follows the ATS/ERS standards for pre/post bronchodilator testing.
The practitioner is aware of the following risks of ordering/performing spirometry including pre and post bronchodilator within the primary care setting in the 2013 CTS guidelines for spirometry in primary care (1):

**Relative Contraindications for spirometry:**

- Cerebral Aneurysm
- Recent brain surgery (Most experts suggest a 3-6 week recovery period following surgery before spirometry testing)
- Recent concussion
- Recent eye surgery
- Significant glaucoma
- Recent sinus surgery or middle ear surgery or infection
- Pneumothorax
- Significant aortic aneurysm (Increases in intrathoracic or intra-abdominal pressures may increase blood pressure)
- Recent thoracic surgery (Postoperative physiotherapy including coughing is actually believed to be beneficial after cardiothoracic and abdominal surgery. Cough generally increases intrathoracic pressures up to 400cmH2O, compared with 70cmH2O-200cmH2O during spirometry. The risk is likely low in most patients)
- Recent abdominal surgery
- Pregnancy (Lung function tests may increase the risk of early delivery in case of cervical incompetence)
- Systemic hypotension or severe hypertension (eg, >200/120mmHg)
- Significant atrial/ventricular arrhythmia
- Non-compensated heart failure
- Recent myocardial infection or pulmonary embolus (Exercise testing one week after myocardial infarction appears to be safe. A shorter period could be appropriate following reperfusion therapy (eg, angioplasty), whereas caution is necessary in case of persistent myocardial ischemia
- Active tuberculosis
- Hepatitis B
- Hemoptysis or oral bleeding
- Inability to follow directions (eg, confusion, dementia, young age, language barrier)

**Clinical Criteria:**

1. The client must be recognized as an existing client of the [ORGANIZATION NAME] with either a diagnosis of asthma indicated in
their chart or an order by a physician for a pre/post spirometry testing to establish the diagnosis.

2. A physician or RN (EC) must be on site during the conducting of a spirometry test in the effect of a medical emergency arising from the test.

3. Informed verbal consent for the test is obtained from the client or the legal guardian.

4. A list of medication to be put on hold prior to testing is provided to patient.

5. Note contraindication for testing.

**Process:**

1. Review chart to confirm spirometry order
2. Assess the client’s ability to perform spirometry considering age and comorbidities.
3. Obtain and document informed verbal consent.
4. Review contraindications
5. Write an order for pre-post spirometry testing
6. Complete the test correctly as per the instructions in the spirometry and salbutamol administration procedure.
7. Make copies of the results with written comments included. Results should be interpreted by the physician and then signed off by a physician and/or RN (EC) before being added to the clients chart in the asthma documentation section.

**Signatures:**
The physician(s) indicated below approves the act of delegating the ordering and performing of pre/post spirometry testing to be used with asthma clients at our center.

I authorize __________ [ORGANIZATION NAME] - RN(EC)s, RNs and RRTs (see attached list) to order and administer spirometry testing according to the ___________ [ORGANIZATION NAME] policy and procedure when all conditions of this directive are met.

Physician authorizing delegation for ___________[ORGANIZATION NAME] :

_________________________________________ Date: _____________________

Executive Director:

_________________________________________ Date: _____________________
List of Authorized Staff for the Medical Directive
Ordering and performing pre/post bronchodilator Spirometry Testing

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Certified</th>
<th>Review Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

References:
**APPENDIX B:** Sample spirometry report form

---

**Family Physicians Clinic**

123 Main St
Anytown, Prov, Z1Z 1Z1
987-321-6540

**Age:** 62 yr  **Male**  
**Name:** Xxxxxxxxx, Xxxx  
**ID#:** 333222111  
**Ht:** 186 cm  **Race:** Caucasian  
**Wt:** 84 kg  **BMI:** 24.3 kg/m²  
**Date of birth:** 1949-Dec-31  
**Non-smoker - pack-yrs:** 0  
**Date of test:** 14:20, 2012-Jan-02  
**Reason for test:** Chronic cough

---

<table>
<thead>
<tr>
<th>Spirometry</th>
<th>Pre-Bronchodilator</th>
<th>Post-Bronchodilator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Best</td>
<td>LLN</td>
</tr>
<tr>
<td>FVC (L)</td>
<td>4.65</td>
<td>3.86</td>
</tr>
<tr>
<td>FEV₁ (L)</td>
<td>3.26</td>
<td>2.91</td>
</tr>
<tr>
<td>FEV₁/FVC</td>
<td>0.70</td>
<td>0.64</td>
</tr>
<tr>
<td>PEF (L/s)</td>
<td>10.2</td>
<td></td>
</tr>
<tr>
<td>FET (s)</td>
<td>15.3</td>
<td></td>
</tr>
<tr>
<td>Test quality</td>
<td>B</td>
<td></td>
</tr>
</tbody>
</table>

Reference values: Quanjer 2012 [Caucasian]

---

**Technologist comments:**

3 acceptable blows with 2 repeatable for both Pre- and Post- tests.

No bronchodilators taken in previous 24 hrs.

---

**Interpretation:** Pre-bronchodilator spirometry is in the normal range. There is a significant response to bronchodilators.
APPENDIX A: Sample Spirometry Requisition Form

Requisition for Spirometry

Family Physicians Clinic
123 Main St
Anytown, Prov, Z1Z 1Z1

Tel (987) 321-6540 Fax (987) 321-1234

Reason for Test

☐ Diagnosis __________________________  ☐ Follow up __________________________

☐ Other ____________________________

Previous Test at this clinic?  Yes ☐ No ☐

Clinical Diagnosis: __________________________

Smoking History:  Current Smoker ☐ Former Smoker ☐ Never Smoker ☐ No. of Pack Years: _______

Spirometry Requested

☐ Pre-bronchodilator    ☐ Post-bronchodilator (400 mcg salbutamol)

Relative Contraindications:

☐ Recent Surgery within 4 weeks (specify)  ☐ Aneurysm - Cerebral, thoracic, abdominal

☐ Pregnant (near term)  ☐ Hemoptysis

☐ Hypertension (uncontrolled)  ☐ Pneumothorax

☐ Unstable Cardiac Status  ☐ M.I. within last month

☐ Cross Infection Concerns  ☐ Other

Respiratory Medications: __________________________

Appointment Date: ________________  Time: ______

Instructions to provide to the patient:

Depending on the reason for doing the test, the patient should be instructed whether or not medications are to be withheld prior to testing, and, if so, precisely which medications should be withheld and for how long. It is important to instruct any patient withholding medications that, if needed for symptom relief, a rescue inhaler should be used and the time of use noted so that it can be reported to the technologist conducting the test.

Withhold medications?  Yes ☐ No ☐

List medications to withhold:

- Short-acting beta agonist 4 hours prior to test
- Anticholinergic 4 hours prior to test
- Long-acting beta agonist 12 hours prior to test
- Long-acting anticholinergic 24 hours prior to test

The patient should be instructed to avoid the following prior to testing:

- Smoking within at least 1 hour of testing
- Consuming alcohol within 4 hours of testing
- Performing vigorous exercise within 30 min of testing
- Wearing clothing that substantially restricts full chest and abdominal expansion
- Eating a large meal within 2 h of testing
Section 3 Spirometry Practicum
Spirometry Interpretation Guide
(Consider patient history in all interpretation decision making)

Pre β₂-agonist FEV₁ / FVC Ratio

Reduced: < LLN (or <0.70)⁵
  β₂-agonist

FEV₁ / FVC Reduced < LLN (or <0.70)⁵
  Improved FEV₁ 12% and 200mL¹
  Yes No
  Consistent with Asthma or COPD or Asthma COPD Overlap (ACO)

FEV₁ / FVC Normal ≥ LLN (or ≥0.70)⁵
  Improved FEV₁ 12% and 200mL¹
  Yes No
  Consistent with Asthma

Consider methacholine challenge

Normal: ≥ LLN (or ≥0.70)⁵
  β₂-agonist

FVC Normal ≥ LLN ⁴
  Yes No (Consistent with restriction)

Improved FEV₁ 12% and 200mL¹

Yes
  Consider FULL PFT (+/- referral to specialist)

No
  Suspect Asthma

Normal Spirometry²,³
  Suspect Asthma

LLN=Lower Limit of Normal

¹ 200mL criteria only necessary for adults (≥ 12 years)
² Reversibility criteria not met. May occur with chronic asthma - consider methacholine challenge or referral
³ Normal Spirometry: in the context of persistent symptoms consider further clinical testing i.e. methacholine challenge
⁴ LLN may not be available on outdated systems – use 80% predicted
⁵ If the LLN is not available use 0.70 in an adult if COPD is suspected and 0.80 in a child

Note: Recommended reference equations: GLI, CHMS, and NHANES III
## PCAP SPIROMETRY OPERATOR CHECKLIST

<table>
<thead>
<tr>
<th>Description</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barometric Pressure, Relative Humidity and Temperature updated daily</td>
<td>☑</td>
</tr>
<tr>
<td>Daily calibration performed according to manufacturer’s and ATS/ERS Standards</td>
<td>☑</td>
</tr>
<tr>
<td>Relative Contraindications (Refer to the list on the reverse side of this page)</td>
<td>☑</td>
</tr>
<tr>
<td>Minimum of three acceptable FVC performed, with two repeatable maneuvers, maximum eight performed (ATS/ERS 2005)</td>
<td>☑</td>
</tr>
</tbody>
</table>

### Assess Patient Performance: (Acceptability)
- Maximum peak effort
- No hesitation or cough within first second of exhalation
- Extrapolated volume < 150 ml or 5% of FVC
- No glottis closure, cough or early termination of effort
- No leak observed or obstruction of mouthpiece
- Six seconds of exhalation collected (3 sec for <10 yrs)

### Assess Measurements: (Repeatability)
- Are the 2 largest FVCs within 150 ml of each other?
  - If \( FVC < 1.0 \text{ L} \) then criteria is within 100 ml of each other
- Are the 2 largest FEV1s within 150 ml of each other?
  - If \( FVC < 1.0 \text{ L} \) then criteria is within 100 ml of each other

- Technical comments recorded on spirometry report ☑
PCAP SPIROMETRY OPERATOR CHECKLIST

Relative Contraindications for Spirometry1

- Recent Indicates within 6 weeks.

<table>
<thead>
<tr>
<th>Relative Contraindications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cerebral aneurysm</td>
<td>Spirometry may lead to increased intraocular pressure in most patients and a 3-4 week recovery post-surgery is recommended before testing</td>
</tr>
<tr>
<td>• Recent brain surgery</td>
<td></td>
</tr>
<tr>
<td>• Recent concussion</td>
<td></td>
</tr>
<tr>
<td>• Recent eye surgery</td>
<td></td>
</tr>
<tr>
<td>• Significant glaucoma</td>
<td></td>
</tr>
<tr>
<td>• Recent sinus surgery or middle ear surgery or infection</td>
<td>There is a risk that forced manoeuvres can cause pain and even ear drum ruptures in cases of middle ear infection</td>
</tr>
<tr>
<td>• Pneumothorax</td>
<td>*Spirometry causes increases in intrathoracic and intra-abdominal pressure that may increase blood pressure †Physiotherapy and coughing has been shown to be beneficial after cardiothoracic and abdominal surgery. Cough increases intrathoracic pressure up to 400cmH2O compared with 70cmH2O-200cmH2O during spirometry. The risk is therefore low in most patients. ‡Lung function tests may increase the risk of early delivery in the case of an incompetent cervix</td>
</tr>
<tr>
<td>• Significant aortic aneurysm*</td>
<td></td>
</tr>
<tr>
<td>• Recent thoracic surgery†</td>
<td></td>
</tr>
<tr>
<td>• Recent abdominal surgery</td>
<td></td>
</tr>
<tr>
<td>• Pregnancy‡</td>
<td></td>
</tr>
<tr>
<td>• Systemic hypotension or severe hypertension (e.g., &gt;200/120mmHg)</td>
<td>§Exercise testing one week after MI appears to be safe, however, caution is necessary where persistent myocardial ischemia exists. The use of beta2- agonists when doing post-bronchodilator spirometry can also be a risk for people with these conditions, although the risk of a single administration is likely to be minimal</td>
</tr>
<tr>
<td>• Significant atrial/ventricular arrhythmia</td>
<td></td>
</tr>
<tr>
<td>• Noncompensated heart failure</td>
<td></td>
</tr>
<tr>
<td>• Recent myocardial infarction (MI), pulmonary embolus</td>
<td></td>
</tr>
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<td>In some cases, successful spirometry can be done with increased coaching and aid of an interpreter</td>
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</tbody>
</table>

---

Get Valid Spirometry Results EVERY Time

A Valid Test has:
3 or More Good Curves and Repeatable FVC and FEV1*

*Use most current American Thoracic Society/European Respiratory Society (ATS/ERS) standards

For a monthly update on news at NIOSH, subscribe to NIOSH eNews by visiting www.cdc.gov/niosh/eNews. For more information about NIOSH-Approved Spirometry Training go to http://www.cdc.gov/niosh/topics/spirometry/training.html

HOW TO CORRECT TEST ERRORS

Poor Initial Blast
Coach: Blast air out HARDER

Hesitation; Slow Start; Large Extrapolated Volume
Delete Curve; Coach: Blast FASTER

Cough in First Second
Delete Curve; Correction: Try a drink of water

Incomplete Inhalation
Coach: Take a DEEPER breath

No Plateau Before 15 Seconds
Coach: Keep blowing until told to stop

Inconsistent Effort
Coach: One continuous blast and keep blowing

Partially Blocked Mouthpiece
Coach: Position mouthpiece between teeth and on top of tongue; secure dentures

Glottis Closure or Breath Holding
Coach: Initial BIG BLAST then RELAX and keep blowing

Leak
Correction: Check equipment and connections

Negative Zero Flow Error
Correction: No airflow through sensor when spirometer zeroing
Hold sensor upright during test

Positive Zero Flow Error
Correction: No airflow through sensor when spirometer zeroing
Hold sensor upright during test

Extra Breaths
Correction: DELETE CURVE; Use nose clips and lips tightly sealed

Delivery on the Nation’s promise: Safety and health at work for all people through research and prevention.

DHHS (NIOSH) Publication No. 2011-135
Section 4 Standards
Standardisation of spirometry


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KEYWORDS: Peak expiratory flow, spirometry, spirometry standardisation, spirometry technique, spirometry traning, ventilation

BACKGROUND

Spirometry is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. The primary signal measured in spirometry may be volume or flow.

Spirometry is invaluable as a screening test of general respiratory health in the same way that blood pressure provides important information about general cardiovascular health. However, on its own, spirometry does not lead clinicians directly to an aetiological diagnosis. Some indications for spirometry are given in table 1.

In this document, the most important aspects of spirometry are the forced vital capacity (FVC), which is the volume delivered during an expiration made as forcefully and completely as possible starting from full inspiration, and the forced expiratory volume (FEV) in one second, which is the volume delivered in the first second of an FVC manoeuvre. Other spirometric variables derived from the FVC manoeuvre are also addressed.

Spirometry can be undertaken with many different types of equipment, and requires cooperation between the subject and the examiner, and the results obtained will depend on technical as well as personal factors (fig. 1). If the variability of the results can be diminished and the measurement accuracy can be improved, the range of normal values for populations can be narrowed and abnormalities more easily detected. The Snowbird workshop held in 1979 resulted in the first American Thoracic Society (ATS) statement on the standardisation of spirometry [1]. This was updated in 1987 and again in 1994 [2, 3]. A similar initiative was undertaken by the European Community for Steel and Coal, resulting in the first European standardisation document in 1983 [4]. This was then updated in 1993 as the official statement of the European Respiratory Society (ERS) [5]. There are generally only minor differences between the two most recent ATS and ERS statements, except that the ERS statement includes absolute lung volumes and the ATS does not.

This document brings the views of the ATS and ERS together in an attempt to publish standards that can be applied more
The spirometer must be capable of accumulating volume for a forced expiration from a position of full inspiration, FEV1 is the maximal volume of air exhaled in the first second, i.e., vital capacity performed with a maximally forced expiratory effort, expressed in litres at body temperature and ambient pressure saturated with water vapour (BTPS; see BTPS correction section).

FEV1 is the maximal volume of air exhaled in the first second of a forced expiration from a position of full inspiration, expressed in litres at BTPS.

**Equipment**

**Requirements**

The spirometer must be capable of accumulating volume for ≥15 s (longer times are recommended) and measuring volumes of ≥8 L (BTPS) with an accuracy of at least ±3% of reading or ±0.050 L, whichever is greater, with flows between 0 and 14 L·s⁻¹. The total resistance to airflow at 14.0 L·s⁻¹ must be <1.5 cmH₂O·L⁻¹·s⁻¹ (0.15 kPa·L⁻¹·s⁻¹; see Minimal recommendations for spirometry systems section). The total resistance must be measured with any tubing, valves, pre-filter, etc. included that may be inserted between the subject and the spirometer. Some devices may exhibit changes in resistance due to water vapour condensation, and accuracy requirements must be met under BTPS conditions for up to eight successive FVC manoeuvres performed in a 10-min period without inspiration from the instrument.

**Display**

For optimal quality control, both flow–volume and volume–time displays are useful, and test operators should visually inspect the performance of each manoeuvre for quality assurance before proceeding with another manoeuvre. This inspection requires tracings to meet the minimum size and resolution requirements set forth in this standard.

Displays of flow versus volume provide more detail for the initial portion (first 1 s) of the FVC manoeuvre. Since this portion of the manoeuvre, particularly the peak expiratory flow (PEF), is correlated with the pleural pressure during the manoeuvre, the flow–volume display is useful to assess the magnitude of effort during the initial portions of the manoeuvre. The ability to overlay a series of flow–volume curves registered at the point of maximal inhalation may be helpful in evaluating repeatability and detecting sub-maximal efforts. However, if the point of maximal inhalation varies between blows, then the interpretation of these results is difficult because the flows at identical measured volumes are being achieved at different absolute lung volumes. In contrast, display of the FVC manoeuvre as a volume–time graph provides more detail for the latter part of the manoeuvre. A volume–time tracing of sufficient size also allows independent measurement and calculation of parameters from the FVC manoeuvres. In a display of multiple trials, the sequencing of the blows should be apparent to the user.

For the start of test display, the volume–time display should include ≥0.25 s, and preferably 1 s, before exhalation starts (zero volume). This time period before there is any change in volume is needed to calculate the back extrapolated volume (EV; see Start of test criteria section) and to evaluate effort during the initial portion of the manoeuvre. Time zero, as defined by EV, must be presented as the zero point on the graphical output.

The last 2 s of the manoeuvre should be displayed to indicate a satisfactory end of test (see End of test criteria section).

