

Spirometry and Flow Volume Measurements

Standards & Guidelines

April 2006



College of
Physicians
& Surgeons
of A l b e r t a

To serve the public and guide the medical profession

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Revision Dates:	April 2006 December 1998
Approval Date:	June 1998
Originating Committee:	Advisory Committee on Pulmonary Function Laboratories

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Spirometry and Flow Volume Measurements

1.0 Preamble

Spirometry is a medical test that measures the volume of air an individual inhales or exhales as a function of time. An estimate of flow, or the rate at which the volume is changing as a function of time can also be calculated with spirometry.

Spirometry provides many parameters, two important ones being *Forced Vital Capacity (FVC)* and *Forced Expiratory Volume* in the first second (FEV_1). FVC is defined as the maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration. FEV_1 is defined as the volume of air exhaled in the first second of FVC. Spirometry provides FVC, FEV_1 , ratio and an estimate of flow.

Flow Volume Measurements refers to systems that measure flow using a pneumotach or a heated wire system. Pneumotachs and heated wire systems are flow sensing devices that are used to integrate flow into volume. Integration is a process whereby flow (ie: volume per unit of time) at small intervals (time) is converted into volume and the volume from each interval is summed. These flow based systems provide a graphic analysis of the flow generated during the FVC maneuver and measure FVC and FEV_1 as well as other parameters. Both inspiration and expiration are measured in a flow volume loop.

Indications for Spirometry or Flow Volume Measurements:

- To assist in the assessment of respiratory diseases such as COPD, asthma, chronic bronchitis, chest wall abnormalities, scoliosis, pulmonary fibrosis and occupational lung disease
- To assist in monitoring the course of some respiratory problems, the response to therapy or changes with growth/aging
- To provide a baseline value pre-op or pre-employment in occupations at high risk of respiratory problems

Spirometry

Spirometry is one test of pulmonary function that does not require physician accreditation for its use or interpretation when performed in the physician's office on his or her own patients. When offered as a service to other physicians and patients however, accreditation to ensure compliance with adequate standards of performance is required.

Spirometry, a test of timed vital capacity, is a useful measure of response to treatment and is one of the tests that should be part of the medical monitoring of patients with asthma and chronic lung diseases. However, the accuracy and reproducibility of spirometry results are affected by calibration and maintenance of the machine, operator technique, and effort provided by the patient.

Each physician utilizing spirometry in the office is ultimately responsible to ensure that:

- Patient results are accurate
- There is a quality control program
- Equipment is properly maintained, calibrated and sterilized
- Patient results are properly recorded
- Staff who administer the test are properly instructed

Flow Volume Measurements

This procedure is not recommended as an office procedure, as the calibration of the equipment is difficult.

Like all tests, the accuracy of the flow-volume loop depends on the machine's capabilities and on its calibration. Moreover, the accuracy of the flow-volume loop is affected by the person performing the test, the effort provided by the patient and, for some patients, the testing procedure itself.

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2.0 Equipment

A variety of equipment can be used to measure forced vital capacity but, regardless of the equipment used, it must meet American Thoracic Society (ATS) standards.

Range and accuracy:

Test	Range (BTPS)	Accuracy (BTPS)	Flow Range (L/s)	Time (s)
FVC	0.5 to 8 L	± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	15
FEV ₁	0.5 to 8 L	± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	1
PEF*		± 10% of reading or 0.400 L/s, whichever is greater	zero to 14	

* PEF – Peak Expiratory Flow – the maximum expiratory flow achieved with effort from a position of maximum inspiration.

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3.0 Procedure/Instructions for Spirometry & Flow-Volume Measurements

Some equipment requires that the patient first inhale to total lung capacity (TLC) before the mouthpiece is inserted and the forced expiration initiated. Other equipment functions by having the patient insert the mouthpiece prior to inhaling to TLC for the forced expiration. Regardless of the type of machine used, the patient must be actively coached to obtain accurate results.

To obtain maximal values for FEV₁ and FVC, you must ensure the patient first inhales to his/her TLC and then performs the forced expiration with maximal effort. The following is an example of instructions to the patient.

3.1 Pre-test Instructions

- “This is a test which will require your maximal effort.”
- “I am first going to ask you to fill your lungs as much as you can.”
- “Then I will tell you to completely empty your lungs as fast as you can. This will require you to use the muscles in your chest and stomach”
- “I will then repeat the instructions as you go through the test.”

