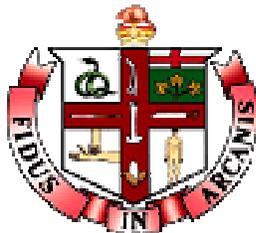


Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Diagnostic Spirometry & Flow Volume Loop Studies – 3rd Edition, April 2008



**THE COLLEGE OF
PHYSICIANS &
SURGEONS
OF ONTARIO**

First Edition, February 1997

Members of the Respiratory Disease Task Force:

Ms. Lori Davis	Toronto, Ontario
Dr. Roger Haddon	Hamilton, Ontario
Dr. Tetsuo Inouye	Mississauga, Ontario
Dr. Robin McFadden	London, Ontario
Dr. Noe Zamel	Toronto, Ontario

Second Edition, September 2001:

Members of the Respiratory Disease Task Force:

Dr. Michael Alexander	Niagara Falls, Ontario
Ms. Lori Davis	Toronto, Ontario
Dr. Lutz Forkert	Kingston, Ontario
Dr. Tetsuo Inouye	Mississauga, Ontario
Dr. Robin McFadden	London, Ontario

Third Edition, April 2008:

Members of the Respiratory Disease Task Force:

Dr. Michael Alexander	Niagara Falls, Ontario
Dr. Meri Bukowskyj	Ottawa, Ontario
Dr. Lutz Forkert	Kingston, Ontario
Mr. David Hu	Toronto, Ontario
Ms. Cathy Koost	Churchill, Ontario

Members of the Sub-Committee Reviewing ATS Manual:

Ms. Laurie Allan	Hamilton, Ontario
Ms. Lori Davis	Gilford, Ontario
Mr. Bernard Ho	Ajax, Ontario

Published and distributed by the College of Physicians and Surgeons of Ontario. For more information about the Independent Health Facilities program, contact:

Wade Hillier
Manager, Government Programs (IHF & Methadone)
The College of Physicians and Surgeons of Ontario
80 College Street
Toronto, Ontario M5G 2E2
Toll free (800) 268-7096
(416) 967-2600 ext. 636
email: whillier@cpsy.on.ca

The College of Physicians and Surgeons of Ontario

Our Strategic Plan

The Council of the College of Physicians and Surgeons of Ontario developed a strategic plan to establish College priorities for the next several years. The priorities articulated in the strategic plan serve as a guide to action and focus our energies toward attaining our new vision – **Quality Professionals, Healthy System, Public Trust**.

Our Mandate

Build and maintain an effective system of self-governance. The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined

Quality Professionals, Healthy System, Public Trust.

Our new vision is the framework by which we organize ourselves. It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek. Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes. We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we, as caring professionals, are actively involved in the design and function of an effective system including:

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation

The public, through legislation, has empowered the profession to regulate itself through the College. Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system. To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

- Coherent alignment of goals, behaviours and outcomes;
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

- An attitude of service;
- Accepting responsibility;
- Transparency of process;
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

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Chapter 1 - Staffing a Facility

Qualifications of Staff performing Spirometry and Flow Volume Loop Studies

Medical Staff Qualifications

Medical staff have a certificate of registration for independent practice in Ontario and

- hold a specialty qualification from the Royal College of Physicians and Surgeons of Ontario (or equivalent) in Respiriology,

or

- hold another specialty qualification from the Royal College of Physicians and Surgeons of Canada (or equivalent) and have a minimum of three months prior training and experience on the respiratory disease services of a university-affiliated teaching hospital, such training including experience in the execution and interpretation of pulmonary function tests,

or

- in lieu of the above, have a minimum of six months prior clinical experience in the execution and interpretation of pulmonary function testing. Documentation must be available in the Independent Health Facility

Technologist Qualifications

Technologists performing these tests are:

- a registered cardiopulmonary technologist (RCPT(P))

or

- a registered respiratory therapist (RRT)

or

- another health care professional whose formal training included studies in the anatomy and physiology of the cardiorespiratory system and whose subsequent experience included one month of training in the performance and quality control of spirometry and flow volume loop testing