When a volume–time curve is plotted as hardcopy, the volume scale must be ≥10 mm·L⁻¹ (BTPS). For a screen display, 5 mm·L⁻¹ is satisfactory (table 2).

The time scale should be ≥20 mm·s⁻¹, and larger time scales are preferred (≥30 mm·s⁻¹) when manual measurements are made [1, 6, 7]. When the volume–time plot is used in conjunction with a flow–volume curve (i.e., both display methods are provided for interpretations and no hand

**FIGURE 1.** Spirometry standardisation steps.
measurements are performed), the time scale requirement is reduced to 10 mm·s\(^{-1}\) from the usually required minimum of 20 mm·s\(^{-1}\) (table 2). The rationale for this exception is that the flow–volume curve can provide the means for quality assessment during the initial portion of the FVC manoeuvre. The volume–time curve can be used to evaluate the latter part of the FVC manoeuvre, making the time scale less critical.

### Validation

It is strongly recommended that spirometry systems should be evaluated using a computer-driven mechanical syringe or its equivalent, in order to test the range of exhalations that are likely to be encountered in the test population. Testing the performance of equipment is not part of the usual laboratory procedures (see *Test signals for spirometer testing* section).

### Quality control

Attention to equipment quality control and calibration is an important part of good laboratory practice. At a minimum, the requirements are as follows: 1) a log of calibration results is maintained; 2) the documentation of repairs or other alterations which return the equipment to acceptable operation; 3) the dates of computer software and hardware updates or changes; and 4) if equipment is changed or relocated (e.g. industrial surveys), calibration checks and quality-control procedures must be repeated before further testing begins.

Key aspects of equipment quality control are summarised in table 3.

Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume and the actual flow or volume.

A calibration check is different from calibration and is the procedure used to validate that the device is within calibration limits, e.g. ±3% of true. If a device fails its calibration check, then a new calibration procedure or equipment maintenance is required. Calibration checks must be undertaken daily, or more frequently, if specified by the manufacturer.

The syringe used to check the volume calibration of spirometers must have an accuracy of ±15 mL or ±0.5% of the full scale (15 mL for a 3-L syringe), and the manufacturer must provide recommendations concerning appropriate intervals between syringe calibration checks. Users should be aware that a syringe with an adjustable or variable stop may be out of calibration if the stop is reset or accidentally moved. Calibration syringes should be periodically (e.g. monthly) leak tested at more than one volume up to their maximum; this can be done by attempting to empty them with the outlet corked. A dropped or damaged syringe should be considered out of calibration until it is checked.

With regard to time, assessing mechanical recorder time scale accuracy with a stopwatch must be performed at least quarterly. An accuracy of within 2% must be achieved.

### Quality control for volume-measuring devices

The volume accuracy of the spirometer must be checked at least daily, with a single discharge of a 3-L calibrated syringe. Daily calibration checking is highly recommended so that the onset of a problem can be determined within 1 day, and also to help define day-to-day laboratory variability. More frequent checks may be required in special circumstances, such as: 1) during industrial surveys or other studies in which a large number of subject manoeuvres are carried out, the equipment’s calibration should be checked more frequently than daily [8]; and 2) when the ambient temperature is changing (e.g. field studies), volume accuracy must be checked more frequently than daily and the BTPS correction factor appropriately updated.

The accuracy of the syringe volume must be considered in determining whether the measured volume is within acceptable limits. For example, if the syringe has an accuracy of 0.5%, a reading of ±3.5% is appropriate.

The calibration syringe should be stored and used in such a way as to maintain the same temperature and humidity of the testing site. This is best accomplished by keeping the syringe in close proximity to the spirometer, but out of direct sunlight and away from heat sources.

Volume-type spirometer systems must be evaluated for leaks every day [9, 10]. The importance of undertaking this daily test cannot be overstressed. Leaks can be detected by applying a constant positive pressure of ≥3.0 cmH\(2\)O (0.3 kPa) with the spirometer outlet occluded (preferably at or including the mouthpiece). Any observed volume loss >30 mL after 1 min indicates a leak [9, 10] and needs to be corrected.

### Table 2: Recommended minimum scale factors for time, volume and flow on graphical output

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Instrument display</th>
<th>Hardcopy graphical output</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Resolution required</td>
<td>Scale factor</td>
</tr>
<tr>
<td>Volume(^a)</td>
<td>0.050 L</td>
<td>5 mm·L(^{-1})</td>
</tr>
<tr>
<td>Flow(^a)</td>
<td>0.200 L·s(^{-1})</td>
<td>2.5 mm·L(^{-1})·s(^{-1})</td>
</tr>
<tr>
<td>Time</td>
<td>0.2 s</td>
<td>10 mm·s(^{-1})</td>
</tr>
</tbody>
</table>

\(^a\): the correct aspect ratio for a flow versus volume display is two units of flow per one unit of volume.

### Table 3: Summary of equipment quality control

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum interval</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>Daily</td>
<td>Calibration check with a 3-L syringe</td>
</tr>
<tr>
<td>Leak</td>
<td>Daily</td>
<td>3 cmH(2)O (0.3 kPa) constant pressure for 1 min</td>
</tr>
<tr>
<td>Volume linearity</td>
<td>Quarterly</td>
<td>1-L increments with a calibrating syringe measured over entire volume range</td>
</tr>
<tr>
<td>Flow linearity</td>
<td>Weekly</td>
<td>Test at least three different flow ranges</td>
</tr>
<tr>
<td>Time</td>
<td>Quarterly</td>
<td>Mechanical recorder check with stopwatch</td>
</tr>
<tr>
<td>Software</td>
<td>New versions</td>
<td>Log installation date and perform test using “known” subject</td>
</tr>
</tbody>
</table>
At least quarterly, volume spirometers must have their calibration checked over their entire volume range using a calibrated syringe [11] or an equivalent volume standard. The measured volume should be within ± 3.5% of the reading or 65 mL, whichever is greater. This limit includes the 0.5% accuracy limit for a 3-L syringe. The linearity check procedure provided by the manufacturer can be used if it is equivalent to one of the following procedures: 1) consecutive injections of 1-L volume increments while comparing observed volume with the corresponding cumulative measured volume, e.g. 0–1, 1–2, 2–3,...6–7 and 7–8 L, for an 8-L spirometer; and 2) injection of a 3-L volume starting at a minimal spirometer volume, then repeating this with a 1-L increment in the start position, e.g. 0–3, 1–4, 2–5, 3–6, 4–7 and 5–8 L, for an 8-L spirometer.

The linearity check is considered acceptable if the spirometer meets the volume accuracy requirements for all volumes tested.

**Quality control for flow-measuring devices**

With regards to volume accuracy, calibration checks must be undertaken at least daily, using a 3-L syringe discharged at least three times to give a range of flows varying between 0.5 and 12 L·s⁻¹ (with 3-L injection times of ~6 s and <0.5 s). The volume at each flow should meet the accuracy requirement of ± 3.5%. For devices using disposable flow sensors, a new sensor from the supply used for patient tests should be tested each day.

For linearity, a volume calibration check should be performed weekly with a 3-L syringe to deliver three relatively constant flows at a low flow, then three at a mid-range flow and finally three at a high flow. The volumes achieved at each of these flows should each meet the accuracy requirement of ± 3.5%.

**Test procedure**

There are three distinct phases to the FVC manoeuvre, as follows: 1) maximal inspiration; 2) a “blast” of exhalation; and 3) continued complete exhalation to the end of test (EOT).

The technician should demonstrate the appropriate technique and follow the procedure described in table 4. The subject should inhale rapidly and completely from functional residual capacity (FRC), the breathing tube should be inserted into the subject’s mouth (if this has not already been done), making sure the lips are sealed around the mouthpiece and that the tongue does not occlude it, and then the FVC manoeuvre should be begun with minimal hesitation. Reductions in PEF and FEV1 have been shown when inspiration is slow and/or there is a 4–6 s pause at total lung capacity (TLC) before beginning exhalation [12]. It is, therefore, important that the preceding inspiration is fast and any pause at full inspiration be minimal (i.e. only for 1–2 s). The test assumes a full inhalation before beginning the forced exhalation, and it is imperative that the subject takes a complete inhalation before beginning the manoeuvre. The subject should be prompted to “blast,” not just “blow,” the air from their lungs, and then he/she should be encouraged to fully exhale. Throughout the manoeuvre, enthusiastic coaching of the subject using appropriate body language and phrases, such as “keep going”, is required. It is particularly helpful to observe the subject with occasional glances to check for distress, and to observe the tracing or computer display during the test to help ensure maximal effort. If the patient feels “dizzy”, the manoeuvre should be stopped, since syncope could follow due to prolonged interruption of venous return to the thorax. This is more likely to occur in older subjects and those with airflow limitation. Performing a vital capacity (VC) manoeuvre (see VC and IC manoeuvre section), instead of obtaining FVC, may help to avoid syncope in some subjects. Reducing the effort part-way through the manoeuvre [13] may give a higher expiratory volume in some subjects, but then is no longer a maximally forced expiration. Well-fitting false teeth should not be routinely removed, since they preserve oropharyngeal geometry and spirometry results are generally better with them in place [14].

With appropriate coaching, children as young as 5 yrs of age are often able to perform acceptable spirometry [15]. The technicians who are involved in the pulmonary function testing of children should be specifically trained to deal with such a situation. A bright, pleasant atmosphere,
including age-appropriate toys, reading material and art, is important in making children feel at ease. Encouragement, detailed but simple instructions, lack of intimidation and visual feedback in the teaching are important in helping children to perform the manoeuvre. Even if unsuccessful at the first session, children will learn to be less intimidated and may perform far better in a subsequent session. Testing children in “adult” laboratories, where no effort is made to cater for the specific needs of the younger subjects, is to be discouraged.

The use of a nose clip or manual occlusion of the nares is recommended, and, for safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. If testing is undertaken with the patient standing or in another position, this must be documented on the report.

**Within-manoeuvre evaluation**

**Start of test criteria**

The start of test, for the purpose of timing, is determined by the back extrapolation method (fig. 2) [1, 3, 9, 16]. The new “time zero” from back extrapolation defines the start for all timed measurements. For manual measurements, the back extrapolation method traces back from the steepest slope on the volume–time curve [17]. For computerised back extrapolation, it is recommended that the largest slope averaged over an 80-ms period is used [18]. Figure 2 provides an example and explanation of back extrapolation and the derivation of EV. To achieve an accurate time zero and assure the FEV1 comes from optimal effort, the EV value. Inspection of the flow–volume curve may be added as a measure of the satisfactory start of test. PEF should be achieved with a sharp rise and occur close to the point of maximal inflation, i.e. the start of exhalation (see Equipment section).

Rapid computerised feedback to the technician when the start criteria were not met is strongly encouraged. In addition to the expiratory manoeuvre, the volume-time curve display (graph) should ideally include the whole preceding inspiratory manoeuvre, but must include ≥0.25 s and preferably ≥1 s prior to the start of exhalation (time zero). The equipment should display the EV value. Inspection of the flow–volume curve may be added as a measure of the satisfactory start of test. PEF should be achieved with a sharp rise and occur close to the point of maximal inflation, i.e. the start of exhalation (see Equipment section).

**End of test criteria**

It is important for subjects to be verbally encouraged to continue to exhale the air at the end of the manoeuvre to obtain optimal effort, e.g. by saying “keep going”. EOT criteria are used to identify a reasonable FVC effort, and there are two recommended EOT criteria, as follows. 1) The subject cannot or should not continue further exhalation. Although subjects should be encouraged to achieve their maximal effort, they should be allowed to terminate the manoeuvre on their own at any time, especially if they are experiencing discomfort. The technician should also be alert to any indication that the patient is experiencing discomfort, and should terminate the test if a patient is becoming uncomfortable or is approaching syncope.

2) The volume–time curve shows no change in volume (<0.025 L) for ≥1 s, and the subject has tried to exhale for ≥3 s in children aged <10 yrs and for ≥6 s in subjects aged >10 yrs.

The equipment should signal to the technician if the plateau criteria were not met. A satisfactory EOT may still have been achieved, but an equipment alert will help the technician to pinpoint where the subject may need more encouragement. It is of note that a closure of the glottis may prematurely terminate a manoeuvre at <6 s, even when the apparent duration of the blow exceeds 6 s.

For patients with airways obstruction or older subjects, exhalation times of >6 s are frequently needed. However, exhalation times of >15 s will rarely change clinical decisions. Multiple prolonged exhalations are seldom justified and may cause light headedness, syncope, undue fatigue and unnecessary discomfort.

Achieving EOT criteria is one measure of manoeuvre acceptability. Manoeuvres that do not meet EOT criteria should not be used to satisfy the requirement of three acceptable manoeuvres. However, early termination, by itself, is not a reason to eliminate all the results from such a manoeuvre from further consideration. Information such as the FEV1 may be useful (depending on the length of exhalation) and can be reported from these early terminated manoeuvres.

Some young children may have difficulty meeting the ATS EOT criteria [3], although they may meet other repeatability criteria [19]. Curve-fitting techniques [20] may prove useful in developing new EOT criteria specific for young children.

**Additional criteria**

A cough during the first second of the manoeuvre can affect the measured FEV1 value. Coughing in the first second or any other cough that, in the technician’s judgment, interferes with the measurement of accurate results [3] will render a test unacceptable.

---

**FIGURE 2.** Expanded version of the early part of a subject’s volume-time spirogram, illustrating back extrapolation through the steepest part of the curve, where flow is peak expiratory flow (PEF), to determine the new “time zero”. Forced vital capacity (FVC)= 4.291 L; back extrapolated volume (EV)=0.123 L (2.9% FVC).

----: back extrapolation line through PEF.
A Valsalva manoeuvre (glottis closure) or hesitation during the manoeuvre that causes a cessation of airflow in a manner that precludes an accurate estimate of either FEV1 or FVC [3] will render a test unacceptable.

There must be no leak at the mouth [3]. Patients with neuromuscular disease may require manual or other assistance from the technician to guarantee an adequate seal.

Obstruction of the mouthpiece, e.g. by the tongue being placed in front of the mouthpiece or by teeth in front of the mouthpiece, or by distortion from biting, may affect the performance of either the device or the subject.

Summary of acceptable blow criteria

The acceptability criteria are a satisfactory start of test and a satisfactory EOT, i.e. a plateau in the volume–time curve. In addition, the technician should observe that the subject understood the instructions and performed the manoeuvre with a maximum inspiration, a good start, a smooth end of exhalation, and the difference between the largest and next largest FEV1 is ≤0.150 L [21]. For those with an FVC of ≤1.0 L, both these values are 0.100 L. If these criteria are not met in three manoeuvres, additional trials should be attempted, until, but usually no more than, eight manoeuvres. Large variability among tests is often due to incomplete inhalations. Some patients may require a brief rest period between manoeuvres.

Manoeuvre repeatability

For FVC measurements, acceptability must be determined by ascertaining that the recommendations outlined previously on performing the FVC test are met. The guidelines of the ATS [3] contain examples of unacceptable volume–time and corresponding flow–volume curves. Figure 3 shows a flow chart outlining how the criteria for blow acceptability are applied before those for repeatability.

The repeatability criteria are used to determine when more than three acceptable FVC manoeuvres are needed; these criteria are not to be used to exclude results from reports or to exclude subjects from a study. Labelling results as being derived from data that do not conform to the repeatability criteria described previously is recommended. In addition, the repeatability criteria are minimum requirements. Many subjects are able to achieve FVC and FEV1 repeatability to within 0.150 L. Manoeuvres with an unacceptable start of test or a cough (unusable curve) must be discarded before applying the repeatability criteria and cannot be used in determining the best values. Manoeuvres with early termination or a Valsalva manoeuvre may be used for selecting the largest FVC and FEV1.

<table>
<thead>
<tr>
<th>TABLE 5</th>
<th>Summary of within- and between-manoeuvre acceptability criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within-manoeuvre criteria</strong></td>
<td></td>
</tr>
<tr>
<td>Individual spiograms are “acceptable” if</td>
<td></td>
</tr>
<tr>
<td>They are free from artefacts [3]</td>
<td></td>
</tr>
<tr>
<td>Cough during the first second of exhalation</td>
<td></td>
</tr>
<tr>
<td>Glottis closure that influences the measurement</td>
<td></td>
</tr>
<tr>
<td>Early termination or cut-off</td>
<td></td>
</tr>
<tr>
<td>Effort that is not maximal throughout</td>
<td></td>
</tr>
<tr>
<td>Leak</td>
<td></td>
</tr>
<tr>
<td>Obstructed mouthpiece</td>
<td></td>
</tr>
<tr>
<td>They have good starts</td>
<td></td>
</tr>
<tr>
<td>Extrapolated volume &lt;5% of FVC or 0.15 L, whichever is greater</td>
<td></td>
</tr>
<tr>
<td>They show satisfactory exhalation</td>
<td></td>
</tr>
<tr>
<td>Duration of ≥6 s (3 s for children) or a plateau in the volume–time curve or</td>
<td></td>
</tr>
<tr>
<td>If the subject cannot or should not continue to exhale</td>
<td></td>
</tr>
<tr>
<td><strong>Between-manoeuvre criteria</strong></td>
<td></td>
</tr>
<tr>
<td>After three acceptable spiograms have been obtained, apply the following tests</td>
<td></td>
</tr>
<tr>
<td>The two largest values of FVC must be within 0.150 L of each other</td>
<td></td>
</tr>
<tr>
<td>The two largest values of FEV1 must be within 0.150 L of each other</td>
<td></td>
</tr>
<tr>
<td>If both of these criteria are met, the test session may be concluded</td>
<td></td>
</tr>
<tr>
<td>If both of these criteria are not met, continue testing until</td>
<td></td>
</tr>
<tr>
<td>Both of the criteria are met with analysis of additional acceptable spiograms or</td>
<td></td>
</tr>
<tr>
<td>A total of eight tests have been performed (optional) or</td>
<td></td>
</tr>
<tr>
<td>The patient/subject cannot or should not continue</td>
<td></td>
</tr>
<tr>
<td>Save, as a minimum, the three satisfactory manoeuvres</td>
<td></td>
</tr>
</tbody>
</table>

FVC: forced vital capacity; FEV1: forced expiratory volume in one second.
No spirogram or test result should be rejected solely on the basis of its poor repeatability. The repeatability of results should be considered at the time of interpretation. The use of data from manoeuvres with poor repeatability or failure to meet the EOT requirements is left to the discretion of the interpreter.

Maximum number of manoeuvres

Although there may be some circumstances in which more than eight consecutive FVC manoeuvres may be needed, eight is generally a practical upper limit for most subjects [22, 23]. After several forced expiratory manoeuvres, fatigue can begin to take its toll on subjects and additional manoeuvres would be of little added value. In extremely rare circumstances, subjects may show a progressive reduction in FEV1 or FVC with each subsequent blow. If the cumulative drop exceeds 20% of start value, the test procedure should be terminated in the interest of patient safety. The sequence of the manoeuvres should be recorded.

