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 (June 2009) - 2 pages
- PCAP Medical Directive for Administration of Salbutamol for Spirometry Testing at a Primary Care Site (June 2009) – 2 pages
- PCAP Medical Directive for Performing Spirometry Pre & Post Bronchodilator at a Primary Care Site (June 2013) – 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

- Spirometry Ins & Outs: Ontario Lung Association Provider Education Program (PEP) Presentation - 9 pages
- Diagnostic Flow Diagrams for Obstruction and Restriction: Ontario Lung Association Provider Education Program (PEP) Presentation - 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
- 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 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 a 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 (2005) (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 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. 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 (2005).

Display (2):
- The Display must show both the flow-volume loop and the volume-time graph with sufficient resolution so that the person conducting the testing can determine whether test results have met the ATS/ERS standards (2005) (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 (2005) (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.

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)
- A Spirometer should have a Calibrating syringe. ATS/ERS standards specify that a 3L syringe be used for checking and calibrating a spirometer daily.
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☐ 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 manufactures 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: CPSO, Infection Control in the Physician’s Office, 2004(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.

☐ Additional barriers - gowns, masks, protective eyewear and plastic aprons when body
2.1.4 Performing the Spirometry Test

Who Can Conduct Spirometry?

- By a trained and qualified personnel in 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), other 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 a % predicted, with the predicted values being derived from standardized data sets. Predicted values should reflect the patient population of your clinic. The current guidelines recommend the use of the 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 spirometer 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). 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 upgrade 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 (12).
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).

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

**Flow (Y) versus Volume (X)**

**Volume (Y) versus Time (X)**
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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)

**Preparation**

- Ensure the spirometer has daily calibration performed
- Contraindications should be listed on the spirometry order requisition form or checklist form (2)
- Additional Patient Preparation/ Documentation (review contraindication as in Appendix 1)

**Operator’s Checklist**

- Ask the patient about:
  - Smoking
  - Recent illness
  - Inhaler/ medication use

**Activities that should preferably be avoided prior to lung function testing**

- Smoking within at least 1 h of testing
- Consuming alcohol within 4 h 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
- Inhaler Medication (Refer to Medication Section: Post Bronchodilator Testing to withhold prior to spirometry testing)
- Measure weight and height without shoes

- Wash hands

- Instruct and demonstrate the test to the subject

**Test Performance**

- Perform maneuver (closed circuit method- most commonly used)
  - Have subject assume the correct seated posture (a chair without wheels, feet flat on the ground)
  - Attach nose clip*, place mouthpiece in mouth and close lips around the mouthpiece, perform 2-4 tidal breaths
  - Inhale completely and rapidly with a pause of 1 s at TLC
  - 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”

- 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

*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

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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.

<table>
<thead>
<tr>
<th>Inhaled bronchodilators (7)</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 Anticholinergic (SAAC)</td>
<td>6 Hours</td>
</tr>
<tr>
<td>Long-Acting Beta2 Agonist (LABA)</td>
<td>24 hours</td>
</tr>
<tr>
<td>Long-Acting Anticholinergic/Muscarinic Antagonist (LAAC/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 Anticholinergic (SAAC) such as Atrovent)
- 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 Atrovent
  *Inhale separate doses from a valved spacer device

ATS does not currently specify any recommendations for the paediatric population.
- Perform post-bronchodilator testing 15 minutes post for SABA and 30 minutes post for SAAC
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. 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.
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**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:**


**Additional Supports:**

- Ontario Lung Association Provider Education Program (PEP). Spirometry Interpretation workshop and e-modules [http://olapep.ca/](http://olapep.ca/)

- College of Physicians and Surgeons of Ontario CPSO recommendation for Technologist Qualifications: [http://www.cpso.on.ca/uploadedFiles/policies/guidelines/facilties/Diagnostic%20Spirometry_Apr08.pdf](http://www.cpso.on.ca/uploadedFiles/policies/guidelines/facilties/Diagnostic%20Spirometry_Apr08.pdf)

- Additionally, 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.on.lung.ca/PCAP](http://www.on.lung.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 \( FVC < 1.0 \text{ L} \) 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
### 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><em>Spirometry causes increases in intrathoracic and intra-abdominal pressure that may increase blood pressure</em></td>
</tr>
<tr>
<td>Significant aortic aneurysm*</td>
<td></td>
</tr>
<tr>
<td>Recent thoracic surgery†</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 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>
<tr>
<td>History of syncope related to forced exhalation/cough</td>
<td></td>
</tr>
<tr>
<td>Active tuberculosis</td>
<td>Infection control procedures must be taken according to local procedures</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td></td>
</tr>
<tr>
<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
Primary Care Asthma Program SPIROMETRY MANUAL

References


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


PCAP Spirometry Policy and Procedures Approved by PCAP Advisory December 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.