<p><i>Note: All technologists must be currently certified in Basic Cardiac Life Support</i></p>

Chapter 2 - Facility Standards for Spirometry and Flow Volume Loop Studies

Overview

Spirometry and flow volume curves are non-invasive techniques for the measurement of vital capacity, forced expired volume in one second and rates of airflow at various lung volumes. Measurement of the forced vital capacity and corresponding flow rates is the most commonly used test to detect the presence of lung disease and to monitor changes in severity and response to treatment.

Spirometric terms and measurements

Term	Name	Description
VC	Vital capacity	The volume change between the position of full inspiration and complete expiration.
IVC	Inspiratory vital capacity	The maximal volume of air inhaled slowly from the point of maximal exhalation achieved by a slow expiration from end-tidal inspiration.
SVC	Slow vital capacity	The maximal volume of air exhaled slowly from the point of maximal inhalation.
FVC	Forced vital capacity	The maximal volume of air exhaled with maximally forced effort from a point of maximal inspiration.
FEV _t	Forced expiratory volume at time t	The maximal volume of air exhaled with maximally forced effort in t seconds; 1 and 6 seconds are the most common.
FEV _t /FVC	Forced expiratory volume in t seconds to forced vital capacity ratio	The ratio of FEV _t to FVC expressed as a percentage (FEV ₁ /FVC is the most commonly used ratio)

FEF _{x%}	Forced expiratory flow x%	The forced expiratory flow when x% of the FVC has been exhaled; FEF _{25%} , FEF _{50%} , and FEF _{75%} are commonly reported.
FEF _{25-75%}	Forced mid-expiratory flow	The average flow over the middle 50% of a FVC manoeuvre.
FET	Forced expiratory time	The time required for the FVC to be expired.
PEF	Peak expiratory flow	The maximal expiratory flow generated during an FVC manoeuvre.
MVV	Maximum voluntary ventilation	The maximum volume of air one can ventilate over a specified period of time (e.g., 12 seconds).

Note: Both PEF and MVV are very effort-dependent requiring substantial cooperation and understanding by the patient.

Instrumentation

The following instrumentation is required to perform spirometry and flow volume loop curves:

- A calibrated spirometer linear from 0.5 to 8 L BTPS and accurate to 3% of the reading or 50 mL, whichever is greater when air is put into the system at flow rates from 0-14 litres/sec. The 8 litre volume applies to recently manufactured instruments.
 - those instruments manufactured prior to 1995 with a 7 litre range may still be used
 - the spirometer is able to accumulate volume for at least 15 seconds for FVC and for at least 30 seconds for SVC. If FEV₁ is being measured, the volume criteria is the same as for the FVC and the resistance to airflow is less than 1.5 cm H₂O/litre/sec at flow rates from 0-14 litres/sec
 - the frequency response of the spirometer is flat to 4 Hz and the time is accurate to within ± 2%
 - the peak expiratory flow accuracy is ± 10% of the reading or 0.4 litres/sec, whichever is greater, at flow rates from 0-14 litres/sec