Test result selection

FVC and FEV1 should be measured from a series of at least three forced expiratory curves that have an acceptable start of test and are free from artefact, such as a cough (i.e. “usable curves”). The largest FVC and the largest FEV1 (BTPS) should be recorded after examining the data from all of the usable curves, even if they do not come from the same curve.

Other derived indices

FEVt
FEVt is the maximal volume exhaled by time t seconds (timed from the time zero defined by back extrapolation) of a forced expiration from a position of full inspiration, expressed in litres at BTPS. Very young children may not be able to produce prolonged expirations, but there is increasing evidence that indices derived from blows with forced expiratory times of <1 s may have clinical usefulness [19]. At present, there are insufficient data to recommend the use of FEV0.5 or FEV0.75.

When the subject does not exhale completely, the volume accumulated over a shorter period of time (e.g. 6 s) may be used as an approximate surrogate for FVC. When such surrogates are used, the volume label should reflect the shorter exhalation time (e.g. FEVs for a 6-s exhalation). FEVs has been increasingly considered a reasonably reliable surrogate for FVC [24] and can be used for normalising FEV1 (e.g. FEV1/FEVs). Recording FEVs seems to have the advantage of being more reproducible than FVC, being less physically demanding for patients and providing a more explicit EOT. Confirmation from other studies is required.

Standardisation of FEV1 for expired volume, FEV1/FVC and FEV1/VC

In some patients, a slow or unforced VC or inspiratory vital capacity (IVC) manoeuvre (see VC and IC manoeuvre section) may provide a larger and more appropriate denominator for calculation of the FEV1/VC%. Some investigators have reported that the VC is slightly higher than the FVC in normal subjects [25].

FEF25–75%
The mean forced expiratory flow between 25% and 75% of the FVC (FEF25–75%) has also been known as the maximum mid-expiratory flow. This index is taken from the blow with the largest sum of FEV1 and FVC. The FEF25–75% must be measured with an accuracy of at least ±5% of reading or ±0.200 L·s⁻¹ whichever is greater, over a range of up to 7 L·s⁻¹. It should be noted that it is highly dependent on the validity of the FVC measurement and the level of expiratory effort.

PEF
PEF is usually obtained from flow–volume curve data. It is the maximum expiratory flow achieved from a maximum forced expiration, starting without hesitation from the point of maximal lung inflation, expressed in L·s⁻¹. When PEF is recorded using a patient-administered portable PEF meter, it is often expressed in L·min⁻¹. PEF is covered in more detail later.

Maximal expiratory flow–volume loops

The shape of a maximum flow–volume loop (MFVL), which includes forced inspiratory manoeuvres, can be helpful in quality control and in detecting the presence of upper airway obstruction. None of the numerical indices from a MFVL has clinical utility superior to FEV1, FVC, FEF25–75% and PEF, and are not considered in detail here.

Definitions

With regard to instantaneous flows, the recommended measure is the instantaneous forced expiratory flow when X% of the FVC has been expired (FEFx%). The maximal instantaneous forced expiratory flow when X% of the FVC remains to be expired (MEFx%) was the term previously recommended in Europe.

Instantaneous forced inspiratory flow when X% of the FVC has been expired (IFIX%) and mid-inspiratory flow when X% of the FVC has been expired refer to the flows measured on the inspiratory limb of a flow–volume loop. FIF25–75%, also
referred to as maximal mid-inspiratory flow, is analogous to FEF25–75% (see Other derived indices section).

Equipment

Instantaneous flows must be measured with an accuracy of ±5% of reading or ±0.200 L·s⁻¹, whichever is greater, over a range of -14–14 L·s⁻¹. The level of minimum detectable flow should be 0.025 L·s⁻¹. When a maximum flow–volume loop is plotted or displayed, exhaled flow must be plotted upwards, and exhaled volume towards the right. A 2:1 ratio must be maintained between the flow and volume scales, e.g. 2 L·s⁻¹ of flow and 1 L of exhaled volume must be the same distance on their respective axes. The flow and volume scales, used in reviewing test performance, must be equivalent to that shown in table 2.

Test procedure

The subject has to make a full expiratory and inspiratory loop as a single manoeuvre. In many laboratories, this is the primary manoeuvre for spirometry. The subject is asked to take a rapid full inspiration to TLC from room air through the mouth, then insert the mouthpiece and, without hesitation, perform an expiration with maximum force until no more gas can be expelled, followed by a quick maximum inspiration. At this point, the manoeuvre is finished.

An alternative procedure is for the subject to insert the mouthpiece while undertaking tidal breathing at FRC, and then, in one continuous sequence, do the following: make a slow expiration to residual volume (RV); followed directly by a slow inspiration to TLC; follow this by a rapid full expiration with maximal effort to RV; and followed by a rapid full inspiration with maximal effort back to TLC.

This procedure is slightly more complicated and may not be suitable for all equipment, but it obtains a measurement of VC as well as FVC.

Within- and between-manoeuvre evaluation

These evaluations are the same as for FVC (see Within-manoeuvre evaluation and Between-manoeuvre evaluation sections). Occasionally, a subject is unable to perform a satisfactory inspiratory limb immediately following a maximal forced expiratory manoeuvre. This is particularly common in the elderly and the infirm. In these circumstances, it may be necessary for the subject to record an inspiratory manoeuvre separately from the expiratory manoeuvre. Equipment should be able to perform these separately and then present three or more loops together on a graphical display or output.

Flow–volume loop examples

The following figures (figures 4–10) give typical examples of commonly encountered flow–volume loop configurations. The advantages of visual pattern recognition from the MFVL can readily be appreciated. The shapes of the manoeuvres must be repeatable (fig. 10) for any interpretation to be made. This is especially true for the plateau effect on expiratory and inspiratory limbs of the manoeuvre found in upper airway obstruction, as this can be mimicked by poor effort, which is usually variable from blow to blow. A further explanation is given in the ATS/ERS statement on lung function interpretation [26].

Reversibility testing

A determination of airflow-limitation reversibility with drug administration is commonly undertaken as part of lung function testing. The choice of drug, dose and mode of delivery is a clinical decision depending on what the clinician wishes to learn from the test.

If the aim of the test is to determine whether the patient’s lung function can be improved with therapy in addition to their regular treatment, then the subject can continue with his/her regular medication prior to the test.

If the clinician wants to determine whether there is any evidence of reversible airflow limitation, then the subject should undergo baseline function testing when not taking any drugs prior to the test. Short-acting inhaled drugs (e.g. the β-agonist albuterol/salbutamol or the anticholinergic agent ipratropium bromide) should not be used within 4 h of testing. Long-acting β-agonist bronchodilators (e.g. salmeterol or formoterol) and oral therapy with aminophylline or slow-release β-agonists should be stopped for 12 h prior to the test. Smoking should be avoided for ≥1 h prior to testing and throughout the duration of the test procedure.

Method

The following steps are undertaken. 1) The subject has three acceptable tests of FEV₁, FVC and PEF recorded as described previously. 2) The drug is administered in the dose and by the method indicated for the test. For example, after a gentle and incomplete expiration, a dose of 100 μg of albuterol/salbutamol is inhaled in one breath to TLC from a valved spacer device. The breath is then held for 5–10 s before the subject exhales. Four separate doses (total dose 400 μg) are delivered at ~30-s intervals. This dose ensures that the response is high on the albuterol dose–response curve. A lower dose can be used if there is concern about any effect on the patient’s heart rate or tremor. Other drugs can also be used. For the anticholinergic agent ipratropium bromide, the total dose is 160 μg (4 × 40 μg).

Three additional acceptable tests are recorded ≥10 min and up to 15 min later for short-acting β₂-agonists, and 30 min later for short-acting anticholinergic agents.

![Figure 4](image-url). Flow–volume loop of a normal subject.
Comment on dose and delivery method

Standardising the bronchodilator dose administered is necessary in order to standardise the definition of a significant bronchodilator response. The rate of pulmonary deposition of a drug with tidal breathing from an unvented nebuliser will depend on drug concentration, rate of nebuliser output, particle-size distribution, and the ratio of the time spent in inspiration over the total respiratory time ($t_i/t_{tot}$) [27]. The fraction of the aerosol carried in particles with a diameter of $\leq 5 \, \mu m$ that is expected to deposit in adult lungs if inhaled through a mouthpiece [28] is defined as the respirable fraction (RF). For example, 2.5 mg of salbutamol (albuterol) in 2.5 mL of solution, placed in a Hudson Updraft II (Hudson RCI, Temecula, CA, USA) driven by a PulmoAide compressor (De Vilbiss, Somerset, PA, USA), would produce $\sim 0.1 \, \text{mg} \cdot \text{min}^{-1}$ in the RF. For a respiratory rate of 15 breaths min$^{-1}$ and a $t_i/t_{tot}$ of 0.45, this would give $\sim 3 \, \mu g$ deposited in the lungs per breath, or $45 \, \mu g \cdot \text{min}^{-1}$. For adults using a metered dose inhaler (MDI) with a valve-holding chamber (spacer), between 10 and 20% [29, 30] of a 100-µg “puff” (or $\sim 15 \, \mu g$ per activation) would be expected to be deposited in the lung of an adult. Without a spacer, the deposition will be less, and heavily technique dependent [31]. Pulmonary deposition from dry-powder inhalers is device specific, and breath-enhanced nebulisers deposit much more than unvented ones [32, 33]. CFC-free MDIs produce a smaller particle-size distribution and improved (up to 50% of dose) lung deposition compared with those with CFC propellant [34]. For children, pulmonary deposition is less than that in adults [35], possibly relating to the size of the upper airway. Each laboratory should be familiar with the pulmonary-deposition characteristics of the devices they use.

Determination of reversibility

This aspect is covered in detail in the interpretative strategy document of the ATS and ERS [26].
**VC AND IC MANOEUVRE**

**Definitions**

**VC and IVC**
The VC is the volume change at the mouth between the position of full inspiration and complete expiration, expressed in litres at BTPS. The slow VC can be derived in two ways. The expiratory vital capacity (EVC) is the maximal volume of air exhaled from the point of maximal exhalation. The IVC is the maximal volume of air inhaled from the point of maximal exhalation, achieved by a slow expiration from end-tidal inspiration. These manoeuvres are unforced, except at the point of reaching RV or TLC, respectively, where extra effort is required [36].

**IC**
Inspiratory capacity (IC) is volume change recorded at the mouth when taking a slow full inspiration with no hesitation, from a position of passive end-tidal expiration, i.e. FRC, to a position of maximum inspiration, expressed in litres at BTPS. IC is an indirect estimate of the degree of lung hyperinflation at rest, and is useful to assess changes in FRC with pharmacological interventions and physical exercise [37–41].

**Equipment**
For measurements of VC and IC, the spirometer or flow meter must comply with the requirements for FVC (as described previously) and be capable of accumulating volume for ≥30 s.

Expiratory manoeuvres or, ideally, both inspiratory and expiratory manoeuvres should be included in the display of VC manoeuvre. Regardless of whether the inspiratory or expiratory manoeuvre is used for deriving measurements, a display of the entire recorded VC manoeuvre must be provided. The maximal expiratory volume must be assessed to determine whether the subject has obtained a plateau in the expiratory effort. For display of the slow VC, the time scale may be reduced to 5 mm·s⁻¹.

**Test procedure**

**VC**
VC can be measured using conventional spirometers. It may also be recorded from equipment used to measure static lung volumes and their subdivisions [42]. For slow VC, a maximum of four manoeuvres is a practical upper limit. It is preferable that VC manoeuvres be performed after VC manoeuvres because of the potential for muscular fatigue and volume history effects, where, after maximal inspiratory efforts, some patients with severe airways obstruction return to a falsely high level of FRC or RV, due to gas trapping or stress relaxation [3]. The VC manoeuvre may be considered either as an IVC, where the subject inhales completely from a position of full expiration, or as an EVC, where the subject exhales completely from a position of full inspiration. Figure 11 shows the recording of IVC and figure 12 shows an EVC recording. Important differences between inspiratory (i.e. IVC) and expiratory (i.e. EVC) manoeuvres may be observed in patients with airways obstruction [43, 44].

The test is begun by instructing the subject in the VC manoeuvre and demonstrating the appropriate technique. It is important that subjects understand they must completely fill and empty their lungs. The VC manoeuvre is performed with the subject using a mouthpiece and wearing a nose clip. The manoeuvre is not forced; it is performed in a relaxed manner, except near end-inspiration and end-expiration. The subject exhales completely to RV, then inhales to TLC, and finally exhales to RV again. The technician should encourage the subject to reach maximal inhaled and exhaled volumes with a relatively constant flow. The exhalation should not be unduly slow, as this can lead to underestimation of VC. Technicians should observe the subject carefully to ensure that his/her lips are sealed, nothing obstructs the mouthpiece, no leaks occur, and that TLC and RV are reached.

Alternatively, the subject inhales maximally, inserts the mouthpiece just past his/her front teeth, seals his/her lips around the mouthpiece, and blows slowly and evenly until there is no volume change (<0.025 L) for a 1-s period (see *End of test criteria section*). Patients with neuromuscular disease may need assistance in maintaining a tight seal at the mouth. The technician must observe the subject’s inhalation to ensure...
that it is complete, and that air is not exhaled while the mouthpiece is being inserted. The technician should assure that the expiratory manoeuvre is not forced. In healthy subjects, adequate maximal inspiratory and expiratory levels are achieved within 5–6 s.

IC

Subjects should be tested in the seated position wearing a nose clip with no air leaks between the mouth and the mouthpiece. Subjects should be relaxed (shoulders down and relaxed) and asked to breathe regularly for several breaths until the end-expiratory lung volume is stable (this usually requires at least three tidal manoeuvres). They are then urged to take a deep breath to TLC with no hesitation. Figure 12 shows a tracing from the recording of IC.

Use of a nose clip

The use of a nose clip is encouraged in VC measurements, since some people breathe through the nose when performing a slow VC manoeuvre. A nose clip must be used when performing inspiratory manoeuvres such as the IVC or IC.

Within-manoeuvre evaluation

These are the same as for FVC EOT criteria as described previously. There must be no leak at the mouth, no hesitation during the manoeuvre, and no obstruction of the mouthpiece (see Additional criteria section). The IC may be underestimated if the inspiratory manoeuvre is too slow due to poor effort or hesitation, or if there is premature closure of the glottis.

Between-manoeuvre evaluation

As with spirometry, a minimum of three acceptable VC manoeuvres must be obtained. If the difference in VC between the largest and next largest manoeuvre is >0.150 L, additional trials should be undertaken. Meeting repeatability criteria may require that up to, but usually no more than, four manoeuvres are performed, with a rest period of ≥1 min between the manoeuvres. Large variability in this test is often due to incomplete inhalations. Volume–time curves from the best two VC manoeuvres must be retained. For the IC, at least three acceptable manoeuvres should be performed. The mean coefficient of variation for IC in chronic airflow obstruction has been found to be 5 ±3% [39].

Test result selection

For VC, the largest value from at least three acceptable manoeuvres should be reported. For IC, the average of at least three manoeuvres should be reported.

PEAK EXPIRATORY FLOW

Studies on the measurement of PEF are ongoing. Recent evidence has suggested that the previously applied standards may allow incorrect measurements to be made [45], and it is possible that more stringent requirements may be required. A further statement will be made when the position on the clinical significance of this is clear. However, since PEF measurements are part of asthma-management programmes, the previous recommendations [3, 46] are reiterated here.

Other instantaneous flow measurements (e.g. FEF50%, FEF75%) are not proven to be superior to conventional spirometric indices in a clinical setting, and, therefore, are not considered further.

Definition

PEF is the highest flow achieved from a maximum forced expiratory manoeuvre started without hesitation from a position of maximal lung inflation [46]. When it is obtained from flow–volume curve data, it is expressed at BTPS in L·s⁻¹. The defining characteristics of the flow–time curve, in relation to PEF, are the time taken for flow to rise from 10% of PEF to 90% of PEF, i.e. the rise time (RT), and the duration that flow is >90% of PEF, called the dwell time (DT). When PEF is obtained with portable monitoring instruments, it is expressed in L·min⁻¹.

Equipment

Ideally, PEF should be recorded by an instrument that primarily records flow. Measuring PEF requires an instrument that has a flat frequency response (±5%) up to 15 Hz [46]. Although there is evidence of significant frequency content in PEF up to 20 Hz [47], it is recommended, at this stage, that manufacturers achieve a goal of recording fidelity up to 15 Hz. The PEF must be measured with an accuracy of ±10% or ±0.3 L·s⁻¹ (20 L·min⁻¹), whichever is the greater. Mean instrument resistance measured across the range of the instrument should be <2.5 cmH₂O·L⁻¹·s⁻¹ (0.25 kPa·L⁻¹·s⁻¹; table 6). PEF is sensitive to the resistance of the meter; for example, a resistance of 0.25 kPa·L⁻¹·s⁻¹ decreases PEF by ~8% compared with PEF measured with a low-resistance pneumotachograph [48].

Intra-instrument repeatability must be <5% or 0.150 L·s⁻¹ (10 L·min⁻¹), whichever is the greater. Inter-device reproducibility must be <10% or 0.300 L·s⁻¹ (20 L·min⁻¹), whichever is the greater. Calculating PEF by differentiating volume–time data may introduce noise; hence, a parabolic-fitting algorithm may be used [2] as a smoothing procedure.

Equipment validation is covered in the Test signals for PEF meter testing section.

Test procedure

PEF is dependent on effort and lung volume, with subject cooperation being essential. PEF must be achieved as rapidly as possible and at as high a lung volume as possible, in order to obtain the maximum value [49]. The subject must be encouraged to blow as vigorously as possible. The neck should be in a neutral position, not flexed or extended, and the subject must not cough. A nose clip is not necessary.

After the point of full lung inflation, the subject must deliver the blow without any delay. Hesitating for as little as 2 s or flexing the neck allows the tracheal visco-elastic properties to relax and PEF to drop by as much as 10% [50]. Tonguing, spitting or coughing at the start of the blow may falsely raise the recorded PEF in some devices.

In the laboratory, the subject must perform a minimum of three PEF manoeuvres. When PEF is a self-administered recording, it is important that the subject has been adequately taught how to perform the test, when to perform it and what action to take depending on the resulting value obtained. Regular checks of the patient’s PEF technique and meter are an important part of the follow-up.
Within-manoeuvre evaluation

The subject must be observed to ensure a good seal at the mouth, no hesitation occurred, and there was no abnormal start to the manoeuvre.