The asthma care program is delivered within a multi disciplinary team of primary care providers with the support of a Certified Asthma Educator. The Certified Asthma Educator assists with program implementation, mentoring, education of patients and staff and ensuring the ongoing sustainability of the program. Key to the success of this program is the expertise of the educator who provides current evidence-based knowledge and assist with on-site objective measurements via spirometry to facilitate accurate diagnosis of asthma. The program is modeled on fostering patient and family self-management.

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 (RN’s, RN (EC) s, RRT’s, and MD’s) are made aware of the policies and procedures concerning spirometry testing.

I authorize the ___ [ORGANIZATION NAME ] RN’s, RN (EC)s and RRT’s 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.

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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 (RNs, RN (EC) s, RRTs 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 ] RN’s, RN (EC) s and RRTs to administer salbutamol via MDI and spacer, 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
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.

The asthma care program is delivered within a multi disciplinary team of primary care providers with the support of a Certified Asthma Educator. The Certified Asthma Educator assists with program implementation, mentoring, education of patients and staff and ensuring the ongoing sustainability of the program. Key to the success of this program is the expertise of the educator who provides current evidence-based knowledge and assist with on-site objective measurements via spirometry to facilitate accurate diagnosis of asthma. The program is modeled on fostering patient and family self-management.

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 an RN (EC) or an RRT.

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 Spirometry in Primary Care journal article (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 asthma diagnosis or 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 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>
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</table>

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

**Family Physicians Clinic**
123 Main St
Anytown, Prov, Z1Z 1Z1
987-321-6540

<table>
<thead>
<tr>
<th>Spirometry</th>
<th>Pre-Bronchodilator</th>
<th>Post-Bronchodilator</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC (L)</td>
<td>4.65</td>
<td>5.01</td>
</tr>
<tr>
<td>FEV1 (L)</td>
<td>3.26</td>
<td>4.04</td>
</tr>
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<td>PEF (L/s)</td>
<td>10.2</td>
<td>14.3</td>
</tr>
<tr>
<td>FET (s)</td>
<td>15.3</td>
<td>14.8</td>
</tr>
</tbody>
</table>

Test quality: B

Reference values: Quanjer 2012 [Caucasian]

Age: 62 yr  **Male**  Name: Xxxxxxxxx, Xxxx
Ht: 186 cm  Race: Caucasian  ID#: 333222111
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

**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.
Requisition for Spirometry

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

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

Patient Name: __________________________________________
Patient ID#: __________________________________________
Referring Dr: __________________________________________
Dr Signature: __________________________________________
Date: _____________ Tel: __________________

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
The In’s & Out’s

All information in this presentation is copyrighted by The Lung Association.
Presenter Disclosure
Objectives

1. How to do spirometry
   • Demonstrate an appropriate forced expiratory maneuver
   • Identify criteria for spirogram acceptability and repeatability
   • Review quality control measures
Spirometry

- Relatively simple, non-invasive test evaluating the relationship between flow and volume (lung mechanics)
- Maximum inspiration followed by a forced expiratory maneuver of at least 6 seconds duration in adults and children <10 for 3 seconds duration
Spirometry

• Effort dependent test requires proper instruction and cooperation of the test subject

• Main objective is to obtain **maximal**, **acceptable and repeatable** efforts

• Minimizing the risk of poorly performed maneuvers which leads to misinterpretation of results
Focus on Quality Results

Areas to focus on for quality results:

• Emphasis on first part of maneuver, ensure complete inspiration

• Maximize the blast during initial part of exhalation

• Encourage patient to continue to end of test (incentive)
Height Measurement - Very Important

- If you have, technically perfect spirometry, select appropriate reference equations, and if height not measured properly, all was for naught. Reference equations depend on value of spirometry and HEIGHT.

- Height measurements
  - Stocking feet standing straight with back against a hard surface (wall) or stadiometer
  - Right angle on top of head with the corner on a measuring tape attached to the wall (or stadiometer)

SCALES WITH ARMS THAT MEASURE HEIGHT ARE NOTORIOUSLY INACCURATE
Spirometry Equipment

• What to consider when purchasing a Spirometer?
  – Purchase from reputable supplier – service and training
  – Portability
  – Provide graphic display of maneuvers
  – Printed report (size, report)
  – Ongoing costs (mouthpieces, paper)
  – Spirometric equipment graphic display of the maneuver MUST include a volume time plot and should include a flow volume curve
• Types of Spirometers available: Office & Portable
• Maintain according to manufacturers’ guidelines including calibration and cleaning procedures
• Adhere to current ATS/ERS Equipment Minimal Standards
• Appropriate choice of reference equations
Quality Assurance

- Daily spirometer calibration checks- if required
- Document repairs, software and hardware updates and all modifications to system
- Have qualified personnel conducting spirometry tests including education and training on all aspects of spirometry
- Document infection control procedures
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

