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Spirometry and Flow Volume Measurements

Best Practice Guidelines

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Preamble

Spirometry 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.

Two important spirometry measures are the 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, the FEV_1/FVC ratio and an estimate of flow.

When pre- and post-bronchodilator spirometry is performed, they are a useful measure of response to treatment, and both tests are part of the ongoing monitoring of patients with asthma and chronic lung diseases.

The accuracy of the results depends on the machine's capabilities and calibration. Moreover, it is affected by the person performing the test, the effort provided by the patient and, for some patients, the testing procedure itself.

Indications for Spirometry

- 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

Accreditation

When performed in the physician's office on their own patients, spirometry is one test of pulmonary function that does not require accreditation.

When offered as a service to other physicians and their patients, however, CPSA accreditation is required to ensure compliance with quality and safety standards.

Each physician utilizing spirometry in their office is ultimately responsible for ensuring 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 trained and competent

Equipment

A variety of equipment can be used to conduct spirometry, as long as it meets the current American Thoracic Society (ATS)/European Respiratory Society (ERS) technical statement: *Standardization of Spirometry 2019 Update*.

This technical statement expects the equipment to meet the requirements of ISO 26782:2009 *Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans*. In addition to the standard's performance requirements of being within ±3.0% for accuracy, linearity, and repeatability, spirometry equipment will have a maximum permissible error of not more than ±2.5% when tested with a 3-L calibration syringe and when using the test profiles of ISO 26782, Section 7, Annex C. If future ISO 26782 revisions specify a maximum permissible error less than ±2.5%, then the lower value should be used.

Quality Assurance

The accuracy and reproducibility of spirometry results are affected by the calibration and maintenance of the machine, operator technique and effort provided by the patient.

Attention to equipment quality assurance and calibration is an important part of current best practices. The minimum requirements are as follows:

1. Maintenance of a log of calibration results.
2. Documentation of repairs or other alterations that return the equipment to acceptable operation.
3. Recording of dates of computer software and hardware updates or changes.
4. Recording the dates that equipment is changed or relocated.

Calibration

Daily calibration verification should be performed at low, medium and high flow using a 3.0 L syringe cycled at least three times to give a range of flows varying between 0.5 and 12.0 L/s (with 3.0 L injection times between 0.5 and 6 s). The measured volume at each flow should meet the accuracy requirement of ±3% for both inspiration and expiration (or for expiration only for volume-based spirometers), i.e., 3.0 L ±3% or ±90 ml.

If an in-line filter is used in spirometry testing, then it should also be used in-line during calibration and verification.

For devices using disposable flow sensors, a new sensor from the supply used for patient tests should be tested each day.

When using a calibrating syringe, the manufacturer's instructions should be followed carefully. It is important that the spirometer be in "Calibration Mode" when calibrating so that it does not convert the volume of dry room temperature gas to the volume at body temperature (37° C) and saturated with water vapour. Otherwise, the result will be overestimated by 4% to 9% of the volume injected.

Calibration Failures

If the calibration verification fails, check for and remediate problems and repeat the calibration verification.

If the change in calibration factor is >6% or varies by more than 2 standard deviations (SD) from the mean, inspect and, if necessary, clean the spirometer according to the manufacturer's instructions; check for errors and recalibrate the spirometer.

If adjustment is necessary, this is done either by software correction or by adjustment of the analog output signal (refer to the manufacturer's instructions).

Linearity

An instrument is considered linear if its output is directly proportional to its input.

Pneumotach systems should have their linearity determined whenever calibration is done. This is done by injecting the volume from a 3.0 L syringe at several different speeds.

Pneumotach systems, at extremes of flow (both high and low) may become inaccurate (i.e. 3.0 L injected at a high or a low speed may produce an inaccurate reading as opposed to 3.0 L injected at a moderate speed). 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 3%.