Between-manoeuvre evaluation

The PEF values and their order must be recorded so that manoeuvre-induced bronchospasm can be detected. If the largest two out of three acceptable blows are not reproducible within 0.67 L·s⁻¹ (40 L·min⁻¹), up to two additional blows can be performed. Ninety-five per cent of untrained healthy subjects and patients can reproduce PEF to within 0.67 L·s⁻¹ (40 L·min⁻¹), and 90% to within 0.5 L·s⁻¹ (30 L·min⁻¹) [48]. If satisfactory repeatability has not been achieved in five attempts, more are not likely to be helpful [51].

Test result selection

The largest value from at least three acceptable blows is recorded.

MAXIMUM VOLUNTARY VENTILATION

This test has been largely superseded by FEV₁, which was defined as the index from a single maximum forced expiratory manoeuvre that best correlated with maximum voluntary ventilation (MVV). If FEV₁ is available, then MVV has little additional contribution to make in a clinical setting. However, it may be useful in those conditions where ventilatory capacity may be impaired by mechanisms that are different from those affecting FEV₁ [26].

Definition

The MVV is the maximum volume of air a subject can breathe over a specified period of time (12 s for normal subjects). It is expressed in L·min⁻¹ at BTPS.

Equipment

A spirometer used for measuring MVV must have an amplitude–frequency response that is flat (±10%) from zero to >4 Hz, at flows of up to 12 L·s⁻¹, over the volume range. The time for exhaled volume integration or recording must be no less than 12 s and no more than 15 s [52]. The indicated time must be accurate to within ±3%. The MVV must be measured with an accuracy of ±10% of reading or ±15 L·min⁻¹, whichever is greater.

The evaluation of equipment is covered in the Test signals for MVV testing section.

Test procedure

The technician should provide proper instructions and demonstrate the manoeuvre prior to the start of testing. The subject should be tested in the sitting position wearing a nose clip. After the subject makes an airtight seal around the mouthpiece, at least three resting tidal breaths should be obtained, followed by breathing as rapidly and deeply as possible. The tongue and teeth must be positioned so as to not obstruct airflow. The technician should enthusiastically coach the subject throughout the manoeuvre, and may need to suggest faster or slower breathing to achieve an ideal rate of 90–110 breaths·min⁻¹ [53, 54], although subjects with disease may not always achieve this rate. The technician will need to carefully observe the subject with occasional glances at the tracing to help the subject to obtain an acceptable manoeuvre. An acceptable manoeuvre should be performed with maximal effort without evidence of leakage, hesitation or measurement artefact. The subject is instructed to breathe as deeply and rapidly as possible and the tidal volume (VT) during the manoeuvre should be greater than the subject’s resting VT.

The test interval (e.g. 12 s) should be reported. A rest between manoeuvres will improve subsequent efforts.

The MVV should be calculated from the sum of all individual exhalations, multiplied by the appropriate BTPS correction factor during the best 12 s of the manoeuvre. From a technical standpoint, changes in respiratory rate or VT during the manoeuvre will influence test results.

Within-manoeuvre evaluation

In normal subjects, the goal for an acceptable MVV should be a VT that is ~50% of the VC, with a breathing frequency that is ~90 breaths·min⁻¹ [54]. It is unlikely that an acceptable manoeuvre will be obtained when the breathing frequency is <65 breaths·min⁻¹ [54]. However, since there are little data on MVV acceptability criteria, no specific breathing frequency or volume is required. The emphasis should be on maximal effort with a goal of 90 breaths·min⁻¹ and a volume representing ~50% of the VC. VT during the manoeuvre is probably not as important as breathing frequency, since patients tend to breathe on the portion of the expiratory curve where air is best moved at a given frequency.

Between-manoeuvre evaluation

The subject should perform a minimum of two acceptable manoeuvres. There are no clinical studies addressing repeatability; however, additional trials should be considered when the variability between acceptable manoeuvres exceeds 20%.

Test result selection

The highest acceptable MVV (L·min⁻¹ BTPS) and MVV rate (breaths·min⁻¹) should be reported. An MVV/(40 × FEV₁) <0.80 indicates that the MVV is low relative to the FEV₁, and suggests disease or poor effort. Volume versus time trajectories from at least two acceptable manoeuvres should be retained and available for inspection.

TECHNICAL CONSIDERATIONS

Minimal recommendations for spirometry systems

Accurate results require accurate equipment. Spirometer equipment recommendations apply to all spirometers and are minimal requirements. In some circumstances, it may be appropriate to exceed these requirements (i.e. in some research/surveillance applications). Instrumentation recommendations should be followed to provide accurate spirometric data and information that is comparable from laboratory to laboratory and from one time period to another [1]. The accuracy of a spirometry system depends on characteristics of the entire system, from the volume or flow transducer and the use of an in-line filter, to the recorder, display or processor. Changes in any aspect of the equipment or errors at any step in the process can affect the accuracy of the results. For example, if the BTPS correction factor is wrong, an accurately measured FVC will be incorrectly reported.
Spirometers and PEF meters are not required to measure all of the indices in Table 6, but must meet the recommendations for those that are measured. Accuracy and repeatability recommendations apply over the entire volume range of the instrument.

**BTPS correction**

All spirometry values should be reported at BTPS by any method (measuring temperature and barometric pressure) proven effective by the manufacturer. For volume-type spirometers, the temperature inside the spirometer should be measured for each breathing manoeuvre. Regardless of the BTPS correction technique used, the ambient temperature must always be recorded with an accuracy of ±1°C. In situations where the ambient air temperature is changing rapidly (>3°C in <30 min), continuous temperature corrections may be necessary. Spirometer users should be aware of potential problems with testing performed at lower ambient temperatures: 17 °C is the lower limit [55–63] for ambient temperature, unless a manufacturer states that their spirometer will operate accurately at lower ambient temperatures. If barometric pressure is not used in calculating the BTPS correction factor, the range of barometric pressures over which the BTPS correction factor is valid must be published by the manufacturer.

**Comments**

The rationale for this recommendation is based, in part, on the problems with finite cooling times of gases in volume-type spirometers [55–57] and the problems of estimating BTPS correction factors for flow devices [58–60]. When a subject performs an FVC manoeuvre, the air leaving the lungs is ∼33–35°C [61, 62] and saturated with water vapour. If the expired gas is assumed to be at BTPS, an error of ∼1% will result. Most volume-type spirometers assume instantaneous cooling of the air as it enters the spirometer. This is not always the case, and FEV1 can be incorrectly reported because of it. For capillary and screen pneumotachometers, the signal depends on gas viscosity, which increases with increasing temperature. Therefore, for pneumotachometers, a different correction factor is needed for recording patients as compared with recording from the calibrating syringe. Also, correction factors will be different for inspiratory and expiratory manoeuvres. It is usually assumed that expired gas does not cool as it passes through the flow sensor. This may not be the case, particularly with unheated flow sensors [58, 59]. The error will increase if the flow sensor is located further from the mouth and more cooling occurs, as is the case when a filter is placed in front of the flow sensor. Water condensation within or on the surfaces of a flow sensor may alter its calibration.

Depending on environmental temperature, the BTPS correction factor may be as large as 10%. The method used to calculate or estimate the BTPS factor can potentially introduce significant errors; examples and a fuller explanation can be found elsewhere [3, 4].

Changes in spirometer temperature can be a source of variability. Spirometer temperature should be measured and not assumed to be constant, even over the course of one testing session.

**TABLE 6** Range and accuracy recommendations specified for forced expiratory manoeuvres

<table>
<thead>
<tr>
<th>Test</th>
<th>Range/accuracy (BTPS)</th>
<th>Flow range L·s⁻¹</th>
<th>Time s</th>
<th>Resistance and back pressure</th>
<th>Test signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC</td>
<td>0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater</td>
<td>0–14</td>
<td>30</td>
<td>Mean resistance at 200, 400, 600 L·min⁻¹ (3.3, 6.7, 10 L·s⁻¹) must be &lt;2.5 cmH₂O·L⁻¹·s⁻¹ (0.25 kPa·L⁻¹·s⁻¹)</td>
<td>3-L Calibration syringe</td>
</tr>
<tr>
<td>FVC</td>
<td>0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater</td>
<td>0–14</td>
<td>15</td>
<td>&lt;1.5 cmH₂O·L⁻¹·s⁻¹ (0.15 kPa·L⁻¹·s⁻¹)</td>
<td>24 ATS waveforms, 3-L Cal Syringe</td>
</tr>
<tr>
<td>FEV1</td>
<td>0.5–8 L, ±3% of reading or ±0.050 L, whichever is greater</td>
<td>0–14</td>
<td>1</td>
<td>&lt;1.5 cmH₂O·L⁻¹·s⁻¹ (0.15 kPa·L⁻¹·s⁻¹)</td>
<td>24 ATS waveforms</td>
</tr>
<tr>
<td>Time zero</td>
<td>The time point from which all FEV1 measurements are taken</td>
<td>0–14</td>
<td>Back extrapolation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEF</td>
<td>Accuracy: ±10% of reading or ±0.30 L·s⁻¹ (20 L·min⁻¹), whichever is greater; repeatability: ±5% of reading or ±0.15 L·s⁻¹ (10 L·min⁻¹), whichever is greater</td>
<td>0–14</td>
<td></td>
<td>26 ATS flow waveforms</td>
<td></td>
</tr>
<tr>
<td>Instantaneous flows (except PEF)</td>
<td>Accuracy: ±5% of reading or ±0.200 L·s⁻¹, whichever is greater</td>
<td>0–14</td>
<td></td>
<td>Data from manufacturers</td>
<td></td>
</tr>
<tr>
<td>FEF25–75%</td>
<td>7.0 L·s⁻¹, ±5% of reading or ±0.200 L·s⁻¹, whichever is greater</td>
<td></td>
<td>15</td>
<td>Same as FEV1</td>
<td>24 ATS waveforms</td>
</tr>
<tr>
<td>MVV</td>
<td>250 L·min⁻¹ at VT of 2 L within ±10% of reading or ±15 L·min⁻¹, whichever is greater</td>
<td>±14 (±3%)</td>
<td>12–15</td>
<td>&lt;1.5 cmH₂O·L⁻¹·s⁻¹ (0.15 kPa·L⁻¹·s⁻¹)</td>
<td>Sine wave pump</td>
</tr>
</tbody>
</table>

BTPS: body temperature and ambient pressure saturated with water vapour; VC: vital capacity; FVC: forced vital capacity; ATS: American Thoracic Society; FEV1: forced expiratory volume in one second; FEV1: forced expiratory volume in 1 s; PEF: peak expiratory flow; FEF25–75%: mean forced expiratory flow between 25% and 75% of FVC; MVV: maximum voluntary ventilation; VT: tidal volume.
session. For volume spirometers, errors up to 6% in FEV1 and FVC can occur if ambient temperature is used instead of internal spirometer temperature [64]. For volume spirometers, the temperature inside the spirometer should be measured for each breathing manoeuvre.

**Test signals for spirometer testing**

The diversity of FVC manoeuvres encountered in clinical practice is currently best simulated by the 24 standard volume–time waveforms developed by the ATS [3] and HANKINSON and GARDNER [65]. These waveforms can be used to drive a computer-controlled mechanical syringe, or its equivalent, for testing actual hardware and software [66, 67], or, when put in a digital form, they can evaluate only the software. Computer-controlled mechanical syringes (i.e. pump systems) used for validation should be accurate within ±50 mL, which is 0.5% of their full range up to 10 L for FVC and FEV1. Pump systems may have accuracy values better than this for many profiles, but reproduce less accurately those test profiles with short DTs and RTs to peak flow [68, 69]. The ATS spirometry statement [3] shows the measured values for each of the 24 standard waveforms. On request, the ATS can provide these waveforms in an electronic format. Appropriate corrections for using gas at the ambient temperature and humidity instead of BTPS may need to be made for some mechanical syringe–spirometer combinations.

**Method**

A production spirometer is connected to the pump system for testing, orientated as it would be to test human subjects. Connecting tubing must be kept to the minimum (<=0.300 L) and must not be distensible. If an in-line filter is required for testing human subjects, one must be included when the instrument is tested. Each of the 24 ATS waveforms is discharged into the spirometer five times under ambient conditions, and all of the readings are recorded.

BTPS conditions are simulated by discharging waveforms 1–4 to the spirometer three times, using air heated to 37 ± 1°C and at >98% relative humidity. The time between each of the three tests should be <2 min.

**Accuracy test**

The average of the five tests under ambient conditions is compared with the standard value in the following way:

\[
\text{Deviation} = \text{average} - \text{standard}
\]  

(1)

Percentage deviation = 100 × (average – standard)/standard  

(2)

The accuracy validation limits for volumes, which include the waveform-generator inaccuracy, are ±3.5% of reading or ±0.100 L, whichever is greater. An accuracy error occurs if the deviation (for volumes <2.857 L) or percentage deviation (for volumes >2.857 L) exceed these limits. These limits include the allowable inaccuracy of the pump system.

Acceptable spirometer performance is defined as fewer than three accuracy errors for either FVC or FEV1 across the 24 waveforms (<5% error rate).

The average FVC and FEV1 values of the three tests simulating BTPS conditions are compared with the standard values. The validation limits for these tests under BTPS conditions are ±4.5% or 0.200 L, whichever is the greater, and these limits include the allowable inaccuracy for the pump system.

Acceptable spirometer performance under BTPS conditions is defined as the accuracy requirement being met for all of the four profiles used.

**Repeatability test**

The FEV1 and FVC data from the accuracy test are used to derive the span of the five recordings:

\[
\text{Span} = \text{maximum} - \text{minimum}
\]  

(3)

Percentage span = 100 × span/average  

(4)

The repeatability validation limits for the volume measured at ambient conditions are ±3.5% or ±0.100 L, whichever is the greater, and, for BTPS conditions, ±4.5% or ±0.200 L, whichever is the greater. A repeatability error occurs if the span (for volumes <2.857 L at ambient or 4.444 L at BTPS) or percentage span (for volumes above this) exceeds these limits.

Acceptable spirometer performance for repeatability under ambient conditions is defined as fewer than three accuracy errors for either FVC or FEV1 across the 24 profiles (<5% error rate). For BTPS conditions, the acceptable spirometer performance for repeatability is defined as the accuracy requirement being met for all of the four profiles.

**Test signals for PEF meter testing**

The 26 flow–time ATS waveforms were chosen to represent a range of PEF profiles suitable for delivery by mechanical syringe or pump systems to test PEF meters [3]. The range of profiles and method of delivery may need to be revised, as research on PEF measurement continues [45]. The mechanical syringe or suitable pump system used to validate PEF measuring equipment must have an accuracy of ±2% in delivering PEF. Pump systems may have difficulty meeting this accuracy standard for profiles more demanding than the set of 26 [68, 69]. Recent evidence suggests that the frequency content in the first second of the blow that contributes to PEF is higher [47] than previously determined [70, 71]. The 26 waveforms may not cover the range of RT and DT found in ~25% of the client population [72], and, hence, more demanding test profiles may be required in future [45].

**Method**

Two randomly chosen production models of the flow meters should each have the 26 waveforms delivered to them five times under ambient conditions and the readings recorded. Any waveforms with a PEF outside the meter’s stated operational range would not be included in the testing sequence. Appropriate correction factors for testing under ambient conditions should be applied as recommended by the manufacturer.

**Accuracy test**

The average reading for each of the two meters is compared with the standard, as for volumes.

The accuracy validation limits are ±12% or ±25 L·min⁻¹, whichever is the larger, and these limits include the 2% inaccuracy limit for the waveform generator. An accuracy error
for a given meter and given waveform occurs if the deviation and percentage deviation exceed these limits.

Acceptable performance is defined as fewer than three accuracy errors out of the total of 52 tests (26 waveforms, two meters).

Repeatability test
Flow waveforms 1, 4, 8 and 25 are discharged three times to each of 10 production meters. The repeatability validation limits are ±6% or ±15 L·min⁻¹, whichever is the greater, and these limits include 1% for waveform-generator variability. A repeatability error occurs if the span and percentage span exceed these limits.

Acceptable performance is defined as six or fewer errors in the 120 tests (i.e. maximum error rate of 5%).

**Test signals for MVV testing**
A spirometry system used to measure MVV should be tested under ambient conditions with a pump producing a sinusoidal waveform, with stroke volumes up to 2 L using the four patterns of delivery previously specified [3]. Testing at BTPS is not required, and each pattern is tested twice. The accuracy validation limits of the spirometer used for measuring MVV with flows up to 250 L·min⁻¹ are ±10.5% of reading or ±20 L·min⁻¹, whichever is greater. The pressure at the mouthpiece must not exceed ±10 cmH₂O (1 kPa) at any point during MVV testing. These requirements apply to volume spirometers throughout their volume range.

Acceptable performance is defined as no errors in the eight tests (four patterns, twice).

**ABBREVIATIONS**
Table 7 contains a list of abbreviations and their meanings, which will be used in this series of Task Force reports.