3.2 Instructions during the Patient’s Performance of the Test

With the patient breathing normally, say:

- “After the next breath I want you to fill your lungs as much as you can. Take a big breath in-in-in-keep inhaling.”

At TLC say:

- “Blow-blow-blow, keep blowing, keep blowing, keep blowing, you’re almost empty, keep blowing. That’s good.”
- “Come off the mouthpiece and rest.”
- “We will be doing this a few more times.”

3.3 Recording Results

Repeat the test until the two highest FEV₁ and FVC results agree within 200 ml.

For patients with moderate to severe airway obstruction, a forced expiration can take more than 10 seconds. It is important to continue until the expiration is complete.

At least three FVC tests should be done and two of these should have FEV₁ and FVC values which agree with the other FEV₁ and FVC values to within 200 ml. It is acceptable to select the highest FEV₁ and the highest FVC from different tests, but with some automatic machines you may not be able to do this. Sometimes more than three tests must be done to satisfy yourself that you have obtained the maximal effort from the patient.

3.4 Cautionary Note

Some patients with asthma may develop bronchospasm during FVC testing. These patients show a progressive decrease in FEV₁, and usually in FVC as well, as repeat tests are done. In these patients the first test will usually give the best results and you will not be able to achieve reproducibility. If you suspect test-induced bronchospasm, give the patient without contraindications a β_2 agonist and, 15 minutes later, repeat the FVC test. You should see an improvement in FEV₁ over the lowest prebronchodilator value but FEV₁ might not reach the highest prebronchodilator value.

Spirometry and Flow Volume Measurements

4.0 Calibration and Quality Control

Quality control of spirometers is closely tied to calibration, the distinction being that calibration (adjustment) may or may not be needed, but quality control must be applied on a routine basis. Calibration implies adjustment or compensation is performed whereas quality control is a means of checking the accuracy and/or precision of the device (and software) after calibration. If a known quantity of air measured by the spirometer approximates the known value then the instrument is considered *accurate*. If the same parameter is measured repeatedly and the consequent values are similar, then the instrument is *precise*.

4.1 Calibration for Spirometry and Flow Volume Measurements

All devices used for both spirometry and flow volume measurements should be calibrated using a large spirometry syringe (usually 3 L) each day the machine is used. If 3 L is injected into the spirometer then the output should read $3 \text{ L} \pm 3\%$ or $\pm 90 \text{ mls}$. If adjustment is necessary, this is done either by software correction or by adjustment of the analog output signal. (Review the operating manual.) *NOTE: The only value that can be measured accurately is FVC.* The FEV₁ value will depend on how rapidly you empty the syringe through, or into the machine. When using a calibrating syringe, the manufacturer's instructions must be followed carefully. It is important that the spirometer be in Calibration Mode when calibrating so that the spirometer does not convert the volume of dry room temperature gas to that at body temperature (37°C) and saturated with water vapour. The result will be an overestimation of 4% and 9% of the volume injected. (*FORM-APPENDIX A Record of Calibration*)

Syringe accuracy: The syringe used to check the volume calibration of spirometers must have an accuracy of at least 0.5% of full scale (15 mls for a 3 L syringe). Calibration syringes should be leak-tested periodically by trying to empty them with the outlet corked.

Spirometry devices need to be checked routinely for leaks. Refer to the manual or to distributor for further information. A leak in the volume chamber will result in volume loss and inaccurate results until repairs are made. If a volume loss occurs and a leak in the volume chamber has been detected, the spirometer cannot be relied upon to give accurate results until repairs are made.

Another common problem with bellows spirometers is inaccuracy resulting from sticking of the folds of the bellows. The bellows should be visually assessed during expansion with the calibration syringe to be sure the bellows inflate smoothly and evenly. If it does not, the bellows should be thoroughly rinsed and dried, or replaced with a new one.

Linearity: Pneumotach systems, at extremes of flow (both high and low), may become inaccurate (i.e. 3 L injected at a high speed or a low speed may produce an inaccurate reading as opposed to 3 L injected at a moderate speed). An instrument is considered *linear* if its output is directly proportional to its input. Pneumotach systems must have their linearity determined whenever calibration is done. This is done by injecting the volume from a 3 L syringe at several different speeds. Most pneumotach systems compensate for this nonlinear flow signal electronically or through software corrections. The linearity is considered acceptable if the volume injected does not vary by more than $\pm 3\%$.