Calibration Syringe

The syringe used to check the volume calibration of spirometers should have an accuracy of at least 0.5% of full scale (±0.015 L [15 ml] for a 3.0 L syringe) verified by the manufacturer on delivery and at intervals recommended by the manufacturer, usually annually.

The syringe should have:

- Daily inspection for displacement of the piston stop.
- Daily check for smooth operation of the syringe with no sticking or catching.
- Leak-tested monthly by trying to empty them with the outlet corked.

Standard Subject Testing

Monthly testing of a "Standard Subject" that records the FEV_1 and FVC values should be performed. Results should be within 2 Standard Deviations (SD) of the calculated means for FEV_1 and FVC (refer to FORM-APPENDIX C Equipment Checks using Standard Subjects).

The chosen standard subject should be capable of generating a peak expiratory flow of at least 550 lpm to test the instrument's linearity at high flows. The ATS *Pulmonary Function Laboratory Management and Procedure Manual* defines a standard subject or biologic control as a healthy, nonsmoking individual capable of performing repeatable spirometry. A standard subject test is not a substitute for the use of a calibration syringe. However, operators are encouraged to know their own

usual FEV_1 and FVC, which allows them to conduct a quick check if they suspect a problem with the spirometer.

Prior to performing these monthly standard subject tests, the normal range for the standard subject should be determined. This is done by performing at least 10 acceptable tests over a period of several days. After the tests have been done, the mean and SD for FEV_1 and FVC are determined (FORM-APPENDIX B Standard Subject Normal Range).

Equipment Maintenance/Repairs

Spirometers should have a routine maintenance schedule at intervals specified by the manufacturer and records should be kept indicating the dates and description of maintenance.

There should be a record of all repairs of the equipment.

Pneumotach Spirometers

The pneumotach should be visually checked daily for moisture or other debris. These can alter the flow sensing characteristics and interfere with the spirometer's ability to detect the start or end of a test.

Spirometry devices need to be checked routinely for leaks. Refer to the manufacturer's instructions for further information.

Bellows Spirometers

For bellows-type spirometers, 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.

Bellows spirometer results may also be inaccurate if the folds of the bellows stick. The bellows should be visually inspected 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.

Cleaning/Sterilization

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

If reusable mouth pieces and nose clips are used, there should be an established protocol for cleaning that will prevent the transmission of disease.

Documentation

- A log is recommended for all quality control findings, maintenance, repairs and adjustments, and hardware and software updates
- After software updates, verification of reference value calculations should be

logged

Procedure for Spirometry

Patient Data

The patient's age, height and weight when wearing indoor clothes without shoes should be recorded. Age should be recorded in years to one decimal place. Height in centimeters to one decimal place and weight to the nearest 0.5 kg should be recorded.

Pre-test Instructions to Patients

- "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."

Instructions during the Patient's Performance of the Test

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 should be actively coached to obtain accurate results.

To obtain maximal values for FEV_1 and FVC, 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.

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."

Recording Results

The goal of testing is to obtain the best maximal effort from the patient. Test results should be acceptable and repeatable.

At least three FVC tests should be done and two of these should have FEV_1 and FVC values which meet the acceptability and repeatability criteria. It is acceptable to select the highest FEV_1 and FVC values from different tests, but with some

automatic machines this may not be possible. Sometimes more than three tests have to be done to ensure that you have obtained the maximal effort from the patient.

Acceptability Criteria

For FEV_1 ensure:

- Back Extrapolated Volume (BEV) is measured at <5% of FVC or 0.100 L, whichever is greater
- no evidence of a faulty zero-flow setting
- no cough in the first second of expiration
- no glottic closure in the first second of expiration
- no evidence of obstructed mouthpiece or spirometer
- no evidence of a leak
- If the maximal inspiration after end of forced exhalation (EOFE) is greater than FVC, then forced inspiratory vital capacity (FIVC) - FVC should be <0.100 L or 5% of FVC, whichever is greater

For FVC ensure:

- BEV <5% of FVC or 0.100 L, whichever is greater
- no evidence of a faulty zero-flow setting
- no glottic closure after 1 s of the initiation of expiration
- one of these three EOFE indicators:
  1. Expiratory plateau (<0.025 L in the last 1 s of expiration)
  2. Expiratory time >15 s
  3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC
- no evidence of obstructed mouthpiece or spirometer
- no evidence of a leak
- If the maximal inspiration after EOFE is greater than FVC, then FIVC - FVC should be <0.100 L or 5% of FVC, whichever is greater

Repeatability

Age >6 yr: The difference between the two largest FVC values should be <0.150 L, and the difference between the two largest FEV_1 values should be <0.150 L

Age <6 yr: The difference between the two largest FVC values should be <0.100 L or 10% of the highest value, whichever is greater, and the difference between the two largest FEV_1 values should be <0.100 L or 10% of the highest value, whichever is greater

For patients with moderate to severe airway obstruction, a forced expiration can take longer than 15 seconds. It is important to continue until the expiration is complete.

Cautionary Note

Some patients with asthma may develop bronchospasm during FVC testing. As repeat tests are done, these patients show a progressive decrease in FEV_1, and usually in FVC as well. 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 $ß_2$ agonist and, 15 minutes later, repeat the FVC test. You should see an improvement in FEV_1 over the lowest prebronchodilator value but FEV_1 might not reach the highest prebronchodilator value.

Records

Records should be kept for:

1. Patient results:
    a. Date and time of the procedure
    b. Name of the person performing the procedure
    c. FEV_1
    d. FVC
    e. FEV_1/FVC ratio

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

Reference Values

The Global Lung Initiative (GLI) reference equations for individuals 3-95 years of age, with the lower limit of normal (i.e. Lower 5% interval) reported are the expected reference set in Alberta.

Interpretation

It is best practice to refer to the *ERS/ATS technical standard on interpretive strategies for routine lung function tests.* Stanojevic S, Kaminsky DA, Miller M, et al Eur Respir J 2021; 2022

Bronchodilator Response

A significant bronchodilator response (BDR) requires a change of >10% relative to the predicted value for FEV_1 or FVC following bronchodilator administration.

$$Bronchodilator\ Response = \frac{(Postbronchodilator\ value\ (l)\ -\ Prebronchodilator\ value\ (l))\ *\ 100}{Predicted\ value\ (l)}$$

A change of >10% is considered a significant BDR response.

The predicted value should be determined using the appropriate GLI spirometry equation.

For example: A 50-year-old male; 170 cm in height has a pre-bronchodilator FEV_1 of 2.0 liters and a post-bronchodilator FEV_1 of 2.4 liters. Their predicted FEV_1 is 3.32 liter[1].

$$Bronchodilator\ Response = \frac{(2.4 - 2.0) * 100}{3.2} = \frac{0.4 * 100}{3.2} = \frac{40}{3.2} = 12.1\%$$

Therefore, their BDR is reported as an increase of 12.1% of their predicted FEV_1 and classified as a significant response.

[1] Taken from ATS/ERS *Interpretative strategies for lung function tests*, R. Pellegrino, et al., Eur Respir J 2005; 26: 948–968. DOI: 10.1183/09031936.05.00035205

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.
    a. Different speeds are necessary only for instruments making flow volume measurements.
    b. 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 requires service or replacement.

Appendix B – Standard Subject Normal Range

Name			**Name**		
Age			**Age**		
Height			**Height**		
Date	**FVC (L)**	**FEV_1 (L)**	**Date**	**FVC (L)**	**FEV_1 (L)**
Mean			Mean		
SD			SD		
Mean -2 SD			Mean -2 SD		
Mean +2 SD			Mean +2 SD		

Appendix C – Equipment Checks Using Standard Subjects

Standard Subject, Name:		
	FVC (L)	**FEV_1 (L)**
Lower Limit, Mean - 2 SD		
Upper Limit, Mean + 2 SD		

Date		