<table>
<thead>
<tr>
<th>TABLE 7</th>
<th>List of abbreviations and meanings</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATPD</td>
<td>Ambient temperature, ambient pressure, and dry</td>
</tr>
<tr>
<td>ATPS</td>
<td>Ambient temperature and pressure saturated with water vapour</td>
</tr>
<tr>
<td>BTPS</td>
<td>Body temperature (i.e. 37°C), ambient pressure, saturated with water vapour</td>
</tr>
<tr>
<td>C</td>
<td>Centigrade</td>
</tr>
<tr>
<td>CFC</td>
<td>Chlorofluorocarbons</td>
</tr>
<tr>
<td>cm</td>
<td>Centimetres</td>
</tr>
<tr>
<td>COHb</td>
<td>Carboxyhaemoglobin</td>
</tr>
<tr>
<td>DL,CO</td>
<td>Diffusing capacity for the lungs measured using carbon monoxide, also known as transfer factor</td>
</tr>
<tr>
<td>DL,CO/VA</td>
<td>Diffusing capacity for carbon monoxide per unit of alveolar volume, also known as Kco</td>
</tr>
<tr>
<td>DM</td>
<td>Membrane-diffusing capacity</td>
</tr>
<tr>
<td>DT</td>
<td>Dwell time of flow &gt;90% of PEF</td>
</tr>
<tr>
<td>EFL</td>
<td>Expiratory flow limitation</td>
</tr>
<tr>
<td>ERV</td>
<td>Expiratory reserve volume</td>
</tr>
<tr>
<td>EV</td>
<td>Back extrapolated volume</td>
</tr>
<tr>
<td>EVC</td>
<td>Expiratory vital capacity</td>
</tr>
<tr>
<td>Fₐ,X</td>
<td>Fraction of gas X in the alveolar gas</td>
</tr>
<tr>
<td>Fₐ,X,t</td>
<td>Alveolar fraction of gas X at time t</td>
</tr>
<tr>
<td>FEF₃₀-75%</td>
<td>Mean forced expiratory flow between 25% and 75% of FVC</td>
</tr>
<tr>
<td>FEF₅₀</td>
<td>Instantaneous forced expiratory flow where 50% of the FVC has been expired</td>
</tr>
</tbody>
</table>

**TABLE 7 (Continued)**

| FEV₁ | Forced expiratory volume in one second |
| FEV₉₅ | Forced expiratory volume in 95% of FVC |
| FEx  | Fraction of expired gas X |
| FIFx%| Instantaneous forced inspiratory flow at the point where X% of the FVC has been inspired |
| FLX  | Fraction of inspired gas X |
| FIVC | Forced inspiratory vital capacity |
| FRC  | Functional residual capacity |
| FVC  | Forced vital capacity |
| H₂O  | Water |
| Hb   | Haemoglobin |
| Hg   | Mercury |
| Hz   | Hertz; cycles per second |
| IC   | Inspiratory capacity |
| IVC  | Inspiratory vital capacity |
| Kco  | Transfer coefficient of the lung (i.e. DL,CO/VA) |
| kg   | Kilograms |
| kPa  | Kilopascals |
| L    | Litres |
| L·min⁻¹ | Litres per minute |
| L·s⁻¹ | Litres per second |
| lb   | Pounds weight |
| MEFX%| Maximal instantaneous forced expiratory flow where X% of the FVC remains to be expired |
| MFVL | Maximum flow-volume loop |
| mg   | Milligrams |
| MIF  | Maximal inspiratory flow |
| mL   | Millilitres |
| mm   | Millimetres |
| MMEM | Maximum mid-expiratory flow |
| ms   | Milliseconds |
| MVV  | Maximum voluntary ventilation |
| PA,CO₂| Alveolar carbon dioxide partial pressure |
| PB   | Barometric pressure |
| PEF  | Peak expiratory flow |
| P₂H₂O| Water vapour partial pressure |
| P₉O₂ | Inspired oxygen partial pressure |
| T (theta) | Specific uptake of CO by the blood |
| RT   | Rise time from 10% to 90% of PEF |
| RV   | Residual volume |
| s     | Seconds |
| STPD | Standard temperature (273 K, 0°C), pressure (101.3 kPa, 760 mmHg) and dry |
| TB   | Tuberculosis |
| TGV (or VRC) | Thoracic gas volume |
| t½ | Time taken for half-life |
| TLC  | Total lung capacity |
| Tr   | Tracer gas |
| ttot | Total time of respiratory cycle |
| VA   | Alveolar volume |
| VA,effective | Effective alveolar volume |
| VC   | Vital capacity |
| Vc   | Pulmonary capillary blood volume |
| Vo   | Dead space volume |
| Vt   | Inspired volume |
| Vs   | Volume of the expired sample gas |
| μg   | Micrograms |
**APPENDIX**

*Proposal for a standard data format for spirometry*

This proposal would not preclude the use of other data formats, but would require that a spirometer should at least be able to output data in the required format. The advantage of a standard format is the ease of moving data into data repositories, such as quality control, healthcare and research databases. It should simplify and reduce the cost of data transfer when users change instrument models and manufacturers. Easier transfer of data into healthcare databases has the potential for improving the utility of lung function by making more complete data readily available to clinicians and healthcare researchers. In research and clinical settings, a standard data format should simplify and reduce the cost of transferring data into quality control software and could contribute to improved overall test quality. Finally, it is time for this change; pulmonary function is one of the last medical arenas without a standard data format.

**Proposed format**

The spirometry data file will consist of an American Standard Code for Information Interchange, comma-delineated file with variable length records. Comma-delineated text files are easily generated and are standard import formats for several database programs. Although some redundancies will exist, each record shall represent one curve and will be terminated with a carriage return and line feed. The ATS will distribute examples of this data format from their web site.

Table 8 shows a list of parameters that must be included in every record. If a parameter is unavailable, the space must remain blank ("."). The flow–time data points must be provided with a sampling interval of 0.01 s (100 samples–s\(^{-1}\)) in mL–s\(^{-1}\). If necessary, interpolation or other techniques must

<table>
<thead>
<tr>
<th>TABLE 8</th>
<th>List of parameters*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID (patient identification)</td>
<td></td>
</tr>
<tr>
<td>Patient name</td>
<td></td>
</tr>
<tr>
<td>Data type (SP followed by E=expiratory or I=Inspiratory, followed by S=single or B=best curve)</td>
<td></td>
</tr>
<tr>
<td>Barometric pressure (mmHg)</td>
<td></td>
</tr>
<tr>
<td>Temperature (°C) used in BTPS calculation</td>
<td></td>
</tr>
<tr>
<td>Relative humidity (%)</td>
<td></td>
</tr>
<tr>
<td>FVC quality attribute (A, B, C, D or F)</td>
<td></td>
</tr>
<tr>
<td>FEV1 quality attribute (A, B, C, D or F)</td>
<td></td>
</tr>
<tr>
<td>Effort attribute (A, B, C, D or F)</td>
<td></td>
</tr>
<tr>
<td>Interpretation code (see ATS interpretation scheme)</td>
<td></td>
</tr>
<tr>
<td>Deleted manoeuvre (Y or N)</td>
<td></td>
</tr>
<tr>
<td>Acceptable manoeuvre (Y or N)</td>
<td></td>
</tr>
<tr>
<td>Technician quality control code (A, B, C, D or F)</td>
<td></td>
</tr>
<tr>
<td>Computer quality code (A, B, C, D or F)</td>
<td></td>
</tr>
<tr>
<td>Plateau achieved (Y or N)</td>
<td></td>
</tr>
<tr>
<td>Review (N or R for “needs review” or “was reviewed”)</td>
<td></td>
</tr>
<tr>
<td>Date of review (DD/MM/YYYY)</td>
<td></td>
</tr>
<tr>
<td>Reviewer initials</td>
<td></td>
</tr>
<tr>
<td>BTPS factor (x.xxx)</td>
<td></td>
</tr>
<tr>
<td>Spirometer manufacturer</td>
<td></td>
</tr>
<tr>
<td>Spirometer model</td>
<td></td>
</tr>
<tr>
<td>Spirometer serial number</td>
<td></td>
</tr>
<tr>
<td>Spirometer type</td>
<td></td>
</tr>
</tbody>
</table>

---

* All text type variables should be enclosed with double quotes (“”) to prevent confusion with control or data separator type characteristics.
be used to provide the 0.01-s sampling interval. The record length will vary, depending on the number of data points present in the flow–time portions of the record. The curve data must include ≥0.25 s of data points prior to the onset of the inspiratory or expiratory manoeuvre.

Volume–time curves may be calculated by adding the flow–time portions of the record. The curve data length will vary, depending on the number of data points be used to provide the 0.01-s sampling interval. The record 0.01 s.

REFERENCES


Leach CL, Davidson PJ, Hasselquist BE, Boudreau RJ. Lung deposition of hydrofluoralkane-134a beclometasone is greater than that of chlorofluorocarbon fluticasone and chlorofluorocarbon beclometasone: a cross-over study in healthy volunteers. *Chest* 2002;122:510-516.


Spirometry in primary care


Canadian Thoracic Society (CTS) clinical guidelines for asthma and chronic obstructive pulmonary disease (COPD) specify that spirometry should be used to diagnose these diseases. Given the burden of asthma and COPD, most people with these diseases will be diagnosed in the primary care setting. The present CTS position statement was developed to provide guidance on key factors affecting the quality of spirometry testing in the primary care setting. The present statement may also be used to inform and guide the accreditation process for spirometry in each province.

Although many of the principles discussed are equally applicable to pulmonary function laboratories and interpretation of tests by respiratory therapists, they are held to a higher standard and are outside the scope of the present statement.

Key Words: Primary care; Pulmonary function; Quality control; Reference values; Spirometry

POSITION STATEMENT DEVELOPMENT PROCESS

The present position statement was developed by the CTS Pulmonary Function Standards Committee, comprised of experts with experience in the development of international spirometry guidelines, the use of spirometry in asthma and COPD, the training of individuals to conduct quality spirometry, the training of physicians and nurse practitioners to interpret spirometry, the development of normal values for spirometry and the evaluation of spirometers. The position statement reflects the key issues found in spirometry training in primary care and interpretation of spirometry testing conducted in primary care.

Consensus process

The present position statement is based on the joint standards for lung function testing by the American Thoracic Society (ATS) and the European Respiratory Society (ERS) published in 2005 (1,2). Where there may be either controversial issues or changes based on new data, these are indicated.

The recommendations were agreed on by consensus from the full committee through extensive discussions, review of the evidence, and review of existing guidelines and accreditation standards.

Who can conduct spirometry

Spirometry is not controlled under medical services regulations and, therefore, there are no legal restrictions on who can perform spirometry testing. Provincial accreditation guidelines are variable across the country. British Columbia, Alberta and Ontario have guidelines that specify that a suitably trained and qualified “Medical Director” or “Quality Advisor” oversee spirometry testing. Because spirometry requires the very active participation of the patient, the technologist must have the skills and ability to proceed well beyond the usual level of patient interaction in medical tests and should have basic life-support training. Spirometry testing can be conducted by the following:

1. Trained health care personnel who are registered respiratory therapists (RRT) or registered cardiopulmonary function technologists (RCFT[P]);
2. Other health care professionals whose formal training included studies in the anatomy and physiology of the cardiorespiratory system, and who subsequently successfully completed a recognized spirometry training course; and
3. Other trained health care technologists who subsequently successfully completed a recognized spirometry training course.

For all of the above, an additional requirement is one month of supervised training in the performance and quality control of spirometry testing (3).

Key Message:

Spirometry should be conducted by trained and qualified personnel in a setting with a regular quality assurance program.

Training courses for conducting quality spirometry testing are available; including the CTS-endorsed SpiroTrec® course which is offered by RESP’Tec® (www.resptec.org). SpiroTrec® teaches individuals how to conduct quality spirometry including knowledge of spirometers, understanding of the ATS/ERS standards for spirometry, quality control, patient instruction and basic interpretation of the results. This course includes 16 h of preworkshop learning and assignments, an 8 h workshop and a subsequent quality assurance review of five to 10 spirometry tests per month for three months.

A recent study (4) found that asthma educators who enrolled in a 4 h course in conducting spirometry were able to meet ATS/ERS spirometry testing standards (2) 77% of the time. Short-term follow-up and supplementary training is important to maintain the quality of spirometry testing (5).
### Table 1  
Relative contraindications for spirometry

<table>
<thead>
<tr>
<th>Relative contraindications</th>
<th>Mechanisms</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral aneurysm</td>
<td>Increases in intracranial/ intraocular pressure due to decreased venous return</td>
<td>Increases in intracranial pressure during weightlifting (5) suggest spirometry testing may lead to clinically significant changes in intracranial pressures in most patients. Most experts suggest a three- to six-week recovery period following surgery before spirometry testing.</td>
</tr>
<tr>
<td>Recent brain surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent concussion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent eye surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Significant glaucoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent sinus surgery or middle ear surgery or infection</td>
<td>Increases in sinus and middle ear pressures</td>
<td>There is a risk that forced manoeuvres cause excessive pain or even ear drum rupture in cases of middle ear infection.</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>Increases in intrathoracic and intra-abdominal pressure</td>
<td>*Increases in intrathoracic or intra-abdominal pressures may increase blood pressure, but are not expected to increase aortic transmural pressure.</td>
</tr>
<tr>
<td>Significant aortic aneurysm</td>
<td>Increases in intrathoracic and intra-abdominal pressure</td>
<td></td>
</tr>
<tr>
<td>Recent thoracic surgery</td>
<td>Increases in intrathoracic and intra-abdominal pressure</td>
<td></td>
</tr>
<tr>
<td>Recent abdominal surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic hypotension or severe hypertension (eg, &gt;200/120 mmHg)</td>
<td>Increases in myocardial demand or changes in blood pressure</td>
<td>Exercise testing one week after myocardial infarction appears to be safe. A shorter period could be appropriate following reperfusion therapy (eg, angioplasty), whereas caution is necessary in case of persistent myocardial ischemia.</td>
</tr>
<tr>
<td>Significant atrial/ ventricular arrhythmia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Noncompensated heart failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent myocardial infarction or pulmonary embolus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of syncope related to forced exhalation/cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active tuberculosis</td>
<td>Infection control issues</td>
<td>General infection control measures should be adopted in accordance to local procedures.</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoptysis or oral bleeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inability to follow directions (eg, confusion, dementia, young age, language barrier)</td>
<td>In some cases, successful spirometry can be obtained with increased coaching and aid of an interpreter</td>
<td></td>
</tr>
</tbody>
</table>

### Key Messages:

Primary care physicians and nurse practitioners who interpret spirometry should have completed a spirometry interpretation course or specific training in spirometry interpretation.

### PATIENT CONDITIONS AND TESTING ENVIRONMENT

**Indications and contraindications**

Spirometry is performed to objectively assess individuals’ pulmonary function. It enables measuring the effect of a disease on lung function, monitoring its course or the result of therapeutic interventions, assessing preoperative risk and prognosticating many pulmonary conditions. Conversely, spirometry may be contraindicated (6). International guidelines regarding contraindications for lung function tests have been proposed; however, their evidence base is generally founded only on expert opinion (1). Moreover, recent developments in patient management, surgical practice and technology have decreased the invasive nature of procedures; therefore, some of the contraindications may no longer be justified. Additionally, patients with contraindications that would prevent testing in the primary care setting can be tested in a pulmonary function laboratory where there is access to resuscitation personnel and equipment.

Potential risks associated with lung function testing primarily relate to the following: maximal pressures generated in the thorax and their impact on abdominal and thoracic organs; venous return and systemic blood pressure; expansion of the chest wall and lung; and active communicable diseases that pose a risk to staff and other patients (eg, tuberculosis). Spirometry and other forced expiratory manoeuvres will result in increased intrathoracic, intra-abdominal and intracranial pressures (7). Performing lung function tests can also be physically demanding for patients, thus increasing myocardial demand. This calls for prudence in patients with medical conditions that could be adversely affected by these physiological consequences (Table 1). Although there is no large-scale registry documenting the incidence of adverse events following pulmonary function testing, such risks are likely to be minimal in most patients. Importantly, the potential risks associated with testing should always be weighed against the benefit of obtaining information about lung function (6). When a spirometry test is unlikely to be of real clinical benefit to a compromised patient, it should be postponed until the patient has recovered from surgery, an infection or, for example, pneumothorax, hypo- or hypertension, or unstable arrhythmias. Conversely, a dogmatic approach of refusal to test patients with any contraindication must be tempered. For cases in which the benefit of obtaining objective measures of lung function may outweigh the risk of testing, referral to a specialist should be considered.

Although pre- and postbronchodilator spirometry testing is common for an initial visit, subsequent testing may not require postbronchodilator testing, depending on the reason for ordering spirometry. Some clinicians may routinely conduct pre- and postbronchodilator testing to improve office efficiency and convenience for the patient (two tests in one session instead of two sessions) unless otherwise indicated.

**Patient preparation**

Contraindications should be listed on the spirometry requisition or checklist form. The requisition should clearly state the reason for requesting spirometry and include comments or questions by the requesting physician or nurse practitioner. Spirometry may give rise to stress incontinence; therefore, appropriate precautions should be taken (see a sample form in Appendix A).

Testing should occur in a bright and comfortable environment. The patient should be seated. A chair with arms (to prevent falling sideways should syncope occur), without wheels and that can be adjusted so that the feet are flat on the floor is recommended.
**Explanations:** Spirometry requires cooperation between the subject and the examiner; the results obtained will depend on technical and personal factors. The test should be fully explained to the patient, and delaying the test should be strongly considered in case of transient confusion or absence of cooperation (1). Videos that demonstrate the test procedure to help educate the patient are available from The Lung Association (www.youtube.com/watch?v=70RNHWVryY).

Details of smoking history and any recent illness that could influence the results should be recorded. Ideally, patients should avoid heavy exercise within 30 min, large meals within 2 h, alcohol consumption within 4 h and smoking within 1 h of testing (1).

**Medications:** The technologist should record the name, dosage and the last administration of any medication that may alter lung function. The decision to avoid bronchodilators before testing is dependent on the reason for the test. If the study is performed to diagnose an underlying lung condition, then avoiding bronchodilators is useful. In this case, short-acting inhaled drugs should not be used within 4 h of testing, whereas long-acting bronchodilators should be stopped for longer periods (eg, 12 h for salmeterol and formoterol, 24 h for tiotropium, indacaterol and montelukast). Conversely, if the test is performed to determine a response to an existing therapeutic regimen, then the referring physician may choose not to withhold bronchodilator medications. The requisition form or checklist should state whether the patient should withhold medications before the test, and, if so, precisely which medications should be withheld and for how long.

**Anthropometric measures:** Before testing, it is essential that height be measured accurately because height, ethnicity, age and sex determine the spirometry reference values. To properly measure height, the subject must be standing without shoes with his/her back flush against a hard surface, such as a wall, with a measuring tape attached to the wall with a right angle device making contact with top of the head and the tape. Ideally, this is accomplished with a proper stadiometer (8). The use of measuring devices attached to scales is inappropriate because it is exceedingly difficult to ensure that the back is held straight. In the presence of chest wall deformities or when height cannot be measured, arm span (middle finger tip to middle finger tip) can be used as an approximation of height (9).

**Key Messages:**
- A checklist including all relative contraindications should be completed before testing
- In the case of a contraindication, the risk and benefit of the test should be weighed by the treating physician or the medical director of the laboratory, and testing should be referred to a laboratory where emergency facilities are available
- Appropriate explanations and coaching are mandatory to obtain reliable pulmonary function tests. Precise anthropometric measurements are mandatory for determining reference values
- Infection control programs should be followed.

**SPIROMETER SELECTION CONSIDERATIONS**

Although some older spirometer systems use volume measurement devices, whereby all of the air that the patient exhales is collected in an expandable chamber, almost all spirometers used in physician office settings (and many pulmonary function laboratories) measure air flow and calculate the volume from this signal. Only flow measurement devices are considered here. Other guidelines to assist in spirometer selection are available (10,11).

**ATS/ERS standards**
The ATS/ERS Standardisation of Spirometry document (2) contains technical specifications for spirometers. All spirometers must meet the most current ATS/ERS standards, which at time of writing is the 2005 edition. Some spirometers are advertised as meeting ATS standards; however, the fine print will say state ‘meets ATS 1994 Standards’.