Patient Name: ____________________________

Patient ID: ______________________________

Referring Dr: ____________________________

Dr Signature: ____________________________

Date: _____________ Tel: __________________

Reason for Test

☐ Diagnosis _____________________________

☐ Other _________________________________

☐ Follow up _____________________________

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)

☐ Pregnant (near term)

☐ Hypertension (uncontrolled)

☐ Unstable Cardiac Status

☐ Cross Infection Concerns

☐ Aneurysm - Cerebral, thoracic, abdominal

☐ Hemoptysis

☐ Pneumothorax

☐ M.I. within last month

☐ 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
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 prior to testing is dependent on the reason for the test. If the study is done to diagnose an underlying lung condition, then avoiding bronchodilators is useful.
## Operator Checklist - Sample

### PRIMARY CARE ASTHMA PROGRAM  
**SPIROMETRY STANDARDS**

### SPIROMETRY OPERATOR CHECKLIST

- Barometric Pressure, Relative Humidity and Temperature updated daily
- Daily Calibration performed according manufacturer’s and ATS/ERS recommendations
- Contraindications – *Recent indicates within 6 weeks*
  - Recent pneumothorax
  - Recent myocardial infarction
  - Recent eye, thoracic or abdominal surgery
  - Hemoptyaxis
  - Presence or suspected active tuberculosis or other communicable respiratory disease
- Minimum of three acceptable FVC performed, with two repeatable manoeuvres, maximum eight performed (ATS/ERS 2005)
- Assess Patient Performance: (Acceptability)
  - Maximal 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

### Reference:

- Quick reference to obtain quality results
- Reminder about updating temperature, barometric pressure and daily calibration
- Highlights acceptability and reversibility criteria
Coaching

• Patient should be seated with both feet flat on the ground, nose clips (strongly encouraged) and lips sealed around mouthpiece
• Explanation of test – Keep instructions simple. Big breath in, blow out hard, and blow all the way out
• Demonstrate: Actions speak louder than words. Demonstrate with animation
• Coach – Appropriately
• Repeat all substandard tests
• No more than 8 attempts (fatigue)
Spirometry Demonstration

Click Image to Play
**Definitions**

**FVC**

*Forced Vital Capacity* – is the volume of air that can be forcibly expelled from the lung from maximum inspiration to maximum expiration.

**FEV₁**

*Forced Expired Volume in first second* – the volume of air that can be forcibly expelled from maximum inspiration in the first second

**FEV₁/FVC** ratio is the FEV₁ expressed as a percentage of the FVC and gives a clinically useful indicator of airflow obstruction

**PEFR**

*Peak Expiratory Flow Rate* – the maximum flow rate attained during an FVC maneuver

**RV** - Residual Volume

**TLC** – Total Lung Capacity
Lung Capacity

TOTAL LUNG CAPACITY

IRV

VC

IC

VT

ERV

FRC

RV

VC

FRC

ERV

VT

IC

IRV

TOTAL LUNG CAPACITY
Pitfalls and Problems

- **Instrument Related**
  - Improper calibration- If daily calibration required
  - Leaks in hose connections
  - Inaccurate zeroing of sensor – drifting from zero line

- **Patient Related Problems**
  - Submaximal effort
  - Leaks / obstruction of mouthpiece
  - Incomplete inspiration/expiration (glottic closure)
  - Hesitation at start of expiration
  - Cough (within first second of expiration)
  - Vocalization during maneuver
Patient Related Problems

Flow/ Volume Curves

Volume/Time Curves
Acceptability Criteria

- Minimum of 3 & maximum of 8 acceptable FVC maneuvers
  - No cough, especially during the first second
- Good ‘start of test’
- Early termination of exhalation unacceptable
  - minimum exhalation of 6 seconds or 3 seconds for children < 10 yrs.
- No flow = < 0.025 L in 1 sec
- No Valsalva maneuver
- No leak
Start of Test Criteria

Quality Control on FEV\(_1\)

- It is essential to define zero time.
- No physical system starts instantaneously.
- Fast start is important.
- Definitions at zero time is where the tangent to the steepest part of the volume-time curve crosses zero.
- The “actual volume” at this point must be < 150 ml.

![Graph showing volume over time with time zero and extrapolated volume marked.]
Repeatability

• Select data from **acceptable** curves only

• Repeatability
  – 2 largest FVC should not vary by more than 150 ml
  – 2 largest FEV\(_1\) should not vary by more than 150 ml

• In children and adults with reduced lung volumes acceptable maneuvers is achievable, only issue is going to total lung capacity (TLC)
  – If FVC <1.0 L - Two highest FVC and FEV\(_1\) must be within 100 ml
  – If FVC >1.0 L - Two highest FVC and FEV\(_1\) must be within 150 ml
Reporting

• Report largest FVC from any acceptable maneuver
• Report largest FEV$_1$ from any acceptable maneuver
• Report values from curve with largest sum of FVC and FEV$_1$
• Provide feedback to physician about patient effort

Example: (Note: trials were all acceptable)