- the $FEF_{25-75\%}$ range must be 7.0 litres/sec with an accuracy of $\pm 5\%$ of the reading or 0.2 litres/sec, whichever is greater, over a minimum time of 15 seconds
 - the flow range must be 14 litres/sec with an accuracy of $\pm 5\%$ of the reading or 0.2 litres/sec, whichever is greater at flow rates from 0 - 14 litres/sec
 - the MVV range must be 250 litres/min at a tidal volume of 2 litres with an accuracy of $\pm 10\%$ of the reading or 15 litres/min whichever is greater at a flow range up to 14 litres/sec
 - the back pressure for MVV system must be less than ± 10 cm H_2O at a 2 litre tidal volume at a frequency of 2 Hz. The resistance to airflow criteria for PEP, $FEF_{25-75\%}$, and flow is the same as for FEV_1
 - flow type spirometers (such as capillary and screen pneumotachometers) where the flow signal is integrated to derive a volume may also be used. These instruments require different BTPS correction factors than volume spirometers as the assumption that no cooling of the air occurs as it passes through the flow sensor is usually made. This assumption can only be made if the flow sensor is heated to 37 degrees Celsius
 - manufacturers must be able to provide documentation that all spirometers meet the current recommendations (ATS/ERS Standardization of Spirometry, 2005)
- A kymograph, X-Y recorder, or printer for providing graphic records of the manoeuvres performed. The volume scale must be at least 10 mm/L (BTPS). The time scale must be at least 2 cm/sec. For flow volume curves, exhaled flow must be plotted upwards and exhaled volume to the right. A 2:1 ratio should be maintained for the volume and flow scales respectively
 - A thermometer to measure ambient temperature, a barometer to measure atmospheric pressure and an hydrometer to measure humidity for the calculation of the BTPS factor. The spirometer itself should also contain a thermometer for a more accurate calculation of the BTPS factor

Note: *Equipment recommendations referred to in this document are for diagnostic spirometers as opposed to those classified as monitoring devices.*

Technique

The technique for the forced expiratory spirogram and forced expired flow volume curve is the same. Using the closed-circuit technique, the patient is seated (preferably) in the upright position and is instructed to place the mouthpiece in the mouth so that no leaks are present. The patient's nose is then occluded with a noseclip. The patient is asked to breathe normally for 3 or 4 breaths to establish a

constant end-tidal point. The patient is then instructed to inhale to total lung capacity and blow out to residual volume as forcefully as possible.

Using the open circuit technique, the patient inspires fully before inserting the mouthpiece and exhaling into the spirometer or pneumotachograph. A noseclip is not necessary when using the open circuit technique. Using this approach the patient does not inhale from the spirometer or flow sensor so no contamination of the inspired air can occur. The technologist must continually urge the patient to exhale until the “end of test” criteria are met. This occurs when there is:

- an obvious plateau in the spirometry tracing with no change in volume for at least 1 second after an exhalation time of at least 6 seconds for patient > 10 yrs of age, or an exhalation time of at least 3 seconds for patient < 10 yrs of age.

or

- the patient cannot continue.

The patient is then disconnected and allowed to rest. The spirometer is flushed between manoeuvres to prevent re-breathing of the carbon dioxide, which has accumulated during the manoeuvre.

<p>Note: <i>If SVCs are performed they must be performed prior to the FVCs to avoid the possibility of premature bronchospasm.</i></p>

Measurements

The test is repeated until three acceptable SVC and three acceptable FVC tracings have been obtained. An acceptable tracing is one in which there is:

- maximal effort with no hesitation (extrapolated volume < 5% FVC or 0.15 L whichever is greater)
- no cough during the first second
- a smooth, continuous exhalation
- no glottis closure, obstruction of the mouthpiece or leaks
- end of test criteria is met

If the curve is deemed acceptable, the reproducibility criteria are then applied. The largest FVC or SVC and second largest FVC or SVC from acceptable manoeuvres must not vary by more than 0.15 L. For forced exhalations, the largest FEV₁ and the second largest FEV₁ must not vary by more than 0.15 L. For patient with FVC or SVC ≤ 1.0 L, a value of 0.10 L instead of 0.15 should be used.

The largest acceptable value is reported in litres at BTPS. FEF_{25-75%} is measured from the curve with the highest sum of FEV₁ + FVC using only the acceptable curves and is reported in litres/second at BTPS. FVL pictures, either printed or on screen must be available to the interpreting physician to review at the time of interpretation.

These pictures must also be available either on screen or in printed format when un-interpreted results are sent to referring physicians as is often the case when patients have testing performed and see the physician on the same day, which means the referring physician is reviewing an un-interpreted copy of the test results. The final report should include the technologist's comments regarding unacceptable or non reproducible data, including a description of the problem.