**Exhalation-only versus full flow-volume loops** Some less expensive spirometers are designed for exhalation-only use. The patient inhales to maximal lung volume; then, while holding his/her breath, inserts the mouthpiece between the teeth, seals his/her lips around the mouthpiece and then forcibly exhales into the spirometer. This requires more coordination on the part of the patient and increases difficulty for the technologist conducting spirometry to assess test quality. Any leakage that occurs after the patient reaches maximal lung volume and before the mouthpiece is in place is lost and, therefore, not included in the calculation of forced vital capacity (FVC) or the back-extrapolated volume. Furthermore, some exhalation-only models are not equipped with real-time displays that permit proper coaching to obtain a best effort. The use of such spirometers is not recommended.

Select a spirometer that enables the patient to take tidal breaths while the technologist can observe that the mouthpiece and nose clip are functioning properly. The technologist then has better control of the manoeuvre and can better coach patients to reach maximal lung volume. Additionally, if any leakage is observed at maximal lung volume before the start of forced exhalation, it will be measured by the spirometer and used to determine whether it is within ATS/ERS standards for the back-extrapolated lung volume. Furthermore, the time spent at total lung capacity can be assessed to determine whether there is a pause at end inspiration and, if >1 s, the manoeuvre can be repeated (12).

**Display**
The spirometer display, whether using a built-in screen or via a connection to a computer screen, must show both the flow-volume loop and the volume-time graph with sufficient resolution for the technologist to distinguish whether end-of-test criteria are met, whether the shape of the flow-volume curve is consistent with a maximal exhalation, and whether a cough or other artefact occurred in the first 1 s of exhalation. In most instances, the display will appear on a computer screen that is not supplied with the system. Most spirometers will have a USB cable to connect to a computer. Ensure that computer hardware and software are compatible with the spirometry system.

It must be possible to position the display so that the technologist can observe both the display and the patient simultaneously during the manoeuvres. This allows for instant coaching and also enables the technologist to terminate a poor effort early, rather than to push the patient to continue a tiring forced expiration.

**Warning messages and suggested corrections:** The spirometer must evaluate each manoeuvre to determine whether ATS/ERS requirements were met and provide warning messages for any condition that is not met. Examples include “true start – don’t hesitate” and “end of test criteria not met – blow out longer”. The spirometer must also analyze the set of manoeuvres to determine whether ATS/ERS repeatability criteria are met. Some systems offer real-time messages to indicate when 6 s of exhalation has been achieved, which can aid the technologist in coaching to achieve a good quality test. Most of the ATS/ERS requirements are based on adults rather than children, and many children can meet these requirements with submaximal efforts and poor quality tests. A good technologist recognizes this and repeats the effort even if the computerized system has accepted the test.

**Calibration** A calibrating syringe is a required accessory for spirometers. ATS/ERS standards specify that a 3 L calibrating syringe be used for checking and calibrating the spirometer and additional specify accuracy requirements, including scheduled accuracy checks of the syringe. If filters are used for patient testing, calibration must be performed with a filter inline. Simple leak tests should be conducted monthly using a stopper in the syringe and checking for changes in syringe volume with pushing or pulling excursions. It may be necessary to purchase a special adaptor to connect the calibration syringe to your spirometer. Some calibrating syringes fit directly onto a disposable mouthpiece or filter.
Some spirometers are equipped with precalibrated disposable breathing-tube inserts that cannot be calibrated by the user. Spirometers using such precalibrated inserts must still be checked daily for accuracy use a 3 L calibrating syringe.

Some spirometers require environmental information such as room temperature, barometric pressure and/or altitude. If so, these parameters should be measured, not estimated. If a barometer is not available, pressure reported from a nearby weather station (refer to the Environment Canada website) must be corrected for altitude (table available at www.engineeringtoolbox.com/air-altitude-pressure-d_462.html).

Normal reference values: To determine appropriate sets of reference values, refer to the following section in the present document. Select a spirometer that has these specific sets of normal reference values, both adult and pediatric, preprogrammed into its software. If these reference value sets are not included in the defaults provided by the spirometer, insist that they be installed before purchase.

Reports
The spirometry system must be capable of producing a report as described in the next section of the present document. When selecting a spirometer, consider whether it is compatible with the electronic medical record (EMR) system used in the facility. Some systems will permit customized EMR reports, other require reports to be printed to a portable document format (ie, PDF) file for attachment to an EMR.

Disposables
In the selection process, consider the cost and availability of mouthpieces, which usually incorporate a filter. Some models have different mouthpieces for adult and pediatric use. Some models have a mouthpiece incorporated into a disposable breathing tube, making a filter unnecessary. Although filters are not required by ATS/ERS standards, many health regions specify their use for infection control. Nose clips are recommended whenever conducting spirometry.

Robustness
The spirometer must be sufficiently robust to be unaffected by incidental bumps or drops. If the spirometer has been dropped or jarred significantly, a calibration check is recommended before continuing the test.

Technical support
The vendor from whom the spirometer is purchased should provide initial training on the use of the spirometer. It should also provide technical support for addressing problems with the operation of the spirometer. Request a ‘loaner’ device in the event that the spirometer needs to be returned to the company for servicing. There should be regular notification of software upgrades or patches to fix problems. The spirometer should be thoroughly checked following any updates to the software.

Key Messages:
• A good quality spirometer is essential for reliable results.
• ATS/ERS technical specifications must be met.
• Choose a spirometer that can display large screen flow-volume and volume-time graphs in real time.
• The software must be able to check for ATS/ERS acceptability and repeatability criteria and provide appropriate warning messages.

PRINCIPLES FOR ROUTINE SPIROMETRY REPORTS
A sample spirometry report form is provided in Appendix B, which is based on the following principles:
1. Report on a minimal set of variables. Do not clutter the report with several extraneous variables.
2. Patient identification should include name, date of birth and institutional identification number.
3. Report observed values in the first column following the variable name. Avoid reporting reference values that can be confused with observed values and do not add any additional information.
4. Height should be reported in cm. Weight should be reported in kg to one decimal place.
5. Report the lower limit of normal (LLN). Per cent of reference values are reported because they are used to determine the degree of obstruction.
6. Report ratios as a decimal fraction so they are not confused with per cent of a reference value.
7. Print flow-volume and volume-time graphs with a sufficient size and scale them to make optimal use of the available plot area while maintaining the proper aspect ratio. For volume-time graphs, show the last second before start of maximal exhalation. Including all manoeuvres in the session rather than only the best pre- and post-curve is optional.
8. Include the source of the reference values on the report. If the age of the patient is outside of the age range for which the reference values were determined, flag the LLN values.
9. Report ethnicity and flag LLN values if the ethnicity does not match the reference value data set. Do not adjust the observed values or LLN for ethnicity by an arbitrary percentage.
10. Report the reason for the test.
11. Report technologist comments, which include an assessment of the quality of the spirometry session.

Order of columns
1. Variable name with measurement units
   Prebronchodilator
2. Observed value (using ATS/ERS selection criteria)
3. Lower limit of normal
4. Per cent of reference value
   Postbronchodilator
5. Observed value
6. Percent of reference value
7. Volume change from prebronchodilator
8. Per cent change from prebronchodilator (the latter two are reported because a change ≥200 mL and ≥12% is required for a response to bronchodilators to be significant [2], although lower absolute volume change is acceptable for children or subjects with small lung volumes)

Spirometry variables to report

<table>
<thead>
<tr>
<th>Variable</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forced vital capacity (FVC)</td>
<td>L</td>
</tr>
<tr>
<td>Forced expiratory volume in first 1 s (FEV₁)</td>
<td>L</td>
</tr>
<tr>
<td>Ratio of FEV₁ to FVC (FEV₁/FVC)</td>
<td>–</td>
</tr>
<tr>
<td>Peak expiratory flow (PEF)</td>
<td>L/s</td>
</tr>
<tr>
<td>Forced expiratory time (FET)</td>
<td>s</td>
</tr>
</tbody>
</table>

Optional variables: The forced expiratory flow from 25% to 75% of exhalation (FEF25-75) is only recommended for children (13,14) and is used in settings primarily designed for children. Interpretation of FEF25-75 requires experience with its high degree of variability and its dependence on FVC.

Although not recommended for office spirometry, some advanced laboratories may report other indexes, particularly the ratio of inspiratory to expiratory flows at 50% vital capacity when upper airway obstruction is suspected.

Graphs
At a minimum, the best pre- and postbronchodilator tests should be displayed. The best manoeuvre is the one with the highest sum of FVC and FEV₁. The individual graphs should be distinguishable by colour or line type (solid versus dashed), or by displacement along the x-axis. There should be an option to plot all acceptable manoeuvres for each of

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Some manufacturers regarding whether the grading is performed for each manoeuvre as a whole, or for the FEV1 and FVC separately (17). Some manufacturers have implemented one or other of the proposed systems. In general, A indicates that ATS/ERS standards were exceeded; B that standards were met; C and D that the data are usable but fall short of ATS/ERS standards (eg, only two acceptable manoeuvres but they are repeatable); and F that the test is not useable for interpretation. These can be used as a guide for technologist comments, but should not be used as a substitute for technologist comments. If the spirometry grade is included in the report, it is important for both the technologist and the interpreter to be familiar with the particular grading system that is being used by the spirometry software.

### Test quality grading (optional)

While various authors have recommended spirometry grading, such as the scholastic grading system (A, B, C, D and F [16]), there is no ATS or ERS standard. Furthermore, there is no uniform agreement regarding whether the grading is performed for each manoeuvre as a whole, or for the FEV1 and FVC separately (17). Some manufacturers have implemented one or other of the proposed systems. In general, A indicates that ATS/ERS standards were exceeded; B that standards were met; C and D that the data are usable but fall short of ATS/ERS standards (eg, only two acceptable manoeuvres but they are repeatable); and F that the test is not useable for interpretation. These can be used as a guide for technologist comments, but should not be used as a substitute for technologist comments. If the spirometry grade is included in the report, it is important for both the technologist and the interpreter to be familiar with the particular grading system that is being used by the spirometry software.

### Reference values

The expected lung volume is most affected by height – the taller the individual, the larger the lung volume. The variation of lung volume with age is more complex. Lung volume increases as the lungs grow from birth to 18 to 20 years of age in females, and 20 to 24 years of age in males. Thereafter, lung volume declines with age because the lungs lose elastic recoil with reduced expiratory flows (18). Adult males have higher lung volumes than adult females of the same age and height. African Americans have lung volumes approximately 10% lower than Caucasians. Asians have lung volumes 2% to 8% lower than Caucasians (15).

Reference values for FEV1, FVC and FEV1/FVC are generated from population studies of healthy, asymptomatic individuals. For most biological measurements, the standard assumption is that for data with a normal distribution, values within 2 SDs of the mean value represent 95% of the population and are considered to be normal. This implies that 5% of the population (2.5% above and 2.5% below 2 SDs) are ‘abnormal’. For spirometry variables, values that are higher than the reference value are not considered to be abnormal. The LLN is defined as the 5th percentile (ie, the value that marks the lower 5% of the normal population). In a normal distribution, LLN is 1.64 SDs below the mean value (Figure 2) (19). Clearly, when using the LLN, 5% of the healthy, asymptomatic population will be classified as below normal. On the other hand, some people with lung disease will have values greater than LLN and will be classified as normal. The SDs graph on the report form helps to determine the likelihood and degree of abnormality (Figure 1). However, spirometry results are but one finding and must be considered in the context of history, symptoms and physical findings to make the diagnosis.

While some studies have produced reference values for adults and others for children, it is recommended that a continuous set of reference values that applies to all ages be used. Errors often arise when trying to extrapolate reference values developed for adults to the adolescent range, or when trying to extrapolate children’s values above 18 or below the age range of the reference equations. The GLI recommends the all-age spirometry values developed by Quanjer et al (15),
larger lung volumes than Caucasians. Research is currently underway.

There are some suggestions that this group has

produces significantly different values in the transition period.

continuity occurs when the pediatric and adult reference equations

disadvantages is the problem of discontinuity between paediatric and

advantage is the problem of discontinuity between paediatric and

which are a composite of spirometry measures worldwide. These reference values are divided into Caucasians, African Americans, Southeast Asians and Northeast Asians.

Some spirometry systems have implemented the reference values from Stanojevic et al (20 [2008]) for ages six to 70 years. The Quanjer et al (15) 2012 reference values are the same over this age range but expand the age range to 3.5 to 90 years. Most major spirometer manufacturers have committed to implementing the Quanjer et al (15) reference values in their newest or forthcoming models (www.lungfunction.org/93-manufacturers.html).

Another choice of reference equations is the National Health and Nutrition Examination Survey (NHANES III) series (Hankinson et al [21]), with values for Caucasian, African Americans and Hispanics between eight and 80 years of age. These equations should not be used outside their age range, particularly for children younger than eight years of age (22). This set is contained in almost all current spirometry systems.

In terms of a ‘Made in Canada’ solution, recently published reference values for Caucasian Canadian adults 20 to 90 years of age (23) supplement those of Gutierrez et al (24) for adults 20 to 80 years of age. The subjects are sufficiently numerous to enable an accurate LLN and agree well with other large series such as NHANES III. Its greatest disadvantage is the problem of discontinuity between paediatric and adult equations because a separate pediatric set is required. The discontinuity occurs when the pediatric and adult reference equations produce significantly different values in the transition period.

There are no reference equations for the Canadian Aboriginal population. Not only is there a scarcity of data, but the various First Nations, Inuit and Métis cannot be considered a physiologically homogeneous population. There are some suggestions that this group has larger lung volumes than Caucasians. Research is currently underway to address this issue.

Key Messages:

• Reference values must be appropriate for the age and ethnicity of the population, and ideally capable of providing the LLN

• The interpretation of spirometric tests should be based on the LLN

• Recommended reference values, in order of preference based on number of subjects studied and age range are:

1. Quanjer et al (GLI [15]), 2012 (age 3.5 to 90 years)
2. Stanojevic et al (20), 2009* (age six to 70 years)
3. NHANES III (21), 1999 (age eight to 80 years)

4. Tan et al (23), 2012 (age 20 to 90 years) or Gutierrez et al (24), 2004 (age 20 to 80 years) adult Caucasians only

• Spirometry tests involving Aboriginal Canadians and other ethnic groups should be interpreted with caution using Caucasian reference values

*The GLI recommends the use of Quanjer et al GLI 2012 (15) reference values for all spirometry. The Caucasian values for the Stanojevic et al 2009 (20) reference set are the same as the Quanjer GLI 2012 set for ages six to 70 years. While some existing spirometry systems have the Stanojevic 2009 reference values implemented, which can be used as an interim measure, almost all manufacturers have agreed to implement the Quanjer GLI 2012 values on their spirometry systems. A reference value calculator for the Quanjer GLI 2012 reference values is available at <www.lungfunction.org/component/content/article/85-equations-and-tools/equations/151-excel-individual-calculator.html>

SPECIAL CONSIDERATIONS FOR SPIROMETRY IN YOUNG CHILDREN

Spirometry testing began mainly in adults as a means to diagnose and monitor the progress of asthma and COPD, and was subsequently used in children even though measurement techniques and principles are not always directly comparable or applicable. Forced expiratory flow depends heavily on the static elastic recoil of the lungs. Various studies involving adults have demonstrated that the FEV1 correlates well with the degree of disability from lung disease. Children have higher elastic recoil than adults with faster emptying of the lung, which means that the FEV1 can be relatively insensitive to early lung disease. Some children are able to exhale completely in 1 s.

While the ATS/ERS standards (2) for the minimum expiratory time allow for 3 s in children ≤10 years of age rather than 6 s in adults, the requirement for a plateau (<25 mL in the final 1 s of exhalation) remains. In young children who empty their lungs in <2 s, it can be very difficult to resist inspiration before the 3 s limit. In such cases, the technologist must override the automatic rejection of the test.

The ATS/ERS standards (2) set tolerances for repeatability of FEV1 and FVC between tests of 150 mL or 100 mL for FVC or FEV1 ≤1 L. The back-extrapolated volume used for the beginning of test criterion must be ≤150 mL or 5% of FVC, whichever is greater. This results in larger percentage errors in children’s spirometry being deemed acceptable by the spirometry software. In a child-friendly environment, a technologist experienced in working with children can frequently exceed these minimal standards and produce high-quality spirometry.

Another challenge in testing children is the inspiratory manoeuvre. The ATS/ERS standards specify a rapid inspiration with no breath hold at end inspiration (2); however, knowing when the child has reached maximal inspiration can be challenging. Often, the technologist continues to encourage the child to breathe in, which translates to breath holding at total lung capacity. This problem is accentuated when using portable spirometers that are inserted in the mouth while at maximal lung volume (which are not recommended). The resulting FVC and FEV1 are lower after a slow inspiration and 4 s breath hold in the presence of any significant disease such as cystic fibrosis (12).

There was a brief spike in enthusiasm for the FEF25-75 in the adult literature; however, this rapidly waned when it was realized that the coefficient of variation of the test, particularly in those with COPD, was excessive because of the dependence of FEF25-75 on FVC. With COPD, where a plateau may not be reached, FVC may depend, in part, on the highly variable expiratory time. For children and young adults with greater elastic recoil, the variability of FVC is less and, hence, the FEF25-75 is more meaningful. Interpretation of this variable may still require an adjustment for the FVC (25).

Environment

It is helpful for the area where testing is taking place to have a bright and pleasant atmosphere (ie, pictures on the wall, children’s art and
1. Has a suitably trained physician or nurse practitioner been appointed as Medical Director/Quality Advisor to oversee spirometry testing?

2. Is there a quality assurance program in place and does it monitor staff competency, equipment performance, laboratory technique and procedure reporting, safety and utilization?

3. Has the individual conducting spirometry testing been adequately trained?

4. Has the individual interpreting the spirometry tests been adequately trained?

5. Does the spirometry requisition form or checklist comply with CTS recommendations?

6. Do spirometry reports comply with CTS recommendations?

7. Are response times established for reporting spirometry test results?

8. Are the reference values used for the report appropriate for the patient population?

9. Are technologists’ comments available for the interpreter?

10. Is there a policy manual, and does the manual include organizational chart staff/office policies and procedures?

11. Are there protocols for frequency of calibration for biological control subjects?

12. Are records of quality control procedures kept and routinely reviewed?

13. Are tolerance limits well defined for quality control checks?

14. Is there a plan of action if tolerance limits are exceeded?

15. Are there manuals available for equipment, policies and procedures, and safety?

16. Are these manuals site specific and updated annually?

17. Do the procedures for spirometry testing define acceptable and reproducible criteria for spirometry tests?

18. Is there an equipment log that details any malfunctions with spirometry equipment and corrective actions taken and does the log provide a history of the maintenance performed and by whom?