<table>
<thead>
<tr>
<th></th>
<th>FVC</th>
<th>FEV&lt;sub&gt;1&lt;/sub&gt;</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1</td>
<td>4.50</td>
<td>3.75</td>
<td>8.25</td>
</tr>
<tr>
<td>Trial 2</td>
<td>4.60</td>
<td><strong>3.85</strong></td>
<td><strong>8.45</strong></td>
</tr>
<tr>
<td>Trial 3</td>
<td><strong>4.65</strong></td>
<td>3.70</td>
<td>8.35</td>
</tr>
</tbody>
</table>

Report: Trial 3    Trial 2    Trial 2
**Sample Spirometry Report Form**

### Family Physicians Clinic
123 Main St.
Anytown, Prov., Z1Z 1Z1
987-321-6540

<table>
<thead>
<tr>
<th>Age: 62 yr</th>
<th>Male</th>
<th>Name: Xxxxxx, Xxxx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ht: 186 cm</td>
<td>Race: Caucasian</td>
<td>ID#: 333222111</td>
</tr>
<tr>
<td>Wt: 84 kg</td>
<td>BMI: 24.3 kg/m²</td>
<td>Date of birth: 1949-Dec-31</td>
</tr>
<tr>
<td>Nonsmoker - pack-yrs: 0</td>
<td>Date of test: 14:20, 2012-Jan-02</td>
<td></td>
</tr>
<tr>
<td>Reason for test: Chronic cough</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Spirometry

<table>
<thead>
<tr>
<th>Metric</th>
<th>Pre-Bronchodilator</th>
<th>Post-Bronchodilator</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC (L)</td>
<td>4.65</td>
<td>5.01</td>
</tr>
<tr>
<td>FEV1 (L)</td>
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<td>0.81</td>
</tr>
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<td>PEF (L/s)</td>
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<td>14.3</td>
</tr>
<tr>
<td>FET (s)</td>
<td>15.3</td>
<td>14.8</td>
</tr>
</tbody>
</table>

**Test quality**: B

**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.
Acceptability and Repeatability

Perform FVC maneuver

Yes

Met within-maneuver acceptability criteria?

No

Achieved three acceptable maneuvers?

No

Met between maneuver repeatability criteria?

Yes

Determine largest FVC and largest FEV$_1$

Select maneuver with largest sum of FVC+FEV$_1$ to determine other indices

Store and interpret

Adapted from “ATS/ ERS Task Force: Standardization of Lung Function Testing” Etd. V. Brusasco, et al, Standardization of spirometry Number 2 in this series.
Resources

PEP Website
www.olapep.ca

SpiroTrec
www.resptrec.org

Follow us on Twitter:
@ONLung_pep
Diagnostic Flow Diagram For Obstruction

Severity of Obstruction
- FEV₁
  - Mild: 70-79% predicted
  - Moderate: 50% to 69% predicted
  - Severe: <50% predicted

Is FEV₁ / FVC Ratio Low? (<LLN)
- Yes: Obstructive Defect
  - Is FVC Low? (<LLN)
    - Yes: Pure Obstruction
    - No: Combined Defect of Obstruction and Restriction or Hyperinflation
      - Reversible Obstruction and improved FEV₁ with β-agonist
        - No: Further Testing with Full PFT’s
        - Yes: Suspect Asthma
      - Yes: Reversible Obstruction with β-agonist
        - No: Suspect COPD

Further Testing with Full PFT’s

Severity of Obstruction
- FVC
  - Mild: 65% to 80% predicted
  - Moderate: 50% to 65% predicted
  - Severe: <50% predicted

Is FEV₁ / FVC Ratio Low? (<LLN)
- No: Restrictive Defect
  - Is FVC Low? (<LLN)
    - Yes: Normal Spirometry
    - No: Further Testing with Full PFT’s and consider referral if moderate to severe

LLN=Lower Limit of Normal

Adapted from Lowry JB, A Primary Care Physician primer on Spirometry
PCAP SPIROMETRY OPERATOR CHECKLIST

- 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 $100\, ml$ of each other
- Are the 2 largest FEV1s within 150 ml of each other?
- If $FVC < 1.0 \, L$ then criteria is within $100\, ml$ of each other

- Technical comments recorded on spirometry report
PCAP SPIROMETRY OPERATOR CHECKLIST

**Relative Contraindications for Spirometry**

- Recent Indicates within 6 weeks.