Calculations

Data calculation is automated in computerized pulmonary function systems, which includes all flow-type spirometers. Older volume-type-spirometer systems may require manually measuring and calculating the volumes and flows from a hard copy of the graphical recording.

For flow volume curves, measure the centimeter deflection on the **X** axis and convert to a volume (*on paper, usually 1 litre = 2 cm deflection*). Measure the centimeter deflection on the **Y** axis and convert to a flow (*on paper, usually 1 litre /sec = 1 cm deflection*).

For spirometry tracings, volume is represented on the **Y** axis and time is represented on the **X** axis (*for time 1 second is usually represented by 3 cm on paper*). Measure and record all acceptable values. Observed values are reported in BTPS and compared to predicted values from a healthy population of the same height, age and gender.

Quality Control

The spirometer volume is calibrated daily with a 3 L syringe. The measured volume should be within $\pm 3.5\%$ of the reading (*includes $\pm 0.5\%$ accuracy of the 3-L syringe*). Volume checks using at least 3 different flow rates from 0.5 -12 L/sec are necessary for flow-type spirometers. This requires 3 L injection times of approximately 0.5 - 6 seconds. The syringe must be accurate to within 15 ml for a 3 L syringe or at least 0.5% of the full scale deflection. The syringe must be re-calibrated as per manufacturer's specifications. The spirometer is checked for leaks daily by applying a pressure of 3 cm H₂O for 1 minute. A volume change greater than 30 ml after 1 minute indicates a leak. At least every 3 months volume spirometers are checked over the entire volume range in 1 L increments.

Flow spirometers must have their linearity checked at least weekly using different flow rates (low, mid, and high-range). Time is calibrated at least 4 times per year for non computerized equipment. Laboratory testing with a healthy subject with known values is recommended. Laboratory testing of biologics should not exceed the established control mean ± 2 SD. If computerized testing is done, (e.g., using a computerized FVC simulator), computer software adheres to ATS recommendations. Calibration procedures and results, calculations, reference values, preventive maintenance and corrective actions plus system hardware and software upgrades are maintained in a laboratory manual. The technical staff maintains records of continuing education, as well as feedback from the Quality Advisor regarding unacceptable test results and corrective action taken.

Infection Control

Nosocomial infections are a potential risk during pulmonary function testing. A clean mouthpiece and noseclip are used for each patient. Disposable filters are to be used unless the circuitry is changed after each patient or a non-rebreathing technique is used.

Note: All staff are encouraged to review the CPSO's "Infection Control in the Physician's Office" 2004 edition (<http://www/cpso.on.ca/Publications/infectioncontroly2.pdf>).

Sterilizing Equipment

There are many methods for sterilizing equipment. Manufacturer's recommendations should be followed. For mouthpieces, valves, tubing, etc., the most practical method is chemical sterilization in which equipment is completely immersed in a cold sterilizing solution for the recommended period of time depending on whether high-level disinfection or sterilization is required. The tubing and valves are processed at least daily. The mouthpieces and noseclips are processed after each use.

If equipment is contaminated with blood or sputum it must be sterilized immediately after it is used. Some chemicals will sterilize faster if they are heated. To eliminate toxic chemical residues, equipment is thoroughly rinsed and air dried before reusing.

Equipment that cannot be subjected to heat or chemicals must be sterilized using ethylene oxide (gas sterilization). The equipment must be thoroughly cleaned and packaged before it is sterilized. Equipment sterilized by this method must be aerated for approximately 48 hours (or less if heat is applied) before use.

Note: All equipment must be properly cleaned before undergoing disinfection and/or sterilization.

Universal/Routine/Standard Precautions (URSP)

As many patients may have a potentially infectious disease, the facility must implement the nationally recognized program of Universal/Routine/Standard Precautions (URSP). Originating from the Center for Disease Control in Atlanta, Georgia, the principles of URSP apply to the management of patients and specimens.