19. Are there default guidelines for cleaning, disinfecting and sterilizing equipment?

20. Are there specific procedures for individuals with known infections?

21. Is there a procedure for medical emergencies?

The above represents a general outline. For more detailed outline of a specific questionnaire, see the College of Physicians and Surgeons of Alberta Questionnaire (www.cpsa.ab.ca/services/Quality_of_Care_Main/Accreditation_Facilities/Pulmonary_Functions/Pulmonary_Standards.aspx) or Diagnostic Accreditation Program of British Columbia (http://www.dap.org/Default.aspx?p=57) for examples of questionnaires in current use for different levels of pulmonary function testing.

Distances travelled in Canada can be extensive, which may preclude onsite inspections for all facilities. In that case, the questionnaire may be a remote way of quality control for the facilities. This could be accompanied by spirometry reports from the facilities to assess the final product.

Where provinces have an accreditation program that monitors the quality of diagnostic testing it is recommended that a questionnaire such as the one outlined above be part of that process.

DISCLOSURE OF COMPETING INTERESTS: Members of the CTS Pulmonary Functions Standards committee declared potential conflicts of interest at the time of appointment and these were updated throughout the process, in accordance with the CTS Conflict of Interest Disclosure Policy. Individual member conflict of interest statements are posted at www.respiratoryguidelines.ca

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APPENDIXES

A. Sample Spirometry requisition form or checklist

APPENDIX A: Sample Spirometry Requisition Checklist

Request for Spirometry

<table>
<thead>
<tr>
<th>Family Physicians Clinic</th>
<th>Patient Name: ____________________</th>
<th>Patient ID: ____________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>123 Main St</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anytown, Prov, Z121 D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tel (987) 321-6540</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax (987) 321-1254</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date: ____________________ Referring Dr: ____________________

Reason for Test

☐ New Diagnoses
☐ Follow up
☐ Other

Previous Test at this clinic? Yes ☐ No ☐

Clinical Diagnoses

☐ Asthma
☐ COPD
☐ Emphysema
☐ IPF
☐ Other

Smoking History

☐ Current Smoker
☐ Former Smoker
☐ Never Smoker
☐ No. of Pack Years: ____________________

Respiratory Medications

☐ Yes ☐ No ☐

Instructions to provide to the patient:

Depending on the reason for doing the test, the patient should be instructed whether or not medications are to be withheld prior to testing, and, if so, precisely which medications should be withheld and for how long. It is important to instruct any patient withholding medications that, if needed for symptom relief, a rescue inhaler should be used and the time of use noted so that it can be reported to the technologist conducting the test.

Withhold medications? Yes ☐ No ☐

Medications to withhold:

☐ Short-acting beta agonist 4 hours prior to test
☐ Long-acting beta antagonist 4 hours prior to test

The patient should be instructed to avoid the following prior to testing:

- Smoking within 1 hour of testing
- Consuming alcohol within 4 hours of testing
- Performing vigorous exercise within 30 min of testing
- Wearing clothing that substantially restricts full chest and abdominal expansion
- Eating a large meal within 2 h of testing

B. Sample Spirometry report form

APPENDIX B: Sample spirometry report form

Family Physicians Clinic

123 Main St
Anytown, Prov, Z121 D
987-321-6540

Date of test: ____________________

Age: 54 yr Male

Name: Xxxxxxxx, Xxx

Ht: 168 cm Race: Caucasian

Wt: 86 kg BMI: 24.3 kg/m²

Reason for test: Chronic cough

Spironography Reported

<table>
<thead>
<tr>
<th>Pre-Bronchodilator</th>
<th>Post-Bronchodilator</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV₁ (L)</td>
<td>3.26</td>
</tr>
<tr>
<td>PEF (L/s)</td>
<td>2.91</td>
</tr>
<tr>
<td>FVC (L)</td>
<td>4.90</td>
</tr>
<tr>
<td>FEV₁/FVC</td>
<td>84%</td>
</tr>
<tr>
<td>FEV₁/Pre</td>
<td>100%</td>
</tr>
<tr>
<td>PEFR (L)</td>
<td>0.70</td>
</tr>
<tr>
<td>FET (s)</td>
<td>4.65</td>
</tr>
<tr>
<td>PEF/Pre</td>
<td>100%</td>
</tr>
<tr>
<td>BMI</td>
<td>19.7</td>
</tr>
</tbody>
</table>

Test quality B

Reference values: Querel 2012 [Caucasian]

BMI Body mass index; Chg Change; FET Forced expiratory time; FEV₁ Forced expiratory volume in 1 s; FVC Forced vital capacity; LLN Lower limit of normal; PEF Peak expiratory flow; Ref Reference; Wt Weight

REFERENCES


CORRIGENDUM


In the ‘Reference values’ section on page 17, the following statements were made: “African Americans have lung volumes approximately 10% lower than Caucasians. Asians have lung volumes 2% to 8% lower than Caucasians (15)”.

These statements should have read: “African Americans have lung volumes approximately 14% lower than Caucasians. South East Asians (southern China, Thailand, Korea) have lung volumes 10% to 14% lower than Caucasians (15).”

The authors apologize for the error.
Background: The American Thoracic Society committee on Proficiency Standards for Pulmonary Function Laboratories has recognized the need for a standardized reporting format for pulmonary function tests. Although prior documents have offered guidance on the reporting of test data, there is considerable variability in how these results are presented to end users, leading to potential confusion and miscommunication.

Methods: A project task force, consisting of the committee as a whole, was approved to develop a new Technical Standard on reporting pulmonary function test results. Three working groups addressed the presentation format, the reference data supporting interpretation of results, and a system for grading quality of test efforts. Each group reviewed relevant literature and wrote drafts that were merged into the final document.

Results: This document presents a reporting format in test-specific units for spirometry, lung volumes, and diffusing capacity that can be assembled into a report appropriate for a laboratory’s practice. Recommended reference sources are updated with data for spirometry and diffusing capacity published since prior documents. A grading system is presented to encourage uniformity in the important function of test quality assessment.

Conclusions: The committee believes that wide adoption of these formats and their underlying principles by equipment manufacturers and pulmonary function laboratories can improve the interpretation, communication, and understanding of test results.

Keywords: pulmonary function testing; reporting spirometry; reference equations; pulmonary function quality grading

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    General Considerations
    Current Spirometry Reference Values
    Using Reference Data in Interpretation of Results

Reference Source Recommendations
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Overview

The American Thoracic Society Committee on Proficiency Standards for Pulmonary Function Laboratories (ATS PFT Committee) has been concerned about the wide variability in pulmonary function test (PFT) reports among laboratories and has discussed the need for a more standardized format, to include information to assist accurate interpretation and to enhance the communication of results to end users. ATS support was granted to develop a technical standard to address this need and also to update reference sources and to propose a standardized quality grading system.

Conclusions

- A uniform format for the presentation of PFT results in reports to users and in the medical record can reduce potential miscommunication or misunderstanding.
- Only information with validated clinical application should be included.
- The normal limit(s) of each test parameter should be displayed.
- Consistent with other laboratory values, the measured value should be shown before reference values, ranges, or normal limits.
- Report and/or display of displacement of the result from a predicted value in standard deviation units (z-score) can help in understanding abnormality.
- For spirometry, many parameters can be calculated but most do not add clinical utility and should not be routinely reported.
- Only FVC, FEV1, and FEV1/VC need be routinely reported.
- Measurement of slow VC and calculation of FEV1/VC are a useful adjunct in patients with suspected airflow obstruction.
- Reporting FEV1/FVC (or FEV1/VC) as a decimal fraction, and not reporting it as a percentage of the predicted value for this ratio, will help to minimize miscommunication.

- Lung volumes
  - The nitrogen washout plot for multibreath tests and the tracings for plethysmograph tests can be shown graphically to aid quality assessment.
- For diffusing capacity the report is consistent with the 2017 European Respiratory Society (ERS)/ATS Technical Standard for this test.
- Barometric pressure should be measured and reported and the measured value corrected to the standard pressure of 760 mm Hg.
- Newer collated reference equations for spirometry and diffusing capacity have been developed since prior ATS documents and warrant wide implementation.
- The Global Lung Function Initiative (GLI)-2012 multietnic spirometry reference values are recommended for use in North America and elsewhere for the ethnic groups represented. Their smooth continuity throughout growth is advantageous for laboratories testing children or adolescents.
- The National Health and Nutrition Examination Survey (NHANES) III reference values (recommended for North America in 2005 ATS/ERS documents) remain appropriate where maintaining continuity is important.
- Regardless of the reference source or lower limit of normal (LLN) chosen, interpreters should be aware of uncertainty when interpreting values near any dichotomous boundary.
- For lung volumes and diffusing capacity, no prior ATS recommendation has been made because of the wide divergence of available reference values. A large compilation of international data has been completed for the diffusing capacity of the lung for carbon monoxide (DlCO) and is underway for lung volumes. The resulting reference equations should be widely adopted when published.

- Pulmonary function tests that fail to meet optimal standards may still provide useful information. A grading system for test quality can allow for this use, while providing an indication of the uncertainty imposed, and is most helpful if widely standardized.

- For spirometry, FVC and FEV1 are graded separately on an A–F scale either manually or by software. There is evidence that grades A–C are clinically useful, whereas grades D and E may have limited value, and grade F should not be used. The same scale, with different criteria values, is used for children.
- For diffusing capacity a similar grading scale is presented on the basis of 2017 ERS/ATS standards.

Introduction

The range of reporting formats currently in use is wide; commercial PFT systems offer differing reports, and some clinical laboratories customize their own. Differently arranged reports can lead to confusion or errors and make comparisons of data from different laboratories unnecessarily difficult. PFT equipment manufacturers have expressed a desire for, and a willingness to implement, a standardized form once it has been established. Newer reference data for spirometry and diffusing capacity have become available since the publication of prior guidelines, and a standardized system for grading the quality of lung function tests would be desirable.

Methods

For several years the ATS PFT Committee has been discussing and sharing ideas for improvement in the reporting of PFT results. A project task force, consisting of the committee as a whole, was approved to develop this new technical standard. The committee included adult and pediatric pulmonologists and physiologists and respiratory therapists with extensive PFT experience. Three working groups addressed the presentation format, the reference data supporting interpretation of results, and a system for grading quality of test efforts. Each group reviewed relevant literature and wrote drafts that were merged into the final document. As there is rather limited literature to support the necessary choices, these were made by consensus; all members approved the final document.

Report Format for Spirometry and Other Lung Function Tests

General Considerations

The following recommendations and rationale are based on developing a format that will be intuitive, will include only information with validated clinical application, will be based on the use of
the LLN, and will be consistent with prior recommendations for PFT interpretation and reporting (1–4). Some recommendations are necessarily arbitrary (e.g., the order of rows or columns) but reflect a consensus of current and prior committee members and an informal survey of others (5). Although individual preferences vary, there is wide agreement that the benefit of uniformity outweighs these.

The report format recommended is presented in test-specific units that can be assembled into a report appropriate for a laboratory’s practice or even an individual test session. It is designed so that for simple testing it can be printed, along with interpretive comments, on a single page as a report to a referring physician or for inclusion in the medical record. Of necessity, this contains limited information and is not intended as the only resource for the interpreter, who should have the option of displaying all individual maneuvers from a given PFT session, increasingly done on digital systems. Standardized electronic formats for the saving of all PFT data, including each individual maneuver, are being recommended (6). This will allow reviewers the flexibility to see additional detail or to reanalyze previous PFTs or apply new reference values as they become available. A standardized methodology to incorporate PFT data into electronic medical records is needed, but is beyond the scope of this report. See Appendix EA in the online supplement for a suggested list of test results to save to the electronic medical record.

In designing the standardized report, the committee recognized that aspects of data presentation can affect decision-making (7). The use of boldface or colored fonts to highlight measured values below the LLN can draw attention to these, but imposes a binary decision on a continuous variable. The number of variables reported can also have an impact because including a large number of outcomes in the report increases the statistical likelihood of one falling below an arbitrary LLN, with the risk of a false positive result (8).

All reports must begin with unambiguous patient identification, including patient name, medical record number, sex, and date of birth; the latter can be compared with previous records as a check for possible identification errors, as well as for calculating patient age (year to one decimal place for children and adolescents, e.g., age 6.3 yr) (9, 10). Other essential information is height (to the nearest centimeter) and weight, ethnicity, and date of the test. Other useful information includes smoking history, reason for the test, and referring physician’s name. Additional information may include oxygen saturation and barometric pressure.

The display will vary with the testing done, but the suggested order is spirometry, slow vital capacity, and/or lung volume measurement, and diffusing capacity of the lung for carbon monoxide (DLCO). Other tests could be added such as forced oscillometry, maximal respiratory system pressure, levels of expired nitric oxide, or other tests, but the philosophy should be similar, that is, reference source, normal limits, graphs that convey quality information, and exclusion of information without clinical value.

The recommended order of the columns in tabular data is the actual value, the LLN, the z-score (optional), and the percent predicted value. The predicted value itself is unnecessary, as it does not aid in the interpretation of abnormality. The z-score of a result is the number of standard deviations it lies away from the mean or, for regression equations, the number of standardized residuals away from the predicted value. Linear graphical displays visualize this in relationship to the normal range and assist in assessing the significance of abnormal values (11, 12). (If newly introduced to the reports, adding a brief explanation may be helpful.) The reference source from which the LLN and percent predicted value are derived must be listed, and whether or not these are adjusted or specific for race/ethnicity must also be stated in technician comments.

**Spirometry**

As shown in Figure 1, numerical values are given only for the FEV₁, the FVC, and the FEV₁/FVC ratio; the latter should be reported as a decimal fraction and the space for percent predicted value left blank to minimize miscommunications. When appropriate, an additional row can be added for FEV₁/(slow) VC (1, 2). Forced expiratory time (FET) is reported to aid quality assessment. If bronchodilators are given, the LLN column need not be repeated; the absolute and percent change should be given only for FEV₁ and FVC. Other numerical values such as the forced inspiratory flow at 75% of FVC (FEF₇₅%) and FEF₂₅–₇₅% have not demonstrated added value for identifying obstruction in adults or children, and therefore are not recommended for routine use (13, 14). The flow–volume curve and the volume–time curve are displayed, from which the peak flow and FET can be seen. These graphs must have sufficient resolution to evaluate the quality of the data. For the volume–time curve, the volume scale should be at least 10 mm/L, the time scale at least 20 mm/s, and 1 second prior to the start of expiration should be displayed (2). On the flow–volume plot, the flow display should be at least 5 mm/L/s, and the ratio of flow to volume should be 2 L/s to 1 L. The scales of the graphs may be adjusted to maximize the image within the available space on the report form, especially for tests on small children. The linear analog scales, where the values for FEV₁, FVC, and their ratio are plotted as z-scores relative to the predicted value (z = 0), give an intuitive sense of severity (12). Because there is always some uncertainty about the application of any prediction to an individual and about the exact LLN, a large star rather than a discrete point is used on the scale to suggest that caution is indicated when interpreting values close to the LLN.

For slow vital capacity, the graph shows baseline tidal breathing to assess whether inspiration occurred from a stable end-expiratory volume (3). The largest vital capacity is reported along with the inspiratory capacity and, when appropriate, the FEV₁/VC.

**Tests of Lung Volume**

Values derived by body plethysmography or gas dilution are displayed with the same column order (Figure 2). We show a full complement of volume parameters listed in a physiologically rational order; however, some laboratories may choose not to report all. With a multibreath nitrogen (N₂) washout the graph of the fall in N₂ concentration gives an indication of any leaks present (3). For helium dilution functional residual capacity (no graph displayed), equilibration is considered to be complete when the change in helium concentration is less than 0.02% for 30 seconds. The histogram displays the actual volume increments beside the predicted volumes as an indication of severity, and z-scores are shown here in a vertical format.
Figure 1. Example of a single-page report for pre- and postbronchodilator spirometry testing. The linear graphic is divided in units of 1 SD, with the LLN shown at a z-score of −1.64. This simplified report is suitable for the medical record or referring physician, but the test interpreter should have access to the data and curves of all acceptable spirometry efforts. FET = forced expiratory time; GLI = Global Lung Function Initiative; IC = inspiratory capacity; LLN = lower limit of normal; SpO2 = oxygen saturation as measured by pulse oximetry; ULN = upper limit of normal; VC = vital capacity.
MULTI-BREATH NITROGEN WASHOUT (Post-Bronchodilator)

<table>
<thead>
<tr>
<th>Result</th>
<th>LLN</th>
<th>ULN</th>
<th>z-score</th>
<th>%Pred</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLC mb (L)</td>
<td>5.95</td>
<td>5.8</td>
<td>8.5</td>
<td>−1.45</td>
</tr>
<tr>
<td>VC (L)</td>
<td>4.05</td>
<td>4.0</td>
<td>6.0</td>
<td>−1.61</td>
</tr>
<tr>
<td>IComb (L)</td>
<td>3.27</td>
<td>3.2</td>
<td>8.8</td>
<td>100%</td>
</tr>
<tr>
<td>FRC mb (L)</td>
<td>2.68</td>
<td>2.2</td>
<td>4.6</td>
<td>−1.03</td>
</tr>
<tr>
<td>ERV (L)</td>
<td>0.78</td>
<td>0.7</td>
<td>6</td>
<td>61%</td>
</tr>
<tr>
<td>RV mb (L)</td>
<td>1.90</td>
<td>1.4</td>
<td>2.9</td>
<td>−0.49</td>
</tr>
<tr>
<td>RV/TLC (%)</td>
<td>32%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference values: Gutierrez 2004; Test quality: QA met

PLETHYSMOGRAPHY (Post-Bronchodilator)

<table>
<thead>
<tr>
<th>Result</th>
<th>LLN</th>
<th>ULN</th>
<th>z-score</th>
<th>%Pred</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLC pl (L)</td>
<td>8.68</td>
<td>6.6</td>
<td>9.3</td>
<td>109%</td>
</tr>
<tr>
<td>VC (L)</td>
<td>4.79</td>
<td>4.5</td>
<td>6.5</td>
<td>−1.15</td>
</tr>
<tr>
<td>IComb (L)</td>
<td>3.42</td>
<td>2.7</td>
<td>4.1</td>
<td>100%</td>
</tr>
<tr>
<td>FRC pl (L)</td>
<td>5.26</td>
<td>2.7</td>
<td>5.0</td>
<td>2.00</td>
</tr>
<tr>
<td>ERV (L)</td>
<td>1.29</td>
<td>1.3</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>RV pl (L)</td>
<td>3.89</td>
<td>1.7</td>
<td>3.2</td>
<td>3.07</td>
</tr>
<tr>
<td>RV/TLC (%)</td>
<td>45%</td>
<td></td>
<td>45%</td>
<td></td>
</tr>
<tr>
<td>Vtg (L)</td>
<td>5.92</td>
<td>3.1</td>
<td>5.5</td>
<td>138%</td>
</tr>
</tbody>
</table>

Reference values: Gutierrez 2004; Test quality: QA met

Figure 2. Examples of the recommended reporting format for lung volume testing in one subject by multibreath nitrogen (N₂) washout and in another subject by plethysmography. The N₂ washout is plotted on a log scale, resulting in a nearly linear profile. On this plethysmography tracing the box pressure has been converted to volume to show the thoracic excursions at a scale of 20 mL per division. The bar graphs on the right show the predicted and observed values of RV, FRC, and TLC, and the arrows show these results in relation to their normal range on vertical linear scales. The graphs depict RV in blue, ERV in orange, IC in grey, and normal range in green. (See Figures E1 and E2 in the online supplement for examples of consolidated reports for full pulmonary function tests.) ERV = expiratory reserve volume; IC = inspiratory capacity; LLN = lower limit of normal; mb = multibreath; pl = plethysmography; QA = quality assurance; RV = residual volume; TLC = total lung capacity; ULN = upper limit of normal; VC = vital capacity; Vtg = thoracic gas volume.