<table>
<thead>
<tr>
<th>Relative Contraindications</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td><strong>Cerebral aneurysm</strong></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><strong>Recent brain surgery</strong></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><strong>Recent concussion</strong></td>
<td><em>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.</em></td>
</tr>
<tr>
<td><strong>Recent eye surgery</strong></td>
<td>†Lung function tests may increase the risk of early delivery in the case of an incompetent cervix.</td>
</tr>
<tr>
<td><strong>Significant glaucoma</strong></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><strong>Significant aortic aneurysm</strong></td>
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<tr>
<td><strong>Recent thoracic surgery†</strong></td>
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<tr>
<td><strong>Recent abdominal surgery</strong></td>
<td></td>
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<tr>
<td><strong>Pregnancy‡</strong></td>
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<tr>
<td><strong>Recent sinus surgery or middle ear surgery or infection</strong></td>
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<tr>
<td><strong>Pneumothorax</strong></td>
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<td><strong>Systemic hypotension or severe hypertension (e.g., &gt;200/120mmHg)</strong></td>
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<tr>
<td><strong>Significant atrial/ventricular arrhythmia</strong></td>
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<td><strong>Noncompensated heart failure</strong></td>
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<tr>
<td><strong>Recent myocardial infarction (MI)§ or pulmonary embolus</strong></td>
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<tr>
<td><strong>History of syncope related to forced exhalation/cough</strong></td>
<td></td>
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<tr>
<td><strong>Active tuberculosis</strong></td>
<td>Infection control procedures must be taken according to local procedures.</td>
</tr>
<tr>
<td><strong>Hepatitis B</strong></td>
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<tr>
<td><strong>Hemoptysis or oral bleeding</strong></td>
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<tr>
<td><strong>Inability to follow direction (e.g., confusion, dementia, young age, language barrier)</strong></td>
<td>In some cases, successful spirometry can be done with increased coaching and aid of an interpreter.</td>
</tr>
</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

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U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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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 training, 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

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Indications for spirometry</th>
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<tr>
<td><strong>Diagnostic</strong></td>
<td></td>
</tr>
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</table>
To evaluate symptoms, signs or abnormal laboratory tests  
To measure the effect of disease on pulmonary function  
To screen individuals at risk of having pulmonary disease  
To assess pre-operative risk  
To assess prognosis  
To assess health status before beginning strenuous physical activity programmes  |
| **Monitoring** |  
To assess therapeutic intervention  
To describe the course of diseases that affect lung function  
To monitor people exposed to injurious agents  
To monitor for adverse reactions to drugs with known pulmonary toxicity  |
| **Disability/Impairment evaluations** |  
To assess patients as part of a rehabilitation programme  
To assess risks as part of an insurance evaluation  
To assess individuals for legal reasons  |
| **Public health** |  
Epidemiological surveys  
Derivation of reference equations  
Clinical research |
The spirometer must be capable of accumulating volume for expressed in litres at BTPS.

FEV1 is the maximal volume of air exhaled in the first second (EV; see BTPS correction 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 submaximal 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 \( \geq 0.25 \text{ s} \), and preferably \( 1 \text{ s} \), 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 \( \geq 10 \text{ mm-L}^{-1} \) (BTPS). For a screen display, 5 mm-L^{-1} is satisfactory (table 2).

The time scale should be \( \geq 20 \text{ mm-s}^{-1} \), and larger time scales are preferred (\( \geq 30 \text{ mm-s}^{-1} \)) 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
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 spiro- 
meters 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 cmH₂O (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.
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 $\pm 3.5\%$ 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 $\sim 6$ s and $<0.5$ s). The volume at each flow should meet the accuracy requirement of $\pm 3.5\%$. 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 $\pm 3.5\%$.

**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 a maximal effort curve, the EV must be <5% of the FVC or 0.150 L, whichever is greater. If a manoeuvre has an obviously hesitant start, the technician may terminate the trial early to avoid an unnecessary prolonged effort.

Rapid computerised feedback to the technician when the start criteria are 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.
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 inspiratory flow-volume curve. The two largest values of FVC must be within 0.150 L of each other or 5% of FVC whichever is greater (fig. 2); 2) without coughing during the first second of the manoeuvre, thereby affecting the measured FEV1 value, or any other cough that, in the technician's judgment, interferes with the measurement of accurate results [3]; 3) without early termination of expiration (see End of test criteria section); 4) without a Valsalva manoeuvre (glottis closure) or hesitation during the manoeuvre that causes a cessation of airflow, which precludes accurate measurement of FEV1 or FVC [3]; 5) without a leak [3]; 6) without an obstructed mouthpiece (e.g. obstruction due to the tongue being placed in front of the mouthpiece, or teeth in front of the mouthpiece, or mouthpiece deformation due to biting); and 7) without evidence of an extra breath being taken during the manoeuvre.

It should be noted that a usable curve must only meet conditions 1 and 2 above, while an acceptable curve must meet all of the above seven conditions.

It is desirable to use a computer-based system that provides feedback to the technician when the above conditions are not met. The reporting format should include qualifiers indicating the acceptability of each manoeuvre. However, failure to meet these goals should not necessarily prevent reporting of results, since, for some subjects, this is their best performance. Records of such manoeuvres should be retained since they may contain useful information.

Between-manoeuvre evaluation

Using the previously described criteria, an adequate test requires a minimum of three acceptable FVC manoeuvres. Acceptable repeatability is achieved when the difference between the largest and the next largest FVC is ≤0.150 L and the difference between the largest and next largest FEV1 is ≤0.015 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, up to, 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.