URSP is a system which consistently interrupts the transmission of infections thus ensuring increased protection for both patients and health care providers. URSP are based on the premise that **ALL** patients are considered potentially infectious. Therefore, patients who are known to have infectious diseases are no longer singled out for special precautions. The exception to this is patients with known or suspected active tuberculosis.

Facility staff who are in contact with potentially infectious patients receive appropriate diagnostic follow-up.

These principles apply to both patients and patient specimens handled by clinical or diagnostic facilities, they include:

- effective handwashing before and after direct patient contact or contact with body substances
- wearing gloves for contact with blood, secretions, mucous membranes, non-intact skin, and moist body substances
- wearing additional barriers such as gowns, masks, protective eyewear, and plastic aprons when body substances are likely to soil clothing, skin, or mucous membranes
- containing soiled reusable articles, linen, and garbage securely enough to prevent leakage
- disposing of syringes and uncapped needles in a labeled puncture resistant container immediately after use

Chapter 3 - Clinical Practice Parameters for Spirometry and Flow Volume Loop Studies

Overview

Spirometry measures the volume of air an individual exhales as a function of time. Flow, or the rate at which the volume is changing as a function of time, may also be measured. Spirometry results correlate well with morbidity and life expectancy, but in certain situations, spirometry does not suffice and more extensive testing is warranted.

Any patient referred for assessment has flow rates measured, either by **spirometry** or a **flow volume loop**. In most instances, and assuming proper test performance and interpretation, spirometry will suffice. If properly performed, flow volume loops more readily detect inconsistent patient effort, and have the capacity to evaluate flow rates at lower lung volumes and during inspiration (to evaluate the extrathoracic upper airway).

<p><i>Note: Postbronchodilator studies (OHIP codes J324 & J327) should not be performed routinely; and neither should they be repeated routinely. (See bronchodilator section in this chapter) Postbronchodilator studies should not usually be performed if baseline spirometry is within normal limits.</i></p>

Prerequisites

There are no prerequisites for this test.

Indications

Indications for spirometry pre or post bronchodilator include the need to:

- evaluate respiratory symptoms, especially dyspnea, wheeze, stridor and persistent cough
- evaluate abnormal laboratory tests, such as hypoxemia, hypercapnia, polycythemia, etc.
- diagnose an obstructive or restrictive ventilatory impairment, or an extrathoracic upper airway obstruction
- help assess peri-operative risk or exercise capacity
- determine baseline lung functions and monitor course of chronic obstructive lung diseases such as asthma and COPD

- monitor the course of chronic restrictive diseases, such as fibrosing alveolitis or a neuromuscular disorder
- evaluate the response to specific therapy for a respiratory condition
- help validate subjective complaints in occupational or environmental settings
- determine reversibility of airway obstruction as demonstrated by a reduced FEV₁/FVC ratio or other indicators of flow limitation
- evaluate alternative drug regimens in patients with known hyperreactive airways

Relative Contraindications

Forced expiratory manoeuvres should be performed with caution in the following circumstances:

- pneumothorax
- recent myocardial infarction or unstable cardiac status, ophthalmic surgery, abdominal surgery
- significant ongoing hemoptysis
- severe asthma
- presence or suspected presence of active tuberculosis or other communicable respiratory disease (febrile and severe respiratory illness)

Relative Contraindications for Bronchodilator Administration

- known or suspected adverse reactions to a specific bronchodilator
- unstable cardiovascular status (e.g., serious arrhythmias, significant tachycardia and elevated blood pressure) that might be aggravated by beta adrenergic stimulation

Reporting Guidelines

The largest vital capacity should be reported from all acceptable curves, including the forced manoeuvres (FVC). The largest FVC and the largest FEV₁ should be recorded after examining the data from all acceptable curves, even if they do not come from the same curve. Other measures, such as the FEF_{25-75%} and the instantaneous expiratory flows, should be obtained from the single curve that meets the acceptability criteria and gives the largest sum of FVC plus FEV₁ (i.e., best test).