When diffusion capacity is measured, a comparison of total lung capacity measured by both techniques can be a useful quality control measure or an indication of maldistribution.

Diffusing Capacity (Transfer Factor)
The display (Figure 3) gives the relevant values, the LLN, and the percent predicted value along with the reference source, a quality assurance indication, and the conditions of the test, in this case post-bronchodilator. The barometric pressure should be given, as well as stating whether the values were corrected to standard barometric pressure (particularly important for laboratories at altitude) (6). Reporting the carbon monoxide transfer coefficient (KCO) is optional, but the term DL/VA (the ratio of diffusing capacity to alveolar volume) should be avoided as it is commonly misunderstood. If measured, the hemoglobin should be shown as well as the adjusted predicted values for both DL/CO and KCO. The display shows the washout of both carbon monoxide and the tracer gas and the sample volume.

DIFFUSING CAPACITY (Post-Bronchodilator)

<table>
<thead>
<tr>
<th>Result</th>
<th>LLN</th>
<th>ULN</th>
<th>z-score</th>
<th>%Pred</th>
</tr>
</thead>
<tbody>
<tr>
<td>DL/CO (mL/min/mmHg)</td>
<td>13.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DL/CO (at standard Pao2)</td>
<td>13.0</td>
<td>23.4</td>
<td>−4.55</td>
<td>42%</td>
</tr>
<tr>
<td>DL/CO (pred adj Hb 13.8 g/dL)</td>
<td>13.0</td>
<td></td>
<td></td>
<td>53%</td>
</tr>
<tr>
<td>VA (L)</td>
<td>5.83</td>
<td>5.75</td>
<td>−1.55</td>
<td>82%</td>
</tr>
<tr>
<td>TLCsb (L)</td>
<td>6.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>W/Vc (%)</td>
<td>85%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KCO (mL/min/mmHg/L)</td>
<td>2.23</td>
<td>3.25</td>
<td>−3.47</td>
<td>52%</td>
</tr>
</tbody>
</table>

Reference values: GLI 2017, Test quality: one grade A test, Pao2 721 mmHg

Figure 3. Example of the recommended reporting format for the single-breath diffusing capacity test. The 2017 Technical Standard for Dl/CO (6) requires that the CO and tracer gas concentrations be graphed versus exhaled volume, rather than versus time as shown here. When hemoglobin is measured, it should be shown on the report with a note indicating whether the predicted value has been adjusted for this. CH4 = methane (tracer gas); DL/CO = diffusing capacity of the lung for carbon monoxide; GLI = Global Lung Function Initiative; KCO = carbon monoxide transfer coefficient; LLN = lower limit of normal; Pao2 = barometric pressure; pred adj Hb = hemoglobin adjusted for predicted value; sb = single breath; TLC = total lung capacity; W/Vc = inspired volume/vital capacity.
Lung function reports should identify the source of reference values, because the same measured values may be interpreted differently based on the reference source used. Furthermore, manufacturers need to be transparent when reference values have been combined from various sources. In the event that a laboratory changes its selected reference equations, this should be noted on the report, and percent predicted values for prior lung function data should be recalculated, if possible. It is preferred that there be no discontinuity between pediatric and adult equations in the reference values selected, and extrapolation of values beyond the age range of the equations should not be done during growth and will increase uncertainty in the elderly (9, 15). Any such extrapolation must be noted in technician comments.

**Current Spirometry Reference Values**

In 2005, the 1999 NHANES III spirometry reference equations (16) were recommended for use in North America (1). This study provided values for whites, African Americans, and Mexican Americans living in the United States. The age span was 8–80 years in two sets of equations with a break at age 18–20 years; a separate recommendation was made for children under age 8. As there was uncertainty whether these equations were a good fit for various European populations, no recommendation was made.

Subsequently, the GLI group was formed with ERS sponsorship and with the participation of the ATS PFT Committee. The goal was to merge available data sets, including the NHANES III data, to develop more broadly applicable reference equations. This effort resulted in new spirometry reference equations using data collected from more than 74,000 individuals, ages 3–95 years, from 26 countries (12). The GLI established reference values for whites, African Americans, North East Asians, and South East Asians. The equations for the white population were shown to be applicable not only in the United States and Europe but in other parts of the world, including Hispanic regions, and for Hispanic Americans. These findings confirm a reanalysis of the NHANES III data, which showed no need for separate reference equations for Hispanic and non-Hispanic whites (17). For individuals not represented by these four groups, or who are of mixed ethnic origin, a composite equation is provided. (See Appendix EB for guidance on the choice of equations.) The GLI data found the FEV₁/FVC ratio to be generally independent of ethnic group, and thus its LLN is a useful indication of airflow limitation even when ethnicity is uncertain.

More recently, the Canadian Health Measures Survey has published population-based spirometry reference equations for whites, using a format similar to NHANES III (18). Average adjustment factors are given for several indigenous and immigrant groups. Of note, they found that individuals of Chinese ancestry living in Canada had values intermediate between white values and those predicted by GLI equations from data collected in China.

Since the GLI-2012 publication, these white reference values have been compared with those of NHANES III. In large clinical populations from Australia and Poland, the values predicted by GLI-2012 and NHANES III were similar and rates of airflow limitation (FEV₁/FVC < LLN) were similar in both men (GLI, 34.5 and NHANES III, 33.3%) and women (GLI, 27.9 and NHANES III, 25.4%) (19). Similar findings have been demonstrated in additional clinical populations from Australia (20), the United States (21), and in children and adolescents (22). The Canadian predicted values compared somewhat more closely with GLI-2012 than NHANES III values, but differences among the three were minor and not likely to be clinically important (18).

In a simulation of NHANES III and GLI-2012 predicted values across a broad range of age and height, the FEV₁ prediction differences were within the recommended repeatability criterion of ±150 ml across a wide range of heights and ages (21). There were larger differences at the extremes of height in older individuals, where more uncertainty would be expected due to relatively few subjects of advanced age in the GLI-2012 data and extrapolation of the NHANES III data beyond the age of its subjects.

**Using Reference Data in Interpretation of Results**

Both the ATS and ERS recommend the use of the LLN, or the upper limit where appropriate (e.g., lung volumes), to delineate between health and suspected disease. These are set at the fifth percentile (equivalent to a z-score of −1.645) so that 95% of a healthy population falls within the normal range.
and the lowest 5% would be false positives. However, clinical PFTs are typically done when disease is suspected, increasing the pretest probability of an abnormal result so that the false positive rate is much lower in this setting. The LLN does not necessarily need to be the fifth percentile but, with adequate outcome data, could be adjusted higher when the pretest probability is high or lower for population screening (23, 24). More important than the applicability of a particular LLN is recognition of the uncertainty that lies near any dichotomous boundary and where caution is required, especially when results are limited to a single test occasion.

The respiratory community is familiar with using the percent predicted value to describe lung function results; however, this value should not be used to define abnormality. The true LLN is age- and/or height-dependent and therefore will occur at varying percent values in different individuals. The fixed values commonly used (e.g., 80% predicted for FVC, 0.70 for FEV1/FVC) are estimates based on middle-aged adults, and therefore erroneous clinical decisions based on these fixed cutoffs are more likely to occur in children and in older or shorter adults. Using fixed cutoffs also introduces a sex bias into clinical assessments (25). Interpretation of individual results relative to the range of values expected can be more appropriately incorporated into PFT reports using the recommended linear analog scale.

Reference Source Recommendations
For spirometry, the GLI-2012 reference values are recommended for use in North America for the ethnic groups represented, as well as in Europe, Australia–New Zealand (26), and other areas with represented populations. For laboratories wishing to maintain continuity, the NHANES III equations also remain recommended for whites (including Hispanics) and African Americans. Use of GLI-2012 is recommended for clinical research studies to facilitate comparisons with international studies (27, 28). The GLI-2012 equations are also preferred for laboratories testing children or adolescents because they permit tracking during this time of rapid lung growth and development without discontinuities due to switching reference sources. The Canadian reference values also provide a useful resource (18). Whatever reference source is used, interpretations must be based on a parameter-specific lower limit determined from the distribution of the reference data.

For DLCO, no prior ATS recommendation has been made because of the wide divergence of available reference values. With ATS and ERS sponsorship a GLI group has assembled data from more than 12,000 individuals in 14 countries to develop new (white-only) reference equations from age 5 to 85 years. Publication of these is expected in 2017 (29) and their rapid adoption is recommended.

For plethysmographic or dilutional lung volumes, no recommendation can be made for reference values at this time. A new international project to address this need is underway. (Values from a Canadian study [30] are used as examples in the accompanying figures.)

Grading the Quality of Pulmonary Function Tests

Spirometry
Whereas considerable attention has been given to guidelines for the procedures to conduct spirometry (2), guidelines to assess the quality of the testing are still needed. The purposes of quality review are to provide feedback to the technicians and, in the clinical setting, to indicate any limitations to the interpretation of the results. In clinical research, quality review helps determine whether a subject can be included in a trial and whether data at any time point can be used in the analysis.

Various quality-grading systems have been reported (31–38) and others have been provided by spirometer manufacturers, but users would benefit from standardized methodology. The system recommended for adults and children is shown in Tables 1 and 2. It is modified from a system that has been used in research and epidemiological studies (16, 18, 38). For younger children, 2–6 years of age, the criteria are modified on the basis of the 2007 ATS/ERS recommendations for spirometry testing in preschool children (39). These systems can be used manually, or as part of spirometry software, assigning a grade (A through F) separately for the quality of FVC and FEV1. In general, tests with a grade of A, B, or C are usable; tests with grade D are suspect; tests with grade E might be used by the interpreter only to show values “within the normal range” or “at least as high as,” without demonstrated repeatability; and tests with grade F should not be used.

The grading system consists of acceptability and repeatability components. An ideal test session conforms to prior ATS/ERS recommendations (2, 39) with at least three acceptable maneuvers and repeatable FVC and FEV1 values. These criteria were intended to guide technicians to achieve the best possible results, and the goal should be to exceed them because many technicians can achieve better quality tests. However, their strict application may also lead to the exclusion of useful results. A grading system allows the user to evaluate the likelihood that spirometry results are representative of true values in the face of test performance that is not ideal. Failure to achieve optimal tests may be due to underlying disease; thus bias may be introduced into clinical research studies by eliminating subjects with more severe disease. The reviewer must consider whether or not the subject’s effort in a maneuver was maximal, and/or whether lack of repeatability could be due to lung disease, using all available information including technician comments. When a test session with a poor-quality grade is used as a baseline for pre/post-bronchodilator or longitudinal comparisons, an apparent improvement in values may be the result of better effort or technique.

While strict application of the grading criteria can be done by computer software, the reviewer’s role is to apply judgment by reviewing the individual curves, which may change the scoring and allow interpretation. For example, if a maneuver in the session is unacceptable only because of excessive back extrapolation volume, it can still be used to confirm repeatability of FVC. Determining whether the subject has inhaled completely is difficult, and one report has suggested that many subjects are unnecessarily excluded by the 2005 ATS/ERS end-of-test criteria (38). The FET is used to determine whether the subject has tried to exhale long enough, and the end of the volume–time curve is assessed to determine whether expiratory flow has ceased, defined as a volume change less than 0.025 L in 1 second. Often the FET is less than 6 seconds, because the software has stopped data collection once this low flow criterion is met, or an artifact during exhalation may be falsely perceived as a...
Table 1. Quality Categories for FVC or FEV\textsubscript{1} in Adults and Children

<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria for Adults and Older Children and for Children Aged 2–6 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>≥3 acceptable tests with repeatability within 0.150 L for age 2–6, 0.100 L, or 10% of highest value, whichever is greater</td>
</tr>
<tr>
<td>B</td>
<td>≥2 acceptable tests with repeatability within 0.150 L for age 2–6, 0.100 L, or 10% of highest value, whichever is greater</td>
</tr>
<tr>
<td>C</td>
<td>≥2 acceptable tests with repeatability within 0.200 L for age 2–6, 0.150 L, or 10% of highest value, whichever is greater</td>
</tr>
<tr>
<td>D</td>
<td>≥2 acceptable tests with repeatability within 0.250 L for age 2–6, 0.200 L, or 10% of highest value, whichever is greater</td>
</tr>
<tr>
<td>E</td>
<td>One acceptable test</td>
</tr>
<tr>
<td>F</td>
<td>No acceptable tests</td>
</tr>
</tbody>
</table>

FVC or FEV\textsubscript{1} are each graded separately. The quality categories for FVC and FEV\textsubscript{1} are the same, but the definition of an acceptable curve differs in that FEV\textsubscript{1} acceptability does not consider anything after the first second, whereas FVC does (see Table 2). The adult quality criteria extend to children age 7 or greater. Information on adults and children age 7 or greater is based on Reference 2. Information on children aged 2 to 6 is based on Reference 39.

plateau, thus stopping data collection and underestimating FET and FVC. Subjects should be verbally encouraged to continue the expiratory effort at the end of the maneuver to obtain optimal results (2). The technician and/or reviewer must make a determination as to whether or not end-of-test criteria were met and whether the data are useful. Some subjects, especially children and adolescents, cannot exhale for the required 3 or 6 seconds. If these subjects have a 1-second plateau, and the reviewer judges that these maneuvers represent a maximum FVC, the grade should be adjusted higher. Subjects with airflow obstruction may never reach a plateau even at the suggested 15-second limit and may have nonrepeatable FVC values only because of a difference in FET. Similarly, subjects with restrictive lung disease may reach an early plateau and may not be able to maintain a 6-second effort. The results may still be considered acceptable in such cases and an appropriate comment by the reviewer should be made.

FEV\textsubscript{1} is graded separately because even test efforts that are clearly unacceptable for FVC may contain a valid measurement of FEV\textsubscript{1} (or FEV\textsubscript{0.75}, the forced expiratory volume exhaled in the first 0.75 s of the FVC maneuver, and a recommended measure in preschool children (2, 39). Anything that occurs later in the flow–time tracing (e.g., early termination, cough artifacts) does not affect the FEV\textsubscript{1} or FEV\textsubscript{0.75} value, and thus these may be used even with end-of-test errors.

Despite the attention paid to expiratory parameters, the most common reason for low FVC, FEV\textsubscript{1}, and PEF values is an incomplete inhalation. Achievement of maximal inhalation is best assessed by measures of repeatability and also by the consistency of the shape of the flow–volume or volume–time curve (40).

FVC maneuvers that have lower PEF values compared with others in a session may produce higher FEV\textsubscript{1} values due to the negative effort dependence of flow. The technician should coach forceful initiation of the FVC maneuver (i.e., blast), to achieve the fastest/highest PEF (41). Rounded peaks on the flow–volume curve may reflect submaximal blasts that can increase variability in both FVC and FEV\textsubscript{1}.

Lung Volumes

Quality review of lung volume measurement is more challenging as a variety of methods are available, including body plethysmography, nitrogen washout, helium dilution, and radiographic imaging. We are not aware of any quality-grading systems that have been validated for the measurement of absolute lung volumes. Until a validated system is available, we recommend adherence to the 2005 ATS/ERS recommendations for the measurement of lung volumes (3). If the acceptability and/or repeatability criteria are not met, a comment should be included to caution users of the test results.

Diffusing Capacity (Transfer Factor)

The D\textsubscript{LCO} (or T\textsubscript{LCO}) test is complex, involving a number of technical factors, and variability can be high. In the absence of quality-grading systems that have been
Table 3. Quality Grading for DLCO Maneuvers

<table>
<thead>
<tr>
<th>Grade</th>
<th>V/VC</th>
<th>Breathhold Time</th>
<th>Sample Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>≥90%*</td>
<td>8–12 s</td>
<td>≤4 s</td>
</tr>
<tr>
<td>B</td>
<td>≥85%</td>
<td>8–12 s</td>
<td>≤4 s</td>
</tr>
<tr>
<td>C</td>
<td>≥80%</td>
<td>8–12 s</td>
<td>≤5 s</td>
</tr>
<tr>
<td>D</td>
<td>≥80%</td>
<td>&lt;8 or &gt;12 s</td>
<td>≤5 s</td>
</tr>
<tr>
<td>F</td>
<td></td>
<td></td>
<td>Any test not meeting Grade A, B, C, or D.</td>
</tr>
</tbody>
</table>

*Defined abbreviations: DLCO = diffusing capacity of the lung for carbon monoxide; V I = largest vital capacity in the same test session; V I/V C = inspired volume.

The Quality Reviewer

In the clinical pulmonary function laboratory, technicians, supervisors/managers, or computer software can assign quality grades, whereas in the clinical research setting, an independent quality reviewer is commonly used. This reviewer should be an expert in pulmonary function testing and have extensive experience, both in direct testing and in monitoring testing performed by others. If more than one reviewer is used, comparisons across reviewers should be done to ensure consistency, for example, with a blinded sample of good and bad test sessions.

This official technical statement was prepared by an ad hoc subcommittee of the ATS Committee on Proficiency Standards for Pulmonary Function Laboratories.

Members of the subcommittee are as follows:

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| ALLAN L. COATES, M.D. (Co-Chair) | CHRISTINE E. BERRY, M.D., M.H.S. |
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References

5. Culver BH. How should the lower limit of the normal range be defined? Respir Care 2012;57:136–145, discussion 143–145.
Primary Care Asthma Program  SPIROMETRY MANUAL

Resource Links:

**ATS:**


**CPSO:**


**CTS:**

Spirometry in Primary Care: [http://www.respiratoryguidelines.ca/sites/all/files/CTS_Spirometry_Primary_Care_2013.pdf](http://www.respiratoryguidelines.ca/sites/all/files/CTS_Spirometry_Primary_Care_2013.pdf)

**Infection Control:**


**Practicum:**

The Lung Association Provider Education Program (PEP) [http://www.olapep.ca](http://www.olapep.ca)