Volume–time or flow–volume curves from at least the best three FVC manoeuvres must be retained. Table 5 gives a summary of the within- and between-manoeuvre evaluation.

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 5 Summary of within- and between-manoeuvre acceptability criteria

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

\[
\text{FEV25–75%}
\]

The mean forced expiratory flow between 25% and 75% of the FVC (FEV25–75%) 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 FEV25–75% must be measured with an accuracy of at least \( \pm 5\% \) of reading or \( \pm 0.200 \text{ L·s}^{-1} \) whichever is greater, over a range of up to 7 \text{ 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 \text{L·s}^{-1}. When PEF is recorded using a patient-administered portable PEF meter, it is often expressed in \text{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, FEV25–75% 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

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**FIGURE 3.** Flow chart outlining how acceptability and repeatability criteria are to be applied. FVC: forced vital capacity; FEV1: forced expiratory volume in one second.
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-maneuvré evaluation
These evaluations are the same as for FVC (see Within-maneuvré evaluation and Between-maneuvré 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.

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 $\sim 0.1 \text{ mg-min}^{-1}$ 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 $\mu g \text{ min}^{-1}$. 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 MANŒUVRE**

**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 inhalation. 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 [3].

**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 before FVC 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 manoeuvres 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 tracings 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 and not assumed to be constant, even over the course of one testing session. 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.

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. Additional, 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>-</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>30</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</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)</td>
<td>24 ATS flow waveforms</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>15</td>
<td>&lt;1.5 cmH₂O·L⁻¹·s⁻¹ (0.15 kPa·L⁻¹·s⁻¹)</td>
<td>Data from manufacturers</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>0–14</td>
<td>15</td>
<td>24 ATS waveforms</td>
<td></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>0–14 (±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; 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 \( \pm 50 \) 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 \( 37 \pm 1^\circ \)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:

\[
\text{Deviation} = \text{average} - \text{standard} \quad (1)
\]

\[
\text{Percentage deviation} = 100 \times (\text{average} - \text{standard})/\text{standard} \quad (2)
\]

The accuracy validation limits for volumes, which include the waveform-generator inaccuracy, are \( \pm 3.5\% \) of reading or \( \pm 0.100 \) 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 \( \pm 4.5\% \) 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:

\[
\text{Span} = \text{maximum} - \text{minimum} \quad (3)
\]

\[
\text{Percentage span} = 100 \times \text{span}/\text{average} \quad (4)
\]