The interpretation of spirometry involves two tasks:

- the classification of the derived values with respect to a reference population and assessment of the reliability of the data, and
- the integration of the spirometric values into the diagnosis, therapy, and prognosis for an individual patient.

- Comparison of patient measurement to predicted normal values, using 95% confidence limits to identify abnormal results.

The first task is the responsibility of the laboratory Quality Advisor or designate and serves not only to communicate information to the referring physician but also is an important aspect of laboratory quality control. The second task is ordinarily the responsibility of the physician requesting the studies and is performed within the context of patient care.

It is the responsibility of the Quality Advisor to develop explicit procedures for interpretation of spirometry and to select appropriate reference values.

The spirometry report includes a description of the type of ventilatory abnormality seen, with a comparison of the patient's results to the predicted values. If a suboptimal performance is suspected or evident, this should be noted. Any current medications, dosage, and time taken should also be noted.

Note: Abnormalities of flow at lower lung volumes (FEF_{25-75%} and instantaneous expiratory flows) are more variable than a FEV₁ and must be interpreted with caution. Small airways dysfunction may be an early indicator of disease, but such abnormalities are not always predictive of future impairment.

Bronchodilator Administration

A standardized assessment of bronchodilator response is necessary as many factors affect the bronchodilator response including type and amount of medication and method of delivery used.

Beta-adrenergic aerosols are the most commonly used form of bronchodilator for pre- and post-testing. The evaluation of other drugs can be conducted if requested by referring physicians. In order to effectively evaluate a response to beta-adrenergic drugs the medications below should be withheld for these recommended times:

MEDICATION		LENGTH OF ABSTENTION
Inhaled bronchodilators	Short-acting	4 to 8 hours
	Long-acting	24 hours
Anticholinergics		6hours
Oral short-acting bronchodilators		8hours
Sustained release beta-agonists		24 hours
Theophyllines	Twice-daily preparation	24 hours
	Once-daily preparations	48 hours

If the aim of the test is to determine whether further improvements in lung function are possible with a specific therapy, the above medications may not need to be withheld. The time between pre and post testing depends on the time to peak effect for the drug used. This is approximately 15 minutes for short-acting beta-agonists. Other drugs, such as anticholinergics may require a longer interval before retesting.

The recommended method for drug administration is 4 separate doses at approximately 30 seconds intervals of 100 µg of a Beta-agonist, inhaled in one breath to total lung capacity via a metered-dose inhaler (MDI). The breath is then

held for 5-10 seconds. This will maximize deposition of the drug in the lungs. A lower dose may be used if side effects of the Beta agonists are of concern for the patient. If anticholinergics are used, the method is the same, but the dose is 8 puffs of 20 µg of medication. The post bronchodilator testing is performed 10-15 minutes after administration of short-acting B₂-agonists and 30 minutes after administration of short-acting anticholinergic medications. If less than the recommended dosage is used the clinical reasons should be reported.

Interpretation of the response to inhaled bronchodilators is based on both absolute and percent change in function. Evaluating the response to bronchodilators is most commonly done by measuring and comparing forced expiratory volume in one second (FEV₁), forced vital capacity (FVC) and peak expiratory flow (PEF) before and after bronchodilator administration.

If postbronchodilator studies are performed, only significant responses are reported as positive. An increase in either FEV₁ or FVC of 12% or more over baseline represents a definite response (provided there is an absolute increase of at least 200 mL). The clinical relevance of 10-12% increases in flow rates is controversial. On the other hand, negative studies also need to be interpreted with caution. In addition, an increase in SGaw of 35% or more over baseline represents a significant bronchodilator response in adult patients.

<p><i>Note: Failure of flow rates to increase by 10-12% at one sitting does not rule out reversibility of airflow obstruction under other circumstances (e.g., time of day, choice of bronchodilator, dose of bronchodilator, ancillary therapy, duration of therapy, etc.)</i></p>

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