Pneumotachs must be visually checked for moisture or other debris. This can alter its flow sensing characteristics and interfere with the spirometer's ability to detect the start or end of a test.

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4.2 Quality Control for Spirometry and Flow Volume Measurements

Checks must be done to test your technique and equipment. This is done using “Standard Subjects”, someone who is readily available (eg: a co-worker) and who has stable and reasonably normal lung function. The chosen standard subject must be capable of generating a peak expiratory flow of at least 550 lpm in order to test the instrument’s linearity at high flows. The standard subjects should be tested every three months and records kept on the values of FEV₁ and FVC. (*FORM-APPENDIX C Equipment Checks using Standard Subjects*)

Prior to performing these periodic standard subject tests, you must determine the normal range for the standard subject. This is done by doing at least 10 acceptable tests over a period of several days. After the tests have been done, the mean and standard deviation (SD) for FEV₁ and FVC are determined (*FORM-APPENDIX B Standard Subject Normal Range*).

5.0 Equipment Maintenance/Repairs

Spirometers should have a routine maintenance schedule and records should be kept indicating the dates and description of maintenance. There should be a record of all repairs of the equipment.

6.0 Cleaning/Sterilization

If your spirometer permits inspiration through it or through any of its parts, then the portions of the inspired pathway that are exposed to expired air must be sterilized between tests on different patients. If the machine itself is not conducive to sterilization then you must use an exchangeable filter assembly between the mouthpiece and the equipment.

If mouth pieces are re-used, there must be an established protocol for cleaning that will prevent the transmission of disease.

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7.0 Records

Records should be kept for:

1. Calibration
 - results
 - name of person performing the calibration
2. Quality Control
 - results from standard subjects
3. Equipment maintenance
4. Patient results:
 - Date and time of the procedure
 - Name of the person performing the procedure

NOTE: All patient results should be filed on the patient's chart

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8.0 Reference Values

Modern microchip-containing equipment relies on a variety of normal reference values for FEV₁ and FVC. The most popular reference manuals are:

Adults (>18 years old)

1. Morris, Koski and Johnson
Am Rev Respir Dis
1971; 103:57-67.
2. Knudson et al.
Am Rev Respir Dis
1983; 127: 725-734.

Children (<18 years old)

1. Polgar and Wang
Am Rev Respir Dis
1979; 120: 625-695.
2. Hsu et al.
J Pediatr
1979; 95: 14-23.

These predicted equations are for the caucasian population. Ethnic groups, especially of East Indian, Oriental or Polynesian descents require adjustment of the predicted equation by multiplying the predicted value for FEV₁ and FVC by 0.90.

9.0 Interpretation

Significant Reversibility of Airway Obstruction – a change of 12% and > 200 ml in the FEV₁ or FVC following bronchodilator.

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Appendix A - Record Of Calibration

Syringe Volume = ____ . ____ ____ L

Date	FVC			Date	FVC		
	Slow	Medium	Fast		Slow	Medium	Fast

1. Empty the calibration syringe into the machine using slow, medium and fast emptying rates.
2. Record the resultant FVC values for the three rates of emptying.
 - Different speeds are necessary only for instruments making flow volume measurements.
 - If the results are outside 3% of the true value or if the rate of emptying causes values to vary by more than 3%, the machine must be serviced or replaced.

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Appendix B - Standard Subject Normal Range

Name			Name		
Age			Age		
Height			Height		
<i>Date</i>	<i>FVC (L)</i>	<i>FEV₁ (L)</i>	<i>Date</i>	<i>FVC (L)</i>	<i>FEV₁ (L)</i>
MEAN			MEAN		
SD			SD		
MEAN \pm2 SD			MEAN \pm2 SD		

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Appendix C - Equipment Checks Using Standard Subjects

Standard Subject, Name:			Standard Subject, Name:		
	<i>FVC (L)</i>	<i>FEV₁ (L)</i>		<i>FVC (L)</i>	<i>FEV₁ (L)</i>
Expected Mean \pm 2 SD			Expected Mean \pm 2 SD		
Date			Date		