The repeatability validation limits for the volume measured at ambient conditions are \( \pm 3.5\% \) or \( \pm 0.100 \) L, whichever is the greater, and, for BTPS conditions, \( \pm 4.5\% \) or \( \pm 0.200 \) 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 \( \pm 2\% \) 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 \( \sim 25\% \) 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 for these tests under BTPS conditions are \( \pm 12\% \) or \( \pm 25 \) 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 cm H₂O (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>FEF25-75%</td>
<td>Mean forced expiratory flow between 25% and 75% of FVC</td>
</tr>
<tr>
<td>MEFX%</td>
<td>Instantaneous forced expiratory flow where X% of the FVC has been expired</td>
</tr>
<tr>
<td>FEFX%</td>
<td>Instantaneous forced expiratory flow at the point where X% of the FVC has been inspired</td>
</tr>
<tr>
<td>Fl,X</td>
<td>Fraction of expired gas X</td>
</tr>
<tr>
<td>FIVC</td>
<td>Forcely expiratory vital capacity</td>
</tr>
<tr>
<td>FRC</td>
<td>Functional residual capacity</td>
</tr>
<tr>
<td>FVC</td>
<td>Forced vital capacity</td>
</tr>
<tr>
<td>H₂O</td>
<td>Water</td>
</tr>
<tr>
<td>Hb</td>
<td>Haemoglobin</td>
</tr>
<tr>
<td>Hg</td>
<td>Mercury</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz; cycles per second</td>
</tr>
<tr>
<td>IC</td>
<td>Inspiratory capacity</td>
</tr>
<tr>
<td>IVC</td>
<td>Inspiratory vital capacity</td>
</tr>
<tr>
<td>Kco</td>
<td>Transfer coefficient of the lung (i.e. DL,CO/Va)</td>
</tr>
<tr>
<td>kg</td>
<td>Kilograms</td>
</tr>
<tr>
<td>kPa</td>
<td>Kilopascals</td>
</tr>
<tr>
<td>L</td>
<td>Litres</td>
</tr>
<tr>
<td>L·min⁻¹</td>
<td>Litres per minute</td>
</tr>
<tr>
<td>L·s⁻¹</td>
<td>Litres per second</td>
</tr>
<tr>
<td>lb</td>
<td>Pounds weight</td>
</tr>
<tr>
<td>MEFX%</td>
<td>Maximal instantaneous forced expiratory flow where X% of the FVC remains to be expired</td>
</tr>
<tr>
<td>MFVL</td>
<td>Maximum flow-volume loop</td>
</tr>
<tr>
<td>mg</td>
<td>Milligrams</td>
</tr>
<tr>
<td>MIF</td>
<td>Maximal inspiratory flow</td>
</tr>
<tr>
<td>mL</td>
<td>Millilitres</td>
</tr>
<tr>
<td>mm</td>
<td>Millimetres</td>
</tr>
<tr>
<td>MMEF</td>
<td>Maximum mid-expiratory flow</td>
</tr>
<tr>
<td>ms</td>
<td>Milliseconds</td>
</tr>
<tr>
<td>MVV</td>
<td>Maximum voluntary ventilation</td>
</tr>
<tr>
<td>Pa,O₂</td>
<td>Alveolar oxygen partial pressure</td>
</tr>
<tr>
<td>PB</td>
<td>Barometric pressure</td>
</tr>
<tr>
<td>PEF</td>
<td>Peak expiratory flow</td>
</tr>
<tr>
<td>PH₂O</td>
<td>Water vapour partial pressure</td>
</tr>
<tr>
<td>Pi,O₂</td>
<td>Inspired oxygen partial pressure</td>
</tr>
<tr>
<td>θ(θ)</td>
<td>Specific uptake of CO by the blood</td>
</tr>
<tr>
<td>RT</td>
<td>Rise time from 10% to 90% of PEF</td>
</tr>
<tr>
<td>RV</td>
<td>Residual volume</td>
</tr>
<tr>
<td>s</td>
<td>Seconds</td>
</tr>
<tr>
<td>STPD</td>
<td>Standard temperature (273 K, 0°C), pressure (101.3 kPa, 760 mmHg) and dry</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>TGV (or Vrg)</td>
<td>Thoracic gas volume</td>
</tr>
<tr>
<td>t₁</td>
<td>Time taken for inspiration</td>
</tr>
<tr>
<td>TLC</td>
<td>Total lung capacity</td>
</tr>
<tr>
<td>Tr</td>
<td>Tracer gas</td>
</tr>
<tr>
<td>TOT</td>
<td>Total time of respiratory cycle</td>
</tr>
<tr>
<td>Va</td>
<td>Alveolar volume</td>
</tr>
<tr>
<td>Va,eff</td>
<td>Effective alveolar volume</td>
</tr>
<tr>
<td>VC</td>
<td>Vital capacity</td>
</tr>
<tr>
<td>Vc</td>
<td>Pulmonary capillary blood volume</td>
</tr>
<tr>
<td>Vo</td>
<td>Dead space volume</td>
</tr>
<tr>
<td>Vl</td>
<td>Inspiréd volume</td>
</tr>
<tr>
<td>Vₜ</td>
<td>Volume of the expired sample gas</td>
</tr>
<tr>
<td>μg</td>
<td>Micrograms</td>
</tr>
</tbody>
</table>
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 be used to obtain data points.

Table 8: List of parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID</td>
<td>Patient identification</td>
</tr>
<tr>
<td>Patient name</td>
<td></td>
</tr>
<tr>
<td>Data type (E=expiratory or I=Inspiratory, followed by S=single or B=best curve)</td>
<td></td>
</tr>
<tr>
<td>Barometric pressure (mmHg)</td>
<td>Barometric pressure used in BTPS calculation</td>
</tr>
<tr>
<td>Temperature (°C)</td>
<td>Temperature used in BTPS calculation</td>
</tr>
<tr>
<td>Relative humidity (%)</td>
<td>Relative humidity used in BTPS calculation</td>
</tr>
<tr>
<td>FVC quality attribute (A, B, C, D or F)</td>
<td>Quality attribute of forced vital capacity</td>
</tr>
<tr>
<td>FEV1 quality attribute (A, B, C, D or F)</td>
<td>Quality attribute of forced expired volume</td>
</tr>
<tr>
<td>Effort attribute (A, B, C, D or F)</td>
<td>Quality attribute of effort</td>
</tr>
<tr>
<td>Interpretation code (see ATS interpretation scheme)</td>
<td>Interpretation code of test</td>
</tr>
<tr>
<td>Deleted manoeuvre (Y or N)</td>
<td>Indicator if manoeuvre was deleted</td>
</tr>
<tr>
<td>Acceptable manoeuvre (Y or N)</td>
<td>Indicator if manoeuvre was acceptable</td>
</tr>
<tr>
<td>Technician quality control code (A, B, C, D or F)</td>
<td>Quality control code of technician</td>
</tr>
<tr>
<td>Computer quality code (A, B, C, D or F)</td>
<td>Quality code of computer</td>
</tr>
<tr>
<td>Plateau achieved (Y or N)</td>
<td>Indicator if plateau was achieved</td>
</tr>
<tr>
<td>Review (N or R for “needs review” or “was reviewed”)</td>
<td>Indicator of review status</td>
</tr>
<tr>
<td>Date of review (DD/MM/YYYY)</td>
<td>Date of review</td>
</tr>
<tr>
<td>Reviewer initials</td>
<td>Initials of reviewer</td>
</tr>
<tr>
<td>BTPS factor (x.xxx)</td>
<td>BTPS factor of test</td>
</tr>
<tr>
<td>Spirometer manufacturer</td>
<td>Manufacturer of spirometer</td>
</tr>
<tr>
<td>Spirometer model</td>
<td>Model of spirometer</td>
</tr>
<tr>
<td>Spirometer serial number</td>
<td>Serial number of spirometer</td>
</tr>
<tr>
<td>Spirometer type</td>
<td>Type of spirometer</td>
</tr>
<tr>
<td>Reference values source</td>
<td>Reference values used for calculation</td>
</tr>
<tr>
<td>Reference values correction factor (x.xx, 1.00 for no correction)</td>
<td>Correction factor for reference values</td>
</tr>
<tr>
<td>Testing position (standing, sitting or supine)</td>
<td>Position of patient during test</td>
</tr>
<tr>
<td>Test type (pre-, post-, bronchodilator, methacholine concentration or dose)</td>
<td>Type of test performed</td>
</tr>
<tr>
<td>FVC (mL)</td>
<td>Forced vital capacity</td>
</tr>
<tr>
<td>Extrapolated volume (mL)</td>
<td>Extrapolated volume</td>
</tr>
<tr>
<td>FEV1 (mL)</td>
<td>Forced expired volume</td>
</tr>
<tr>
<td>FEV1 (mL)</td>
<td>Forced expired volume</td>
</tr>
<tr>
<td>PEF (mL-s⁻¹)</td>
<td>Peak expiratory flow</td>
</tr>
<tr>
<td>FEF25–75% (mL-s⁻¹)</td>
<td>Forced expiratory flow between 25% and 75% of FVC</td>
</tr>
<tr>
<td>VC (mL)</td>
<td>Vital capacity</td>
</tr>
<tr>
<td>Forcd expiratory time (s)</td>
<td>Forced expiratory time</td>
</tr>
<tr>
<td>Time to PEF (ms)</td>
<td>Time to peak expiratory flow</td>
</tr>
<tr>
<td>Predicted FVC (mL)</td>
<td>Predicted forced vital capacity</td>
</tr>
<tr>
<td>Predicted FEV1 (mL)</td>
<td>Predicted forced expired volume</td>
</tr>
<tr>
<td>Predicted FEV1 (mL)</td>
<td>Predicted forced expired volume</td>
</tr>
<tr>
<td>Predicted FEV1/FVC% (xxx.x%)</td>
<td>Predicted FEV1/FVC percentage</td>
</tr>
<tr>
<td>Predicted FEV1/FVC% (xxx.x%)</td>
<td>Predicted FEV1/FVC percentage</td>
</tr>
<tr>
<td>Comments text</td>
<td>Additional comments</td>
</tr>
<tr>
<td>Original sampling interval (ms)</td>
<td>Original sampling interval of test</td>
</tr>
<tr>
<td>Blank 1 or FEF25%</td>
<td>Blank value for FEF25%</td>
</tr>
<tr>
<td>Blank 2 or FEF50%</td>
<td>Blank value for FEF50%</td>
</tr>
<tr>
<td>Blank 3 or FEF75%</td>
<td>Blank value for FEF75%</td>
</tr>
<tr>
<td>Blank 4 or FEF90%</td>
<td>Blank value for FEF90%</td>
</tr>
<tr>
<td>Blank 5</td>
<td>Blank value for FEF25%</td>
</tr>
<tr>
<td>Blank 6</td>
<td>Blank value for FEF50%</td>
</tr>
<tr>
<td>Blank 7</td>
<td>Blank value for FEF75%</td>
</tr>
<tr>
<td>Blank 8</td>
<td>Blank value for FEF90%</td>
</tr>
<tr>
<td>Blank 9</td>
<td>Blank value for FEF25%</td>
</tr>
<tr>
<td>Blank 10</td>
<td>Blank value for FEF50%</td>
</tr>
<tr>
<td>Number of data points</td>
<td>Number of data points</td>
</tr>
<tr>
<td>Flow data points (mL-s⁻¹; variable number contained in number of data points)</td>
<td>Flow data points</td>
</tr>
<tr>
<td>Carriage return</td>
<td>Carriage return code</td>
</tr>
<tr>
<td>Line feed</td>
<td>Line feed code</td>
</tr>
</tbody>
</table>

Note: 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 \( \geq 0.25 \) 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 values (mL·s\(^{-1}\)) and multiplying the sum by 0.01 s. To obtain the highest precision, the sum of the flow values should be calculated for each volume data point before multiplying by 0.01 s.

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